Berlin Heart®

INCOR®

Implantable
Ventricular Assist Device

Instructions for clinical use
Edition 8

INCOR®

EXCOR® Adult

EXCOR® Pediatric

Technical and medical emergencies:

HOTLINE **Contact the emergency hotline! +49 (0)30 81 87 27 72**

Product questions:

Central telephone number	**+49 (0)30 8187 2600**
Office hours	Mon - Fri 8.00 am - 6.00 pm
Sales Team • Orders, deliveries, complaints • Prices, quotes	**sales@berlinheart.de**
Clinical Affairs Team • Technical and medical queries	**service@berlinheart.de**
Training	**academy@berlinheart.de** **+49 (0)30 8187 2778**

These instructions for use apply to the INCOR system.

• Motor controller software:	version 4.23 or higher
• Control unit software:	version 6.106 or higher
• Monitor program software:	version 2.4 or higher

Approval and declaration of conformity

CE 0123

The INCOR implantable ventricular assist device (UMDNS number 10-847) fulfills the basic operational requirements of Directive 90/385/EEC dated June 20, 1990, for active implantable medical devices. The INCOR carries the CE mark since 2003.

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Wiesenweg 10
12247 Berlin
Germany

These clinical instructions for use are intended for information purposes only. The contents of the instructions for use may be supplemented, modified or updated at any time without prior notice.
Previous editions of these instructions for clinical use are superseded by the publication of this edition.

All translations of these clinical instructions for use have been prepared and checked to the best of our knowledge. Only the German edition of these clinical instructions for use is considered to be legally binding, however.

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All other trade names mentioned in these instructions are subject to the rights of their respective owners. These rights are expressly recognized and respected when referring to these names in the present publication.

Table of Contents

1 Introduction

These instructions for use are intended for everyone involved in the implantation of an INCOR® implantable ventricular assist device or the care of an INCOR patient.

These instructions for use provide information on the setup, functionality and use of INCOR. In the interests of patient safety, please carefully read and observe these instructions for use.

Only professional medical personnel with specific product training may use INCOR. Training dates can be arranged with the Manufacturer.

Note: the recommendations made in these instructions for use are based on the experience the manufacturer has gained from use of INCOR. Decisions concerning implantation, the components to be used and patient care remain the responsibility of the attending physician.

Explanation of the safety information and signal words:

DANGER	Indicates a hazardous situation which, if not avoided, **will result in** death or serious injury.
WARNING	Indicates a hazardous situation which, if not avoided, **may result in** death or serious injury.
CAUTION	Indicates a hazardous situation which, if not avoided, may result in minor or moderate injury. The device may suffer damage.
NOTICE	Indicates practices that do not entail personal injury. The device may suffer damage.
ADVICE	This logo indicates measures and working techniques that have proven effective in relation to INCOR and which we therefore recommend.
HOTLINE	**Contact the emergency hotline! +49 (0)30 81 87 27 72**

This hotline is intended for medical personnel and should be used only in the event of technical and medical emergencies. The line is open 24 hours a day. It may take up to 90 seconds to connect.

You can reach Berlin Heart GmbH on **+49 (0)30 81 87 26 00**. Please use this number if you have any questions about INCOR.

1. The instructions are numbered incrementally.

IMPORTANT: Refer to the reference lists! The reference lists contain descriptions of the product in the respective local languages. Article numbers of the reference lists:

- 5000100 Implantation set 1
- 5000101 Implantation set 2
- 5000102 Explantation set
- 5000103 Unsterile components
- 5000203 Implantation set part 1, inflow side
- 5000204 Implantation set part 2, outflow side
- 5000205 Surgical set

Definitions of terms

Product life	The product lifetime of unsterile products begins on the date of initial shipment, and that of sterile products on the date of implantation. All sterile products are intended for single use.
Expiration date (sterility in storage)	The time until which the unused sterile product remains sterile.

Tab. 1-1 Definitions of terms

Further designations in these instructions for use:

- References to other documents as well as designations on the devices are written in *italics*.
- Keys: **<Key1>**
- Short cuts: single keys are combined with a +: **<Key1>** + **<Key2>**.
- Software strings are indicated as follows: **Software string**
- Any other highlighting is done in **bold** type.

2 Important Safety Information

WARNING

Only professional medical personnel with specific product training may work with INCOR. In any other circumstances the smooth operation of INCOR cannot be guaranteed.

Only use intact components! Do not use components that are visibly damaged. Replace defective or damaged external components immediately. In any other circumstances the smooth operation of INCOR cannot be guaranteed.

Only use sterile components with packaging that is not damaged and a use-by date that has not expired!

Devices that are delivered sterile are not intended for reuse and may not be resterilized. Otherwise there is a risk of infection and of impairment of the structural integrity of the device.

2.1 Conditions of use

WARNING

Patients with a critical hemodynamic status must be continually monitored by professional medical personnel with specific product training! Otherwise the patient may not receive adequate support.

If a patient is not physically or mentally capable of operating INCOR correctly, Make sure that therapy is permanently monitored by personnel trained in the use of the INCOR system. Otherwise, patient support is not guaranteed.

Only connect the power supply unit to sockets with a voltage as specified on the INCOR identification plate! Only use sockets that comply with local specifications! Otherwise the power supply unit may fail.

Protect all components from humidity and moisture! Only operate and store electrical components in closed, dry rooms! Otherwise there is a risk of electric shock or failure of the power supply unit, charging unit and operator terminal.

Always ensure that the power supply unit, charging unit, and operator terminal are kept dry. Never clean any of these components with a damp cloth. Otherwise there is a risk of electric shock or failure of the power supply unit, charging unit and operator terminal.

Never cover the power supply unit, charging unit or operator terminal! Otherwise there may be a build-up of heat.

Always keep the space between the standing surface and underside of the power supply unit, charging unit and operator terminal clear. Otherwise there may be a build-up of heat.

Protect all the components from contamination! Prevent foreign bodies from infiltrating connection sockets and air vents! Otherwise there is a risk of electric shock or failure of the system.

Protect all INCOR components against the influence of strong electromagnetic radiation (activated mobile phones and cordless telephones, magnetic resonance imaging scanners, etc.)! Otherwise there may be a temporary loss of functionality.
This also applies to currently inactive INCOR components such as spare batteries. See chapter 12: EMC Tables, page 177.

Do not operate INCOR in the immediate vicinity of, or stacked together with other electrical equipment. If this cannot be avoided, the function of INCOR must be observed and monitored.

Do not use INCOR in the vicinity of flammable gases! Otherwise, there is a risk of explosion from ignition of the gas mixture.

2.2 Configuration

⚠ WARNING

Only operate INCOR with the components that belong with the INCOR system and are supplied by Berlin Heart.

Do not make any alterations to the components of INCOR. Alterations to the components may lead to loss of function and directly injure the patient or user.

Only use a pump and control unit with the same AP number!
The AP number of the pump is located on the driveline above the plug, and the AP number of the control unit is located on the identification plate of the control unit. The AP number is also stated on all the packaging elements of these components.

Only use the connection cables, plugs and components supplied with the device! INCOR must not be operated with multiple-outlet power strips or extension cables.

In any other circumstances the smooth operation of INCOR cannot be guaranteed.

2.3 Implantation

⚠ WARNING

If the temperature indicator has changed color: do not use the components! In any other circumstances the smooth operation of INCOR cannot be guaranteed.

Do not bring the blood pump and cable into contact with pointed or sharp-edged objects (surgical instruments, etc.)! Otherwise there is a danger of consequential damage such as technical failures, interruptions, or failure of the INCOR pump function.

Ensure that the entire crown of the inflow cannula is positioned within the ventricle and is not touching the surrounding tissue (trabeculae, septum, lateral myocardial wall). Remove any excess trabeculae. Otherwise the opening of the cannula may be displaced.

After inserting the cannula into the apex of the ventricle, do not fill the protection balloon any further! Otherwise the protection balloon may burst.

Empty the protection balloon prior to removal! Otherwise the protection balloon may burst.

Ensure that the system is free of air when connecting the pump and outflow cannula. Otherwise embolisms may develop.

For each snap-in connector: Ensure that the snap-in connector is correctly engaged! Otherwise bleeding may occur.

Ensure that the driveline is inserted subcutaneously! Otherwise, there is a risk of perforating the surrounding organs (peritoneum, liver).

⚠ CAUTION

For de-airing (venting) via the pump or outflow angle section, always use the supplied vent tube adapter. Never insert the vent tube directly into the pump or outflow angle section! In particular, avoid touching the coated inner sides of the pump or outflow angle section with the vent tube. Otherwise the CBAS coating[1] may be damaged.

VAD management

⚠ WARNING

Allow the systems to acclimatize for 2 hours! In any other circumstances the smooth operation of INCOR cannot be guaranteed.

If the system has been unused for more than 2 months: Charge the main and backup batteries, as well as the battery of the operator terminal, prior to commencing surgery! In any other circumstances the smooth operation of INCOR cannot be guaranteed.

Put the control unit into operation only if the control unit acknowledges the connection of the first battery with a short audible alarm and the display has no errors (incomplete letters or numbers) when connected. If this is not the case, messages may not be properly acknowledged. In this case, use a replacement system.

Never pull on the plug/cable during offset correction! Otherwise the monitor program will display incorrect flow values, and the messages **E20**/**E21**/**E22** will not appear, or will be displayed erroneously.

Do not retrospectively modify the value configured for the offset of the rotor position! Otherwise the monitor program will display incorrect flow values, and the messages **E20**/**E21**/**E22** will not appear, or will be displayed erroneously.

1. CBAS - Carmeda® BioActive Surface

During weaning from ECC: monitor the system and adjust the settings if necessary. Otherwise, support may be inadequate.

Transfer the settings to the replacement control unit as soon as the patient is in the intensive care unit! Otherwise the pump will fail to start when the control unit is exchanged for the replacement control unit.

2.4 Working with the operator terminal

⚠ WARNING

Do not install any other software on the operator terminal! Use another computer with Internet access for data transfer. Otherwise the operator terminal may fail to function correctly.

Only use the supplied communication cable for transferring data between the control unit and operator terminal! Otherwise there is a risk of electric shock.

Immediately update any modified settings in the replacement control unit! Always keep the replacement control unit, programmed with patient data and the latest settings, within reach of the patient! Otherwise the patient will not be adequately supported after replacing the control unit.
Exception: settings which are selected during implantation should be transferred only during post-implantation care.

PC, PFC, and SP

⚠ WARNING

Insufficient filling of the left ventricle may be an indication of right ventricular dysfunction! In this case, only activate pulsatility control if taking appropriate medical action at the same time.

Do not activate PC in the presence of severe cardiac dysrhythmias! Otherwise the patient may not receive adequate support.

If the residual myocardial activity is insufficient, pulsatility control may reduce the speed permanently until the minimum speed (5000 rpm) is reached and a low mean flow is achieved. Therefore, always check the **Alarm threshold flow** setting when activating pulsatility control. The alarm threshold flow should be 50% of the flow achieved, but must be adjusted on an individual basis.

2.5 Handling

Daily routine

⚠ WARNING

Ensure that both buzzers on the control unit are functioning correctly! Otherwise messages may not be properly recognized. See section 5.1: Buzzer checks, page 45.

For each plug: check immediately, by pulling gently on the kink protection sleeve, that the plug is firmly positioned in the socket! Otherwise the system may fail.

In noisy environments: pay attention to the display panel of the control unit in order not to miss any messages!

Do not clean the INCOR device with pointed or sharp-edged objects (needles, etc.)! Otherwise there is a risk of electric shock or failure of the system.

Attach the driveline to the body, close to the wound, Use drainage fixation tape for this (e.g., Secutape®). Otherwise there is an increased risk of infection at the transcutaneous exit site.

Before the patient washes or showers, disconnect the power supply unit from the control unit (switch to battery operation)! Otherwise there is a risk of electric shock or failure of the system.

⚠ CAUTION

If the ambient temperature is high, parts of the battery and control unit may become very hot. Avoid prolonged contact with hot components. Otherwise there is a risk of burns.

Protecting the driveline

⚠ WARNING

When connecting the control unit and pump with the plug coupling, ensure that the cable is not twisted. The blue longitudinal marking on the driveline helps to ensure that the cable is aligned. If this is not the case, the cable may be damaged.

Ensure that the driveline and plug coupling are intact. Otherwise the pump may need to be replaced.
In particular, avoid any tensile stress, twisting, bending or kinks. See Fig. 2-1 , page 17.

Replace the cable protector (at the clinic) after 6 months. When doing so, check the driveline, control unit cable and plug guard: the cables must not be twisted and the markings on the plug coupling must be aligned. Otherwise the system may fail.

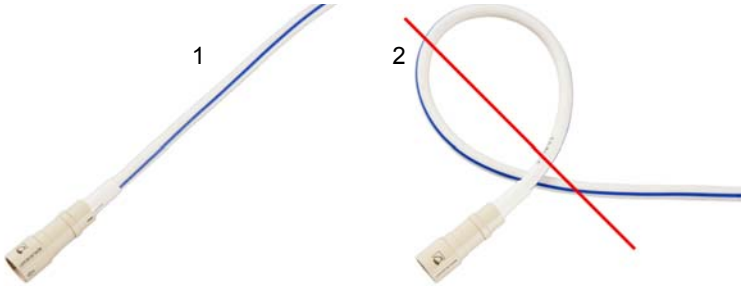


Fig. 2-1 Driveline

Power supply

WARNING

Always ensure that the power supply to the control unit is sufficient! Never disconnect both batteries from the control unit simultaneously! Recharge any discharged batteries immediately! Otherwise the pump may stop!

Ensure that – even during mains operation – one intact, alarm-free main battery and backup battery are always connected to the control unit! Otherwise a power failure may cause the pump to stop.
Only when changing the batteries, restarting and replacing the control unit is one or no battery connected.

If the planned duration of battery operation exceeds the remaining operating time of the main battery: carry a further power source (fully charged battery or power supply unit) in addition to the backup battery.

INCOR Smart Bag

WARNING

Ensure that the INCOR Smart Bag is always firmly secured to the body when it is being carried. The length of the carrying strap must be adjusted to prevent the INCOR Smart Bag from falling. Otherwise the components could be damaged. The transcutaneous exit site may be injured as a result.

Always close the click fastener correctly: The buckle must click audibly into place. Otherwise the components could fall out and be damaged. The transcutaneous exit site may be injured as a result.

If the inner compartment is used on its own: Always suspend the inner compartment by both fastening loops. Otherwise the components could fall out and be damaged. The transcutaneous exit site may be injured as a result.

2.6 Messages and Measures

WARNING

A01/**A11**: Never disconnect both batteries from the control unit simultaneously! Otherwise the pump may stop.

A01/**A11**: Replace the empty battery as quickly as possible! Otherwise the pump may stop.

A11/**HA14**: Always replace the backup battery under mains operation! Otherwise the pump may stop.
If the backup battery is empty, the main battery will also be empty!

E24: Never heat the control unit by applying heat directly (lighter, heating, etc.)! Otherwise the control unit may fail to function correctly.

EA03/**EA13**: Never use water or other fluids to cool a battery! Otherwise there is a risk of short-circuit or failure of the system.

E23: Never use water or other fluids to cool the control unit! Otherwise there is a risk of short-circuit or failure of the system.

EF30 and **EF40**: If messages persist after undertaking all the other measures described: determine by auscultation whether the pump has actually stopped before replacing it. Only replace the pump if it has actually stopped. Otherwise it does not need to be replaced.

Replacing the control unit

WARNING

Whenever a control unit is to be used/replaced: connect the batteries! It is not possible to activate the pump with the power supply unit only.

Whenever a control unit is to be used/replaced: check the speed and adjust as necessary. If the settings and patient information have not first been transferred from the active control unit, the pump will not start automatically. The operator terminal must then be used to start the pump.

If the hemodynamic status of the patient is found to be critical, the control unit must be replaced within 30 seconds! Otherwise, support may be inadequate.

Replacing the pump

Safety information as described in section 2.7: Explantation, page 19.

2.7 Explantation

DANGER

For BTR: It is essential to use the INCOR weaning set for explantation of the INCOR system. Only in such a way is it possible to close the truncated inflow cannula that remains in the ventricle.
IMPORTANT: The weaning set is not supplied with the INCOR device. If needed, it can be obtained from the manufacturer.

WARNING

For BTR: Ensure that the remainder of the cannula is completely free of air! An embolism may otherwise develop.

For BTR: Do not puncture the seal plug! Otherwise the seal plug may leak.

Before cutting through the driveline, remove it from the control unit! Otherwise there is a risk of electric shock.

2.8 Combination with other products/procedures

2.8.1 Combination not possible

- Mechanical heart valve prostheses
- Magnetic resonance imaging
- Radiotherapy
- Nuclear diagnostics/nuclear therapy
- Electro-stimulation therapy
- Therapeutic ultrasound (e.g., lithotripsy)
- High-frequency surgery (cauterization); except for implantation and explantation

WARNING

When using a cauterization knife: the current must not flow directly through the pump. Therefore, do not attach the electrode of the cauterization knife to the back of the patient! Avoid contact between the cauterization knife and pump! Otherwise there is a risk of electric shock.

When using a cauterization knife, operate INCOR from the batteries! Otherwise the pump may stop.

Therapeutic ultrasound is contraindicated. The implanted components may concentrate the ultrasound. The patient may be injured by this.

Therapeutic, ionizing radiation is contraindicated. The radiation may damage the components. This damage may not always be immediately recognized and may lead to the failure of the components later on.

2.8.2 Restricted combinations

WARNING

Before using an external defibrillator: disconnect the pump from the control unit (open the plug coupling). Otherwise the control unit may fail.
IMPORTANT: Such action causes the pump to stop!

For X-ray and CT: ensure that the control unit is kept out of the path of the X-rays and is shielded on all sides by lead! Otherwise the control unit may fail to function correctly.

ADVICE

We recommend that during the examination the control unit be placed next to the patient or between his or her thighs.

IMPORTANT: Once the INCOR device has been implanted, there is a relative contraindication to the use of an intra-aortic balloon pump (IABP).

IMPORTANT: When combining INCOR with biological heart valve prostheses, the risk of thromboembolic complications is increased.

2.8.3 Feasible combinations

- Cardiac pacemaker
- Implantable defibrillator
- Stents
- Diagnostic ultrasound

3 General Product Information

3.1 Intended use

INCOR is an implantable left ventricular assist device for human use.

INCOR may be implanted with medial or lateral access.

INCOR must be operated only with the components mentioned herein, and must be used in accordance with the indications, contraindications and instructions for use. Components used by different patients must not be interchanged.

INCOR is a single-use product.

When using the graft outflow cannula

The vascular graft prosthesis is required for connecting the INCOR blood pump to the aorta.

3.2 Potential therapeutic objectives

Bridge to transplant (BTT)

In patients already on the transplant waiting list who can no longer be managed with conservative drug treatment, INCOR will bridge the waiting time to transplantation.

Bridge to recovery (BTR)

Owing to the relief provided, the myocardium can recover to the extent that INCOR can be explanted after variable lengths of treatment.

Destination therapy (DT)

Patients in whom transplantation is contraindicated should be provided with mechanical circulatory support for an unlimited period.

3.3 Indication

Terminal, conservatively uncontrollable left ventricular insufficiency of varying etiologies, of NYHA[1] stage III or IV, with probable medium-term to long-term need for assistance.

3.4 Contraindication

- Predominantly right ventricular failure
- Biventricular heart failure
- Signs of infection that do not correspond to a sepsis-like syndrome
- Sepsis
- Irreversible multi-system organ failure
- Intolerance to any form of anticoagulation therapy
- When using the graft outflow cannula: Known sensitivity to the components of the vascular graft prosthesis; the vascular graft prosthesis is contraindicated for coronary vessel construction, dialysis fistulas (e.g. hemodialysis) and pulmonary shunts.

1. New York Heart Association

Relative contraindication

- Coagulation system disorder

3.5 Risks and side effects

The following complications are known to be possible:

- Bleeding and pericardial fluid accumulation
- Peripheral thromboembolic complications
- Wound healing disorders and infections at the driveline
- Hemolysis
- Sensitivity to the components of the vascular graft prosthesis
- Equipment malfunctions
- Damage to the driveline
- Pump thrombosis
- Ventricular arrhythmias
- Neurological dysfunction
- Psychiatric complications
- Restriction of the function of the kidneys
- Restriction of the liver function
- Restriction of the respiratory function
- Restriction of the right ventricular function

3.6 Clinical standards

In order to provide an INCOR patient with optimal care, the treating clinic must comply with the following standards:

Patient care

Treatment of the patient is the responsibility of a specialized VAD team consisting of a surgeon, ICU physicians, cardiologists, perfusionists and nursing staff.

The clinic must have an appropriately specialized outpatient department to care for the patient following discharge.

Diagnostics/anticoagulation therapy

- TEG
- Platelet aggregation studies

Other

Right ventricular function can be supported with medication, e.g., NO[1], phosphodiesterase inhibitors (e.g., milrinone).

1. Nitric oxide

3.7 Warranty and guarantee

Warranty

The General Terms and Conditions of Business of Berlin Heart GmbH apply.

The warranty is only valid if

- the product is stored as directed (check the temperature indicators!)
- the product is used as intended.
- the packaging is intact.

The latter applies in particular to the sterile packaging of sterile products and aluminum-coated outer packaging of the pump and outflow angle section.

Warranty period

All warranty claims expire after 12 months, calculated from the date of transferring the risk (for further information, see GTC,). An exception are the batteries (parts subject to wear) and sterile accessories (single-use products).

Guarantee

The manufacturer offers a warranty of 6 months for the batteries, calculated from the date of risk transfer.

3.8 Expiration date and product lifetime

Expiration date

This period covers 3 years in the case of the pump, cannulae and sterile accessories.

Product lifetime

The lifetime of the product is 5 years, and is thus compliant with legal requirements. If the product is left untouched during storage, the INCOR pump will not suffer any systematic wear. The manufacturer has experience of more than 5 years of faultless operation. This is subject to careful and appropriate handling of the system, however. The external electronic components should be replaced after 5 years.

3.9 Operator requirements

3.9.1 General

During implantation, another INCOR system must always be available at the clinic as a replacement.

At all times, the patient must be in possession of an active control unit and a replacement control unit programmed with the patient data and current settings, 4 batteries, 2 power supply units, a charging unit and an operator terminal. If a component is damaged, the emergency hotline must be informed immediately.

The patient must be instructed in the operation of the INCOR system. The instruction and care of the patient are the responsibility of the operator. If a patient is not physically or mentally capable of operating INCOR in the appropriate way, the operator must ensure that the patient is cared for by a suitable person.

Before implanting an INCOR system, the patient must be clinically evaluated in accordance with the latest version of the ISHLT Guidelines.[1]

3.9.2 Training of personnel

Only medically qualified personnel who have received specific product training from the manufacturer may work with INCOR. In particular, replacement of the control unit must be practiced thoroughly by all care personnel.

3.9.3 Patient training

WARNING

To ensure the success of therapy with the INCOR system, the patient must receive training in particular concerning the main points of:
- the power supply for the INCOR pump, and
- cautionary measures
. The circulatory support may otherwise fail or be interrupted, and wound infections may occur.
It must be demonstrated that the patient has received training in all the points listed in section 13.5, page 201ff..

The patient must be informed about the safety risks and precautionary measures (relating to humidity, temperature, electromagnetic fields, etc.). This must also cover the various aspects of daily life (wound care, choice of clothing, behavior in public places and while traveling, handling pets, etc.).

Before being transferred to outpatient care, the patient and his or her caregiver must have a solid command of the appropriate use of INCOR and all the necessary measures as specified in the patient's instructions for use.

The patient must be informed about the consequences of incorrect use (wound infections, damage to and failure of components, failure of the power supply, etc.).

As part of patient training, replacement of the control unit must be practiced thoroughly. This exercise must be repeated with the patient at later checkups.

ADVICE

We recommend that this checklist be signed by your patient and the attending physician, and filed in the patient's records, once training is successfully completed.

1. The Journal of Heart and Lung Transplantation (J Heart Lung Transplant 2013;32:157-187)

3.9.4 Transferral to outpatient care

Before transferral to outpatient care

- The patient and his or her caregiver must have a solid command of the appropriate use of INCOR and all the necessary measures as specified in the patient's instructions for use.
- The current settings of the control unit and the replacement control unit must be checked and adjusted, as necessary.
- The patient must be given the patient's instructions for use, short instructions and patient ID card on which the telephone number of the hospital contact person is noted.

See section 13.5: Checklists: Transferral to outpatient care, page 201.

3.10 Packaging and sterility

The sterile components of the INCOR system are single-use products and are not intended for reuse.

The sterile components are sterilized with ethylene oxide (ETO) and packaged in double sterile packaging. The integrity of the sterile packaging must be verified before opening. Sterile parts in damaged sterile packaging must not be used. This also applies to sterile parts in sterile packaging which has exceeded the given use-by date.

Sections of the pump and outflow angle section are coated with CBAS. For this reason, the pump and outflow angle section are placed in additional aluminum-coated packaging.

The packaging and outer sterile packaging are unsterile and must be removed before being handed to the sterile person!

3.11 Transportation and storage

⚠ WARNING

Storage and transport must be in the area specified by the manufacturer. Otherwise, functioning of the components is not guaranteed.

With the exception of the sterile components, INCOR must be stored at temperatures above -10°C and below +40°C, and also be protected from fluctuations in temperature and humidity.

The following applies to storage of the sterile components: temperature +15°C to +25°C, relative humidity 35% to 50%, stored in a dry place.

The following applies to transport of the sterile components: Temperature -10 °C to +40 °C

When transporting by air, it must be ensured that INCOR is transported at cabin pressure (equivalent to 2000 m above mean sea level).

The packaging of some components includes a temperature indicator. If a component is exposed to inadmissibly high temperatures, the temperature indicator will change color. The component may not be used in such a case. Next to each temperature indicator is a description of how to recognize a change in the indicator.

Fig. 3-1 Example of a temperature indicator

3.12 Maintenance

WARNING

INCOR does not require maintenance. Do not perform any service or maintenance work! Interventions or alterations to the components may lead to loss of function and directly injure the patient or user.

The power supply unit and charging unit are also designed to be maintenance-free when used as intended. The infiltration of dust may lead to wear on the fan, causing an increase in fan noise.

Messages **HA05** and **HA15** indicate that new batteries are required. In such a case, contact the Sales Team:

@ SERVICE **service@berlinheart.de**

If you notice anything unusual in the components, e.g., defective casing or an increase in fan noise:

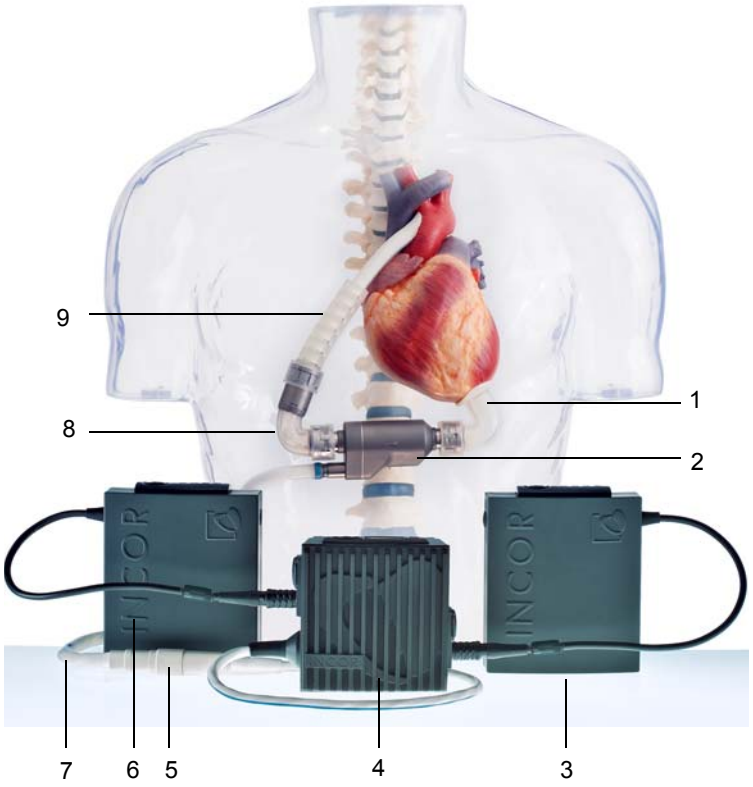
HOTLINE **Contact the emergency hotline! +49 (0)30 81 87 27 72**

3.13 Disposal

Electronic components may be returned to the Manufacturer for professional disposal. Professional disposal of all other components is the responsibility of the operator.

4 Description

Permanently active components



1 Inflow cannula
2 Blood pump
3 Backup battery
4 Control unit
5 Plug coupling
6 Main battery
7 Driveline
8 Outflow angle section (not used with lateral access)
9 Outflow cannula

Fig. 4-1 INCOR in situ (configuration for medial access) with all permanently active components

Occasionally active components

- Power supply unit
- Charging unit
- Operator terminal with monitor program

Overview

The inflow cannula runs from the left ventricle to the pump. The pump is first connected to the outflow angle section, then the outflow cannula. The outflow cannula is anastomosed with the ascending aorta (medial access) or the descending aorta (lateral access). The percutaneous driveline connects the pump to the control unit. The main and backup batteries provide the system with power and must always be connected to the control unit. The control unit, main battery and backup battery are placed in the INCOR Smart Bag. The power supply unit may also be connected to the control unit (mains operation). Empty batteries are recharged in the charging unit. The pump is activated, monitored and adjusted via the operator terminal.

4.1 INCOR pump

The INCOR pump is an electrically operated axial pump. The magnetically supported impeller (rotor) rotates at a constant speed. The difference between systolic and diastolic blood pressure only arises as a result of the residual contractility of the heart and is superimposed by the pressure generated by the pump.

Fig. 4-2 Blood pump, cross-sectional view

The parts of the inner tube which come into contact with the blood are coated with CBAS. The CBAS coating reduces or prevents acute thrombotic complications, which can be caused by artificial blood contacting surfaces. The long-term effectiveness of this heparin coating thereby needs further investigating.

Driveline

The percutaneous driveline is permanently attached to the pump. It is completely sheathed in silicone. The part of the cable inside the body is additionally coated by an adhesion-promoting sheathing made from polyester velour. The driveline ends at the pump socket.

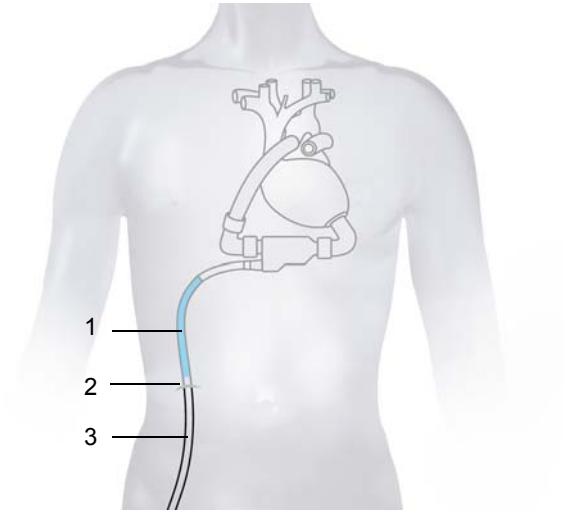
The serial number of the blood pump is on the driveline. The serial number enables clear identification of the blood pump. The identification is also possible after implantation.

The plug coupling is used to connect the pump socket with the plug on the cable of the control unit. See section 7.4.7: Mounting the pump socket ready for connection, page 124. The cable of the control unit is permanently attached to the control unit.

Fig. 4-3 Serial number on the driveline

Polyester velour on the driveline

The polyester velour sheathing of the INCOR driveline is 19 cm in length, starting at the pump. This should enable the surgeon to tunnel the driveline such that the silicone reaches as far as the skin. Recent studies demonstrate that such an approach can reduce the risk of infection.[1,2,3,4]



1 Polyester velour
2 Transcutaneous exit site
3 Driveline

Fig. 4-4 Driveline with polyester velour sheathing

4.2 INCOR cannulae

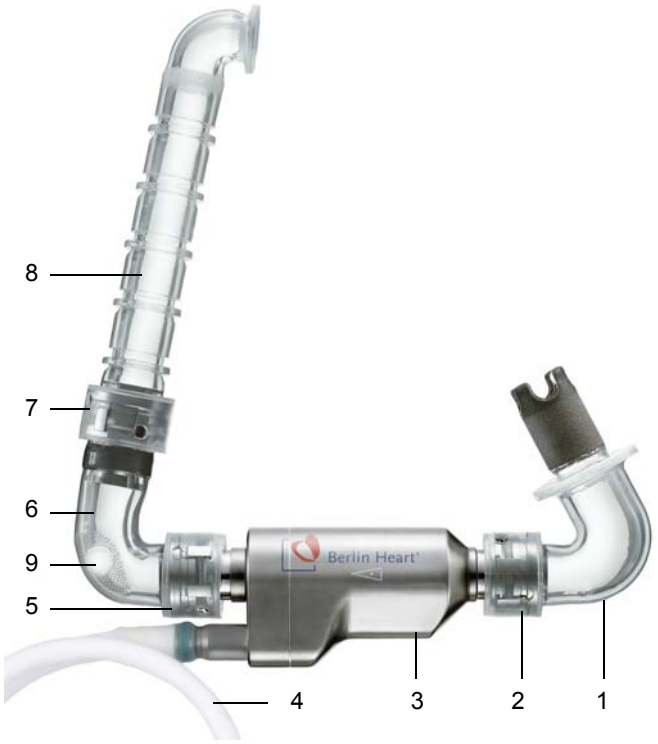
4.2.1 General

Two variants are available for connecting the pump with the aorta.

- Silicone outflow cannula
- Graft outflow cannula

1. Avoiding Driveline Infections in Patients with Left Ventricular Assist Devices; A.J. Tatooles, C.T. Gallagher, P.S. Pappas, M.A. Bresticker; The Journal of Heart and Lung Transplantation - April 2011 (Vol. 30, Issue 4, Supplement, Page S44)
2. Driveline Infections in LVADs: Is It the Pump or the Patient?; D.J. Goldstein, D.C. Naftel, W.L. Holman, L. Bellumkonda, S.V. Pamboukian, F.D. Pagani, J.K. Kirklin; The Journal of Heart and Lung Transplantation - April 2011 (Vol. 30, Issue 4, Supplement, Page S10)
3. Differential Infection Rates between Velour Versus Silicone Interface at the HeartMate II Driveline Exit Site: Structural and Ultrastructural Insight into Possible Causes; I.D. Ledford, D.V. Miller, N.O. Mason, R.A. Alharethi, B.Y. Rasmusson, D. Budge, S.L. Stoker, S.E. Clayson, J.R. Doty, G.E. Thomsen, W.T. Caine, A.G. Kfoury, B.B. Reid; The Journal of Heart and Lung Transplantation - April 2011 (Vol. 30, Issue 4, Supplement, Pages S10-S11)
4. Technique of HeartMate II Percutaneous Lead Externalization Is Associated with Incidence of Infection; S. Akhter, T. Valeroso, B. Pisarski, G. Kim, S. Fedson, A. Anderson, J. Raman, M. Russo, V. Jeevanandam; The Journal of Heart and Lung Transplantation - April 2011 (Vol. 30, Issue 4, Supplement, Page S46)

4.2.2 Silicone outflow cannula



1 Inflow cannula
2 Snap-in connector
3 Blood pump
4 Driveline
5 Snap-in connector
6 Outflow angle section
7 Snap-in connector
8 Outflow cannula
9 Felt pledget

Fig. 4-5 Pump with cannulae, joined with snap-in connectors

The outflow angle section has a felt pledget to enable puncturing. The pump and cannulae are joined with one other intraoperatively using snap-in connectors. See section 7.4: Surgery, page 115.

Inflow cannula

The inflow side of the inflow cannula bears a titanium crown. The outer side of the crown has a textured surface. The rough surface of the sintered titanium promotes ingrowth of the myocardium. The spikes of the crown are cast in silicone. The entire inner side of the inflow cannula, including the area of the crown, is made of silicone. A suture ring made of polyester velour is positioned below the crown.

Outflow angle section

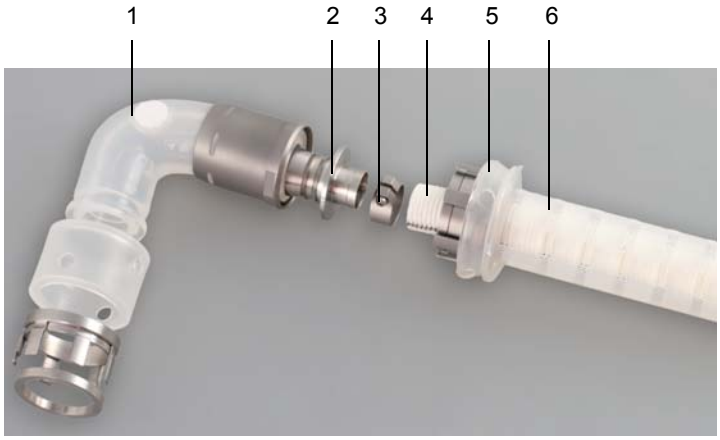
The outflow angle section connects the pump to the outflow cannula.

Outflow cannula

The inflow side of the outflow cannula has collars with which the cannula can be cut to the required length.

4.2.3 Graft outflow cannula

The graft outflow cannula consists of the following components:



1 Outflow angle section
2 Graft connector
3 Screw clip
4 Vascular graft prosthesis
5 Silicone cover
6 Kink protection

Fig. 4-6 Graft outflow cannula with outflow angle section

Note: The silicone cover must be turned back, as illustrated in Figure Fig. 4-6 , prior to assembly.

Fig. 4-7 Outflow angle section mounted on the graft outflow cannula

Vascular graft prosthesis

The vascular graft prosthesis is indicated for the systematic reconstruction of vessels.

The vascular graft prosthesis is made of woven polyester. Each prosthesis is impregnated with an absorbable protein. The aim of the impregnation is to provide a polyester vascular prosthesis which does not require preclotting. The protein is a modified mammalian gelatin which has been cross-linked to a set level to control its rate of removal. It substitutes the fibrin that is used to seal the polyester vascular prosthesis during normal preclotting. The gelatin is hydrolyzed within approximately 14 days and replaced by normal tissue. Gelatin has been chosen as it is a non-toxic protein, a fact which is reflected by its extensive use as a safe plasma expander.

The vascular graft prosthesis may only be used in combination with INCOR.

Origin of the gelatin in the vascular graft prosthesis

Only gelatin from animals born and reared in Australia is used in the vascular graft prosthesis. Australia is one of only a few countries recognized as free of animals infected with TSEs (transmissible spongiform encephalopathies), including BSE and scrapie. The EU Scientific Steering Committee has conducted a geographical BSE

risk (GBR) assessment and concluded that Australia has the most favorable level 1 rating in relation to BSE risk.

Notes on the handling of the vascular graft prosthesis

The vascular graft prosthesis can be damaged by clamps. Therefore, only atraumatic clamps, ideally with soft shod jaws, should be used while applying minimal force. Excessive force should be avoided so as to prevent damage to the polyester fibers and gelatin impregnation.

Excessive tension on the vascular graft prosthesis should be avoided.

Sterilization

The vascular graft prosthesis is sterilized with ethylene oxide and supplied in sterile condition. It must not be resterilized. The Tyvek® seal on the middle and inner bowls must be intact. The sterility of the vascular graft prosthesis will be lost if the bowls are damaged. If the outer packaging is damaged, the product must not be used and should be returned to the supplier immediately.

Packaging

The bowls are wrapped in a foil pouch that serves as a moisture barrier and preserves the optimal properties of the prosthesis. For this purpose, a sachet of desiccant is also included in the packaging.

Note: The foil pouch and outer bowl are not sterile. Only the inner bowl may be used in the sterile area.

4.3 INCOR control unit

INCOR is supplied with 2 identical control units. One control unit is active, the second control unit serves as replacement control unit.

1 Control unit
2 Socket for the communication cable
3 Heat sink
4 Control unit cable
5 Control unit plug

Fig. 4-8 Control unit with control unit cable and control unit plug

Functions of the control unit

The control unit controls the pump, magnetic bearing and power supply.

Data relating to the status of the pump are stored in the control unit. These data can be queried via the operator terminal. See section 6.9.4: Submenu items: Read/display event memory, page 85

The control unit generates messages in the event of a malfunction or empty battery.

User and display elements of the control unit

1 Socket for power supply unit
2 Socket for backup battery

Fig. 4-9 Connection sockets of control unit (I)

1 Indicator
2 Display
3 Button

Fig. 4-10 Indicator, display and button on control unit

Possible displays

Normal display: Run time of the active battery in hours: minutes (e.g., 2:30)

Mean blood flow in L/min (e.g., 4.9).

Messages (e.g. A 01). The indicator next to the display is illuminated. An acoustic signal sounds.

When first connecting the control unit or after restarting (e.g., when replacing the control unit): Set speed

Switching the display: press the button to switch from the normal display to that of the mean blood flow, as well as to all current and a maximum of 5 resolved messages. With every press of the button, you can scroll one step further. If no button is pressed within 10 seconds, the normal display reappears.

Acoustic alarms of the control unit; acoustic signal controls

- Fast repetitive tone (- - -): battery message or error message
- Continuous tone (_____): Notification message
- Interval tone (. . .): no power supply
- One short audible alarm every time the button is pressed and released (acoustic alarm check)

Settings

All the settings of the control unit, such as set speed, operating mode or alarm thresholds are entered via the monitor program installed on the operator terminal. Always update any modified settings, both in the active control unit and replacement control unit. The current settings are maintained on a control unit, even if this is separate from the power supply.

Safety plug

All plugs (battery, power supply unit, operator terminal) connected to the control unit are functionally equivalent safety plugs. They cannot be removed from the socket by pulling on the cable. To remove them from the socket, grip them by the ribbed plug sleeve with white marking.

Shutdown - Turning off the control unit

The **Shutdown** function turns off the control unit without an interval tone being emitted. The function can be used

a. following an offset correction during the implantation,
b. following a system stop for medical reasons (e.g. transplantation),
c. following the transfer of the settings from control unit 1 to 2.

➢

1. **Disconnect the control unit from the blood pump, if it is connected, see points a) and b)**
2. Disconnect the power supply unit from the control unit.
3. Disconnect the main battery from the control unit.
4. Acknowledge the alarms (e.g. H 50 - Pump not connected, A 02 - Main battery not connected)
5. Press down the button on the control unit for approx. 10 seconds, until the **SHd** display appears and an acoustic alarm is emitted.
6. Immediately after the acoustic alarm stops, remove the backup battery from the control unit.
7. The display will disappear and the acoustic alarm will go silent.

Heat development

In high ambient temperatures (maximum permitted is 40°C), the control unit's heat sink may heat to temperatures as high as 56°C. At this temperature, up to 10s contact is safe. The remaining plastic housing parts may heat to temperatures as high as 60°C when the device is used in high-temperature environments. Uninterrupted contact is safe for up to one minute.

4.4 INCOR batteries

Each INCOR device has 2 main batteries and 2 backup batteries with identical performance data. The operating time of a new battery is around 3.5 hours, and the charging time is around 2 to 4 hours.

The actual capacity of the batteries is reduced over time due to electrochemical processes that take place in the individual cells. The capacity (operating time) offered by a battery between the charge cycles steadily drops. No compensation can be made for such a loss of capacity (ageing process), hence it does not represent a material defect.

IMPORTANT: The actual operating time of the battery is influenced by the set speed.

Main battery and backup battery

The main battery has the cable to the control unit on the left-hand side (viewed from the front), and the backup battery has the cable on the right-hand side. The main battery is connected on the same side of the control unit as the pump, and the backup battery is connected on the opposite side. A logo above the cable outlet on the control unit indicates where the main battery has to be connected.

The control unit always recognizes that the battery connected on the same side as the driveline is the main battery. Apart from the positioning of the cable outlet, all of the supplied batteries are identical.

1 Main battery
2 Backup battery

Fig. 4-11 Main battery and backup battery

1 Socket for main battery
2 Pictogram: here, main battery

Fig. 4-12 Connection socket for main battery

Battery operation

If the power supply unit is not connected, the main battery first supplies the control unit and pump with power. The normal display is permanent. If the remaining operating time of the main battery is less than 10 minutes, the backup battery automatically begins powering the system while the message **A01 Change main battery** appears at the same time. A new, charged main battery will supply the system with power as soon as it is connected.

Battery operation for:

- implantation/explantation
- transportation of the patient
- personal hygiene
- mobilization
- medical procedures

Charging the battery

The batteries can be charged as follows:

- in the charging unit, see: chapter 4.6: INCOR charging unit, page 39
- on the control unit if this is connected to the mains.

Charging on the control unit: If the charge level is lower than 85 %, the battery is charged. If the main and backup batteries need to be charged, the backup battery is charged first. When charging, the battery LEDs will indicate the charge level. The charging time is six hours per battery on average. The lower the speed of the blood pump, the quicker the charging process.

Charging after delivery

Batteries are delivered fully charged and can be used immediately.

Exception: According to the IATA Dangerous Goods Regulations, batteries must not be fully charged when shipped by air. Fully charge batteries with low charge levels immediately after receiving them.

Checking the charge level from the LEDs (light-emitting diodes)

When the button is pressed, the LEDs indicate the charge level of the batteries. During the charging process, they permanently display the charge level. If the battery is completely charged, the LEDs go out.

Fig. 4-13 View of battery from above

Charge level	Display
> 75%	4 LEDs illuminated
> 50 %	3 LEDs illuminated
> 25 %	2 LEDs illuminated
> 8 %	1 LED illuminated
> 8%	1 LED flashes

Tab. 4-1 LED display depending on charge level

4.5 INCOR power supply unit

INCOR is delivered with 2 identical power supply units. One is used to supply the system with power and is connected directly to the control unit (mains operation). The other is used to supply the charging unit with power. A control LED can be found on the top of the power supply unit. If the output voltage of the power supply unit is correct, the control LED will be green.

Set up the power supply units so that they can be easily disconnected from the mains. This is done by pulling the plug.

Mains operation if:

- the patient is immobile
- when 2 empty batteries are being replaced or if the backup battery is disconnected from the control unit

1 Connector for plug of power supply unit (2-pin)
2 Power supply unit
3 Indicator LED
4 Connector plug for control unit/charging unit

Fig. 4-14 Power supply unit

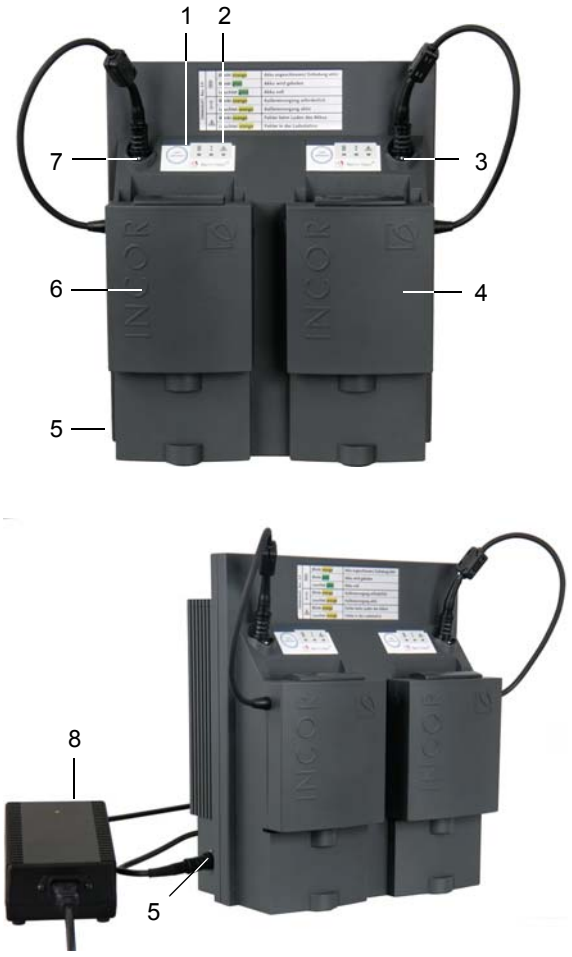
1 Mains plug (shaped plug without protective contact)
2 Cable
3 Plug for power supply unit (2-pin, compliant with IEC60320 C17)

Fig. 4-15 Mains power cable (2-pin)

4.6 INCOR charging unit

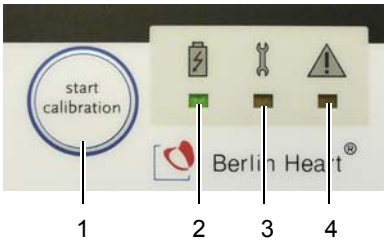
The charging unit is used to charge empty batteries and for calibration, as necessary. The charging unit has 2 identical charging slots, each of which holds one battery. Three LEDs above each charging slot indicate the status of the charging unit and the batteries. Each LED is assigned its own symbol. See Tab. 4-2 , page 40. During the charging process, the battery LEDs indicate the charge level of the battery.

The charging time for an empty battery is around 4 hours, and full calibration takes up to 16 hours. The times depend on whether one or two batteries are in the charging unit.



1 *Start calibration* key
2 LEDs
3 Connection socket for backup battery
4 Backup battery
5 Connection socket for safety plug of the power supply unit
6 Main battery
7 Connection socket for main battery
8 Power supply unit

Fig. 4-16 Charging unit with 2 batteries



1 *Start calibration* key
2 Battery LED
3 Calibration LED
4 Error LED

Fig. 4-17 Detailed view of control panel

Symbol	Description	Color
	Battery	■ / ■
	Calibration	■
	Error	■

Tab. 4-2 LEDs of the charging unit

			**Status**	**Action**
Flashing orange	OFF	OFF	**Battery connected**	Wait
	ON		**Calibrating,** battery discharging	May be interrupted if necessary by removing the battery.
Flashing green	OFF	OFF	**Battery charging**	May be interrupted if necessary by removing the battery.
	Flashing		**Battery charging**, calibration required	Start calibration by pressing*Start calibration* key.
	ON		**Battery charging**, calibrating	May be interrupted if necessary by removing the battery.
Green ON	OFF	OFF	**Battery fully charged**	Battery may be removed.
	Flashing		**Battery fully charged**, calibration required	Start calibration by pressing the *Start Calibration* key.
OFF	OFF	OFF	**No battery connected**	Connect the battery.
		Flashing	**Battery charging error**	See section 11.4, page 167.
		ON	**Charging unit error**	See section 11.4, page 167.

Tab. 4-3 LED displays – status and action

4.7 INCOR Smart Bag

The INCOR Smart Bag is used for safely storing and transporting the control unit and batteries.

Fig. 4-18 INCOR Smart Bag

1 Cover flap with transparent window
2 Inner compartment, removable
3 Pocket for short instructions
4 Zipper
5 Front flap (right)
6 Front flap (left)
7 Waist and shoulder strap, adjustable
8 Padded belt
9 Side opening
10 Press-studs for securing the inner compartment

The cover flap of the INCOR Smart Bag can be opened using the all-round zipper. The bag can also be opened from the front using the two front flaps, enabling quick and easy access to the control unit connectors.

The length of the carrying strap can be adjusted, enabling the INCOR Smart Bag to be carried over the shoulder or on the hip. A removable padded belt provides increased comfort. The carrying strap can be easily and safely opened and closed with the aid of two click fasteners.

4.8 INCOR cable protector set

The INCOR cable protector set is designed to protect the cable.

1 End of cable protector on the kink protection sleeve
2 End of cable protector on the control unit
3 Cable protection

Fig. 4-19 Cable protection - full view

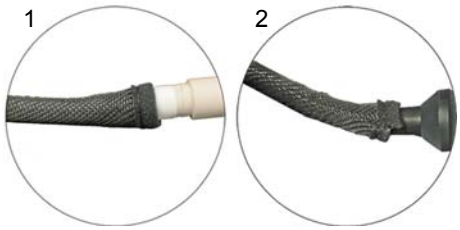


Fig. 4-20 Close-up - ends of cable protector

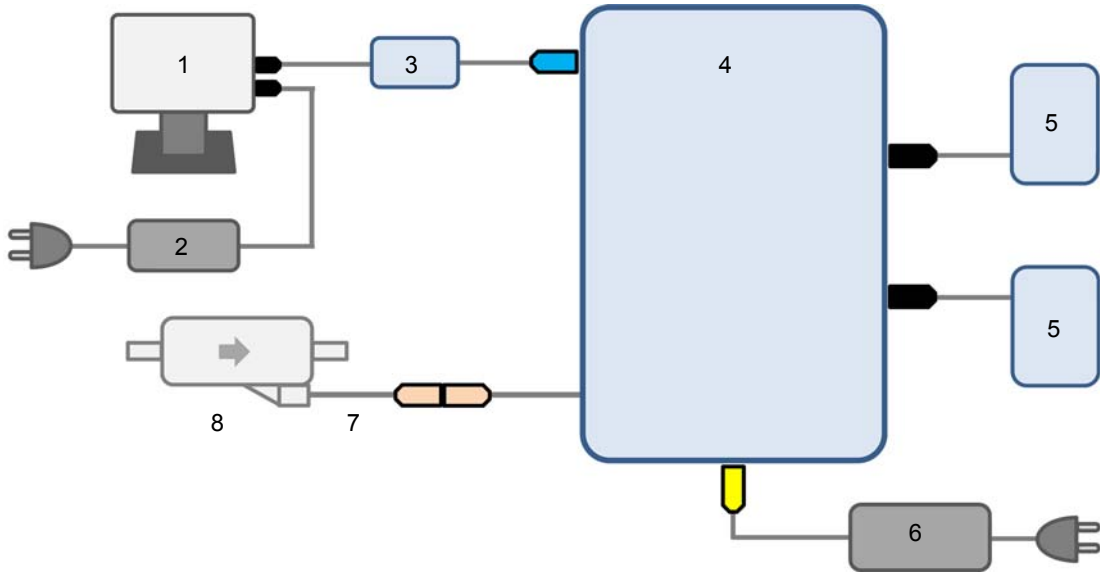
4.9 INCOR Control & Monitoring Station

The INCOR Control & Monitoring Station (shortened hereafter to: operator terminal) has a pre-installed monitor program and used to activate, monitor and configure the pump. The control terminal is used for starting the pump, continuously monitoring the pump during intensive and intermediate care, as well as for routine monitoring during inpatient and outpatient care.

When the operator terminal is connected to the control unit, it provides the user with continuous data about the status and operation of the implanted device as well as detailed information about all events and malfunctions. The data are simultaneously stored on the hard disk for later evaluation. See chapter 6: Using the Operator Terminal, page 63.

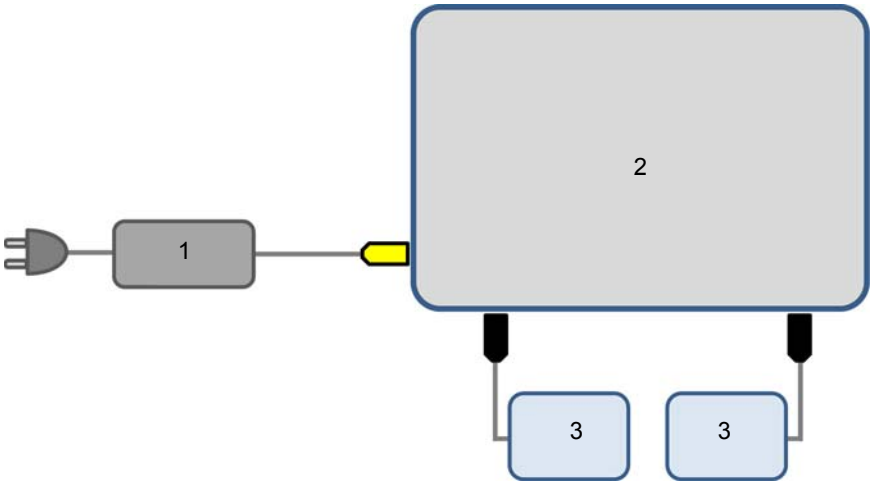
Fig. 4-21 Operator terminal with stand

4.10 Connecting the system components



1 Operator terminal
2 Power supply unit of the operator terminal including mains power cable
3 Communication cable
4 Control unit
5 Battery
6 Power supply unit including mains power cable
7 Driveline
8 Blood pump

Fig. 4-22 Connecting the system components I



1 Power supply unit including mains power cable
2 Charging unit
3 Battery

Fig. 4-23 Connecting the system components II

4.11 Accompanying documents

See table 14-3 page 207

5 Routine Use

This chapter describes the routine handling of INCOR. For specific information on activating the pump: See chapter 7: Implantation, page 95

WARNING

Refer to the conditions of use! See section 2.1: Conditions of use, page 13.

Ensure that both buzzers on the control unit are functioning correctly! Otherwise messages may not be properly recognized.

Ensure that the driveline and plug coupling are intact. Otherwise the pump may need to be replaced.
In particular, avoid any tensile stress, twisting, tight bends or kinks. See Fig. 2-1 , page 17.

NOTICE

Treat all INCOR components with care. Protect the components from knocks, dropping from a great height, etc.! Only transport the operator terminal, power supply unit and charging unit in the designated transport case!

Keep unused sockets closed at all times to prevent the infiltration of dirt!

Protect all the components from extreme temperatures (less than -10°C, more than +40°C), direct sunlight and fluctuations in temperature!

ADVICE

We recommend that patients eligible for outpatient care, as well as their caregivers, be familiarized with such activities at an early stage.

IMPORTANT: immediately replace any external components that are visibly damaged.

5.1 Buzzer checks

1. Press the button on the control unit. An audible alarm sounds each time the button is pressed or released. Each of these alarms is produced by a buzzer. If one of the audible alarms fails, the corresponding buzzer must be faulty. In this case, replace the control unit. See section 11.6.1: Replacing the control unit, page 170

5.2 Connecting the power supply unit to the mains power supply

WARNING

Only connect the power supply unit to sockets with a voltage as specified on the INCOR identification plate! Only connect to sockets that comply with local specifications! Otherwise the power supply unit may fail.

Only use the connection cables, plugs and components supplied with the device! In any other circumstances the smooth operation of INCOR cannot be guaranteed.

1. During use: Connect the power supply unit to the mains. Check the connection: power supply connector plug to power supply unit. If correctly connected, the control LED should be green.
2. After use: Remove the plug.

5.3 Inserting and removing the safety plug

NOTICE

Keep unused sockets closed at all times to prevent the infiltration of dirt!

Inserting the plug into the socket

WARNING

For each plug: check immediately, by pulling gently on the kink protection sleeve, that the plug is firmly positioned in the socket! Otherwise the system may fail.

Ensure that the marks on the plug and socket are aligned. Otherwise the safety plug is not in the correct position. There is a risk of damage to the control unit. The control unit may need to be replaced.

If more force than customary is required, this indicates an operating error. Check the position of the plug!

1. Insert **the plug (2)** into the socket so that the **markings on the plug and the socket (3, 4)** are aligned. Push the plug firmly into the socket as far as it will go.
2. Check the position of the plug by gently pulling on the **kink protection sleeve (1)**. The connector must not detach from the socket. Correct, if necessary.

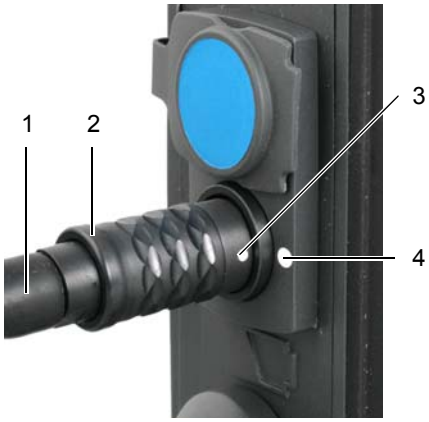


Fig. 5-1 Safety plug, opened

Fig. 5-2 Safety plug, closed

Removing the plug from the socket

1. Grip the front end of the plug and pull it out of the socket.
2. If the safety plug proves difficult to remove: push the plug back in as far as it will go. Then make another attempt to remove the plug.

ADVICE

We recommend practicing this procedure with the patient by pulling the plug of the main battery out of the control unit and plugging it back in again under mains operation and with an alarm-free backup battery.

For information on how to use the plug coupling, See section 7.4.7: Mounting the pump socket ready for connection, page 124 and section 11.6.1: Replacing the control unit, page 170.

5.4 Using the INCOR Smart Bag

NOTICE

Only store INCOR components in the INCOR Smart Bag. Otherwise the components could be damaged.

Do not cover the INCOR Smart Bag with textiles, since this may cause the components to become overheated.

5.4.1 Inner compartment

WARNING

Always suspend the inner compartment by both fastening loops. Otherwise the components could fall out and be damaged. The transcutaneous exit site may be injured as a result.

The inner compartment is secured in the INCOR Smart Bag by three press-studs and a strip of Velcro. The control unit, main battery and backup battery are secured to the inner compartment of the INCOR Smart Bag. The inner compartment can be suspended separately using the two fastening loops.

1 Compartment for backup battery
2 Right fastening loop
3 Pocket for patient ID card
4 Pocket for short instructions
5 Compartment for control unit
6 Left fastening loop
7 Compartment for main battery
8 Press-studs for securing the inner compartment

Fig. 5-3 Inner compartment when empty

1 Main battery
2 Backup battery
3 Fastening loops
4 Control unit

Fig. 5-4 Inner compartment with batteries and control unit

Removing the inner compartment for separate use

1. Open the INCOR Smart Bag from the side by releasing the press studs and Velcro strip on the side of the bag. Release the press studs on the rear of the INCOR Smart Bag and remove the inner compartment.
2. Using the two fastening loops **3** (Fig. 5-4), suspend the inner compartment on a suitable bracket.

Securing the control unit and batteries

1. Attach the control unit **4** (Fig. 5-4) to the inner compartment using the clip on the rear panel.
2. Place the main battery**1** and backup battery**2** (Fig. 5-4) into the appropriate compartment.

Positioning the inner compartment in the INCOR Smart Bag

1. Place the inner compartment in the INCOR Smart Bag and fasten the press studs on the rear of the bag.
2. Feed the driveline through the opening on the side of the bag. Fasten the press studs and Velcro strip on the side of the bag.
3. Close the INCOR Smart Bag.

5.4.2 Carrying strap and click fastener

WARNING

Ensure that the INCOR Smart Bag is always firmly secured to the body when it is being carried. The length of the carrying strap must be adjusted to prevent the INCOR Smart Bag from falling. Otherwise the components could be damaged. The transcutaneous exit site may be injured as a result.

Always close the click fastener correctly: The buckle must click audibly into place. Otherwise the components could fall out and be damaged. The transcutaneous exit site may be injured as a result.

Fig. 5-5 Carrying the INCOR Smart Bag over the shoulder or on the hip

Carrying the INCOR Smart Bag over the shoulder

1. If required: lengthen the carrying strap: See below.
2. Place the INCOR Smart Bag over the shoulder. IMPORTANT: The carrying strap must be worn diagonally across the upper body.
3. If required: readjust the length of the carrying strap. See below.

Carrying the INCOR Smart Bag on the hip

1. If required: shorten the carrying strap: See below.
2. Open the click fastener by pressing on the center of the buckle.
3. Place the carrying strap around the hips.
4. Close the click fastener. IMPORTANT: The buckle must click audibly into place. This is the only way to ensure that it is fastened correctly. See Fig. 5-6 .
5. If required: readjust the length of the carrying strap. See below.

Fig. 5-6 Click fastener open (left) and closed (right)

Adjusting the length of the carrying strap

1. If required: remove the padding by opening the Velcro strip.
2. **To lengthen the carrying strap**: hold the inner ribbon of the carrying strap firmly. Grip the pull strap firmly and pull in the opposite direction until the desired length is reached.
3. **To shorten the carrying strap**: hold the ring with pull strap firmly. Grip the single ribbon of the carrying strap firmly and pull in the opposite direction until the desired length is reached.
4. If necessary, reattach the padding to the carrying strap.

Fig. 5-7 Shortening (left) and lengthening (right) the carrying strap

5.4.3 Securing the control unit and batteries

Replacing the battery

1. To access the battery, release the cover flap by opening the zipper.
2. Open the front flap to access the battery plug on the control unit.
3. Replace the battery. See section 5.6: Changing a battery, page 53. Close the cover flap and front flap.

5.5 Switching between battery and mains operation

WARNING

Only connect the power supply unit to sockets with a voltage as specified on the INCOR identification plate! Only connect to sockets that comply with local specifications! Otherwise the power supply unit may fail.

Only use the connection cables, plugs and components supplied with the device! In any other circumstances the smooth operation of INCOR cannot be guaranteed.

Ensure that – even during mains operation – one intact, alarm-free main battery and backup battery are always connected to the control unit! Otherwise a power failure may cause the pump to stop.
Only when changing the batteries, restarting and replacing the control unit is one or no battery connected.

NOTICE

Do not place any objects on the power supply unit!

Switching from battery operation to mains operation

1. Connect the power supply unit to the mains power supply The control LED should turn green.
2. Open the power supply unit socket of the control unit (with yellow protective cap) and connect the power supply unit to the control unit. See Fig. 4-9 , page 33. This is acknowledged by a short audible alarm on the control unit. The normal display flashes: Mains operation. The LEDs of a battery may be illuminated: the battery is charging. If the operator terminal is connected to the control unit, notification of mains operation appears in the monitor program.
3. After use: Disconnect the power supply unit from the mains.

Switching from mains operation to battery operation

1. Ensure that the main and backup batteries are sufficiently charged: the battery LEDs indicate the charge level at the touch of the button. Change the batteries if necessary.
2. Disconnect the power supply unit from the control unit. This is acknowledged by a short audible alarm on the control unit. The normal display is permanently visible: battery operation.
3. Close the socket of the power supply unit with the yellow protective cap.
4. Disconnect the power supply unit from the mains.

5.6 Changing a battery

WARNING

Always ensure that the power supply to the control unit is sufficient! Never disconnect both batteries from the control unit simultaneously! Recharge any discharged batteries immediately! Otherwise the pump may stop!

Always replace the backup battery under mains operation! Otherwise the pump may stop.
If the backup battery is empty, the main battery will also be empty!

Precautions

- Immediately after removing a discharged battery: connect a fully charged battery!
- Recharge any discharged batteries immediately!
- If the patient is forced to rely on battery operation for a prolonged period: Allow for an operating time of one hour as a safety reserve. If necessary, change the batteries or carry an additional battery.

A battery needs to be replaced if the message **A01 Change main battery** or **A11 Change backup battery** appears.

Changing the main battery

IMPORTANT: When powering the system with the backup battery, replace the empty main battery as quickly as possible!

1. Locate a new battery and check that it is fully charged: When pressing the button on the battery, all 4 battery LEDs must light up.
2. Disconnect the main battery from the control unit. This is acknowledged by an interval tone on the control unit. Message **A02 Main battery not connected** appears.
3. Connect the main battery, fully charged, to the control unit. This is acknowledged by a short audible alarm on the control unit. Message **A02** is extinguished.
4. Check the position of the plug by gently pulling on the kink protection sleeve. See 5.3, page 46. The connector must not detach from the socket. Correct, if necessary.
5. Recharge the empty main battery in the charging unit.

Changing the backup battery

1. Operate INCOR from the mains. To do so, connect the power supply unit to the mains power supply, and connect the power supply unit to the control unit.
2. Locate a new backup battery and check that it is fully charged: All 4 battery LEDs must light up when the button on the battery is pressed.
3. Disconnect the empty backup battery from the control unit. This is acknowledged by an interval tone on the control unit. Message **A12 Backup battery not connected** appears.
4. Connect the fully charged backup battery to the control unit. This is acknowledged by a short audible alarm on the control unit. Message **A12** is extinguished.
5. Check the position of the plug by gently pulling on the kink protection sleeve. See 5.3, page 46. The connector must not detach from the socket. Correct, if necessary.
6. Recharge the empty backup battery in the charging unit.
7. If both batteries are empty, Repeat the procedure with the second battery

When connecting a battery to the control unit, it takes a few minutes until a reliable value for the remaining operating time is displayed.

5.7 Charging and calibrating a battery

NOTICE
Operate and store the charging unit in a stable, level position!
Operate and store the charging unit in a dust-free environment!
Only operate the charging unit in an upright position (as positioned when in use)!
Do not place or deposit any objects on the charging unit! In particular, do not stand any liquid containers on the charging unit!

5.7.1 Charging a battery in the charging unit

1. Connect the power supply unit to the charging unit.
2. Connect the power supply unit to the mains. The charging unit will perform a self-test: the LEDs are briefly illuminated. The fan briefly switches on and then off.
3. Insert the empty battery into the free charging slot of the charging unit in an upright position. The guide rails of the charging unit engage with the grooves on the rear of the battery. Push the battery down until it sits on the base of the charging slot.

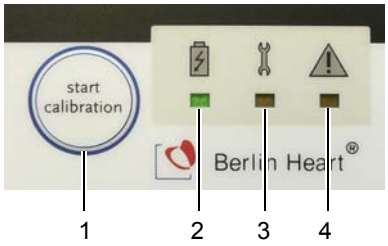


Fig. 5-8 Control panel of charging unit: charging

4. Insert the battery plug into the socket above the charging slot. Ensure that the white markings on the plug and socket are perfectly aligned. After about one minute, the battery LEDs will indicate the charge level of the battery. The **battery LED (2)** of the charging unit flashes green. The battery is charging.
5. The **calibration LED (3)** of the charging unit may flash orange: the battery must be calibrated. See section 5.7.2, page 55.
6. Once the battery is fully charged, the **battery LED (2)** remains green. Pull the battery plug out of the socket of the charging unit.
7. Switch off the charging unit by removing the plug from the mains power supply.

If the battery LED flashes green: the battery is charging. If the battery LED is permanently green: the battery is fully charged. See table 4-2, “LEDs of the charging unit,” page 40.

The charging time depends on the charge level of the battery and can take 2 to 4 hours.

If a fully charged battery is inserted into the charging unit, the battery LEDs will not display the charge level automatically. When pressing the button on the battery, all 4 battery LEDs light up.

5.7.2 Calibrating a battery in the charging unit

A battery should be calibrated as soon as possible if

- the control unit displays the message **HA04** or **HA14**.
- the calibration LED of the charging unit flashes.

The calibration process ensures optimal charging of the battery and takes a maximum of 16 hours per battery. The process may be interrupted at any time by removing the battery.

1. If the battery is not yet positioned in the charging unit: perform steps 1 to 4 as described in section 5.7.1: Charging a battery in the charging unit, page 55.
2. Press the **Start Calibration (1)** key. The **battery LED (2)** will flash green, and the **calibration LED (3)** will turn orange. The battery is calibrating.

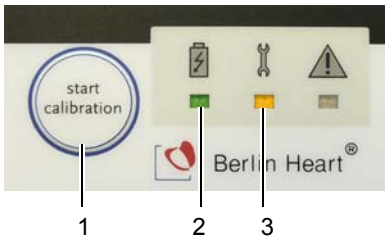


Fig. 5-9 Control panel of charging unit: calibration

3. Once the battery is fully calibrated, the **battery LED** is green and the **calibration LED** is extinguished. Pull the battery plug out of the socket of the charging unit. If the **battery LED** is permanently green and the **calibration LED** flashes orange, further calibration is necessary. See below.
4. Switch off the charging unit by disconnecting the mains plug from the mains power supply.

See table 4-2, “LEDs of the charging unit,” page 40.

ADVICE

If two batteries need to be calibrated, we recommend calibrating one battery after the other using only one charging slot. In this way the second charging slot remains available for standard battery charging.

If further calibration is required

1. **Either**: Press the *Start Calibration* key to immediately start the second calibration. After the end of the second calibration, separate the charging unit from the mains power supply. **Or**: Remove the battery and separate the charging unit from the mains power supply in order to perform the second calibration at a later time. Then proceed with steps 1 to 4 as described above.

5.8 Exercise particular caution when …

5.8.1 ... the patient washes or takes a shower

WARNING

Before the patient washes or showers, disconnect the power supply unit from the control unit (switch to battery operation)! Otherwise there is a risk of electric shock or failure of the system.

CAUTION

Safeguard the applied cable protector against moisture!

Precautions

- Ensure that the sockets of the power supply unit and the operator terminal socket of the control unit are closed.
- The control unit and batteries are splash-proof. Nevertheless, avoid splashing with water of any kind.
- Wrap the components or control unit and batteries for showering in watertight packaging (plastic bag), but not for longer than approx. 20 minutes (heat accumulation).
- When showering, position the packaged bag with the components and/or the control unit and batteries so that the cable sags. This will encourage any water to drip off the cable.
- Dry all the components (control unit, batteries, plug coupling) thoroughly after showering!

5.8.2 ... the patient is sleeping

➢

1. If possible, connect the operator terminal to the control unit for data recording.

Precautions

- Switch the system to mains operation.
- Suspend the bag containing the batteries and the control unit on a suitable bracket on or beside the bed.
- Ensure that the control unit, batteries and power supply unit are not covered by any blankets. This helps to prevent the system from overheating.

5.8.3 ... the patient must rely on battery operation for a prolonged period

Precautions

- The patient must keep the replacement control unit with him.
- Check the charge level by pressing the button on the batteries. Allow for an operating time of one hour as a safety reserve. Change the batteries if necessary. If necessary, carry a further power source (fully charged battery or power supply unit).
- At regular intervals: check the charge level of the batteries.

IMPORTANT: If the planned duration of battery operation exceeds the remaining operating time of the main battery: carry a further power source (fully charged battery or power supply unit) in addition to the backup battery.

5.9 Using the INCOR cable protector set

⚠ WARNING

Replace the cable protector (at the clinic) after 6 months. When doing so, check the driveline, control unit cable and plug guard: the cables must not be twisted and the markings on the plug coupling must be aligned. Otherwise the system may fail.

⚠ CAUTION

Safeguard the cable protector against moisture.

5.9.1 Attaching the cable protector

1. Attach the cable protector. See Fig. 5-10 , page 58 to Fig. 5-12 , page 58.
2. Use adhesive tape to affix the cable protector to the kink protection sleeve of the cable.

Fig. 5-10 Cable protector on the kink protection sleeve

3. Wind the adhesive tape in circles around the cable protector and kink protection sleeve. IMPORTANT: Do not adhere the tape to the cable!

Fig. 5-11 Attaching the cable protector

Fig. 5-12 Close-up - cable protector in place

5.9.2 Cleaning the cable protector

ADVICE

The cable protector can be washed by hand in lukewarm water. Remove the cable protector from the driveline to do this. Let it dry thoroughly before attaching it again.

IMPORTANT: During wound care: disinfect the exposed cable and cable protector at least once a week.

1. Peel back the cable protector from the cable at the pump end as far as the fixation point, or remove it (Fig. 5-14). To do so, loosen the fixation material and remove any residual adhesive.

Fig. 5-13

Fig. 5-14

2. Spray the cable with disinfectant until it is moistened completely.

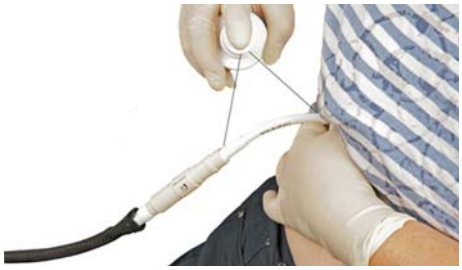


Fig. 5-15

3. Clean and dry the cable with a soft cloth.

Fig. 5-16

4. Spray the inner surface of the cable protector with disinfectant until it is moistened completely.
5. Clean and dry the cable protector with a soft cloth.

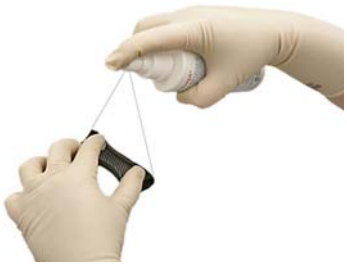


Fig. 5-17

6. Attach the disinfected cable protector to the disinfected cable. See section 5.9.1: Attaching the cable protector, page 58.

Fig. 5-18

5.10 Cleaning the components

WARNING

Always ensure that the power supply unit, charging unit, and operator terminal are kept dry. Never clean any of these components with a damp cloth. Otherwise there is a risk of electric shock or failure of the power supply unit, charging unit and operator terminal.

Do not clean the INCOR device with pointed or sharp-edged objects (needles, etc.)! Otherwise there is a risk of electric shock or failure of the system.

NOTICE

Do not use acetone or mineral oil products in the immediate vicinity of the transcutaneous exit site and driveline. Do not use corrosive agents or solutions containing dyes for cleaning purposes, since they may affect the surface of the product.
Clean the **transcutaneous exit site** with disinfectant.
Clean the **driveline** with water, alcohol (e.g. a 70 % solution) or disinfectant.
Disinfectant, see list of materials section 8.3: Wound Care and Dressing Changes, page 136

Cautionary measure

The control unit and batteries are splash-proof. Nevertheless, avoid splashing with water of any nature.

Overview of cleaning and disinfection

Components	Frequency	How
Driveline	during wound care	water, alcohol (e.g. 70 % solution), disinfectant chapter 8.3: Wound Care and Dressing Changes, page 136
Control unit cable	as required, at least once a week	dry, soft, lint-free cloth wiping disinfection with an alcohol-based solution is possible.
Cable protection	during wound care, at least once a week	chapter 5.9.2: Cleaning the cable protector, page 58
Control unit and batteries	as required1	dry, soft, lint-free cloth wiping disinfection with an alcohol-based solution is possible.
Smart Bag	as required1	empty the Smart Bag, clean with water and a brush, let the Smart Bag dry completely before use

Tab. 5-1 Cleaning and disinfection

Components	Frequency	How
All other components (power supply unit, cable, operator terminal, charging unit)	as required1	dry, soft, lint-free cloth
1 in the event of visible contamination such as dust, stains, drips, deposits		

Tab. 5-1 Cleaning and disinfection

6 Using the Operator Terminal

This chapter explains how to operate the operator terminal and monitor program. For specific information on activating the pump: See chapter 7: Implantation, page 95

WARNING

Do not install any other software on the operator terminal! Use another computer with Internet access for data transfer. Otherwise the operator terminal may fail to function correctly.

Only use the supplied communication cable with integrated insulation barrier for transferring data between the control unit and operator terminal! Otherwise there is a risk of electric shock.

The operator terminal is required if the settings of the INCOR pump are to be changed. A proper understanding and command of the steps required to commission and use the operator terminal is necessary.

NOTICE

Operate and store the operator terminal in a stable, level position!

Operate and store the operator terminal in a dust-free environment!

Only use the operator terminal when positioned on its stand (as positioned when in use)!

Do not place or deposit any objects on the operator terminal! In particular, do not place any liquid containers on the operator terminal!

Precautions

- Only use the operator terminal belonging to the system for each control unit (active control unit and replacement control unit)!
- Always end the monitor program in order to shut down the operator terminal!
- When removing from the operator terminal: log off from the monitor program.

IMPORTANT: Never base therapeutic decisions solely on the values displayed. Always check the displayed values (pressure, flow and speed) for plausibility, both against each other and with respect to the overall condition of the patient.

6.1 Overview of operator terminal

1 On/off switch
2 Battery LED
3 USB port, top (for USB stick)
4 USB port, bottom (marked blue for communication cable)
5 Connection for power supply unit

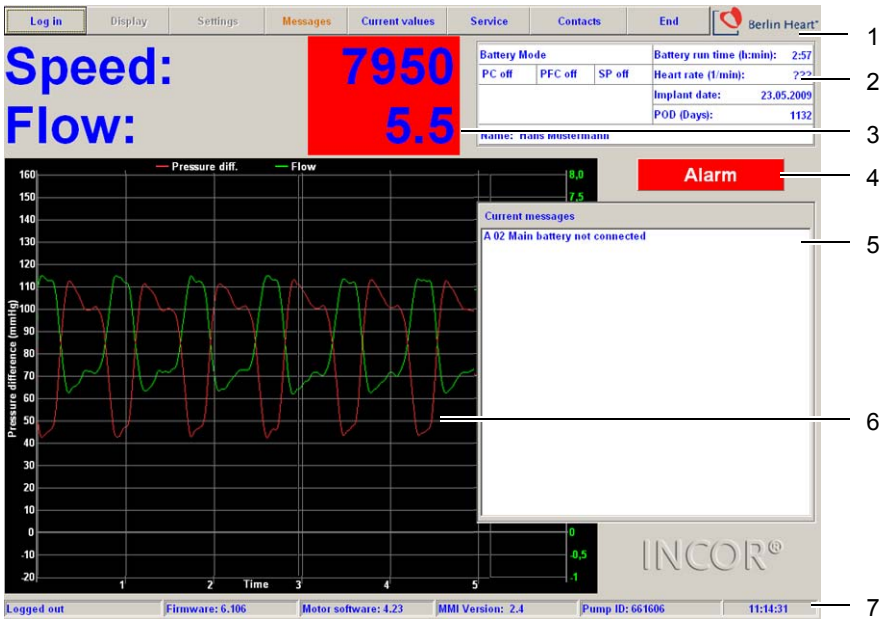
Fig. 6-1 Overview of operator terminal

Battery LED

Mains operation		Battery operation	
100 %	1 % - 99 %	100 % - 11 %	10 % - 1 %
			 flashing

Tab. 6-1 Battery LED

6.2 Overview of monitor program



1 Menu bar.

2 Display screen: mains operation/battery operation, remaining operating time of main battery, heart rate, implantation date, number of postoperative days (POD), patient name, status of PC, PFC, SP.

3 Speed and flow.

4 Alarm display: visible if there is a battery message or error message.

5 Current messages: the window appears if there is a battery message or error message.

6 Curve diagram: depending on the selection, shows the curves for pressure difference, flow and diastolic level (primary diagram) as well as speed (secondary diagram).

7 Status bar: contains the following information (left to right): log-in status, version number of firmware, motor software and interface software, pump ID, time.

Fig. 6-2 Overview of monitor program

6.2.1 Functions of the monitor program

- Pump activation
- Adjustment of settings
  - Operating mode
  - Speed
  - Alarm threshold pressure difference
  - PC, PFC, SP
- System monitoring (measurements, messages)
- Transferring data from the active control unit to the replacement control unit

6.2.2 Users and passwords

The monitor program contains different user profiles with different authorizations.

User not logged in

Users who are not logged in can view messages and end the monitor program. They also have other, restricted authorizations (see corresponding menu).

User – Incor and user profiles

Users log in with their unique usernames and passwords defined by the administrator. Alternatively, **Incor** can be entered as the user, The name and password of this user cannot be changed.

The user can make use of all the features of the monitor program. Exceptions: **Offset rotor position**, **Manage user profile**, **Manage contacts** as well as setting the parameters for **PC**, **PFC** and **SP**. If, after 10 minutes, no changes have been made to the settings and no data have been transferred between the operator terminal and control unit, the user is automatically logged out of the monitor program.

Up to 6 user profiles can be created in the monitor program. Each user can change his own password. See section 6.9.6: Submenu item: Manage user profile, page 89.

Engineer – tech

The engineer (**tech**) can make use of all the features of the monitor program. Exceptions: managing user profiles and hospital contacts. If, after 10 minutes, no changes have been made to the settings and no data have been transferred between the operator terminal and control unit, the user is automatically logged out of the monitor program.

If the engineer is logged in, the secondary messages corresponding to the message codes (such as: **A01**) are displayed (depending on the message: Irrespective of such a scenario, proceed with such messages as described for the relevant message codes. See chapter 10: Messages and Measures, page 145.

OR user – OR

This user profile should be used during implantation and explantation. The OR user can make use of all the features of the monitor program. Exceptions: **Manage user profile**, **contacts**. If no entry is made for 6 hours, the user is automatically logged out of the monitor program.

The password of the OR user cannot be changed.

Administrator – admin

The administrator (**admin**) can make use of all the features of the monitor program. Exceptions: **Offset rotor position** as well a setting the parameters for **PC**, **PFC** and **SP**. The administrator can manage the user profiles and contacts. See section 6.9.6: Submenu item: Manage user profile, page 89 or section 6.10: Menu item: Contacts, page 94. If no entry is made for 10 minutes, the user is automatically logged out of the monitor program.

The password of the administrator cannot be changed.

Password envelope

The name and password for logging in as a user, engineer, OR user and administrator can be found in the password envelope included with the OR accompanying documentation.

ADVICE We recommend keeping the password envelope in a safe place.

6.2.3 Entering information in the monitor program

- **Selecting menu items/dialog boxes**: select and activate the desired item on the touch screen of the operator terminal using a finger or stylus.
- **Alphanumerical entries**: using the displayed alphanumerical keyboard
- **Adjust the parameter values**: using the virtual numerical keyboard or virtual arrow keys (**<↑>** / **<↓>**) or page up/down keys (**<Pg↑>** / **<Pg↓>**)

The numerical keypad and alphanumerical keyboard automatically appear when a dialog box is opened, into which an appropriate entry must be made.

Fig. 6-3 Alphanumerical keyboard

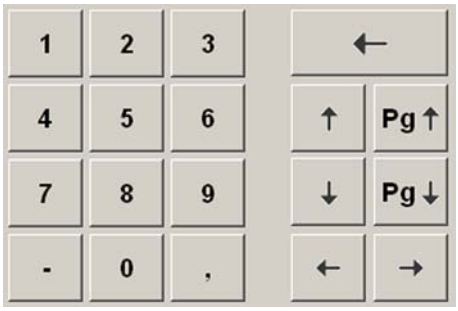


Fig. 6-4 Numerical keypad

Some inputs (e.g., log off, settings ...) require additional confirmation. If **Cancel** is selected instead of **Apply**, the dialog box is closed. The entry is not applied.

While a submenu or dialog box is open, a second submenu cannot be opened. The corresponding keyboard also remains open while a submenu or dialog box is open.

6.3 Switching the operator terminal on/off: starting/ending the monitor program

WARNING

Ensure that the plug and socket markings are aligned. Otherwise the safety plug is not in the correct position. There is a risk of damage to the control unit. The control unit may need to be replaced.

For each plug: check immediately, by pulling gently on the kink protection sleeve, that the plug is firmly positioned in the socket! Otherwise the system may fail.

Switching the operator terminal on: starting the monitor program

1. Connect the operator terminal to the mains using the power supply unit.
2. Take hold of the control unit. Remove the **blue protective cap (1)** from the socket.
3. Insert the **safety plug (4)** of the **communication cable (3)** with the blue ring into the designated socket of the control unit with a **blue protective cap (1)**.
4. Insert the plug (4) into the socket so that the markings on the plug and the socket (3,4) are aligned. Push the plug firmly into the socket as far as it will go.
   IMPORTANT: If more force than customary is required, this indicates an operating error. Check the position of the plug!
5. Check the position of the plug by gently pulling on the **kink protection sleeve**. The connector must not detach from the socket. Correct, if necessary.

Fig. 6-5 Control unit with operator terminal socket, communication cable

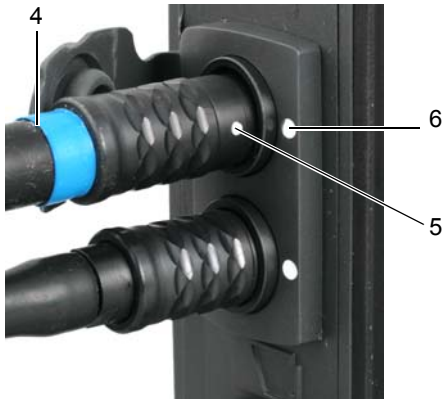


Fig. 6-6 Safety plug in socket

6. Insert the **USB plug of the communication cable** (2 in Fig. 6-5 , page 67) into the lower USB port of the operator terminal. The USB port for the communication cable is marked blue; see Fig. 6-7 .

Fig. 6-7 USB symbol on operator terminal and communication cable

7. Switch the operator terminal on at the on/off switch to access the start-up screen of the monitor program.

On start-up, the monitor program queries all of the settings (set values) of the control unit. Subsequently, the control unit only transfers the actual values to the monitor program.

Switching the operator terminal off: ending the monitor program

1. Select **End**.
2. Confirm the **End program?** query. The monitor program ends and the operator terminal switches itself off.

6.4 Menu item: log in/out

Logging in

1. Select **Log in** from the menu. The log-in screen appears. A window appears with pre-programmed users.
2. Log-in
   - **Pre-programmed user**: select name from the selection window and enter password.
   - **User with personal profile**: enter name and password.

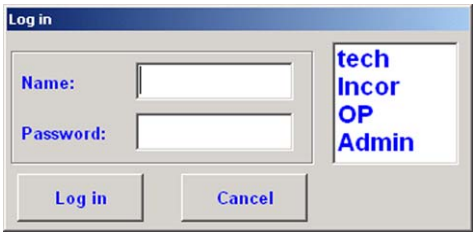


Fig. 6-8 Log-in dialog box

3. Select **Log in**. Log in has been successful if the name of the logged-in user is displayed in the status bar. Instead of **Log in**, **Log out** now appears in the menu.
   If **Cancel** is selected in the log-in screen instead of **Apply**, the dialog box closes. No user is logged in (menu item **Log in** is visible).

All of the entries made by a user who is logged in are recorded by name.

If no entry is made for 10 minutes, the user is automatically logged out of the monitor program. Exception: when logging in as an OR user, automatic log-off occurs after 6 hours if no entries have been made.

Menu items appearing in light gray cannot be selected with the current log-in status.

Logging out

1. Select **Log out** from the menu, and confirm or dismiss the query **Do you really want to log out?** Log out has been successful if **Logged out** appears on the left of the status bar.

6.5 Menu item: Display

This menu item is only accessible to users who are logged in.

The display dialog is accessed by selecting **Display** from the menu. In the display dialog, the user can select which curves are displayed in the primary diagram and whether a secondary diagram should be displayed. The curve display can also be frozen (**Stop display**) and reactivated (**Start display**) in the display dialog.

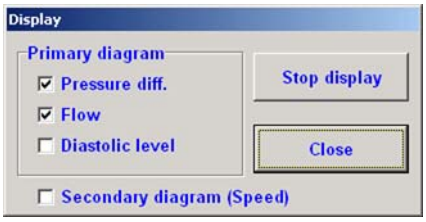


Fig. 6-9 Display dialog, main window with primary and secondary diagram

Pressure difference (primary diagram)

The pressure difference (Δ P) is the difference between the pressure before the pump (P_{input}) and the pressure after the pump (P_{output}).

The pressure P_{input} is the pressure with which the blood from the left ventricle reaches the inflow cannula. This depends, among other things, on residual cardiac contractility. The stronger the contractions of the heart, the greater the fluctuation in pressure before the pump.

Pressure P_{output} is determined by the pump speed and systemic resistance.

The pressure difference results from the calculation $\Delta P = P_{output} - P_{input}$.

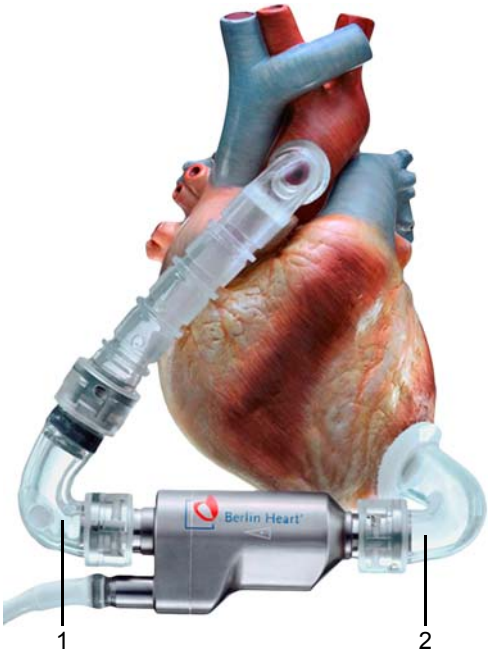
The lower the pressure of the blood on entering the inflow cannula, the greater the pressure difference displayed in the curve. This means that the pressure difference is

- higher during diastole than during systole.
- pulsing if there is sufficient volume in the ventricle.

A low amplitude in the pressure difference curve may be caused by:

- insufficient volume
- tamponade
- restricted right heart function

The *pressure difference* curve indicates that the pump is pumping blood. If the volume supplied is too low or there are cross-sectional changes at the impeller, the *pressure difference* value may drop. The **Alarm threshold pressure difference** describes the value below which the message **E22 Pressure difference too low** is triggered. See section 10.20: E22 Pressure difference too low, page 156.



1 P_{output}
2 P_{input}

Fig. 6-10 $\Delta P = P_{output} - P_{input}$

Flow (primary diagram)

Discharge rate of the blood flowing through the pump in L/min.

Diastolic level (primary diagram)

Mean level of the diastolic plateau over several cycles

Speed (secondary diagram)

Actual speed in rpm.

The time in seconds is displayed on the x-axis of the primary and secondary diagrams. Depending on the setting, one graduation line corresponds to one second or half a second.

6.6 Menu item: Settings

WARNING

Immediately update any modified settings in the replacement control unit! Always keep the replacement control unit, programmed with patient data and the latest settings, within reach of the patient! Otherwise the patient will not be adequately supported after replacing the control unit.
Exception: settings which are selected during implantation should be transferred only during post-implantation care.

By selecting **Settings** from the menu, a submenu with individual modifiable settings and operating parameters will appear.

This menu item is only accessible to users who are logged in.

Fig. 6-11 Settings submenu

6.6.1 Operating mode

Halt mode

The halt mode stops the blood pump. It is preset at the time of delivery. Halt mode can be selected from constant mode for the purposes of intraoperative corrective measures. Message **H26 Halt mode** then appears.

Constant mode

Constant mode is used for routine pump operation. The first time the pump is operated in constant mode, it works at 5000 rpm. The speed can then be adjusted. When activating constant mode thereafter, the pump will operate at the previously set speed.

Changing the operating mode

1. Select **Settings** from the menu, then **Operating mode** from the submenu. The operating mode dialog will appear.
2. Select the desired operating mode, then confirm the selection in the dialog. INCOR will now work in the selected operating mode.

6.6.2 Set speed or maximum speed

This setting is used to determine the set speed of the impeller in constant mode.

When pulsatility control is activated, the entered speed represents only the maximum speed up to which the pump accelerates if the supplied volume is sufficient. The following therefore applies:

- **Pulsatility control inactive**: the entered speed is displayed as the **Set speed**.
- **Pulsatility control active**: the entered speed is displayed as the **Max. speed**.

The speed entered in each case is adopted if pulsatility control is activated or deactivated.

Adjusting the set speed/max. speed

1. Select **Settings** from the menu, then **Set speed** or **Max. speed** from the submenu, or click on the large speed display. The set speed dialog appears.
2. Change the value by direct numeric input or by using the arrow keys (**<↑>** / **<↓>**: ±50) or page up/down keys (**<Pg↑>** / **<Pg↓>**: ±500).
3. Confirm the entry in the dialog.
4. Confirm the security check with **<o>**. INCOR will now function at the specified speed.
5. Check that the desired value is displayed. To do this, first close the **Settings** submenu, then select **Current values** from the menu. See section 6.8: Menu item: Current values, page 82.

6.6.3 Pulsatility control (PC)

Pulsatility control (PC) helps to prevent myocardial suction. Suction phenomena occur if the selected speed is too high for the supplied volume in the ventricle and there is a threat of ventricular collapse.

When PC is activated, INCOR monitors the progress of the pressure difference across several cycles, calculating the mean pressure difference value and then the mean deviation from the mean value of the pressure difference. This value is displayed as the actual degree of pulsatility. See Fig. 6-13 , page 73.

Assuming residual cardiac contractility, a high degree of pulsatility indicates an adequate volume supply and low risk of myocardial suction, whereas a low degree of pulsatility indicates a low volume status. If the degree of pulsatility falls below a specified level, INCOR reduces the speed. If the degree of pulsatility rises again, the speed is also increased until the selected maximum speed is restored.

PC is deactivated as a default setting.

If PC is activated, the **Max. speed** is derived from the selected **Set speed**.

PC only comes into effect if the pressure difference exceeds 30 mm Hg at all times.

The PC is no protection against acute myocardial suction.

PC, PFC, and SP can all be activated simultaneously.

WARNING

Insufficient filling of the left ventricle may be an indication of right ventricular dysfunction! In this case, only activate pulsatility control if taking appropriate medical action at the same time.

Do not activate PC in the presence of severe cardiac dysrhythmias! Otherwise the patient may not receive adequate support.

If the residual myocardial activity is insufficient, pulsatility control may reduce the speed permanently until the minimum speed (5000 rpm) is reached and a low mean flow is achieved. Therefore, always check the **Alarm threshold flow** setting when activating pulsatility control. The alarm threshold flow should be 50% of the flow achieved, but must be adjusted on an individual basis.

ADVICE

We recommend activating PC as soon as the patient is hemodynamically stable, does not require medication to stabilize his circulation, and exhibits good pulsatility. In such a case it is essential to observe the safety information!

We recommend deactivating PC, PFC, and SP prior to further surgical procedures.

Display

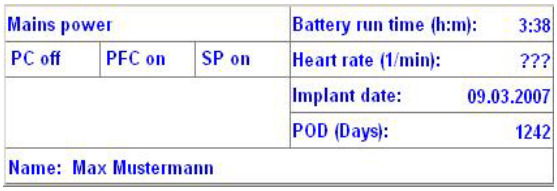


Fig. 6-12 Display: PC, PFC, SP on/off

PC OFF	PC is deactivated
PC ON	PC is activated
∇	The triangle appears when the speed begins to drop and persists until the selected maximum speed has been restored.

Tab. 6-2 Explanation of display: PC on/off

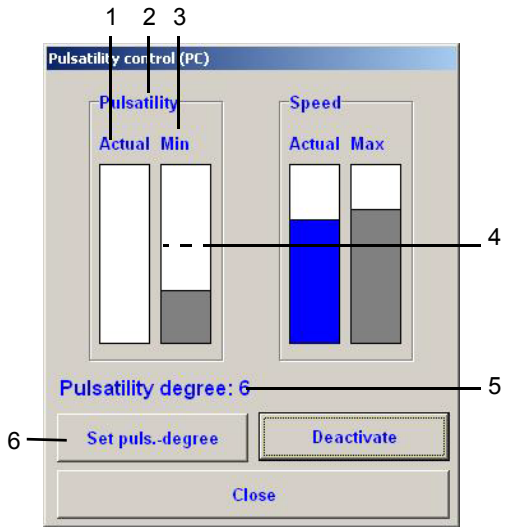


Fig. 6-13 Pulsatility control

1 Bar chart: set degree of pulsatility; bar extends from 0 to 20
2 window: degree of pulsatility
3 Bar chart: minimum degree of pulsatility; bar indicates 0 to 10 depending on the setting
4 At a minimum degree of pulsatility of 10 (maximum possible value), the bar fills up to half of the window
5 Selected minimum degree of pulsatility
6 The minimum degree of pulsatility can be adjusted here

Activating and deactivating pulsatility control

1. Select **Settings** from the menu, then **Pulsatility control** from the submenu. The pulsatility control dialog appears.
2. Select **Activate** or **Deactivate**.
3. Confirm the entry in the dialog. Pulsatility control is activated or deactivated.
4. Next: set the minimum degree of pulsatility (see below).

Determining and configuring the minimum degree of pulsatility

This feature is only available to users who are logged in.

The degree of pulsatility is a measure of pulsatility of the pressure difference via the INCOR pump and indicates the filled level of the heart. The degree of pulsatility corresponds to the mean deviation from the mean value of the pressure difference. PC is used to ensure that the speed is reduced when a selectable minimum degree of pulsatility is not reached.

The degree of pulsatility must be selected while accounting for the residual contractility of the heart:

- The greater the contractility and aortic pressure, the higher the actual degree of pulsatility and consequently the higher the minimum degree of pulsatility that can be selected.
- The lower the mimimum degree of pulsatility is set, the later the onset of pulsatility control and the shorter the distance to myocardial suction.
- If the minimum degree of pulsatility is set too high, pulsatility control will be triggered unintentionally. If the actual degree of pulsatility is permanently below the minimum degree of pulsatility, INCOR will operate constantly at the lowest possible speed (5000 rpm).
- Experience with INCOR has shown that a minimum degree of pulsatility of 5 is sufficiently low for most patients without resulting in unwanted pulsatility control, but still protecting them from myocardial suction.

1. In the pulsatility control dialog: select the option **Set puls.-degree**.
2. Change the desired value by direct numeric input or using the arrow keys (**<↑>** / **<↓>**: ±1).
3. Confirm the entry in the dialog.
4. Confirm the security check with **<o>**. The degree of pulsatility is now set.

6.6.4 Periodic flow change (PFC)

Periodic flow change (PFC) permits the speed to be reduced at specified time intervals. This reduction in speed leads to a brief drop in the flow of the INCOR pump. This is compensated by an increase in ventricular output, causing the aortic valve to open. In addition, blood flows back through the pump towards the left ventricle, flushing the pump and ventricle. After reduction, the set speed is restored.

PFC is deactivated as a default setting.

PC, PFC, and SP can all be activated simultaneously.

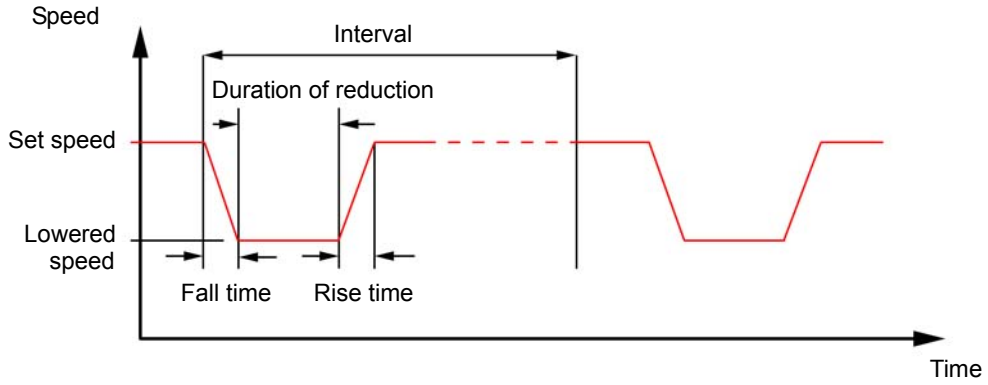


Fig. 6-14 Operating principle PFC

WARNING

PFC must be deactivated if it is causing negative hemodynamic effects or a relevant, transient drop in blood pressure. If not, congestion may result or support may prove to be inadequate. The following information must be heeded to ensure that PFC is applied correctly.

ADVICE

We recommend activating PFC within 24 h following implantation.

We recommend that the preset values be maintained. See Fig. 6-18 , page 76.

We recommend deactivating PC, PFC, and SP prior to further surgical procedures.

Display

Mains power			Battery run time (h:m):	3:38
PC off	PFC on	SP on	Heart rate (1/min):	???
			Implant date:	09.03.2007
			POD (Days):	1242
Name: Max Mustermann				

Fig. 6-15 Display: PC, PFC, SP on/off

PFC OFF	PFC is deactivated
PFC ON	PFC is activated

Tab. 6-3 Explanation of display: PFC on/off

Activating and deactivating PFC

1. Select **Settings** from the menu.
2. Select **Periodic flow change (PFC)** from the submenu. The dialog box **Periodic flow change (PFC)** opens.

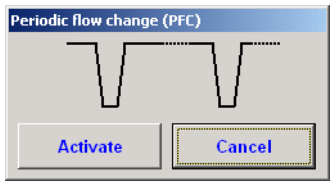


Fig. 6-16 Dialog: activating PFC

3. Select **Activate** or **Deactivate**.
4. Confirm the security check with **<o>**. PFC is activated or deactivated.

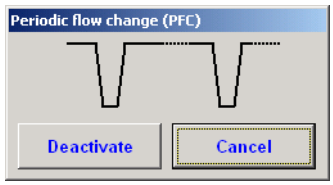


Fig. 6-17 Dialog: deactivating PFC

Setting parameters

INCOR is delivered with default settings for PC, PFC and SP as recommended by the manufacturer. See Fig. 6-18 , page 76. If necessary, these parameters can be modified. In this case, please call the emergency hotline.

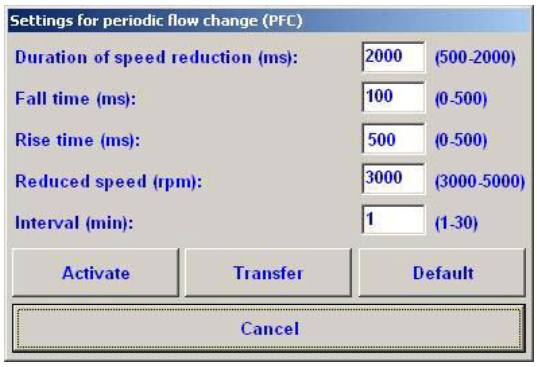


Fig. 6-18 Default settings PFC

HOTLINE **Contact the emergency hotline! +49 (0)30 81 87 27 72**

6.6.5 Suction protection (SP)

Suction protection (SP) is used to identify and immediately respond to any myocardial suction on the inflow cannula. When SP is activated, INCOR will register the fact that the pressure difference is exceeding a certain limit (**Pressure threshold** in the **Suction protection settings** menu). The speed of the pump will then be reduced for a specified period by the preset value for **Speed reduction**. See Fig. 6-19 , page 77.

If myocardial suction occurs at least 5 times within a short period, the speed is reduced for 15 min by a third of the preset speed reduction. See Fig. 6-20 , page 77. The speed is then automatically increased until the set speed is reached.

If myocardial suction recurs within the 15-minute reduction period, message **E21 Pressure difference too high** will appear.

SP is deactivated as a default setting.

PC, PFC, and SP can all be activated simultaneously.

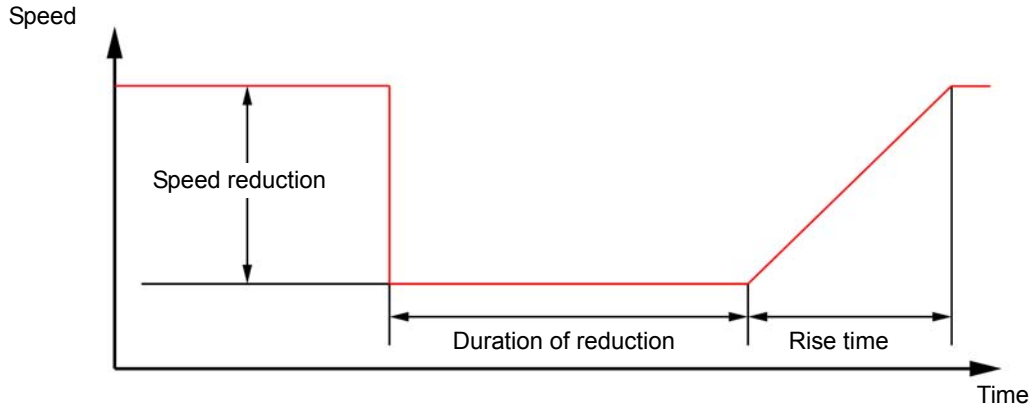


Fig. 6-19 Operating principle SP: speed reduction after 1 to 4 incidents of myocardial suction

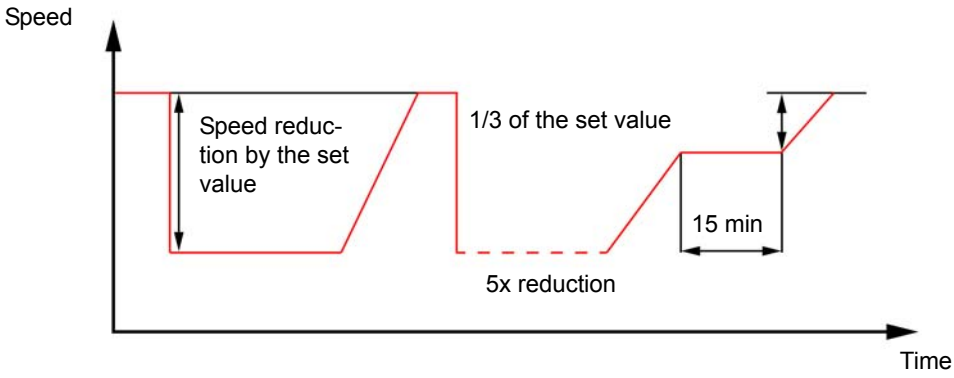


Fig. 6-20 Operating principle SP: speed reduction after 5 incidents of myocardial suction

WARNING

If the maximum value of the pressure difference curve exceeds 100 mm Hg and the **Pressure threshold** in the **Suction protection settings** menu is not adjusted, unwanted speed reductions may occur. The pressure threshold should be at least 20 mm Hg above the maximum value of the pressure difference curve.

If myocardial suction occurs repeatedly while SP is activated, the speed will be reduced for 15 minutes by a third of the **Speed reduction** value. The **Alarm threshold flow** should therefore be checked and adjusted, if necessary, prior to activating SP. The alarm threshold flow should be 50 % of the target flow, but must be adjusted on an individual basis. See section 6.6.6: Alarm threshold flow, page 79.

If SP is activated: if the message **E22 Pressure difference too low** is permanently displayed, check the pressure difference alarm threshold.
If the value is high (> 30 mm Hg): lower the pressure difference alarm threshold.
If the value is low (< 20 mm Hg): take appropriate medical action. Otherwise, hemodynamic complications may result.

ADVICE	
	We recommend activating SP immediately after implantation.
	We recommend that the preset values be maintained. See Fig. 6-24 , page 79.
	We recommend deactivating PC, PFC, and SP prior to further surgical procedures.

Display

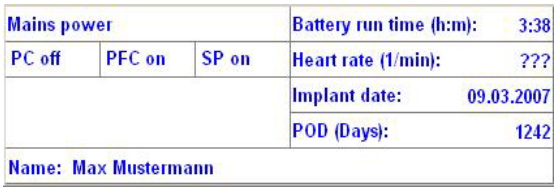


Fig. 6-21 Display: PC, PFC, SP on/off

SP OFF	SP is deactivated
SP ON	SP is activated
∇	If myocardial suction occurs at least 5 times within a short period, the speed is reduced for 15 min by a third of the preset speed reduction. The triangle remains visible during this period.

Tab. 6-4 Explanation of display: SP on/off

Activating and deactivating SP

1. Check the maximum value of the pressure difference curve in the main window of the monitor program. If the value exceeds 100 mm Hg, the **Pressure threshold** in the menu **Suction protection settings** must be adjusted: call the emergency hotline.
2. Select **Settings** from the menu.
3. Select **Suction protection (SP)** from the submenu. The dialog box **Suction protection (SP)** opens.
4. Select **Activate** or **Deactivate**.
5. Confirm the security check with **<o>**. SP is activated or deactivated.

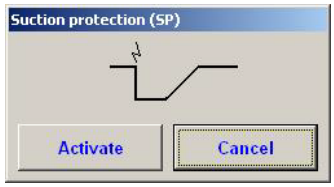


Fig. 6-22 Activating SP

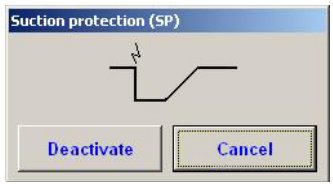


Fig. 6-23 Deactivating SP

Setting parameters

INCOR is delivered with default settings for PC, PFC and SP as recommended by the manufacturer. See Fig. 6-24 , page 79. If necessary, these parameters can be modified. In this case, please call the emergency hotline.

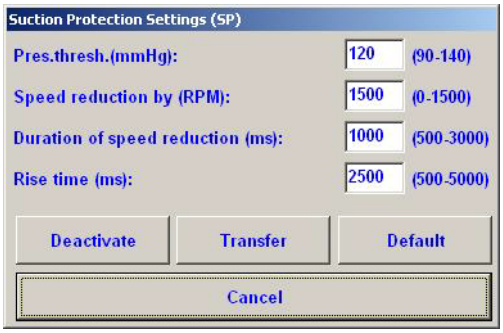


Fig. 6-24 Default settings for suction protection

HOTLINE

Contact the emergency hotline! +49 (0)30 81 87 27 72

6.6.6 Alarm threshold flow

WARNING

Do not set the parameter to an extreme value that makes the alarm system unusable. Otherwise the patient may not receive adequate support.

If this value is not reached, message **E20 Mean flow too low** will be triggered. The triggered flow alarm is only canceled when the mean value is at least 0.2 L/min above the set limit.

Adjusting the alarm threshold flow

1. Select **Settings** from the menu, then **Alarm threshold flow** from the submenu. The alarm threshold flow dialog appears.
2. Adjust the value using the virtual keyboard in the display (**<↑>** / **<↓>**: ±0.1 l/min; **<Pg↑>** / **<Pg↓>**: ±1 L/min). Confirm the entry in the dialog.
3. Confirm the security check with **<o>**. The set value is saved.
4. Check that the desired value is displayed. To do this, first close the **Settings** submenu, then select **Current values** from the menu. See section 6.8: Menu item: Current values, page 82.

As a rule, the flow will be 4 to 5 L/min. Recommended value for alarm threshold flow: 50% of maximum attainable flow. Set the alarm threshold flow as high as possible without triggering the alarm.

6.6.7 Alarm threshold pressure difference

WARNING

Do not set the parameter to an extreme value that makes the alarm system unusable. Otherwise the patient may not receive adequate support.

The pressure difference is the difference between the pressures before and after the pump. See section 6.5: Menu item: Display, page 69. Alarm threshold pressure difference describes the mean value below which the message **E22 Pressure difference**

too low is triggered. The preset value is 0 mm Hg. This value must be adjusted to the needs of the patient. Message **E22 Pressure difference too low** is only registered as resolved when the mean value is at least 10 mm Hg above the set threshold value.

Adjusting the alarm threshold pressure difference

1. Select **Settings** from the menu, then **Alarm threshold pressure difference** from the submenu. The **Alarm threshold pressure difference** dialog box will appear.
2. Adjust the value using the virtual keyboard in the display (**<↑>** / **<↓>**: ±1 mmHg; **<Pg↑>** / **<Pg↓>**: ±10 mm Hg). Confirm the entry in the dialog.
3. Confirm the security check with **<o>**. The input window shows the current value of the corresponding setting; the cursor no longer appears in the input window. The pump will operate at this setting. The displayed value should be further corrected: Access the setting by entering with the short cut and repeat step 2 to step 3.
4. Check that the desired value is displayed.

ADVICE

We recommend a value of about 0 to 10 mmHg as a guideline for the alarm threshold pressure difference.

6.6.8 Offset rotor position

This function is only available in the user profiles **tech** or **OP**.

To enable the pump and control unit to work together flawlessly, the measurement of the pressure difference must be corrected when a control unit is first put into operation. IMPORTANT: This adjustment must be made for the active control unit and the replacement control unit!

With a clamped outflow cannula and pump in halt mode, the pressure difference across the pump is approximately 0 (even for a heart with residual cardiac contractility). Before adjustment, the pressure difference curve will not coincide with the zero line. After adjustment, the displayed pressure difference curve must coincide with the zero line.

Instructions for offset correction: See section 7.5.1: Aligning the control units with the pump: offset correction, page 125.

Fig. 6-25 Pressure difference curve before offset correction

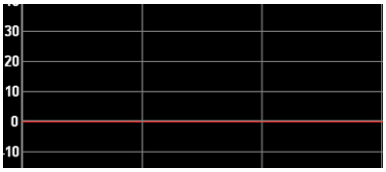


Fig. 6-26 Pressure difference curve after offset correction

6.7 Menu item: Messages

If there is a battery or error message,

- the **Messages** menu item will be displayed in red font.
- the alarm display appears.
- the **Current messages** window will appear.

If there is only one notification message, the **Messages** field of the menu bar will be displayed in red font, while the alarm display and current alarms window will not appear. Select **Messages** to obtain more information.

In the **tech**user profile, the secondary messages corresponding to the message codes (such as: **A01**) are displayed (depending on the message: Irrespective of such a scenario, proceed with such messages as described for the relevant message codes. See chapter 10: Messages and Measures, page 145.

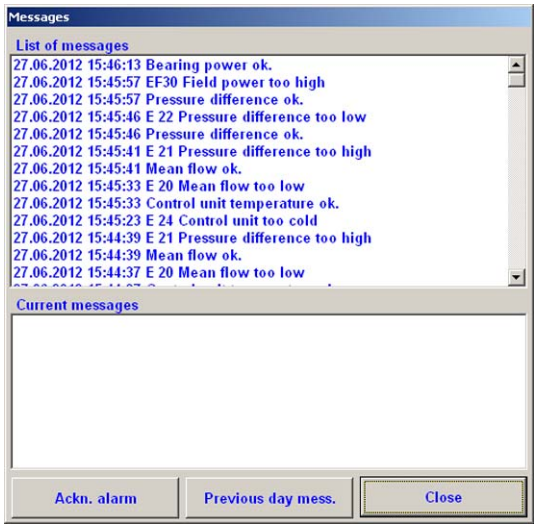


Fig. 6-27 Messages submenu

The Messages submenu contains 2 list boxes:

- **List of messages**: all messages received over the course of the day are displayed here in chronological order (with the most recent message first).
- **Current messages**: all messages which have not been resolved are displayed here.

The Messages submenu also contains 3 buttons:

- **Ackn. alarm**: use this button to mute an acoustic alarm (indicating the existence of a message) for 8 minutes. If the cause of the message persists, the acoustic alarm will sound again. If no user is logged in, this field is inactive and grayed out.
- **Prev. day messages**: click on this button to open a list box containing all messages from the previous day in chronological order (most recently saved message appears first).
- **Close**: select this button to close the **Messages** submenu.

A scroll bar to the right of the list boxes allows navigation through the boxes.

6.8 Menu item: Current values

Select this menu item to display all of the current values and settings.

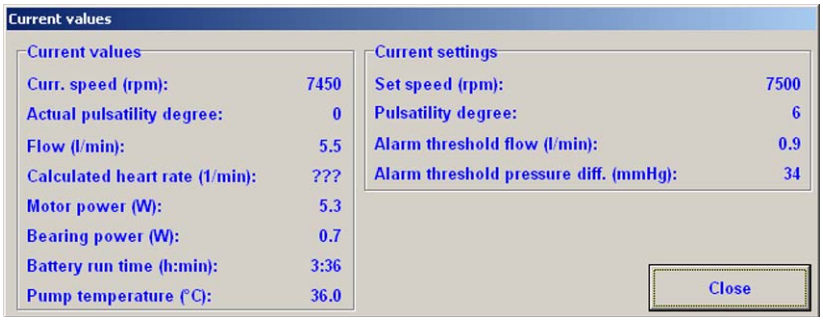


Fig. 6-28 Current values

IMPORTANT: The value displayed under **Calculated heart rate [1/min]** is calculated on the basis of the measured course of the pressure difference. This value is purely informative and is not a substitute for the appropriate diagnostic procedures.

6.9 Menu item: Service

The **Service** menu item is accessible without logging in, but only the following options can then be selected: **Start data recording**, **Save data to USB memory stick**, **Select language**, **Set date and time**.

The **Service** submenu contains all the data administration and system control options.

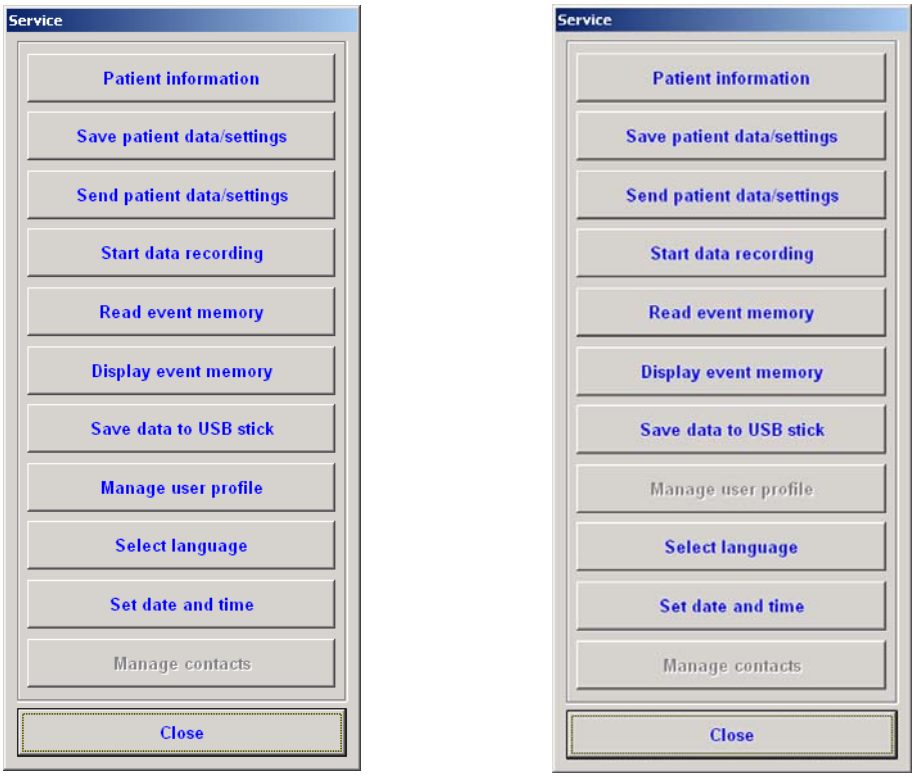


Fig. 6-29 Submenu Service (left: Admin logged in; right: other user logged in)

6.9.1 Submenu item: Patient information

Select this submenu item to display the patient data.

Every time the monitor program is started, the connected control unit sends the **Control unit ID** and **Pump ID** data to the monitor program. These data cannot be changed via the monitor program.

The **Patient name** and **Implantation date** are entered during implantation and may be changed at any time. The patient name may not exceed 31 characters.

Entering patient name and implantation date

1. Select **Patient information** from the submenu.
2. Enter the patient's name and/or implantation date.
3. Select **Apply** to confirm the entry.
4. The patient data are stored directly in the control unit.

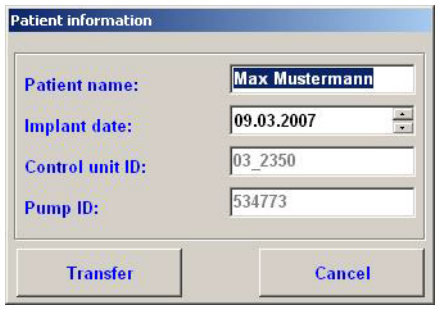


Fig. 6-30 Patient information

6.9.2 Submenu items: Save/send settings and patient data

Use the **Save settings and patient data** and **Send settings and patient data** submenu items to transfer the settings and patient data, including operating mode, to the replacement control unit. This is necessary in order to enable the replacement control unit to operate the system.

The data are first transferred from the active control unit to the hard disk of the operator terminal (**Save settings and patient data**) and are then sent to the replacement control unit by the monitor program (**Send settings and patient data**). By confirming data transfer in the dialog box, the data are stored in the control unit and previous data are overwritten.

The user data are not transferred. For information on transferring data to the replacement control unit: See section 6.9.6: Submenu item: Manage user profile, page 89.

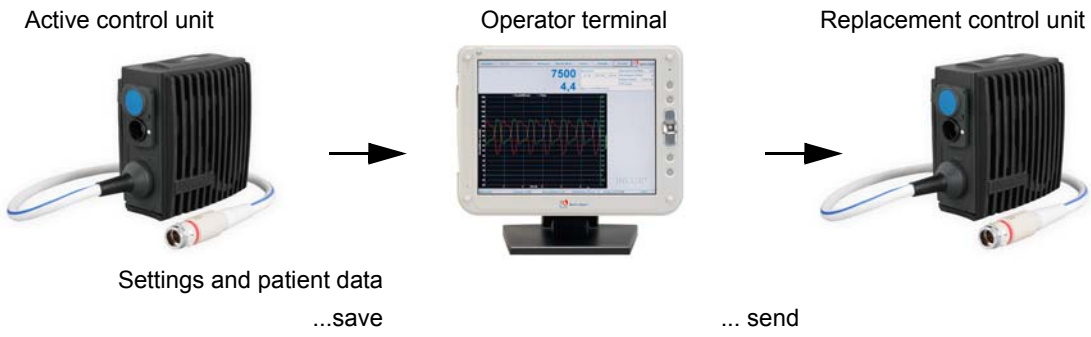


Fig. 6-31 Transferring settings and patient data from the active control unit to the replacement control unit

Saving settings and patient data from the active control unit to the hard disk of the operator terminal

1. Select **Save settings and patient data** from the submenu. All current settings and patient data are displayed.
2. Check the displayed data.
3. Select **Save** to save data to the hard disk of the operator terminal. The data are saved to the hard disk of the operator terminal.

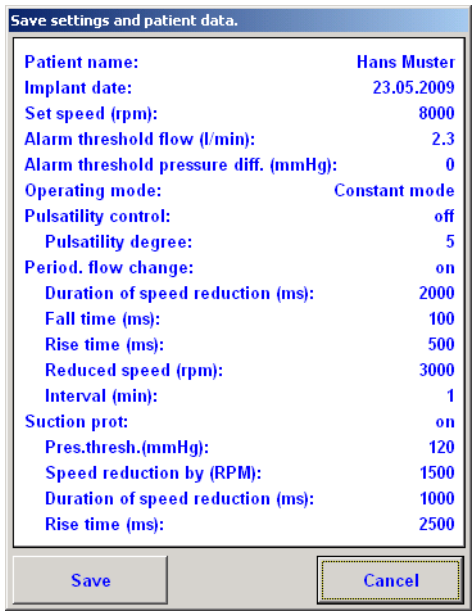


Fig. 6-32 Saving settings and patient data

When saving a new data record to the hard disk of the operator terminal, the previous data record will be overwritten.

Sending settings and patient data to the replacement control unit

1. Remove the backup battery from the charging unit and connect it to the replacement control unit. Do not remove the battery from the active control unit!
2. Acknowledge messages **H50 No pump connected** and **A02 Main battery not connected**.
3. Disconnect the communication cable from the active control unit and connect it to the replacement control unit.
4. Log in to the monitor program.
5. Select **Service** from the menu. Select **Send settings and patient data** from the submenu. A dialog appears in which the currently saved settings and patient data are displayed.

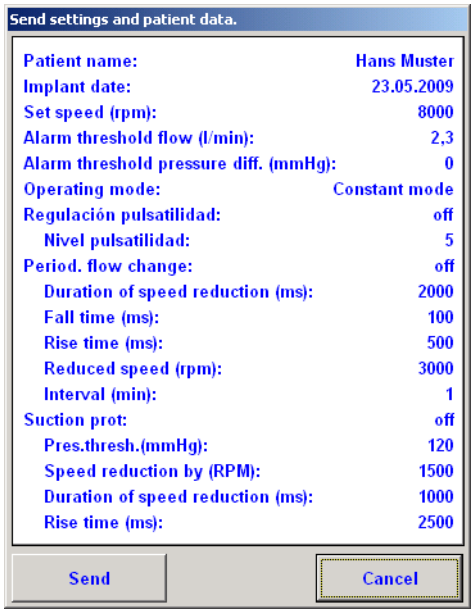


Fig. 6-33 Sending settings and patient data

6. Select **Send** to transfer the data to the replacement control unit. The data are sent to the replacement control unit.

7. Check the data in the white window (see Fig. 6-33 , page 84).
8. Disconnect the communication cable from the replacement control unit.
9. Disconnect the backup battery from the control unit and wait until the interval tone ceases.

6.9.3 Submenu item: Start data recording

The monitor program saves the current curve data every 9 milliseconds. These data are normally overwritten every 3 minutes. In the case of events (specific messages, changes to settings), the data for the period covering 3 minutes before the event to 3 minutes after the event are automatically saved to the hard disk. The option **Start data recording** can be used to manually trigger this process.

This submenu item can also be accessed without logging in.

The existing files can be made available to the manufacturer for evaluation purposes. See section 6.9.5: Submenu item: Save data to USB stick, page 86.

1. Select **Start data recording** from the submenu. Data recording starts.

For the duration of the manually initiated data recording process, a window is displayed with the message **Data recording active! Do not disconnect the control unit from the computer! Do not turn the computer off!** This message cannot be disabled, but is extinguished once data recording is complete.

6.9.4 Submenu items: Read/display event memory

The control unit records all messages, battery replacements and setting changes. For each of these events, the event memory of the control unit records all the relevant settings, measurements, etc. The event memory of the control unit contains the 400 most recent entries. The operator terminal reads the newly added event entries from the control unit every 15 minutes and saves them to its hard disk. All the events of the day are stored here.

Manual saving function: read event memory

The submenu item **Read event memory** can also be used to manually save events, thereby transferring the events added since the last automatic saving process to the hard disk of the operator terminal.

This feature is only accessible to users who are logged in.

1. Select **Read event memory** from the submenu. The contents of the event memory are stored on the hard disk.

Display event memory

This option displays the event memory file of the current day, which is stored on the hard disk of the operator terminal.

This menu item is only accessible to users who are logged in.

1. Select **Display event memory** from the submenu. The most recent entry in the event memory file for the current day is displayed.
2. Use the arrow keys to switch to the next oldest (**<↑>**) next most recent (**<↓>**) display. Use the page up/down arrows **<Pg↑>** / **<Pg↓>** to move the cursor up or down 10 elements at a time.
3. Select **Close** to return to the submenu **Service**.

There may be a large number of entries, even if the control unit has only just been put into operation.

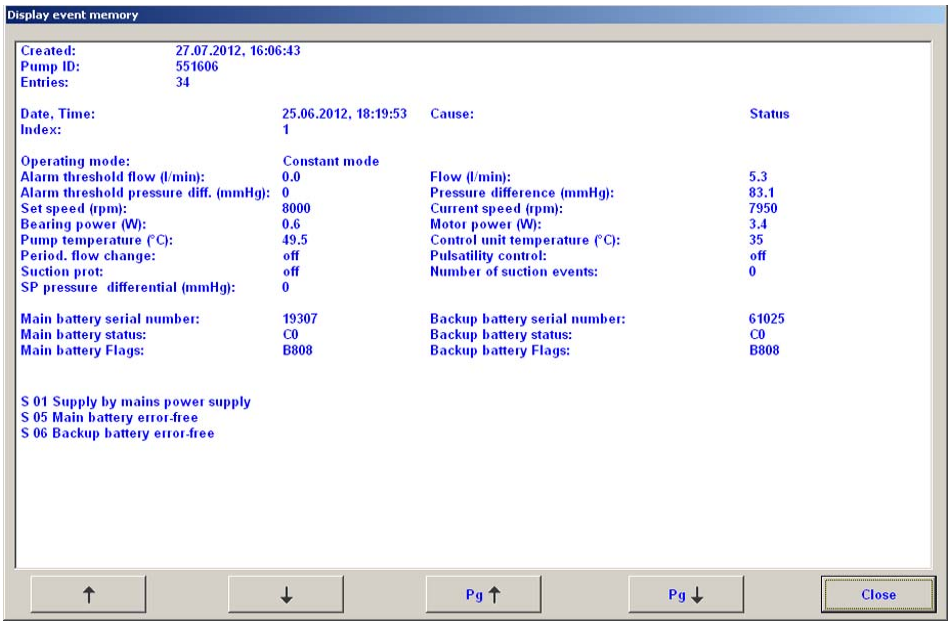


Fig. 6-34 Event memory

6.9.5 Submenu item: Save data to USB stick

This feature is used to transfer all the data saved in the monitor program to a USB stick. The event memory is automatically read during this process.

This submenu item can be accessed, irrespective of whether the user is logged in. When this submenu item is selected, a check is made to ensure that a USB stick is inserted. If this is not the case, a dialog box will appear and request that a USB stick be inserted.

The data in the control unit will be read and compressed. The USB stick inserted in the operator terminal will be checked to ensure that sufficient storage space is available. If sufficient space is available, the compressed data will be stored in the *Log* file on the storage media. The data can now be transmitted to the manufacturer's Service Department for evaluation purposes.

IMPORTANT: Only use the supplied USB stick for this purpose.

Cautionary measure

Do not base therapeutic decisions solely on the values which have been read. Always check the displayed values (pressure, flow and speed) for plausibility, both against each other and with respect to the overall condition of the patient.

Saving data to the USB stick

1. Insert the USB stick into the **upper** USB port of the operator terminal.
2. Select **Save data to USB memory stick** from the submenu. Once the data from the control unit have been transferred and compressed, the monitor program will check whether there is enough free storage space on the USB stick. If this is not the case, a corresponding response will appear and the saving process will not be started.
3. Wait for the dialog: **Data transfer to USB stick was successful. Should the saved data be removed from the hard disk?** On confirmation, all data except for those from the last 2 days will be deleted from the hard disk. If not, all the data will remain on the hard disk. The USB stick can then be removed from the operator terminal.

If a large quantity of data is transferred, the window **n of m events are being read** is briefly displayed. Once data transfer is complete, the window closes automatically.

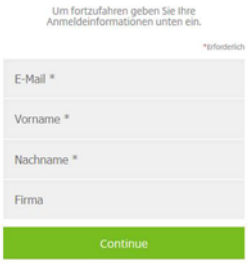
The transfer duration depends on the volume of data being transmitted. Transmission times of an hour or more are possible. Read out data regularly to reduce data volumes and thus shorten transmission times.

Transferring data to the manufacturer's Service Department

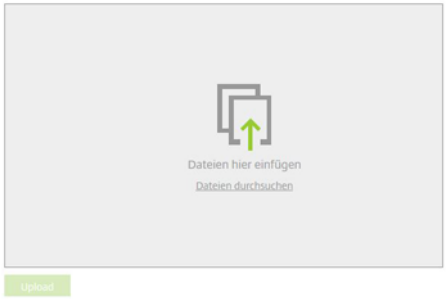
The data can be sent to Berlin Heart for evaluation purposes. For this purpose, send the files to Berlin Heart via e-mail or Sharefile. Please contact the hotline for access to Sharefile. The analysis of the data will be made available to the clinical user. The system data will be archived at Berlin Heart.

Filing the data in Sharefile

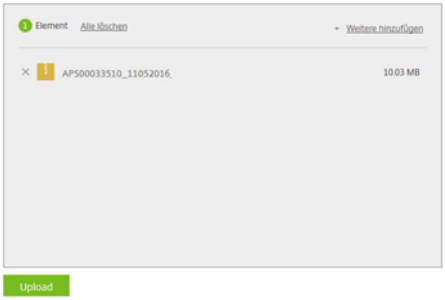
1. Transfer the data to a USB stick.
2. Remove the USB stick from the operator terminal and connect it to a computer with Internet access.
3. Use the link sent from Berlin Heart and activate Sharefile.
4. Enter the credentials:
   - E-mail
   - First name
   - Last name



5. Drag the files into the **Upload** field.



6. Start the upload. After the complete transfer of the files, a confirmation message is displayed. Berlin Heart Clinical Affairs will be informed of the data transfer automatically.



Transmission of data by e-mail

1. Transfer the data to a USB stick.
2. Remove the USB stick from the INCOR operator terminal and connect it to another computer with Internet access.
3. Establish an Internet connection.
4. Send the *Log* folder in an attachment by e-mail to **service@berlinheart.de**. If necessary, include information on the clinical condition of the patient in the e-mail.
5. Disconnect from the Internet as necessary.

IMPORTANT: Do not delete the data from the USB stick until receipt has been confirmed by the manufacturer!

6.9.6 Submenu item: Manage user profile

This menu item is only available to the administrator and users with a personal profile.

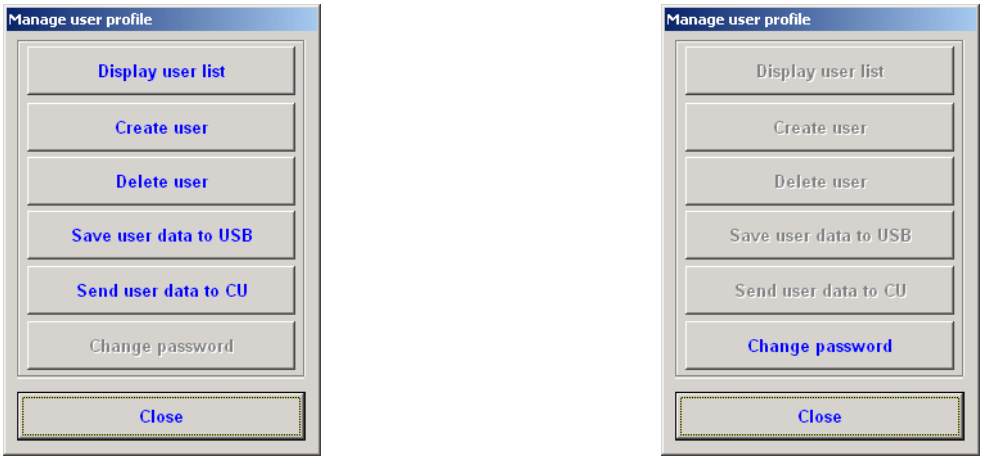


Fig. 6-35 Submenu: Manage user profile (left: administrator, right: personal user profile)

The “Manage user profile” submenu contains the following options:

- **Display user list**: displays a list of all user profiles created by the administrator.
- **Create user**: accesses the input screen for creating a new user profile.
- **Delete user**: deletes a user profile from the user list.
- **Save user data to USB**: saves the user profiles stored in the control unit to a USB stick connected to the operator terminal and thus permits the user profiles to be transferred to different control units.
- **Send user data to CU**: transfers the user profiles previously stored on the USB stick to the control unit.
- **Change password**: permits users with personal profiles to change their set password.

Submenu item: Display user list

This submenu item is only accessible if logged in as an administrator.

1. Select **Display user list** from the submenu. A list of all created users is displayed.
2. Select **Close** to close the user list.

Submenu item: Create user

This submenu item is only accessible if logged in as an administrator.

1. Select **Create user** from the submenu. The **Create user** input screen will appear.
2. Enter username (max. 8 characters, letters and numerals).
3. Enter password (max. 4 characters, numerals only) and repeat.
4. Select **Set up** to add new users to the user list.
5. Select **Cancel** to close the dialog box.

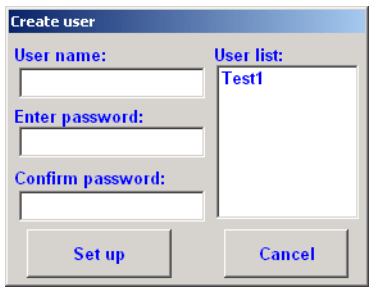


Fig. 6-36 Create user

Submenu item: Delete user

This submenu item is only accessible if logged in as an administrator.

1. Select **Delete user** from the submenu. The **Delete user** screen will appear.
2. Select the desired user.
3. Select **Delete** to delete the user from the user list.
4. Select **Cancel** to close the dialog box.

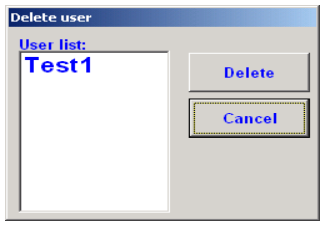


Fig. 6-37 Delete user

Submenu items: Save user data to USB/Send user data to CU

These submenu options are only accessible if logged in as an administrator.

These submenu items are only accessible if a USB stick is connected to the operator terminal.

These submenu items are used to transfer the user data to another control unit. This may be the replacement control unit of the same patient, but may also be the control unit of another patient. To do so, the user data are first transferred from the source control unit to a USB stick connected to the operator terminal (**Save user data to USB**) and then transferred from there to the target control unit (**Send user data to CU**).

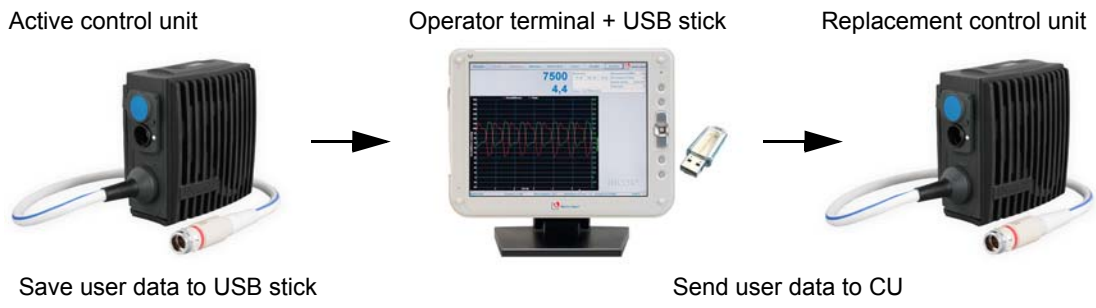


Fig. 6-38 Transferring user data from source control unit to target control unit

Transferring user data from source control unit to USB stick (Save user data to USB)

1. Insert the USB stick into the **upper** USB port of the operator terminal.
2. Select **Save user data to USB**. The user profiles are transferred to the USB stick (userdata.txt).
3. Wait for the response: **User data successfully saved!** The USB stick can then be removed from the operator terminal.

Transferring user data from the USB stick to the target control unit (Send user data to CU)

The user data created in the target control unit are overwritten by this process.

1. Connect the target control unit to the corresponding operator terminal, start the operator terminal and log in as an administrator.
2. Select **Service** from the menu, then **Manage user profile** from the submenu, and select the option **Send user data to CU**.
3. Confirm the query in the dialog to start data transfer. The user data stored on the USB stick are transferred to the target control unit.
4. Remove the USB stick from the operator terminal once transfer is complete.

Submenu item: Change password

This menu item is only accessible to users with personal profiles, but not to engineers, OR users or administrators.

The password must consist of numerals and contain no more than 4 digits.

1. Select **Change password** to access the **Change password** input screen.
2. Enter the old password, then enter and confirm the new password.
3. Confirm the change with **Change password**. The password has now been changed.
4. Select **Cancel** to close the dialog box.

6.9.7 Submenu item: Select language

The language setting sets the language of the user interface. The following languages can be selected:

- German
- English
- French
- Italian
- Dutch
- Portuguese
- Spanish

This menu item is accessible whether a user is logged in or not.

When rebooting the operator terminal, the language setting last selected will be applied.

1. Select **Select language**. The **Select language** list will appear.
2. Select the desired language, then confirm with **Apply**. The texts of the monitor program are now displayed in the chosen language

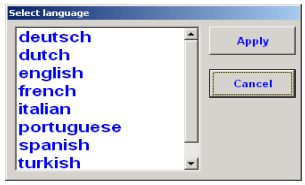


Fig. 6-39 Language selection

6.9.8 Submenu item: Set date and time

This submenu item can be accessed irrespective of whether the user is logged in.

Before starting the monitor program for the first time, the date and time must be checked. The set time is displayed in the status bar. In addition, all dates and times transferred from the control unit (in file names, messages, etc.) refer to the values configured here.

1. Select **Date and time**. The **Set date and time** input screen will appear.
2. Enter the date: select the desired format (day/month/year).
   Adjust the value for the chosen format using the **<↑>** / **<↓>** keys.
3. Enter the time: select the desired format (hours/minutes/seconds). Adjust the value for the chosen format using the **<↑>** / **<↓>** keys.
4. Confirm the displayed values with **Apply**.

6.9.9 Submenu item: Manage contacts

This submenu item is only accessible if logged in as an administrator.

The input screen for the information displayed under **Contacts** will appear here. Up to 20 contacts with names and telephone numbers can be entered here.

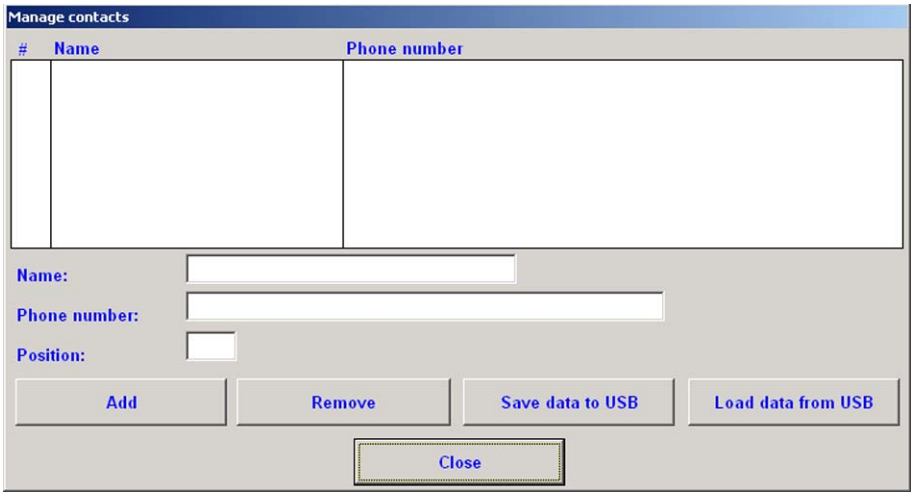


Fig. 6-40 Manage contacts

Adding contacts

This option is used to add a contact to the list.

1. Select **Manage contacts**.
2. Enter the name, telephone number and desired position of the contact in the list, then confirm with **Add**. The new contact is added to the list.

Removing contacts

This option is used to remove a contact from the list.

1. Select **Manage contacts**.
2. Select the desired contact.
3. Select **Remove** to remove the contact from the list. The contact is removed from the list.

Submenu items: <1>imk 72>;}Save data to USB /Load data from USB

These submenu items can only be used if a USB stick is connected to the operator terminal.

These submenu items are used to transfer the contacts to another operator terminal. To do so, the user data are first transferred from the source operator terminal to a connected USB stick (**Save data to USB**) and from there are sent to the target operator terminal (**Load data from USB**).

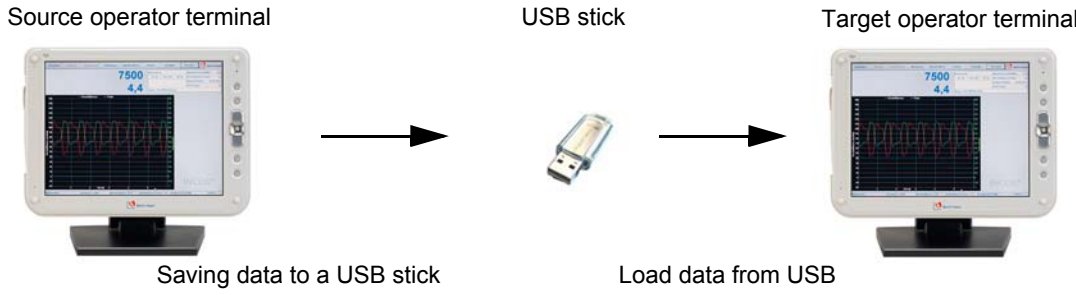


Fig. 6-41 Transferring user data from the source operator terminal to target operator terminal

Transferring contact data from the source operator terminal to a USB stick (Save data to USB)

1. Insert the USB stick into the **upper** USB port of the operator terminal.
2. Select **Save data to USB**. Confirm the query in the dialog. The contact data are transferred to the USB stick (contactdata.txt).
3. The USB stick can then be removed from the operator terminal.

Transferring contact data from a USB stick to the target operator terminal (Load data from USB)

1. Start the target operator terminal, log in as an administrator and insert the USB stick containing the file **contactdata.txt**.
2. Select **Service** from the menu, then **Manage contacts** from the submenu, and select the option **Load data from USB**. The contact data stored on the USB stick are transferred to the target operator terminal.
3. The USB stick can then be removed from the operator terminal.

IMPORTANT: The contact data stored on the target operator terminal are overwritten by this process.

6.10 Menu item: Contacts

Select this menu item to display a list of all contacts created by the administrator.

6.11 Menu item: End

See section 6.3: Switching the operator terminal on/off: starting/ending the monitor program, page 67.

7 Implantation

WARNING

Refer to the conditions of use! See section 2.1: Conditions of use, page 13.

This chapter describes the product-specific measures applicable during implantation of INCOR. Unless described otherwise, all actions must be taken as is customary for major thoracic interventions.

7.1 Preoperative preparations

7.1.1 Preparing and checking the components

WARNING

Check the packaging and use-by date! Only use sterile components with packaging that is not damaged and a use-by date that has not expired! Otherwise the functioning of the sterile components is not guaranteed.

Some components include a temperature indicator. If the color of the temperature indicator has changed, the respective component may not be used. In any other circumstances the smooth operation of INCOR cannot be guaranteed. Next to each temperature indicator is a description of how to recognize a change in the indicator.

Only use the control unit compatible with the corresponding pump. The pump and control unit must have the same AP number! In any other circumstances the smooth operation of INCOR cannot be guaranteed. The AP number of the pump is located on the driveline above the plug and on the upper side of the blood pump body, and the AP number of the control unit is located on the identification plate of the control unit. The AP number can also be found on all the packaging elements of these components.

Allow the systems to acclimatize for 2 hours! In any other circumstances the smooth operation of INCOR cannot be guaranteed.

Whenever a control unit is to be used/replaced: connect the batteries! It is not possible to activate the pump with the power supply unit only.

Charge the main and backup batteries, as well as the battery of the operator terminal, prior to commencing surgery! In any other circumstances the smooth operation of INCOR cannot be guaranteed.

IMPORTANT: Schedule 6 hours of preparation for surgery in order to account for 2 hours of acclimatization of the INCOR components, and up to 4 hours for charging the 2 INCOR batteries and battery of the operator terminal!

1. Prepare:
   - case 1 (sterile components) and case 2 (unsterile components) with the same AP number.
   - Replacement system (case 1 and 2)
2. Allow the systems to acclimatize for 2 hours.
3. For case 1: check the temperature indicators. Do not use a component if the temperature indicator has changed color!
4. For case 2: check the charge level by pressing the button on the INCOR batteries. If all the LEDs do not illuminate: charge the battery in the charging unit. Observe the battery LED of the charging unit for a few minutes. If the battery LED does not flash green after a few minutes: do not use the battery. Use the battery of the replacement system instead.
5. Check the charge level of the battery in the operator terminal, and charge the battery if necessary. Tab. 6-1 , page 64
6. Prepare a suitable roll table with
   - Inner compartment of INCOR Smart Bag with 2 charged batteries and control unit 1 (do not yet insert the battery plug into the control unit!)
   - Operator terminal with accompanying power supply unit and communication cable
   - Charging unit with batteries (one main battery, one backup battery)
   - 2 x power supply unit (for charging unit and control unit)
   - Control unit 2
   - Outer compartment of INCOR Smart Bag
   - Boxes with sterile INCOR components
   - Instructions for clinical use and OR accompanying documentation (including Latest News, if applicable)

ADVICE

In the event that the batteries are discharged, we recommend charging one main and one backup battery prior to implantation, and charging the second main and backup batteries during implantation.

7.1.2 Preparing the control units and operator terminal

1. Connect the operator terminal to the mains using the power supply unit, then boot.
2. Take the password envelope out of the OR accompanying documentation.
3. Log in with the **OP** user profile.
4. Set the correct date and time, if necessary.
5. Do not turn the operator terminal off.

If the operator terminal cannot be started

1. Use the operator terminal of the replacement system.

HOTLINE **Contact the emergency hotline! +49 (0)30 81 87 27 72**

Entering the patient's information into the control units

WARNING Put the control unit into operation only if the control unit acknowledges the connection of the first battery with a short audible alarm and the display has no errors (incomplete letters or numbers) when connected. If this is not the case, messages may not be properly acknowledged. In this case, use a replacement system.

IMPORTANT: Here, control unit 1 implies the default control unit delivered in the INCOR Smart BagSmart Bag. Control unit 1 and control unit 2 are identical in their default settings. After starting the pump, control unit 2 remains the active control unit on the pump, while control unit 1 becomes the replacement control unit.

1. Connect the backup battery to control unit 1. This is acknowledged by a short audible alarm on the control unit. The control unit displays very high battery operating times (> 10:00h). Messages **A02 Main battery not connected** and **H50 No pump connected** appear. IMPORTANT: Do not yet acknowledge the messages.
2. Connect control unit 1 to the operator terminal.
3. Acknowledge messages **A02** and **H50**.
4. Enter the patient's information (**Service** menu item) and apply. The patient's information is now stored in control unit 1.
5. Save the patient data to the hard disk of the operator terminal (menu item **Service**, option **Save patient data/settings**).
6. Remove the plug of the operator terminal from the control unit. Do not turn the computer off!
7. Disconnect the battery from the control unit. The control unit emits a non-acknowledgeable interval tone, which ceases after approx. 5 minutes.
8. Repeat steps 1 to 3 with control unit 2.
9. Transfer the patient data from the hard disk of the operator terminal to the control unit 2 (**Service** menu item, option **Send patient data/settings**).
10. Repeat steps 6 and 7 with control unit 2.

7.1.3 Preparing the unsterile components

1. Use the communication cable to connect control unit 1 with the operator terminal.
2. Secure the inner compartment of the INCOR Smart Bag to the operating table.

7.2 Intraoperative preparations - outflow cannula made from silicone

7.2.1 Unpacking, checking and laying out the sterile components

WARNING

Do not bring the components into contact with pointed or sharp-edged objects (surgical instruments, etc.)! Otherwise there is a danger of consequential damage such as technical failures, operating interruptions or failure of the INCOR pump function.

The aluminum-coated outer packaging provides additional unsterile outer packaging for components coated with CBAS. The outer packaging contains double sterile packaging. The outer packaging and external sterile packaging are not sterile!

The following sterile components are required:

- Implantation set 1
  - Pump
  - Sealing cap
  - Outflow angle section
  - Angle section key
  - Apex coring knife
  - Protection balloon
  - Vent tube adapter
  - Trocar
  - Sleeve
- Implantation set 2
  - Inflow cannula
  - Outflow cannula
  - Suture ring on holder
  - 10mL single-use syringe
  - Three-way stop cock
  - Ring set
- Sterile table for preparing the components with a basin with NaCl solution to moisten all silicone parts as well as the clamp and tweezers for placing the protection balloon

3. Check the temperature indicator of the unsterile outer packaging. Do not use the pump if its temperature indicator has changed color.
4. Ensure that the pump and control unit have identical AP numbers.

5. Have a non-sterile person open the aluminum-coated outer packaging and remove the components in the sterile packaging.
6. Check the sterile packaging. Do not use components with damaged sterile packaging or a use-by date that has expired.
7. Check the contents of the sterile packaging against the packing list.
8. Have a non-sterile person open the outer sterile packaging.
9. The inner sterile packaging should be opened by a sterile person and the components laid out ready for use.
10. Ring set: remove and lay out the seal rings and guide rings. Take care when handling the guide rings: do not grip the ring by the claws, but rather by the section covered in silicone. The silicone cover must remain intact on the ring. Do not bend the claws by applying pressure.
11. The suture ring from implantation set 2 is secured on the suture ring holder by a protective ring. Remove the protective ring from the suture ring holder.

7.2.2 Preparing the inflow cannula

NOTICE

Do not touch the protection balloon with tweezers or other pointed or sharp-edged objects!

12. Moisten the cannula.
13. Attach the **guide ring (4)** to the pump end of the cannula. The claws should be pointing toward the pump. The silicone cover should remain retracted. It must completely enclose the smooth side of the guide ring.
14. Attach the **seal ring (3)** to the pump end of the cannula. The seal ring should sit perfectly in the groove.
15. Take the **protection balloon (1)** and remove the protective cap from the end of the tube.

Fig. 7-1 Prepared inflow cannula

16. Insert the free end of the tube into the inflow cannula from the inflow side. The entire protection balloon should still be protruding from the cannula.
17. Fill the single-use syringe with 10 mL NaCl solution, attach to the three-way stop cock, and de-air. Screw the three-way stop cock onto the free end of the tube. In doing so, ensure that the tube is not twisted.
18. Fill and de-air the protection balloon and tube.

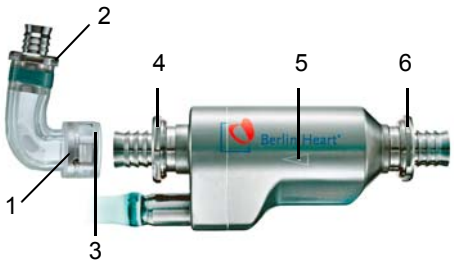
19. Bring the protection balloon into position, see Fig. 7-1 , page 99. Around half of the protection balloon must protrude above the **crown(2)** of the cannula.
20. Build up the pressure in the protection balloon. The correct filled level is shown in Fig. 7-1 . The protection balloon must not slip into the cannula due to pulling on the tube or pressure on the balloon. If the protection balloon is too large, it will not easily glide into the ventricle and may lift the sealing lip on the suture ring. If it is too small, it will slide back into the cannula when pushed.

7.2.3 Connecting the pump to the outflow angle section

WARNING Ensure that the snap-in connector is correctly engaged! Bleeding may otherwise occur.

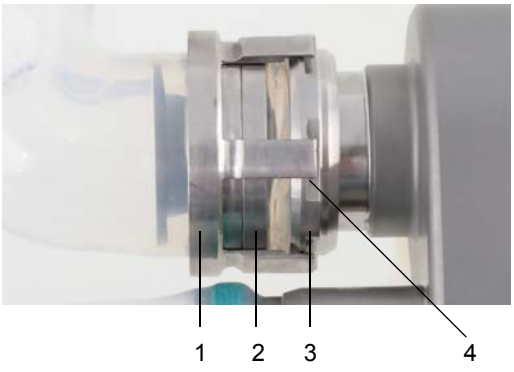
The actions described in this section are not applicable if the outflow angle section is not being used.

Each snap-in connector consists of a detent ring, a guide ring with silicone cover and a seal ring. The detent rings are integral components of the pump and outflow angle section. Guide rings with silicone cover and seal rings are included as a ring set.



1 Guide ring of the outflow angle section
2 Detent ring of outflow angle section
3 Seal ring of the outflow angle section
4 Detent ring of the pump, outflow side
5 Arrow: points in direction of blood flow
6 Detent ring of the pump, inflow side

Fig. 7-2 Pump and outflow angle section



1 Guide ring
2 Seal ring
3 Detent ring
4 Snap-in position on detent ring

Fig. 7-3 Close-up of snap-in connector: guide ring snapped onto detent ring (without silicone cover)

1. Moisten the outflow angle section.
2. Attach the guide ring with silicone cover to the inflow side of the outflow angle section. The claws should be pointing toward the pump. The silicone cover should remain retracted. It must completely enclose the smooth side of the guide ring.
3. Attach the seal ring to the inflow side of the outflow angle section. The seal ring should sit perfectly in the groove.
4. Attach the outflow angle section to the outflow side of the pump. Note in this case: the arrow on the pump body is pointing in the direction of blood flow. The collar of the outflow angle section must be flush with the detent ring of the pump.
5. Allow the guide ring of the outflow angle section to snap into place. All the claws of the guide ring must be fully engaged.
6. Ensure that the snap-in connector is correctly engaged: a correctly engaged snap-in connector can easily be turned back and forth within the snap-in position!
7. Turn back the silicone cover of the guide ring. Ensure that the silicone cover is concealing the entire guide ring.

Fig. 7-4 Snap-in connector open

Fig. 7-5 Snap-in connector closed

Fig. 7-6 The silicone cover should conceal the guide ring

7.3 Preoperative preparations - graft outflow cannula

7.3.1 Safety information

WARNING

The graft outflow cannula may not be used in patients with known hypersensitivity to polyester or materials of bovine origin. Otherwise there is a risk of allergies.

The vascular graft prosthesis must not be precoagulated. The vascular graft prosthesis is a sealed implant. Precoagulation can give rise to malfunctions.

Do not bring instruments for RF surgery into direct contact with the graft outflow cannula. The graft outflow cannula can be perforated or inflamed by RF surgery. A cauterization knife may be used to shorten the vascular graft prosthesis.

The vascular graft prosthesis has a woven structure and should therefore be cut with a cauterization knife so as to prevent fraying. Fraying may result in a suture being inadequate.

Only atraumatic clamps may be used for handling the graft outflow cannula. They should be handled with minimal force. If not, the graft outflow cannula may be damaged.

Check the connections of the assembled graft outflow cannula, of the outflow angle section and the correct position of the silicone covers. Inadequate connections can give rise to leaks in the system. Missing or incorrectly positioned silicone covers can cause damage to the surrounding tissue.

Only suitable suture material and round-bodied, taper-point needles may be used for anastomosing the vascular graft prosthesis. Otherwise there is a risk of damage to the vascular graft prosthesis as well as inadequate suturing.

The material of the vascular graft prosthesis must not be frayed. Threads that appear when expanding or shortening the vascular graft prosthesis must be removed. When doing so, take care to ensure that no threads enter the patient's bloodstream. Thrombembolic complications may otherwise develop.

7.3.2 Unpacking, checking and laying out the sterile components

⚠ WARNING

Do not bring the components into contact with pointed or sharp-edged objects! Otherwise there is a risk of consequential damage, such as technical failures, interruptions, or failure of the
INCOR pump function. Shortening the vascular graft prosthesis and the kink protection sleeve are the exception.

The vascular graft prosthesis must be used within one month from removing it from the foil packaging. Otherwise its functioning is not guaranteed.

The following sterile components are required:

INCOR implantation set 1 inflow side

- Pump
- Inflow cannula
- Suture ring on holder
- Ring set 2
- Sleeve

INCOR implantation set 2 outflow side

- Outflow angle section
- Graft connector
- Screw clip
- Vascular graft prosthesis
- Kink protection

INCOR surgical set

- Apex coring knife
- Vent tube adapter
- Angle section key
- Trocar
- Protection balloon
- Single-use syringe
- Three-way stop cock
- Sealing cap
- Expanding mandrel
- Torque screwdriver

Sterile table for preparation of the components with a basin of NaCl solution for moistening all silicone components, as well as clamp and tweezers for positioning the protection balloon

Unpacking the sterile components

The aluminum-coated outer packaging is an additional, non-sterile layer of outer packaging for the components. The outer packaging contains double sterile packaging. The outer packaging and external sterile packaging are not sterile!

1. Check the temperature indicators. Do not use a component if the temperature indicator has changed color.
2. Ensure that the pump and control unit have identical AP numbers.
3. Have a non-sterile person open the aluminum-coated outer packaging and remove the components in the sterile packaging.
4. Check the sterile packaging. Do not use components with damaged sterile packaging or a use-by date that has expired.
5. Check the contents of the sterile packaging against the packing list.
6. Have a non-sterile person open the outer sterile packaging.
7. The inner sterile packaging should be opened by a sterile person and the components laid out ready for use.
8. A protective ring is used to stabilize the anastomosis ring on the anastomosis ring holder. Remove the protective ring from the suture ring holder.

7.3.3 Preparing the inflow cannula

The necessary work steps are described in section 7.2.2: Preparing the inflow cannula, page 99.

7.3.4 Assembly of the graft outflow cannula including outflow angle section

The graft outflow cannula must be assembled prior to implantation.

ADVICE

Before assembly, immerse the vascular graft prosthesis for a maximum of 5 minutes in a physiological saline solution. Immersion in saline solution simplifies assembly and prevents possible overheating when a cauterization knife is used.

WARNING

The vascular graft prosthesis may not dry out before implantation. Otherwise the vascular graft prosthesis can be overheated and ignite when a cauterization knife is used.

1. Tools
   - Torque screwdriver (1)
     Note: Only use the supplied torque screwdriver. The torque has been designed specifically for this purpose. Otherwise, the screw of the screw clip may be tightened too far.
   - Expanding mandrel (2)

Fig. 7-7 Tools

2. Components
   - Seal ring (3)
   - Guide ring (4)
   - Silicone cover (5)
   - Outflow angle section (6)
   - Graft connector (7)
   - Screw clip (8)
   - Vascular graft prosthesis (9)
   - Kink protection (10)

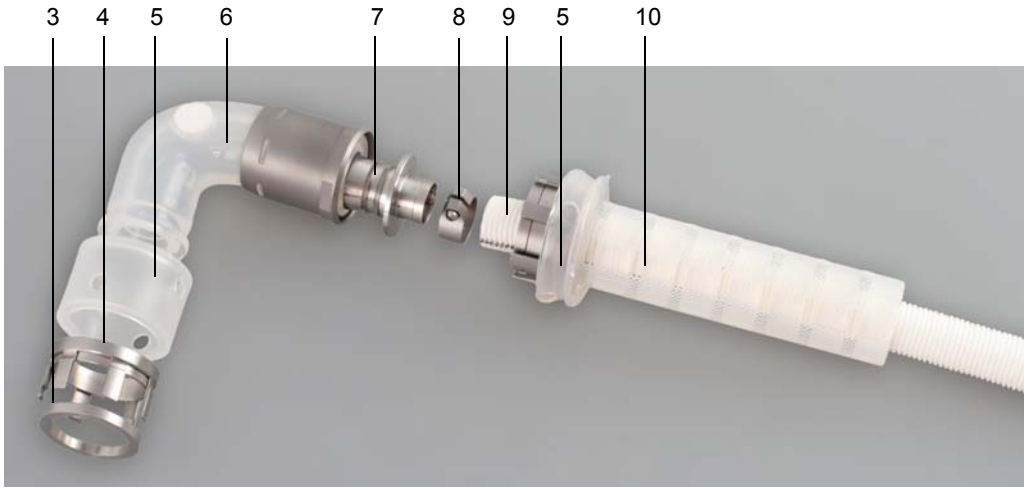


Fig. 7-8 Components of the graft outflow cannula including outflow angle section

3. Push the guide ring and seal ring onto the outflow angle section. The seal ring must be positioned in the groove of the outflow angle section.
    - Seal ring (3)
    - Guide ring (4)
    - Silicone cover (5)
    - Outflow angle section (6)

    Turn back the silicone cover of the kink protection sleeve as illustrated in Figure Fig. 7-8 .

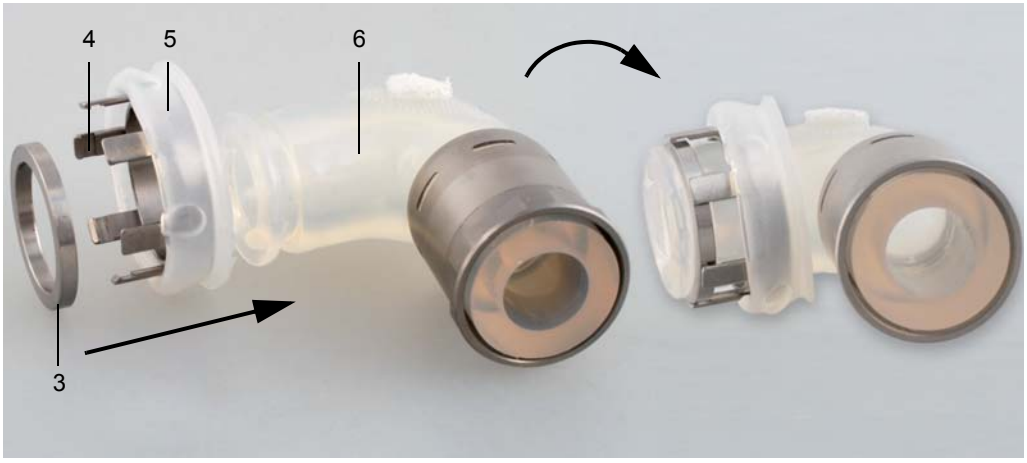


Fig. 7-9 Guide ring and seal ring assembly

4. Fully immerse the vascular graft prosthesis for a maximum of 5 minutes in saline solution. This improves its handling properties. Make sure that the vascular graft prosthesis no longer dries out until it is implanted.

5. Pull the vascular graft prosthesis through the screw clip.

Fig. 7-10 Guide the vascular graft prosthesis through the screw clip

Fig. 7-11 Pull the vascular graft prosthesis through the clip

Fig. 7-12 Slide the screw clip down by about 4 cm

6. Push the vascular graft prosthesis about half way onto the expanding mandrel. The following procedure has proven itself:
   - Push the vascular graft prosthesis onto the expanding mandrel
   - Smooth the creases of the vascular graft prosthesis
   - Grip the crease-free end of the vascular graft prosthesis
   - Push the vascular graft prosthesis with moderate force

   Pushing on the vascular graft prosthesis causes it to expand and it can thus be pushed more easily onto the graft connector.

Fig. 7-13 Push the vascular graft prosthesis onto the expanding mandrel and smooth the creases

Fig. 7-14 Grip the crease-free end of the vascular graft prosthesis and push it further onto the expanding mandrel

Fig. 7-15 Expanded vascular graft prosthesis

7. Cut off any excess threads.

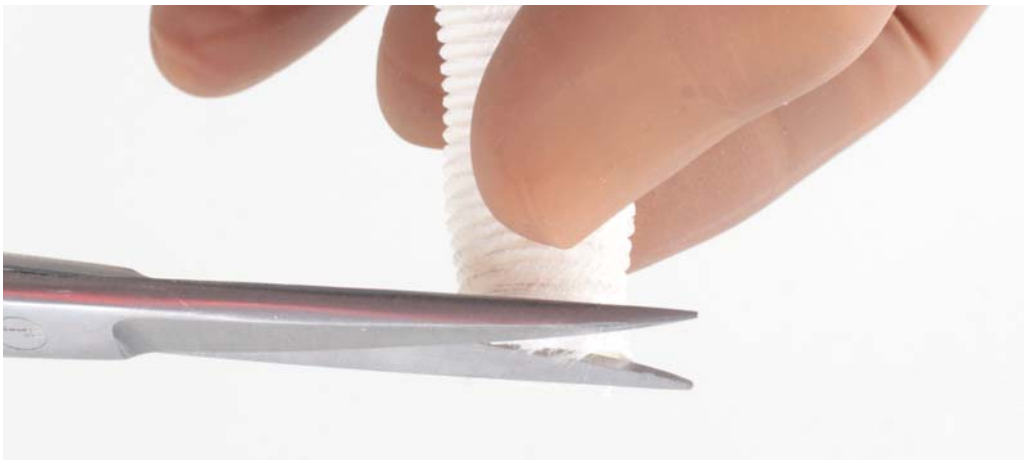


Fig. 7-16 Removal of threads

8. Push the vascular graft prosthesis onto the graft connector until it is 2 mm away from the stop position (11). Note: The following steps explain how to push the vascular graft prosthesis onto the graft connector as far as the stop position.

Fig. 7-17 Pushing the vascular graft prosthesis onto the graft connector

Fig. 7-18 Preliminary end position of the vascular graft prosthesis, approx. 2 mm away from the stop position

9. Push the screw clip onto the graft connector. Leave a gap of around 1 mm between the stop position and screw clip. The gap is required later to check that the vascular graft prosthesis has been pushed on far enough at all places. Make sure that the vascular graft prosthesis is positioned without creases on the graft connector. The stop position of the graft connector and the screw clip must be parallel to each other.

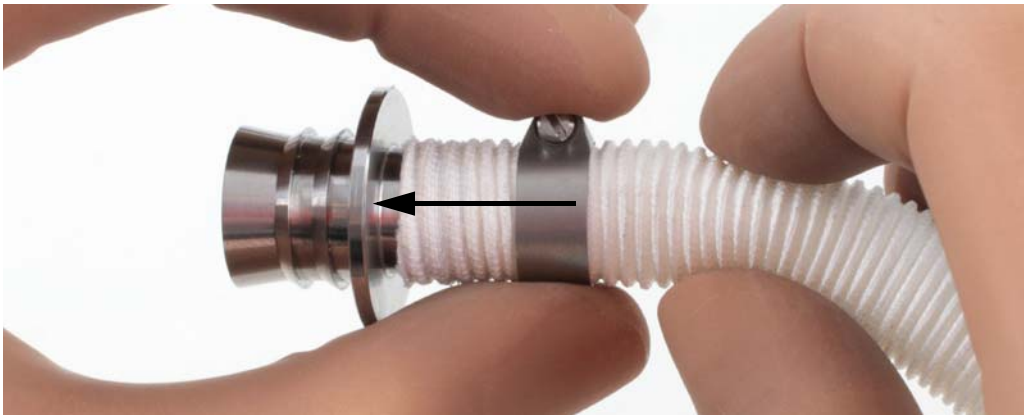


Fig. 7-19 Sliding the screw clip into position

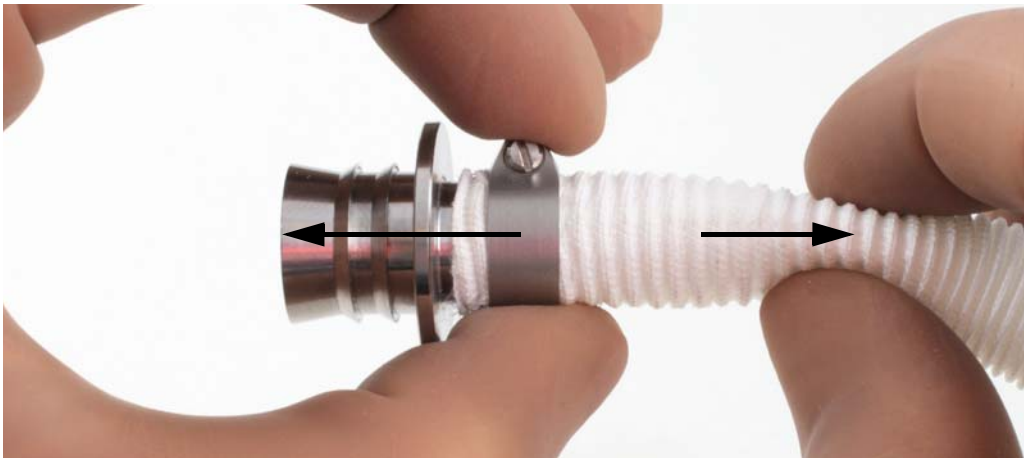


Fig. 7-20 Sliding the screw clip into position while carefully pulling out the creases

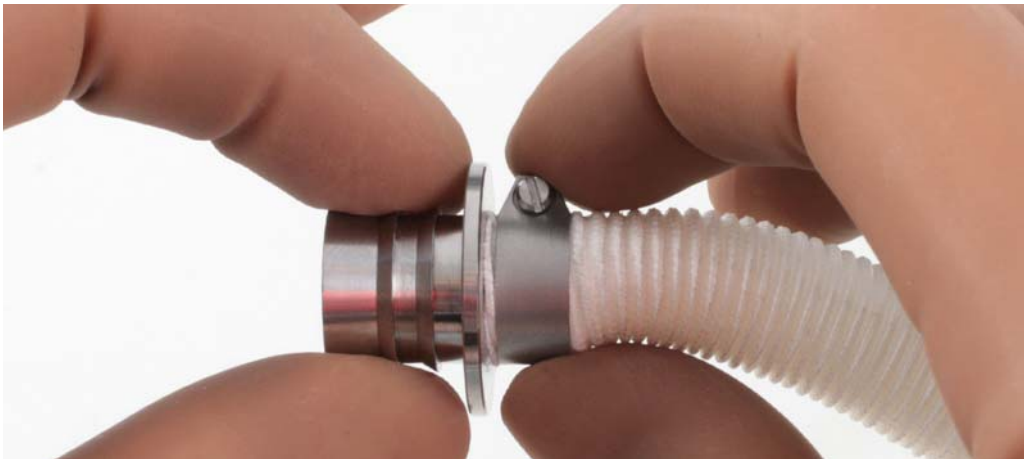


Fig. 7-21 End position

10. Tighten the screw with the torque screwdriver. The screw is tight when the torque screwdriver responds with a click. Stop turning after a single click.

Fig. 7-22 Tightening the screw

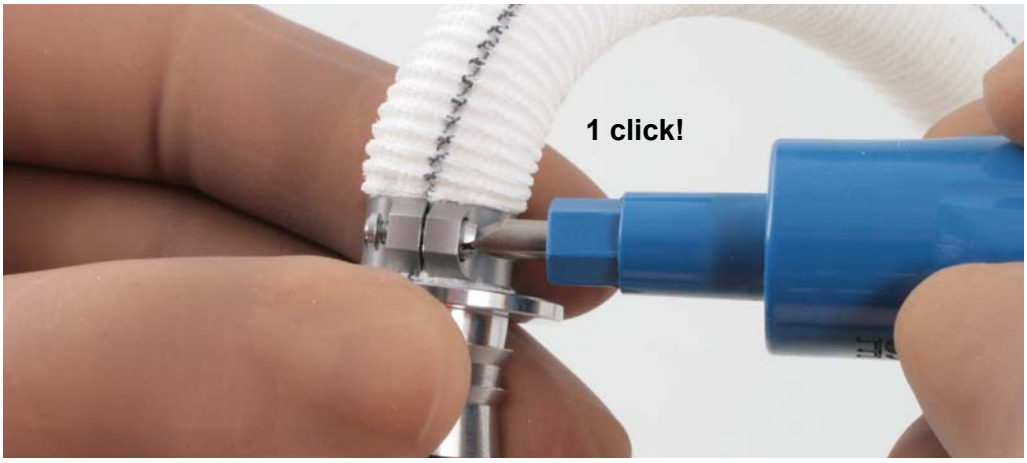


Fig. 7-23 Secured screw clamp

11. Check correct assembly. The vascular graft prosthesis must be visible from all sides; check that the screw clip is firmly in position.

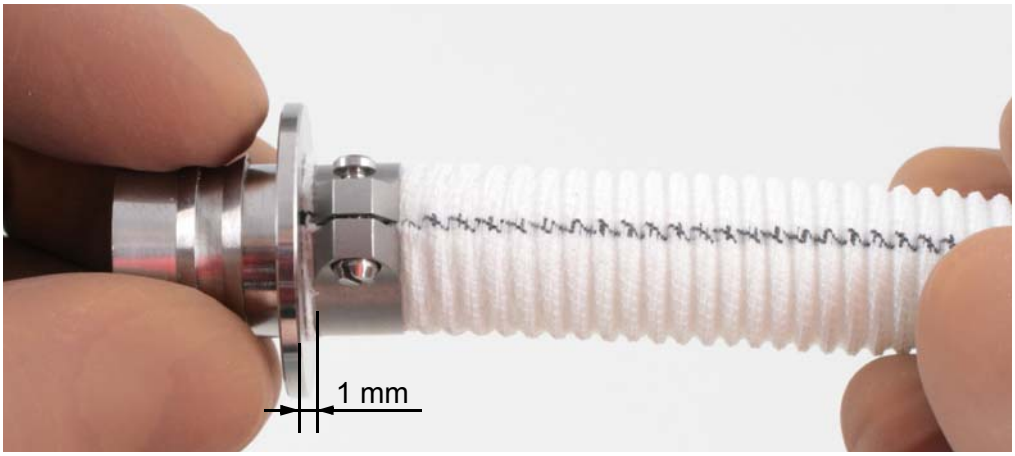


Fig. 7-24 Gap for visually checking the quality of the assembly.

12. Push the graft connector into the outflow angle section up to the stop.

Fig. 7-25 Assembly of graft connector and outflow angle section

Fig. 7-26 Graft connector completely attached

13. Where required, shorten the kink protection sleeve to the desired length. Cut off the connection web so that it is flush.

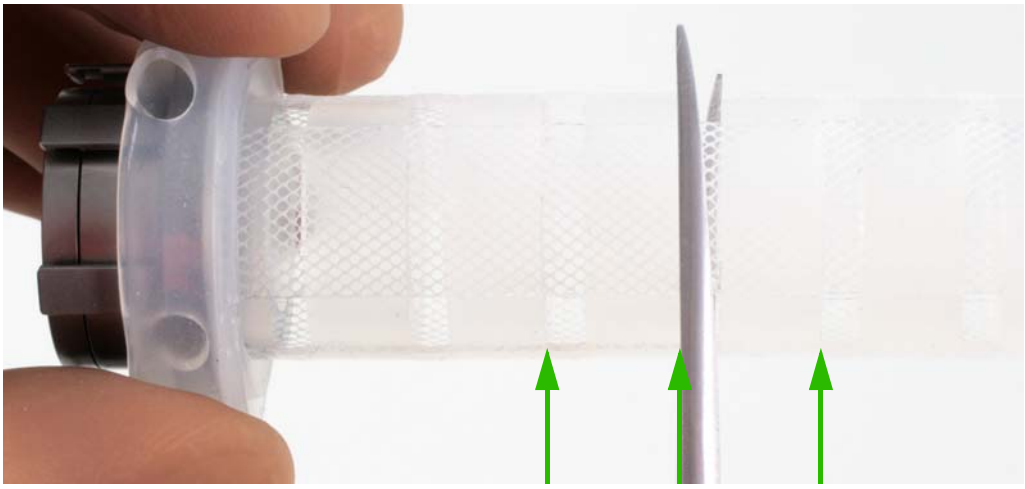


Fig. 7-27 Shortening the kink protection sleeve

14. Push the kink protection sleeve over the vascular graft prosthesis as far as the outflow angle section.

Fig. 7-28 Attaching the kink protection sleeve

15. Connect the kink protection sleeve to the outflow angle section. The guide ring must snap onto the stop ring. Check the connection. All 6 claws must be fully engaged.

Fig. 7-29 Engaged guide ring

16. Pull the silicone cover over the guide ring. Check that the silicone cover fully covers the connection.

Fig. 7-30 Positioning the silicone cover

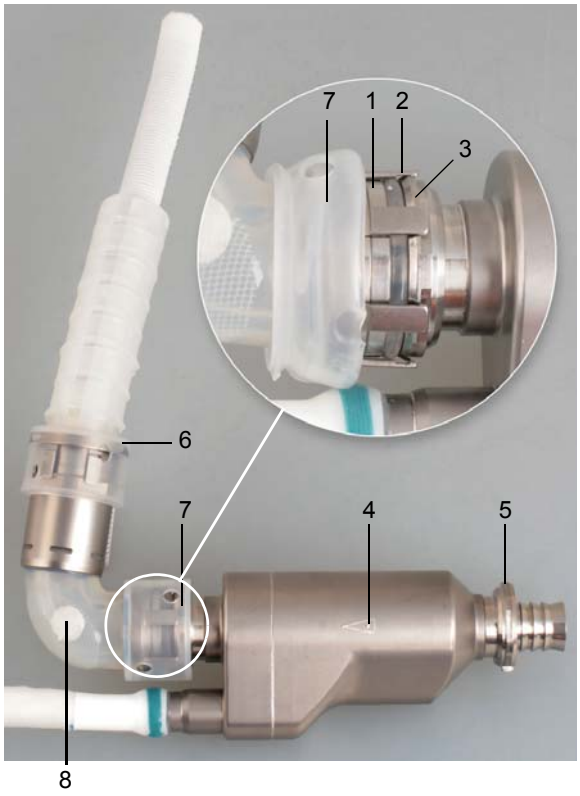
17. The graft adapter may be shortened to suit the anatomical conditions. This can also be done after connecting the pump.

7.3.5 Connecting the pump to the outflow angle section

WARNING

Ensure that the snap-in connector is correctly engaged! Bleeding may otherwise occur.

The graft outflow cannula must be run free of tension, kinks and torsion. Otherwise support may be inadequate and bleeding may occur.



1 Detent ring of outflow angle section
2 Guide ring of the outflow angle section
3 Detent ring of the pump, outflow side
4 Arrow: points in direction of blood flow
5 Detent ring of the pump, inflow side
6 Graft outflow cannula
7 Silicone cover
8 Felt pledget

Fig. 7-31 Blood pump with outflow cannula

1. Position the graft outflow cannula with outflow angle section on the blood pump.
2. Attach the graft outflow cannula with outflow angle section to the outflow side of the pump. The arrow on the pump body points to the outflow side.
3. Allow the guide ring of the outflow angle section to snap into place. All the claws of the guide ring must be fully engaged.

Fig. 7-32 Snap-in connector closed

4. Ensure that the snap-in connector is correctly engaged: a correctly engaged snap-in connector can easily be turned back and forth within the snap-in position!
5. Turn back the silicone cover of the guide ring. Ensure that the silicone cover is concealing the entire guide ring.
6. Clamp the outflow side of the graft outflow cannula.

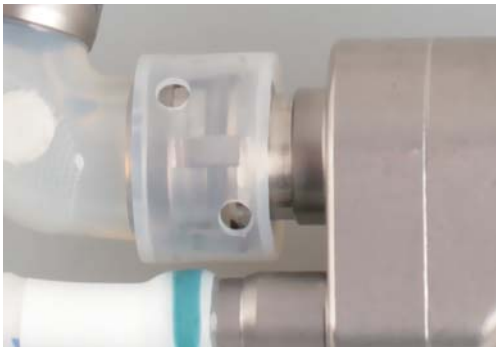


Fig. 7-33 The silicone cover should conceal the guide ring

7.4 Surgery

The INCOR is implanted using standard cardiosurgical techniques. It may be implanted via medial or lateral access. Implantation may be performed under induced ventricular fibrillation or on the beating heart. Ensure that the spatial end position of the system is stable as well as free of kinks and tension!

The following surgical procedure describes implantation with medial access. For lateral access, implantation is performed in the corresponding way.

WARNING

When using a cauterization knife: the current must not flow directly through the pump. Therefore, do not attach the electrode of the cauterization knife to the back of the patient! Avoid contact between the cauterization knife and pump! Otherwise there is a risk of electric shock.

When using a cauterization knife, operate INCOR from the batteries! Otherwise the pump may stop.

Do not bring the blood pump and cable into contact with pointed or sharp-edged objects (surgical instruments, etc.)! Otherwise there is a danger of consequential damage such as technical failures, interruptions, or failure of the INCOR pump function.

Visually inspect all the in situ connections. Otherwise blood can escape through an inadequate suture.

CAUTION

For de-airing (venting) via the pump or outflow angle section, always use the supplied vent tube adapter. Never insert the vent tube directly into the pump or outflow angle section! In particular, avoid touching the coated inner sides of the pump or outflow angle section with the vent tube. Otherwise the CBAS coating may be damaged.

NOTICE

Only activate the pump after air-free filling with blood or NaCl! Running when empty will damage the pump!

ADVICE

We recommend performing implantation under extracorporeal circulation (ECC).

It is advisable to consider the position of the transcutaneous exit site of the driveline when applying sterile covering to the patient.

7.4.1 Anastomosis of the suture ring to the ventricle

The suture ring permits later anastomosis of the inflow cannula to the left ventricular apex (LV apex). The inflow cannula is inserted into the opening of the suture ring with the aid of the protection balloon. The suture ring has a sealing lip on its inner side. IMPORTANT: Do not damage the sealing lip with the protection balloon or surgical instruments!

1. Start extracorporeal circulation.
2. If necessary, place a vent in the pulmonary artery or in the left atrium.
3. If indicated, start fibrillation.
4. Opening the left ventricle (LV) using the apex coring knife.
5. Inspection of the LV. The opening to the LV should be free from potential inflow impediments, e.g. trabeculae and thrombi.

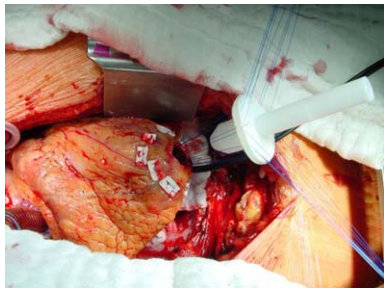


Fig. 7-34 Suture ring on holder

6. Apply 10-12 felt-underlaid, double-reinforced sutures (non-absorbable suture material, e.g. prolene(R) 3-0 SH-1) circularly around the apical incision. Do not tie.
7. Place the applied sutures synchronously on the suture ring. The suture ring is held by the ring holder.
8. Push the holder with the suture ring down and tie all the sutures. Do not tie four sutures with 90° spacing. Ensure that the ring is sitting smoothly and is free of creases, and that the sealing lip on the inner side of the ring is not damaged.
9. To vent, insert the free end of the vent tube into the ring holder (minimum inner diameter: 7 mm, outside diameter: approx. 12 mm)

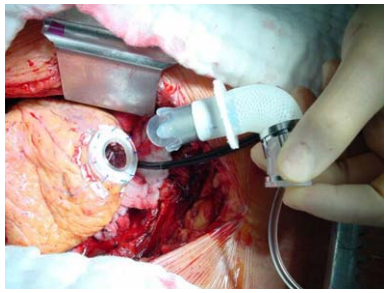


Fig. 7-35 Suture ring on apex

10. Remove the ring holder. To do so, cut through the retention stitches and ensure that they have all been removed.

7.4.2 Fastening the inflow cannula to the suture ring

WARNING

After inserting the cannula into the apex of the ventricle, do not fill the protection balloon any further! Otherwise the protection balloon may burst.

Ensure that the entire crown of the inflow cannula is positioned within the ventricle and is not touching the surrounding tissue (trabeculae, septum, lateral myocardial wall). Remove any excess trabeculae. Otherwise the opening of the cannula may be displaced.

Empty the protection balloon prior to removal! Otherwise the protection balloon may burst.

1. Insert the prepared inflow cannula together with the protection balloon into the apex of the ventricle.
2. Rotate the inflow cannula to the optimal position so that the pump can be placed in the anterior lower mediastinum. IMPORTANT: Following anastomosis of the inflow cannula, the position of the cannula can no longer be adjusted.

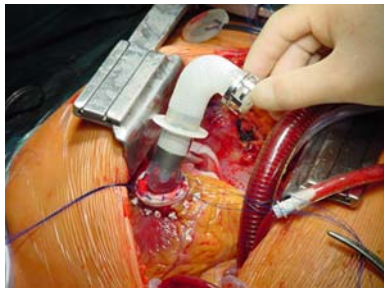


Fig. 7-36 Positioning the inflow cannula

3. Suture the four threads left on the suture ring with the suture edge of the inflow cannula and tie. Check the sufficiency of the anastomosis.
4. Empty and remove the protection balloon.

7.4.3 Connecting the pump with inflow cannula and de-airing

7.4.3.1 Variant with silicone outflow cannula

WARNING

Ensure that the snap-in connector is correctly engaged! Bleeding may otherwise occur.

1. Pick up the pump.
2. Connect the pump to the inflow cannula using the snap-in connector. Proceed in a similar way to connecting the outflow angle section and pump. See section 7.2.3: Connecting the pump to the outflow angle section, page 100. The collar of the inflow cannula must be flush with the detent ring of the pump! Take care with the direction: the arrow on the pump body points in the direction of blood flow!

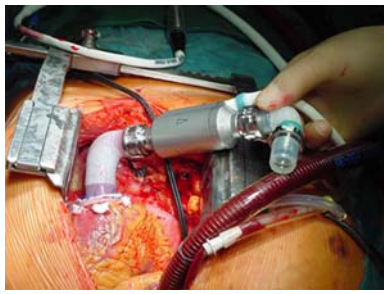


Fig. 7-37 Connect the blood pump with the inflow cannula

3. Allow the guide ring to snap into place. All the claws of the guide ring must be fully engaged.
4. Ensure that the snap-in connector is correctly engaged: a correctly engaged snap-in connector can easily be turned back and forth within the snap-in position!
5. Turn back the silicone cover of the guide ring. Ensure that the silicone cover is concealing the entire guide ring.

De-airing the system

6. Stop the vent in order to fill and de-air the pump and outflow angle section. Then reactivate the vent.
7. Defibrillate, if indicated.
8. Attach seal caps to the outflow angle section or use a vent tube adapter.

If required: de-air the pump and outflow angle section with the vent

CAUTION

For de-airing (venting) via the pump or outflow angle section, always use the supplied vent tube adapter. Never insert the vent tube directly into the pump or outflow angle section! In particular, avoid touching the coated inner sides of the pump or outflow angle section with the vent tube. Otherwise the CBAS coating may be damaged.

9. Attach the supplied vent tube adapter to the outflow side of the pump or outflow angle section.
10. Connect the vent tube to the vent tube adapter.

Fig. 7-38 Vent tube adapter and outflow angle section separated

Fig. 7-39 Vent tube adapter and outflow angle section connected

Diameter of the vent tube adapter on the outflow side:

- 9.5 mm internally
- 14.3 mm externally

7.4.3.2 Variant with graft outflow cannula

WARNING

Ensure that the snap-in connector is correctly engaged! Bleeding may otherwise occur.

1. Take the pump with assembled graft outflow cannula.
2. Connect the pump to the inflow cannula using the snap-in connector.
3. Allow the guide ring to snap into place. All the claws of the guide ring must be fully engaged.

4. Ensure that the snap-in connector is correctly engaged: a correctly engaged snap-in connector can easily be turned back and forth within the snap-in position.
5. Turn back the silicone cover of the guide ring. Ensure that the silicone cover is concealing the entire guide ring.
6. Clamp the vascular graft prosthesis of the graft outflow cannula.

De-airing the system

1. Open the clamp on the vascular graft prosthesis.
2. Defibrillate, if indicated.
3. Clamp the vascular graft prosthesis.

7.4.4 Tunneling the driveline

WARNING

Ensure that the driveline is inserted subcutaneously! Otherwise, there is a risk of perforating the surrounding organs (peritoneum, liver).

ADVICE

We recommend tunneling the driveline in such a way that the polyester velour comes to an end just below the level of the skin. This helps to significantly reduce any infections at the transcutaneous exit site.

We recommend selecting the site for transcutaneous exit in such a way that the patient has an optimal range of movement.

1. Screw the **trocar (3)** onto the **trocar adapter (2)** of the **driveline (1)**.
2. Moisten the driveline including the velour and trocar adapter with NaCl solution.
3. Prepare the tunnel. The tunnel should lead subcutaneously in the direction of the right iliac wing.

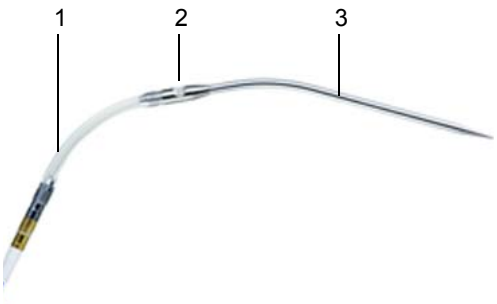


Fig. 7-40 Driveline with connected trocar adapter

4. Select the site for transcutaneous exit of the driveline. The transcutaneous exit site should be lateral to the medioclavicular line at the level of the umbilicus. Make the skin incision here. The length of the skin incision should be approx. 8-10 mm. IMPORTANT: If greater force is required to tunnel the lead through the skin, the incision should be somewhat larger and, if necessary, the larger incision must then be corrected by a single button suture laterally, next to the lead.

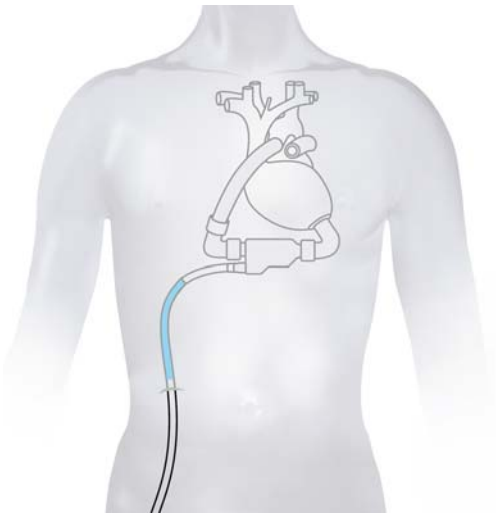


Fig. 7-41 Position of the driveline, velour

5. Use the trocar to tunnel the driveline. IMPORTANT: Quickly grip the trocar as it exits the skin and hold the lead as close to the body as possible when pulling. As far as possible, avoid exerting any force on the pump socket. IMPORTANT: A distance of at least 10 cm is required subcutaneously to prevent ascending infections.
6. Unscrew the trocar from the trocar adapter.

7.4.5 Silicone outflow cannula - anastomose and connect with system

7.4.5.1 Anastomosis and length adaptation

WARNING

Ensure that the snap-in connector is correctly engaged! Bleeding may otherwise occur.

ADVICE

We recommend using the head of the outflow cannula as a gage for the length of the incision: the incision should be approx. 5 mm shorter than the compressed head of the outflow cannula (length: approx. 30 mm)

1. Clamp the aorta tangentially and make a longitudinal incision. In doing so, use the head of the outflow cannula as a gage: the length of the **incision (1)** should be at least 25 mm, i.e., no more than 5 mm shorter than the **compressed head of the outflow cannula** (**2**, length: approx. 30 mm). IMPORTANT: If the incision is too short, bleeding may occur at the site of anastomosis.

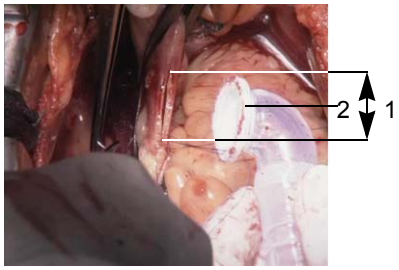


Fig. 7-42 Size ratios for aortic incision

2. Perform end-to-side anastomosis of the outflow cannula with the aorta. A running suture or single button sutures can be used.

3. Determine the required length of the outflow cannula.

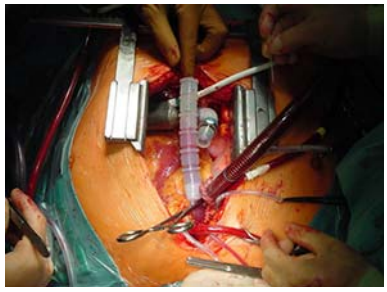


Fig. 7-43 Determining the required length of the outflow cannula

4. Adapt the length of the outflow cannula. To do so, cut off the necessary number of **collars (1)**. Cut immediately before the **front surface (2)**. The cut should be a maximum of 0.5 mm away from the front surface. IMPORTANT: The excess on the cut surface may not be more than 0.5 mm! Make sure that the cut is straight. IMPORTANT: At least one collar must remain on the cannula!

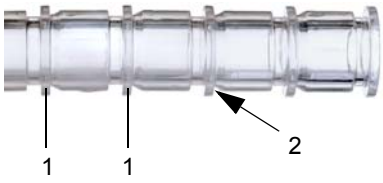


Fig. 7-44 Collars of the outflow cannula

7.4.5.2 Connecting the outflow cannula to the system

WARNING

Ensure that the system is free of air when connecting the pump and outflow cannula. Otherwise embolisms may develop.

1. First attach the guide ring, then the seal ring to the inflow side of the outflow cannula. The claws should be pointing toward the pump. De-air the outflow cannula in a retrograde direction.
2. Remove the seal cap or vent tube adapter from the outflow angle section or pump.

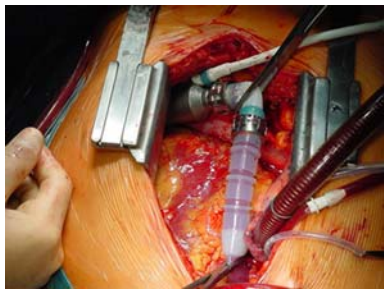


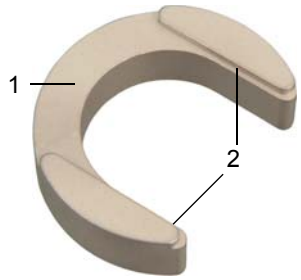
Fig. 7-45 Connecting the outflow cannula to the pump

3. Connect the outflow cannula to the outflow angle section or pump. In doing so, carefully de-air the cannula and the pump (feed in NaCl solution or fill the cannula and pump with blood). The front side of the cannula must be flush with the detent ring of the pump.
4. Allow the guide ring to snap into place. All the claws of the guide ring must be fully engaged.
5. Check the position of the snap-in connector: a correctly engaged snap-in connector can easily be turned back and forth within the snap-in position!
6. Turn back the silicone cover of the guide ring. Ensure that the silicone cover is concealing the entire guide ring.
7. If there is still air in the system: de-air the system. To do so, puncture the outflow angle section. If the outflow angle section is not being used, only the felt pledget of the outflow cannula may be punctured. Size of the puncture cannula 21G. Ensure that the puncture is made at a 90° angle to the felt pledget. Keep the number of punctures to the minimum.

If the snap-in connector of the outflow angle section/outflow cannula has to be opened

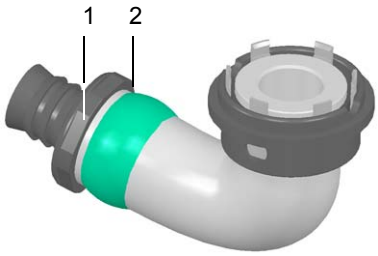
NOTICE

If the snap-in connector between the outflow angle section and the outflow cannula must be opened, this may only be done using the supplied angle section key. Otherwise, the outflow angle section may be damaged!



1 Contact surface: this surface presses against the detent ring of the outflow angle section.
2 Key surface: the detent ring of the outflow angle section is inserted between the key surfaces of the angle section key.

Fig. 7-46 Angle section key with contact surface and key surface



1 The key surface of the angle section key grips here.
2 The contact surface of the angle section key is positioned here.

Fig. 7-47 Detent ring of outflow angle section

1. Retract the **silicone cover (2)** between the **outflow angle section (4)** and **outflow cannula (1)** to expose the detent ring of the **outflow angle section (3)**.

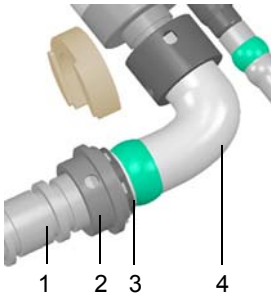


Fig. 7-48 Outflow angle section with retracted silicone cover

2. Push the angle section key onto the outflow angle section. The **key surfaces of the angle section key (1)** enclose the detent ring from the side, and the **contact surface of the angle section key (2)** pushes against the detent ring from below. Hold the key and outflow angle section firmly in this position. Note: the angle section key can be affixed to all surfaces of the detent ring.

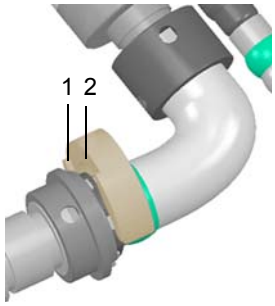


Fig. 7-49 Angle section key enclosing the detent ring of the outflow angle section

3. Grip the guide ring. Twist the guide ring slightly towards the detent ring, then tighten. Do not compress the guide ring.
4. Remove the key.
5. Grip the detent ring and outflow cannula, then remove the outflow cannula.
6. Inspect before reconnecting: is the silicone edge of the outflow angle section flush with the edge of the detent ring? If not: replace the outflow angle section.

7.4.6 Anastomosis and de-airing of the graft outflow cannula

WARNING The graft outflow cannula must be anastomosed corresponding to the instructions. Otherwise a safe connection of the vascular graft prosthesis to the aorta is not guaranteed.

Anastomosis

ADVICE Use round needles with tapered ends for anastomosis.

1. Shorten the distal portion of the vascular graft prosthesis to suit the anatomical conditions. The goal is a connection with the target artery free of tension, kinks and torsion. Torsion can be detected by the dark woven strip of the vascular graft prosthesis.
2. Check the incision edge. The incision edge must be homogeneous to avoid leaks which can lead to bleeding and/or to an air embolism.

3. Clamp the aorta tangentially and make a longitudinal incision. Use the diameter of the vascular graft prosthesis as a scale.
4. Perform end-to-side anastomosis of the vascular graft prosthesis with the aorta. Use a running suture or single button sutures.

De-airing the system

WARNING

Make sure that after the anastomosis the graft outflow cannula is free of air. Otherwise embolisms may develop.

ADVICE

If de-airing is necessary, the smallest possible needle should be used; 19 gage is normally sufficient. Needles for subcutaneous injection have a cutting tip that can result in blood leakage and may require repair by suturing.

De-airing can be:

- by puncturing the graft outflow cannula
- by puncturing in the area of the outflow angle section (felt pledget)
- through the suture of the anastomosis

7.4.7 Mounting the pump socket ready for connection

In order for the pump to be connected to the control unit, the pump socket must be fitted with a sleeve. When combined, the pump socket, sleeve, and control unit plug form the plug coupling. The assembly must be carried out in a dry environment. Avoid the entry of fluids into the pump socket!

- Pump socket at the end of the driveline: see Fig. 7-53 , page 125.
- Sleeve: See Fig. 7-53 , page 125
- Plug for control unit: see Fig. 7-55 , page 126.

Removing the trocar adapter from the pump socket

1. Baseline situation: The **trocar adapter (1)** and **pump socket (4)** are still connected and covered by the silicone tube. Remove the **silicone tube (2)** by rolling the silicone tube back as far as possible, but at least as far as the metal section of the **pump socket (3)**. If the resistance to this action is too great, the silicone tube can be cut carefully with a scalpel. IMPORTANT: Do not bring the scalpel into contact with the kink protection sleeve at the point where the socket and cable meet!

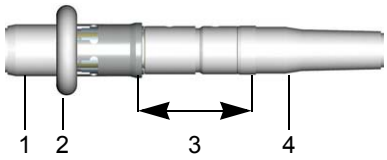


Fig. 7-50 Trocar adapter with retracted silicone tube

2. Grip the trocar adapter and retract the **closing sleeve (1)** as far as the end of the slit.

Fig. 7-51 Trocar adapter with retracted closing sleeve

3. Now grip the pump socket and exposed section of the trocar adapter and pull gently to separate one from the other. In doing so, gently maneuver the trocar adapter from side to side as necessary. The **core of the pump socket (1)** will now be exposed.

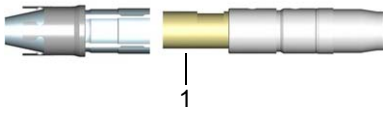


Fig. 7-52 Exposed core of pump socket

Affix sleeve to pump socket

1. Guide the **sleeve (1)**, narrow end first, onto the **pump socket (4)** so that the markings on the **sleeve (2)** and pump socket (3) are perfectly aligned. IMPORTANT: The sleeve can only be positioned on the pump socket if the markings on the pump socket and sleeve are precisely aligned.

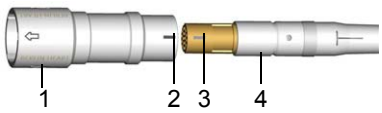


Fig. 7-53 Sleeve and pump socket

2. Now apply force to push the sleeve onto the pump socket so that it is aligned. After overcoming any initial, palpable resistance, continue to push until it engages, i.e., as far as the **end mark (1)**. Rather than twisting the sleeve against the pump socket or cable, make sure that the markings are constantly aligned. Otherwise, the sleeve cannot be brought into the snap-in position.

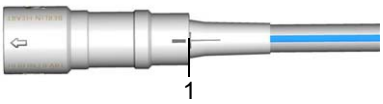


Fig. 7-54 Pump socket ready for connection

3. Pull on the sleeve to check it. The sleeve is now inextricably connected to the pump socket, and the socket is ready to be plugged in.

7.5 Activating and configuring the pump

7.5.1 Aligning the control units with the pump: offset correction

WARNING

Never pull on the plug/cable during offset correction! Otherwise the monitor program will display incorrect flow values, and the messages E20/E21/E22 will not appear, or will be displayed erroneously.

Do not retrospectively modify the value configured for the offset of the rotor position! Otherwise the monitor program will display incorrect flow values, and the messages E20/E21/E22 will not appear, or will be displayed erroneously.

When connecting the control unit and pump with the plug coupling, ensure that the cable is not twisted. The blue longitudinal marking on the driveline helps to ensure that the cable is aligned. If this is not the case, the cable may be damaged.

NOTICE

When connecting the control unit and pump by means of the plug coupling, ensure that the arrow markings on the plug and socket are precisely aligned! Otherwise the plug may be damaged.

When first connecting the control unit to a pump, the pump will be automatically calibrated (offset correction).

IMPORTANT: Perform offset correction under ECC.

Connecting the pump to the control unit

1. Prepare the INCOR Smart Bag with control unit 1 and batteries.
2. The outflow cannula must be clamped by the surgeon.
3. Connect the pump and control unit 1 to each other by means of the plug coupling. To do this, insert the **control unit plug (1)** into the **pump socket (4)**. IMPORTANT: The arrow markings on the **control unit plug (2)** and the arrow markings on the **pump socket (3)** must be aligned! See Fig. 7-56 .

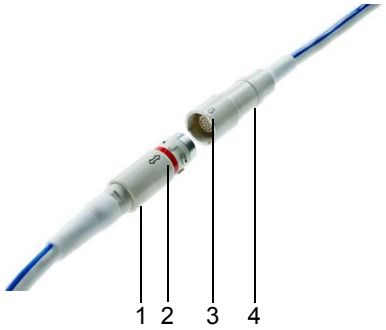


Fig. 7-55 Plug coupling open

Fig. 7-56 Plug coupling closed

Performing offset correction on control unit 1

1. Connect the operator terminal to control unit 1.
2. Connect the backup battery to control unit 1. Once the pump and backup battery are connected to the control unit, do not pull on the plug or cable! Auto-calibration of the control unit commences; wait 30 seconds.

Fig. 7-57 Pressure difference curve before offset correction

3. Log in as an OR user.
4. Ensure that the system is in halt mode (displayed speed = 0).
5. Select **Offset rotor position** from the **Settings** menu. The **Offset of rotor position** window opens. The pressure difference curve will most likely not coincide with the zero line.
6. To adjust the displayed pressure difference,
   press **<↑>** / **<↓>** until the pressure difference curve coincides with the zero line. Every step corresponds to 2 mmHg.
7. After adjustment: select **Close**. The configured value is applied.

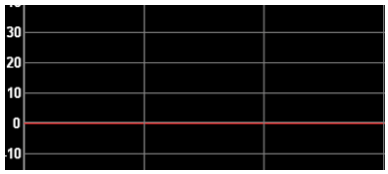


Fig. 7-58 Pressure difference curve after offset correction

8. Prepare control unit 2.
9. Firstly, disconnect the battery from control unit 1, then pull the plug of control unit 1 out of the pump socket (plug coupling open). To open the plug coupling, retract the sleeve of the control unit plug marked with the double arrow (see Fig. 7-55 , page 126). Only then can the control unit plug be removed from the pump socket by pulling.
10. Remove control unit 1 from the bag and put to one side. The control unit will emit an acoustic alarm for about 5 minutes.

Performing offset correction on control unit 2

1. Take control unit 2 and place it in the bag.
2. Connect control unit 2 to the pump by means of the plug coupling.
3. Repeat steps 1 to 7 for control unit 2, as described for control unit 1.
4. Remove the clamp from the outflow cannula. The pump is now sufficiently prepared that it can be activated. Control unit 2 remains connected to the pump as the active control unit. Control unit 1 serves as the replacement control unit.

With a clamped outflow cannula and inactive pump, the pressure difference across the pump is approximately 0 (even for a heart with residual contractility).

If no pressure difference display can be seen when the **Offset of rotor position** window is open: disconnect all plugs from the control unit and then reconnect. Acknowledge message **EF50**.

7.5.2 Starting the system via the monitor program, setting the parameters

WARNING

During weaning from ECC: monitor the system and adjust the settings if necessary. Otherwise, support may be inadequate.

ADVICE

We recommend transferring the settings and patient data to the replacement control unit in the intensive care unit.

We recommend a low-flow regime: select as low a speed as possible in order to prevent myocardial suction and septal shift (and the right ventricular failure that could thus result). Keep the speed as low as possible so that the aortic valve occasionally opens and the left ventricle is sufficiently flushed.

We recommend that the speed be slowly adjusted to the hemodynamics of the patient.

Perfusion

1. Select continuous pumping mode. The pump will operate at 5000 rpm.
2. In agreement with the surgeon: adjust the speed to the requirements, while simultaneously weaning from ECC. Avoid myocardial suction!
3. Enter alarm threshold flow.
4. Enter the pressure difference alarm threshold
5. If necessary, the alarm thresholds for flow and pressure difference must again be checked and readjusted in the intensive care unit.

Parameter	Guideline value
Alarm threshold flow	approx. 50 % of the maximum achievable flow; never < 2.5 l/min.
Alarm threshold pressure difference	Approx. 20 to 30 mm Hg

Tab. 7-1 Guideline values for parameter settings

IMPORTANT: The flow must be at least 3.5 L/min.

Dimensions of the inflow cannula for outer diameter transesophageal echocardiography: 19.6 mm, inner diameter inflow side: 16 mm, inner diameter outflow side: 11.3 mm

If applicable, INCOR will indicate any flow exceeding the operating limits (e.g., negative flow) if

- offset correction has not been carried out successfully.
- INCOR is being operated at too low a speed.
- INCOR is being operated in combination with ECC.

Possible measures:

- if necessary, repeat offset correction. See section 7.5.1: Aligning the control units with the pump: offset correction, page 125.
- if necessary, increase the speed.
- if necessary, slowly reduce and wean from ECC.

Surgery

1. Before switching to continuous pumping mode: insert a left atrial pressure measurement line, if necessary.
2. Switch to continuous pumping mode. The pump will operate at 5000 rpm. Adjust the speed.
3. Slowly reduce and wean from ECC.

7.6 Postoperative care on the intensive care unit

7.6.1 Transferring the settings and user data to the replacement control unit

WARNING

Transfer the settings to the replacement control unit as soon as the patient is in the intensive care unit! Otherwise the pump will fail to start when the control unit is exchanged for the replacement control unit.

IMPORTANT: The replacement control unit can only be accessed via the personal user profiles if they have been transferred to the replacement control unit! If passwords are subsequently changed, such changes must also be transferred to the replacement control unit. Otherwise, different passwords will exist in the active and replacement control units for the same user.

Saving data to a USB stick

1. Start the operator terminal and connect it to the active control unit, then log in as a user or administrator.
2. Insert the USB stick into the upper USB port of the operator terminal.
3. Save the settings and patient data to the USB stick (menu item **Service**, submenu item **Save settings and patient data**).
4. If personal passwords have been created: save the user data to the USB stick (menu item **Manage user profile**, submenu item **Save user data to USB**).
5. Disconnect the operator terminal from the active control unit.

Transferral of data to the replacement control unit

1. Remove the backup battery from the charging unit and connect it to the replacement control unit (do not remove the battery from the active control unit!).
2. Acknowledge message **H50 No pump connected** and **A02 Main battery not connected** on the replacement control unit.
3. Connect the operator terminal to the replacement control unit, and log in again as an administrator if necessary.
4. Transfer the settings and patient data to the replacement control unit (menu item **Service**, submenu item **Send settings and patient data**).
5. Retrieve the menu item **Current values** to check whether the settings have been transferred successfully.
6. If personal passwords have been created: save the user data to the replacement control unit (menu item **Manage user profile**, submenu item **Send user data to CU**).
7. Remove the USB stick from the operator terminal.
8. Disconnect the operator terminal from the replacement control unit.
9. Disconnect the backup battery from the replacement control unit. Tone sequence ceases after about 5 minutes. The control unit is switched off.

7.6.2 Further follow-up measures

1. Complete and fax the implantation record form to the manufacturer.
2. Write the patient's name on the active control unit and the replacement control unit.
3. Check whether the control unit and replacement control unit have been programmed correctly (patient name, implantation date, alarm threshold flow, alarm threshold pressure difference).
4. Note the number of the active control unit.
5. Place the inner compartment of the INCOR Smart Bag in the outer compartment.
6. Store the replacement control unit securely in the immediate vicinity of the patient.
7. Store the INCOR instructions for clinical use and the INCOR short instructions for clinical use in the immediate vicinity of the patient.
8. Clean the driveline (remove bloodstains).

7.7 Anesthesia

Recommendations

- Sufficient quantities of cross-matched packed red blood cells, fresh frozen plasma (FFP) and platelet concentrates should be available at short notice.
- Keep the number of blood transfusions to a minimum. Blood transfusions have a pro-inflammatory effect.
- Devices for autotransfusion (e.g., Cellsaver) should be readily available in the OR.
- Drugs for treating pulmonary hypertension should be readily available in the OR.
- Drugs for supporting right ventricular function should be readily available in the OR.
- After weaning from ECC, start ventilation with nitric oxide (NO concentration). It should be possible to provide temporary mechanical right ventricular support, where needed.

7.7.1 Monitoring procedures

Intraoperative monitoring should be consistent with the standard monitoring procedures for major cardiosurgical interventions:

- Central venous line (CVL)
- Sheath and pulmonary artery catheterization (Swan-Ganz catheter)
- Arterial catheter
- Electrocardiogram (ECG)
- Pulse oximetry
- Central temperature
- Foley catheter

Further recommended monitoring procedures

- Cardiac output measurement
- Intraoperative transesophageal echocardiography (position of inflow cannula, valve function, intracardiac shunts, volume status, right ventricular function).
- Other monitoring procedures (e.g., neuromonitoring) at the discretion of the anesthesiologist.

7.7.2 Pre- and intraoperative anticoagulation

Preoperative

Perform thrombelastography to check for a hypercoagulable state.

Intraoperative

While the patient is on ECC: administer heparin.

At the end of surgery, administer protamine to completely antagonize the heparin effect and to achieve a normal activated clotting time (ACT).

8 Intensive Care and Postoperative Care

WARNING

Patients with critical hemodynamic status must be continually monitored by professional medical personnel with specific product training! Otherwise, support may be inadequate.

If the hemodynamic status of the patient is found to be critical, the control unit must be replaced within 30 seconds! Otherwise, support may be inadequate.

All information in this chapter entails recommendations derived from the experience gained with INCOR. It is essential, however, to adjust therapy individually according to the patient's age, weight, general state of health, organ function and infection status.

8.1 Anticoagulation therapy and inhibition of platelet aggregation

As in all patients with a ventricular assist device, INCOR patients also require anticoagulation therapy. Treatment for inhibiting platelet aggregation is also recommended.

Anticoagulation should be commenced 12 - 24 hours after surgery, depending on the patient's coagulation status.

So that this can be done without risk to the patient, precise hemostasis is required, i.e., postoperative bleeding should be avoided as far as possible.

Heparin

The heparin dosage should be checked at regular intervals. As a guideline, the recommendation is to check every 6 hours during the first 10 days until the activated partial thromboplastin time (aPTT) has stabilized, and thereafter once daily or subsequent to each dose adjustment. This can be done either in the laboratory or with the aid of an aPTT fast test (bedside).

Coagulation status

At a platelet count of 50 000-100 000/µL, the aPTT should be increased to 50 s - 60 s, and at a platelet count of more than 100 000/µL it should
be 60 s - 80 s. Depending on the thrombelastograph values, an aPTT of up to 90 s may be necessary over the further course.

Other methods and tests, empirical values

The doses of the platelet aggregation inhibitors acetylsalicylic acid, dipyridamole® (a phosphodiesterase inhibitor which increases cAMP levels in the platelets) and, if applicable, clopidogrel, should be adjusted on an individual basis. This can be checked by means of platelet mapping or platelet aggregation tests.

Since each patient reacts differently to platelet aggregation inhibitors, the optimal dose should minimize the risk of thrombembolic complications (in the case of sub-therapeutic dosage) or bleeding complications (in the case of overdose).

Growing experience with INCOR shows that varied strategies for anticoagulation and, if necessary, inhibition of platelet aggregation, can be successfully applied. Long-term administration of a vitamin K antagonist as a single anticoagulant has proven benefi-

cial in some patients, whereas the subcutaneous administration of low molecular weight heparin and a platelet aggregation inhibitor has been successful in others.

8.1.1 Example of anticoagulation therapy

Regimen for anticoagulation and inhibition of platelet function

In addition to its anticoagulant effect, heparin also has an unfavorable effect in that it activates the platelets.

Starting therapy

- Do not administer heparin in the first 12 - 24 h postoperatively.
- Thereafter: start heparin administration (IV), depending on postoperative bleeding (< 50 mL/h), and thrombelastography (normal hemostasis)
- Start unfractionated heparin at 5-7 IU/kg/h IV, no bolus
- aPTT monitoring every 6 h until aPTT is stable within the target range (1.5 to 2.5 times the initial value) or the heparin level is 0.35 to 0.50 IU/mL
- Platelet count normal
  - Target aPTT postop. day 1: 50 to 60 s
  - Target aPTT postop. day 2: 60 to 80 s
- Thrombocytopenia < 50 k/µL: keep aPTT within the normal range (no platelet transfusion); refer to the literature concerning the effects of platelet transfusion on platelet function and the side effects of such a procedure!
- Platelet count 50 k/µL to 100 k/µL: target aPTT 50 to 60 s (no platelet transfusion)
- Platelet count > 100 k/µL: target aPTT 60 to 80 s

Oral anticoagulation

Once fully stabilized, the patient can be switched to a vitamin K antagonist (target INR: 2.5 to 3.0).

Check the INR value once per day. Until the target INR is reached, the simultaneous administration of a vitamin K antagonist and heparin is necessary (duration approx. 4 days).

Once the target value is reached, heparin can be discontinued. If the value drops considerably below the reference value, the patient must be administered heparin temporarily:

INR 2.5 to 3.0	Vitamin K antagonist, administered orally
INR 2.0 to 2.4	Low molecular weight heparin, administered subcutaneously at a prophylactic dose
INR < 2.0	Low molecular weight heparin, administered subcutaneously at a therapeutic dose

Tab. 8-1 Heparin administration if target INR is not reached

8.1.2 Example of platelet aggregation inhibiting therapy

Inhibition of platelet aggregation

Monitoring with platelet aggregation tests (shortened hereafter to: PAT - platelet aggregation test). PAT target value: inhibition of arachidonic acid (shortened hereafter to: ARA) induced PAT by more than 70% (epinephrine 40-50%, collagen not inhibited).

Starting therapy

Postoperative day 2: Start dipyridamole PO. Initial dose 150 mg/d (4 x 37.5), maximum 1.2 g/d (4 x 300 mg).

Postoperative day 4: If ARA inhibition is less than 50%: start acetylsalicylic acid (shortened hereafter to: ASA), initial dose 50 mg/d (2 x 25 mg), possibly increasing until effective (ASA is administered in 2 daily doses due to increased platelet consumption).

If effective inhibition (according to PAT) cannot be achieved: Start clopidogrel 75 mg/d in order to inhibit adenosine diphosphate (shortened hereafter to: ADP) induced aggregation by more than 70% (then stop ASA administration).

Frequency of PAT and TEG monitoring

- Week 1 postoperatively: once daily
- Week 2 postoperatively every second day
- Week 3 postoperatively: twice per week
- Subsequently: once per week

Certain drugs for treating cardiac insufficiency intensify anticoagulation, and inhibition of platelet aggregation in particular.

Since specific therapy with the following medications is highly recommended, their impact on coagulation must be considered:

- Beta blockers
- ACE (angiotensin-converting enzyme) inhibitors
- Aldosterone antagonists
- AT II receptor blockers

8.1.3 Laboratory values

The following laboratory values should be monitored on a daily basis during the first postoperative week:

- Antithrombin III level (target value > 75%)
- Fibrinogen
- D-dimers
- Leukocytes
- C-reactive protein (CRP)

IMPORTANT: Any infection will activate the coagulation system. Careful and regular monitoring of the blood values is therefore essential. If necessary, appropriate corrective action must be taken immediately.

8.2 Antibiotic therapy

ADVICE

We recommend perioperative antibiotic prophylaxis with staph antibiotics (e.g., cephalosporin, 2nd generation).

If there are signs of a local infection in the area of the transcutaneous exit site or evidence of systemic infection, we recommend targeted antibiotic therapy after pathogen isolation in all accessible media (blood culture, swab).

In the event of infection in the area of the transcutaneous exit site, we recommend targeted oral antibiotic therapy and antimicrobial dressing of the wound. The infection may otherwise recur.

8.3 Wound Care and Dressing Changes

WARNING

Attach the driveline to the body, close to the wound, Use drainage fixation tape for this (e.g., Secutape®, Hollister®). Otherwise there is an increased risk of infection at the transcutaneous exit site.

NOTICE

Do not use acetone or mineral oil products in the immediate vicinity of the transcutaneous exit site and driveline. Do not use corrosive agents, solutions containing dyes, or organic solvents for cleaning purposes, since they may affect the surface of the product.
Clean the **transcutaneous exit site** with chlorhexidine.
Clean the **driveline** only with water or alcohol (e.g. a 70 % solution).

ADVICE

For wound care, ensure strict compliance with aseptic techniques. Wear sterile disposable gloves, surgical cap and a face mask. Otherwise there is an increased risk of infection at the transcutaneous exit site.

Do not apply the tape directly on the driveline. Residues from tape lead to the contamination of the cable. Contamination increases the risk of infection.

IMPORTANT: Include the cable protector in wound care procedures. See section 5.9.2: Cleaning the cable protector, page 58.

Treat the area of the transcutaneous exit site under sterile conditions. In the inpatient setting, wound care should always be performed by the same limited group of people. If the patient is discharged to outpatient care, the patient himself as well as his relatives should be instructed accordingly. Only careful wound care can minimize the risk of infection.

Frequency:

POD1 1 - 10	1x daily
POD 11 - 20	Every 2 days
POD 21 -	2x weekly
infected transcutaneous exit site	2x daily
additional change	in the event of a contaminated dressing
1 postoperative day	

Tab. 8-2 Wound care and dressing changes

Material:

- 1 cap
- 1 face mask
- 1 pair of disposable gloves
- 1 pair of sterile disposable gloves
- 1 sterile drape (75 x 90 cm)
- suitable disinfectant (e.g. chlorhexidine or octenidine-containing solution) in sterile bowls
- 1 sterile-packaged band-aid (approx. 7 x 5 cm)
- 2 sterile-packaged band-aids (approx. 10 x 15 cm)
- 7 sterile packaged gauze compresses
- 1 slit compress
- 1 drain fixation tape for relieving tensile stress on the driveline

Removing old dressings

1. Put on disposable gloves, a cap and a face mask.
2. Removing old dressings. Non-touch technique
3. Remove the disposable gloves.
4. Unpack all the materials required for wound care in a sterile environment and lay them out on the sterile drape.
5. Put on sterile, disposable gloves.
6. Examine the transcutaneous exit site and, if there are any changes, take the appropriate action.
7. Clean the driveline at the transcutaneous exit site using a sterile compress soaked with disinfectant.
8. Clean the skin in the area of the transcutaneous exit site using a compress soaked with disinfectant, starting from the site of the wound and working outwards. Observe the application time of the disinfectant.

Applying a new dressing and fixation tape

1. Place the slit compress around the driveline, The slit faces towards the head. Fix the compress with a band-aid above the driveline.

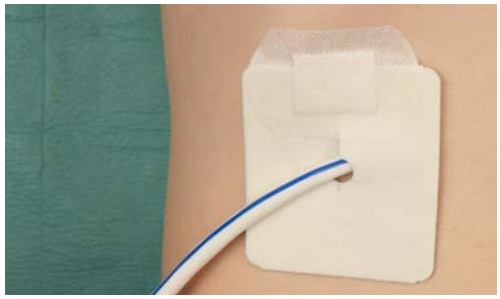


Fig. 8-1

2. Place a folded compress beneath the driveline for padding and positioning.

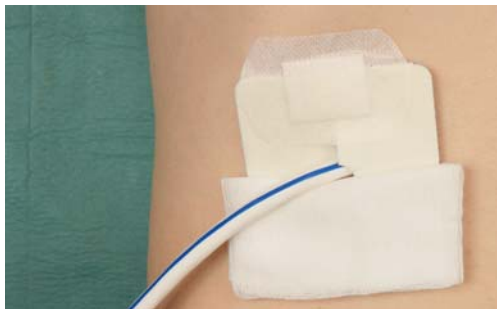


Fig. 8-2

3. Position 3 folded compresses around the driveline, each at a 90° angle to the other.

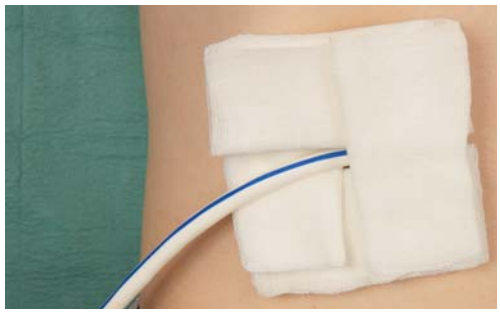


Fig. 8-3

4. Place a compress over the driveline and padding.

Fig. 8-4

5. Liberally apply tape to the compress to secure.

Fig. 8-5

6. Liberally apply slit tape to the compress to secure. The driveline should be positioned over the tape. The tapes should overlap.

Fig. 8-6

7. Attach the driveline to the body, close to the wound, Use drain fixation tape for this. In doing so, heed the manufacturer's instructions. The fixation tape should be directly adjacent to the compress.

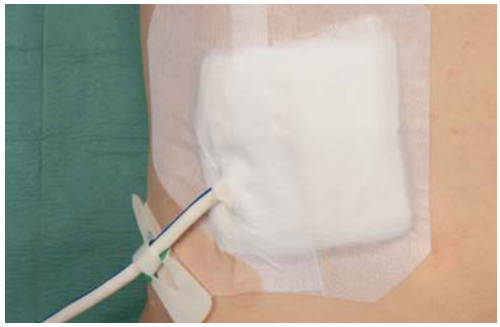


Fig. 8-7

8.4 Controlling the pump function via the monitor program

1. Check all the curves.
2. Read and display the event memory.
3. Adjust the settings if necessary. Transfer the modified settings to the replacement control unit.
4. If the operation of the system is stable: record the pressure and flow values, speed, bearing power and motor power. Always keep the values updated!

ADVICE

We recommend that the pressure and flow values, as well as bearing power and motor power, be recorded on a regular basis. Modified values may necessitate diagnostic measures.

Frequency of monitoring:

- Intensive care: constantly, but at least every 2 hours
- Inpatient care: 3 times daily
- The monitoring intervals during outpatient care should be determined by the physician.

9 Explantation

WARNING

When using a cauterization knife, the current must not flow directly through the pump. Therefore, do not attach the electrode of the cauterization knife to the back of the patient! Avoid contact between the cauterization knife and pump! Otherwise there is a risk of electric shock.

When using a cauterization knife, operate INCOR from the batteries! Otherwise the pump may stop.

Before cutting through the driveline, remove it from the control unit! Otherwise there is a risk of electric shock.

ADVICE

We recommend deactivating PC, PFC, and SP prior to further surgical procedures.

Explantation may be performed under induced ventricular fibrillation or on the beating heart.

Workplace equipment:

- Explantation set
  - 1 scraper, sterile
  - 1 cutting tool
  - 2 seal caps, sterile
- 1 transport container
- For BTR: weaning set: the weaning set can be obtained from the manufacturer. For weaning, see section 9.2: Weaning (BTR), page 141.
- Possibility of ECC

9.1 Transplantation (BTT)

1. Disconnect the driveline from the control unit.
2. Cut through the driveline with the supplied cutting tool.
3. Completely remove the heart, pump and cannulae. Stitch over the anastomosis of the outflow cannula if necessary.
4. Using the supplied scraper, loosen adhesions from the driveline, and remove the distal portion of the driveline from its bed.
5. Pull the cable outwards.

9.2 Weaning (BTR)

DANGER

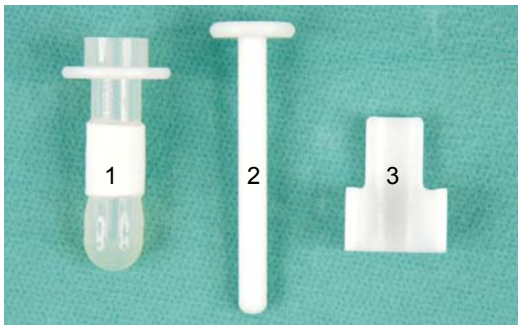
It is essential to use the INCOR weaning set for explantation of the INCOR system. Only in such a way is it possible to close the truncated inflow cannula that remains in the ventricle.
IMPORTANT: The weaning set is not supplied with the INCOR device. If needed, it can be obtained from the manufacturer.

WARNING

Ensure that the remainder of the cannula is completely free of air! An embolism may otherwise develop.

Do not puncture the seal plug! Otherwise the seal plug may leak.

Depending on the implanted inflow cannula, the appropriate position spacer from the weaning set must be used. See Tab. 9-1 , page 142. To ascertain which cannula has been implanted, the manufacturer can be contacted (service@berlinheart.de; please quote the AP number).



1 Seal plug
2 Insertion tool
3 Position spacer

Fig. 9-1 Weaning set

Length of inflow cannula	Designation of position spacer	Length of position spacer
65°, 70 mm	S (short)	37 mm
65°, 75 mm	L (long)	32 mm

Tab. 9-1 Implanted inflow cannula, designated position spacer

Explanting the outflow cannula

1. Disconnect the driveline from the control unit.
2. Clamp off the outflow cannula.
3. Clamp the aorta tangentially, immediately below the anastomosis.
4. Cut through the outflow cannula immediately above the anastomosis.
5. **Either:** Apply a single button suture with felt pledget beneath the suture ring. If leaking, patch with Teflon and fix with a running suture.
6. **Or:** completely remove all parts of the outflow cannula and stitch over the site of the incision.

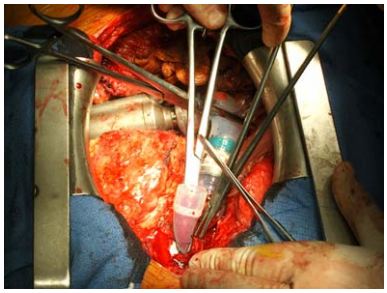


Fig. 9-2 Transected outflow cannula

Fitting the inflow cannula with a weaning plug

1. Clamp off the inflow cannula immediately beneath the suture ring.
2. Cut off the inflow cannula. IMPORTANT: Sufficient material must still be available in order to suture the seal plug.
3. Moisten the seal plug. Position the insertion tool on the seal plug.
4. Insert the seal plug into the inflow cannula as far as the clamp. Push the insertion tool into the seal plug to taper its diameter.
5. Carefully loosen the clamp, while at the same time pushing the seal plug a little further into the inflow cannula. Ensure that the ventricle remains free of air.
6. Clamp the position spacer onto the inflow cannula so that it is flush against the suture edge of the inflow cannula.
7. Push the seal plug into the cannula until the seal ring of the seal plug abuts against the position spacer. The seal plug is now positioned correctly.

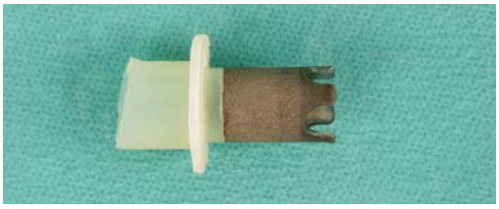


Fig. 9-3 Truncated inflow cannula

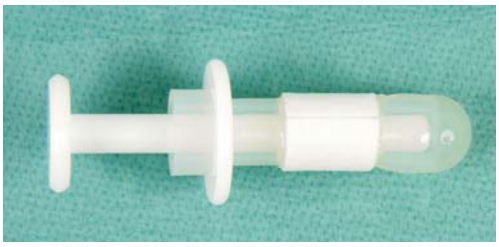


Fig. 9-4 Seal plug with insertion tool

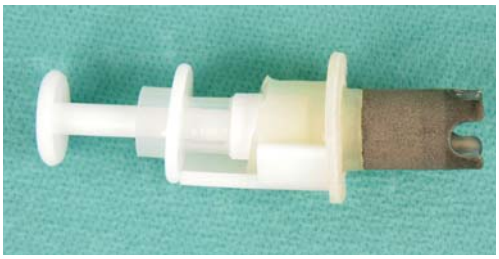


Fig. 9-5 Correctly positioned seal plug

8. Remove the insertion tool and position spacer.
9. Cut off the seal plug immediately below the edge of the cannula. Stitch the seal plug to the edge of the cannula. When doing so, apply a felt-backed Mersilene suture (matte finish, non-absorbable).

Explanting the pump

1. Cut through the driveline in the thorax using the supplied cutting tool.
2. Using the supplied scraper, loosen adhesions from the driveline, and remove the distal portion of the cable from its bed.
3. Pull the cable outwards.

10 Messages and Measures

- Carefully practice all the measures described here!
- Remain calm!
- If you have any urgent questions about INCOR,

HOTLINE **Contact the emergency hotline! +49 (0)30 81 87 27 72**

If INCOR is working perfectly,

- the display on the control unit shows the normal display (remaining battery operating time in h:min).
- the control unit will not emit any acoustic alarms.
- the indicator on the control unit will not be illuminated.
- a short audible alarm will sound every time the button on the control unit is pressed and released.

IMPORTANT: If one of the above conditions does not apply, appropriate action must be taken immediately. If an error scenario is not accompanied by a message: See chapter 11: Detecting and Eliminating Errors, page 165.

If INCOR is not working perfectly,

- the display on the control unit immediately shows a message,
- the control unit immediately sounds an acoustic alarm,
- the connected operator terminal immediately displays a message.

Message and message code

INCOR will generate a message to inform you that a specific measure must be carried out. For this purpose, a message code will appear in the display. This code consists of a combination of 1 or 2 letters and 2 numerals (e.g., **A01**). An acoustic signal will also sound.

Automatic saving of messages

Messages are saved in the control unit. The memory contains 400 messages. If the memory is full, the oldest message will be overwritten each time. If an operator terminal is connected to the control unit, all messages are sent from the control unit to the operator terminal and saved on the operator terminal.

If components are turned off or there is a power cut, the messages are retained on both the control unit and the operator terminal

Order of priority of the signaling

- Errors have "high" priority.
- If errors and indications occur at the same time, the error is signaled as a priority.
- Error messages are displayed in various orders of priority, see Tab. 10-1 , page 146 There are three types of errors:
  - Fatal errors
  - Error
  - Battery message
- In the event of the same level of priority, the most recent message is displayed.

Types of messages

Order of priority of the messages	Type	Description	Acoustic alarm and volume	Unresolved, acknowledged messages...
	EF: Fatal error message	Faulty control unit or pump stop imminent/pump has stopped - take immediate action!	Short audible alarms in rapid succession (- - -) Approx. 69 dB(A)	… recur after 30 s.
	E, EA: Error message	Malfunction. Take action immediately!	Short audible alarms in rapid succession (- - -) Approx. 69 dB(A)	... recur after 30 s, and if re-acknowledged will recur after double the amount of time in each case (max. 8 min).
	A: Battery message	No malfunction. Battery empty or not connected. Take action immediately!	Short audible alarms in rapid succession (- - -) Approx. 69 dB(A)	... recur after 30 s, and if re-acknowledged will recur after double the amount of time in each case (max. 8 min).
	H, HA: Notification message	Faulty status, breakdown not imminent, take action as soon as possible.	Continuous tone (____) Approx. 69 dB(A)	… do not recur.

Tab. 10-1 Types of messages

Suppressed signaling in the event of an active PFC

If the PFC function is active, the signaling regarding the flow and pressure is suppressed for the period of the speed change +1 s.

What to do when a message appears

- Whenever an error message appears, always proceed as described in this chapter.
- Check the status of the patient!
- Use the control unit and monitor program to determine whether the pump is functioning properly!
- Acknowledge the message and take the appropriate action!

IMPORTANT: If the engineer is logged in, the secondary messages corresponding to the message codes (such as: **A01**) are displayed (depending on the message: Irrespective of such a scenario, proceed with such messages as described for the relevant message codes.

Acknowledging a message

A message can be acknowledged by pressing the button on the control unit. The acoustic alarm is muted, and the display remains visible for a few more seconds. If there are battery and error messages, the cause of which cannot be eliminated quickly, the messages will reappear (see below). Notification messages do not reappear once acknowledged.

IMPORTANT: Read the message in the display before acknowledgment. Then take the necessary action.

1. Check the display to see which message has appeared.
2. Acknowledge the message and rectify its cause.
3. By pressing the button on the control unit, check whether there are any other current messages: if there is a current message, it will now be displayed. Otherwise, the message most recently resolved will appear. After 10 seconds, the display will return to normal.
4. Connect and start the operator terminal; retrieve **Messages**.

ADVICE

If a message appears, we recommend that the displayed code be noted. This helps when making inquiries within the hospital or when contacting the INCOR emergency hotline.

In the event of battery, error and fatal error messages, whereby the acoustic alarm is muted via the operator terminal, the acoustic alarm will only recur after 8 minutes.

Current messages and resolved messages

Once the cause of a message has been rectified, the message is stored as "resolved" in the event memory of the control unit.

- Current message: A01
- Message resolved: A:01 (colon!)

10.1 A01 Change main battery

Message **A01 Change main battery** appears if the main battery is empty or faulty. The backup battery will begin to power the system.

WARNING

Never disconnect both batteries from the control unit simultaneously! Otherwise the pump may stop.

Replace the empty main battery as quickly as possible! Otherwise the pump may stop.

1. Remove the empty main battery from the control unit and connect a fully charged battery.
2. Recharge the empty main battery in the charging unit. See section 5.7: Charging and calibrating a battery, page 54.

If a message appears when connecting a charged battery:

See section 11.1.1: On connection of a charged battery, the control unit displays A01 or A11, page 165.

If a message appears when the power supply unit is connected:

See section 5.2: Connecting the power supply unit to the mains power supply, page 45.

10.2 A11 Change backup battery

Message **A11 Change backup battery** appears if the remaining operating time of the active backup battery is less than approx. 10 minutes, or if the backup battery is faulty. The message will also appear if the charge level of a backup battery is less than 50% when the main battery is active.

WARNING

Never disconnect both batteries from the control unit simultaneously! Otherwise the pump may stop.

Always replace the backup battery under mains operation! Otherwise the pump may stop.
If the backup battery is empty, the main battery will also be empty!

1. Connect the power supply unit to the mains. connect the power supply unit to the control unit.
2. Remove the empty backup battery from the control unit and connect a fully charged battery.
3. Check: is the main battery also empty? If any messages have appeared, likewise replace it with a fully charged battery.
4. Charge the empty battery/batteries in the charging unit. See section 5.7: Charging and calibrating a battery, page 54.
5. Disconnect the power supply unit from the control unit. Disconnect the power supply unit from the mains.

If a message appears when connecting a charged battery:

See section 11.1.1: On connection of a charged battery, the control unit displays A01 or A11, page 165.

If a message appears when the power supply unit is connected:

See section 5.2: Connecting the power supply unit to the mains power supply, page 45.

10.3 A02 Main battery not connected

When changing a battery:

The message will disappear once the new battery is connected.

When not changing a battery:

1. Check the position of the battery plug. Insert the battery plug if it is loose.
2. If the battery plug is loose: connect another main battery.
3. Order a new battery. If this is the case:

HOTLINE **Contact the emergency hotline! +49 (0)30 81 87 27 72**

10.4 A12 Backup battery not connected

When changing a battery:

The message will disappear once the new battery is connected.

When not changing a battery:

1. Check the position of the battery plug. Insert the battery plug if it is loose.
2. If the battery plug is loose: connect another backup battery.
3. Order a new battery. If this is the case:

HOTLINE **Contact the emergency hotline! +49 (0)30 81 87 27 72**

10.5 HA01 Main battery remaining run time < 20 minutes

Message **HA01 Main battery remaining run time < 20 minutes** appears if the remaining operating time of the main battery is less than 20 minutes.

1. Ensure that a charged main battery is available.
2. After a further 10 minutes, the message **A01 Change main battery** appears and the backup battery starts powering the system. Then replace the empty main battery with a charged main battery.

If a message appears when connecting a charged battery:

1. Check the position of the battery plug and rectify if necessary.

ADVICE

We recommend that the main battery only be replaced if the message **A01 Change main battery** appears, since frequent incomplete discharge cycles can cause the remaining operating time to be incorrectly displayed.

10.6 HA04 Main battery calibration cycle required

Message **HA04 Main battery calibration cycle required** appears if a battery has often only been partly discharged. It can continue to supply power, but will display an inaccurate charge level. It must be calibrated in the charging unit to ensure that it will again function properly. Calibration takes a maximum of 16 hours per battery. See section 5.7: Charging and calibrating a battery, page 54.

1. Acknowledge the message.
2. Disconnect the affected main battery from the control unit, then connect an intact main battery.
3. Calibrate the affected main battery in the charging unit. To do so, connect the battery to the charging unit and press the *Start calibration* button. The battery will now be calibrated and charged. Once the green LED on the charging unit is permanently illuminated, the battery can again be used as normal.

10.7 HA14 Backup battery calibration cycle required

Message **HA14 Backup battery calibration cycle required** appears if a battery has often only been partly discharged. It can continue to supply power, but will display an inaccurate charge level. It must be calibrated in the charging unit to ensure that it will again function properly. Calibration takes a maximum of 16 hours per battery. See section 5.7: Charging and calibrating a battery, page 54

WARNING

Always replace the backup battery under mains operation! Otherwise the pump may stop.
If the backup battery is empty, the main battery will also be empty!

1. Acknowledge the message.
2. Connect the power supply unit to the mains. connect the power supply unit to the control unit.
3. Disconnect the affected backup battery from the control unit, and connect an intact backup battery.
4. Disconnect the power supply unit from the control unit. Disconnect the power supply unit from the mains.
5. Calibrate the affected backup battery by To do so, connect the battery to the charging unit and press the *Start calibration* button. The battery will now be calibrated and charged. Once the green LED on the charging unit is permanently illuminated, the battery can again be used as normal.

10.8 HA05 Main battery old

Message **HA05 Main battery old** appears if the main battery has lost some of its capacity. It can still be used, but is no longer fully efficient.

1. Acknowledge the message. Leave the battery connected for the time being.
2. Order a new battery. To do so, contact the Sales Team:

@ SERVICE	**service@berlinheart.de**

10.9 HA15 Backup battery old

Message **HA15 Backup battery old** appears if the backup battery has lost some of its capacity. It can still be used, but is no longer fully efficient.

1. Acknowledge the message. Leave the battery connected for the time being.
2. Order a new battery. To do so, contact the Sales Team:

@ SERVICE	**service@berlinheart.de**

10.10 H26 Halt mode

Message **HA26 Halt mode** appears if the pump is placed in halt mode via the operator terminal. IMPORTANT: If this message appears, the pump is inactive.

1. Acknowledge the message on the control unit. The message will not reappear.

10.11 H27 Event memory not readable

Message **H27 Event memory not readable** appears if the event memory cannot be read due to a fault in the control unit.

1. Repeat the read-out.

If message H27 still appears:

HOTLINE	**Contact the emergency hotline! +49 (0)30 81 87 27 72**

10.12 H30 Temporary malfunction of control unit

Message **H30 Temporary malfunction of control unit** appears if there is a temporary malfunction in the control unit. The pump will initially continue to function as normal. If the malfunction lasts for more than 10 seconds, message **EF30** will appear. See section 10.24: EF30 Control unit malfunctioning, page 160.

Possible causes:

- Fault in the control unit
- Bearing power too high
- Myocardial suction

1. Briefly press the button on the control unit to determine whether there are any further messages (in particular: **H40**; see section 10.14: H40 Temporary pump stop, page 152): take action in accordance with these messages.
2. Connect the operator terminal to the control unit; start the monitor program and evaluate the curves.
3. Note the circumstances in which the message occurred.

If the message appears repeatedly:

HOTLINE	**Contact the emergency hotline! +49 (0)30 81 87 27 72**

10.13 H31 Reset due to internal error

Message **H31 Reset due to internal error** appears if the control unit restarts as a result of an internal error in the control unit software. The pump will stop for a brief period (1 to 2 seconds). The pump will then continue to operate with the current parameter settings. The message and the circumstances which resulted in this message are stored in the event memory and can be queried via the monitor program.

1. Acknowledge the message.
2. Connect the operator terminal to the control unit; start the monitor program and evaluate the curves.
3. Log in and take action as necessary.
4. Select **Service** from the menu, then activate **Start data recording** from the submenu.
5. Transfer the data to the manufacturer for analysis. See section 6.9.5: Submenu item: Save data to USB stick, page 86.
6. Note the circumstances in which the message occurred (Handling of INCOR? Electromagnetic radiation? etc.)

10.14 H40 Temporary pump stop

Message **H40 Temporary pump stop** will appear as soon as the pump comes to a stop. Depending on the cause of the message

- the pump will restart automatically after 7 to 15 seconds (e.g., after the pump temporarily overloads). The message then disappears.
- the pump will stop for longer (e.g., due to a fault in the control unit). Message **EF40 Pump stop** will appear after a few seconds.

IMPORTANT: If message **H40 Temporary pump stop** appears, the pump has stopped.

Possible causes:

- Short-term pump overload (e.g., strong suction due to hypovolemia, poor positioning of the cannula, or repositioning).
- Due to the magnetic bearing of the impeller, INCOR is very sensitive in detecting flow obstructions. Flow obstructions can occur, for example, from cross-sectional changes that arise due to deposits at the inflow or outflow points, or at the impeller. This can also cause message **H40** to appear. In this case, further diagnostic measures are required, and if necessary the patient's medication should be reviewed (anticoagulation, inhibition of platelet aggregation).
- Short-term technical failure of the control unit
- Short-term technical failure of the pump
- Bearing power > 5 W

1. Check for further messages and take the appropriate action.
2. Connect the operator terminal to the control unit; start the monitor program and evaluate the curves.
3. Log in and take action as necessary.
4. Read the event memory.
5. Transfer the data to the manufacturer. See section 6.9.5: Submenu item: Save data to USB stick, page 86.
6. Note the circumstances in which the message occurred (Where was the patient? Mains/battery operation? Were there any other messages? etc.).

If the message appears repeatedly:

HOTLINE

Contact the emergency hotline! +49 (0)30 81 87 27 72

10.15 H50 No pump connected

Message **H50 No pump connected** will appear if batteries are connected to a control unit to which no pump is connected, such as during data administration. It will also appear if, during replacement of the control unit, the batteries are connected to the control unit before closing the pump coupling. This message will be accompanied by a continuous tone and will not reappear once acknowledged.

For data administration

1. Acknowledge the message.
2. After data entry/transfer: end the monitor program, then disconnect the batteries from the control unit.

When replacing the control unit

WARNING

Check that the driveline is not twisted. The blue longitudinal marking on the driveline helps to ensure that the cable is aligned. Otherwise the driveline may be damaged.

NOTICE

Check that the driveline is not twisted. The blue longitudinal marking on the driveline helps to ensure that the cable is aligned. Otherwise the control unit may be damaged.

1. Connect the driveline to the control unit using the plug coupling.
2. Proceed with replacement of the control unit. See section 11.6.1: Replacing the control unit, page 170.

10.16 EA03 Main battery too hot

Message **EA03 Main battery too hot** will appear if the main battery overheats beyond the admissible temperature. Batteries usually overheat due to external factors such as direct heat (e.g., sunlight or heating) or a high ambient temperature. Overheating due to a battery fault is possible, but rare.

⚠ WARNING

Never use water or other fluids to cool a battery! Otherwise there is a risk of short-circuit or failure of the system.

1. Check the conditions: direct heat, high ambient temperature?
2. Make adjustments as necessary (remove heating, move away from sunlight, etc.). Ensure adequate ventilation. Acknowledge the message. The battery will require a few minutes to cool down (if the message reappears, acknowledge it once again).

If the surrounding conditions are not the cause:

1. Disconnect the main battery from the control unit and connect the other main battery to the control unit. See section 5.6: Changing a battery, page 53.

10.17 EA10 Backup battery voltage error

Message **EA10 Backup battery voltage error** will appear if either the backup battery is actually faulty or the control unit is erroneously displaying an error in the backup battery.

1. Connect the power supply unit to the mains. connect the power supply unit to the control unit.
2. Check the position of the battery plug. Remove the plug of the backup battery from the control unit, then reinsert.
3. Wait for 20 minutes.

If the error recurs after 20 minutes:

1. Disconnect the backup battery from the control unit and connect the other backup battery to the control unit. See section 5.6: Changing a battery, page 53.
2. Wait for 20 minutes.

If the message does not reappear within 20 minutes, the original backup battery was actually faulty.

If the message reappears within 20 minutes, there is an error in the control unit. In such a case, replace the control unit. See section 11.6.1: Replacing the control unit, page 170.

HOTLINE **Contact the emergency hotline! +49 (0)30 81 87 27 72**

10.18 EA13 Backup battery too hot

Message **EA13 Backup battery too hot** will appear if the backup battery overheats beyond the admissible temperature. Batteries usually overheat due to external factors such as direct heat (e.g., sunlight or heating) or a high ambient temperature. Overheating due to a battery fault is possible, but rare.

WARNING Never use water or other fluids to cool a battery! Otherwise there is a risk of short-circuit or failure of the system.

1. Check the conditions: direct heat, high ambient temperature?
2. Make adjustments as necessary (remove heating, move away from sunlight, etc.). Ensure adequate ventilation. Acknowledge the message. The battery will require a few minutes to cool down (if the message reappears, acknowledge it once again).

If the surrounding conditions are not the cause:

1. Disconnect the backup battery from the control unit and connect the other backup battery to the control unit. See section 5.6: Changing a battery, page 53.

10.19 E00 Power supply unreliable

Message **E00 Power supply unreliable** will appear if no batteries (or 2 empty or faulty batteries) are connected to the control unit and the power from the mains power supply unit – if connected – is insufficient. When the message appears, the system is still being supplied with power but a continued supply is not guaranteed.

IMPORTANT: The required replacement of the components may cause the pump to stop!

During battery operation

1. Connect the power supply unit to the mains. connect the power supply unit to the control unit.
2. Replace the main battery. See section 5.6: Changing a battery, page 53.
3. Change the backup battery. See section 5.6: Changing a battery, page 53.

During mains operation

1. Replace the main battery. See section 5.6: Changing a battery, page 53.
2. Change the backup battery. See section 5.6: Changing a battery, page 53.
3. Disconnect the power supply unit from the control unit; disconnect the power supply unit from the mains.

10.20 E22 Pressure difference too low

WARNING

If SP is activated: if the message **E22 Pressure difference too low** is permanently displayed, check the pressure difference alarm threshold.
If the value is high (> 30 mm Hg): lower the pressure difference alarm threshold.
If the value is low (< 20 mm Hg): take appropriate medical action. Otherwise, hemodynamic complications may result.

Possible causes for the message **E22 Pressure difference too low**:

- Low blood pressure
- Pressure difference alarm threshold is set too high (recommended value: 20 to 30 mm Hg)
- Due to the magnetic bearing of the impeller, INCOR is very sensitive in detecting flow obstructions. Flow obstructions can occur, for example, from cross-sectional changes that arise due to deposits at the inflow or outflow points, or at the impeller. This can also cause message **E22** to appear. In this case, further diagnostic measures are required, and if necessary the patient's medication should be reviewed (anticoagulation, inhibition of platelet aggregation).

During implantation (at low speed), this message can be caused by the effects of ECC; if so, the message does not refer to a malfunction and once acknowledged should not recur at higher speeds.

The displayed pressure difference should not be below 20 mm Hg. If the pressure difference curve suddenly falls below the mean value, this may be an indication of a cross-sectional change in the impeller.

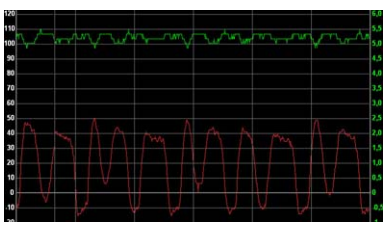


Fig. 10-1 Typical curve progression if case of deposits on the impeller

1. Acknowledge the message.
2. Connect the operator terminal to the control unit, then start the monitor program.
3. Evaluate the circulatory status of the patient. Evaluate the hemodynamic curves in the monitor program.
4. Take appropriate medical action if necessary.
5. Reconsider anticoagulation therapy if necessary.
6. Increase the speed if necessary and observe whether the pressure difference increases.
7. Reduce the pressure difference alarm threshold, if necessary.
8. Deactivate pulsatility control, if necessary.

If none of the causes described here apply:

HOTLINE	**Contact the emergency hotline! +49 (0)30 81 87 27 72**

10.21 E20/E21 Mean flow too low/Pressure difference too high

Possible causes for the messages **E20 Mean flow too low** and **E21 Pressure difference too high**:

- Unfavorable hemodynamic status
- Myocardial suction on the inflow cannula (e.g., due to hypovolemia, excessive speed or unfavorable positioning of the cannula)
- Offset of rotor position was not configured during implantation
- **E20** only: flow alarm threshold is set too high (recommended value: 50% of the max. achievable flow, but not lower than 2.5 L/min.) or pulsatility control is activated and has reduced the speed. See section 6.6.3: Pulsatility control (PC), page 72.

Message **E21** appears if the pressure difference rises above 150 mm Hg.

If SP is activated: If more than 5 events occur within a short period of time, the speed is reduced by a third of the preset speed reduction value for a period of 15 minutes. If myocardial suction recurs when such a reduction is taking place, message **E21** will appear.

During implantation (at low speed), message **E21** may appear due to the effects of ECC; if so, the message does not imply a malfunction and should not recur when ECC is reduced. If ECC has already been stopped, the speed may need to be reduced.

A continuously high pressure difference may indicate an unfavorable cannula position or a high afterload (mean arterial pressure, MAP).

Evidence of myocardial suction:

- E20 and E21 appear together, possibly with H30 (see section 10.12: H30 Temporary malfunction of control unit, page 151) and/or H40 (see section 10.14: H40 Temporary pump stop, page 152).
- Recurring pressure difference peaks (see Fig. 10-2 , page 158)

WARNING

For X-ray and CT: ensure that the control unit is kept out of the path of the X-rays and is shielded on all sides by lead! Otherwise the control unit may fail to function correctly.

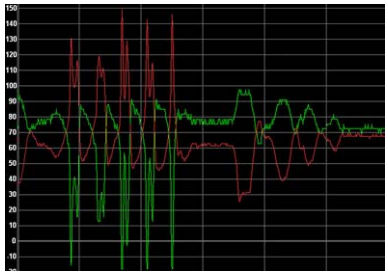


Fig. 10-2 Typical curve progression with myocardial suction

1. Acknowledge the message.
2. Briefly press the button on the control unit to determine whether there are any other current messages. IMPORTANT: If message H40 appears (see section 10.14: H40 Temporary pump stop, page 152), the pump has stopped! After 7 to 15 seconds, it will automatically restart with the set parameters.
3. Connect the operator terminal to the control unit, then start the monitor program.
4. Evaluate the circulatory status of the patient. Evaluate the hemodynamic curves in the monitor program.
5. Reduce the speed if necessary.
6. Reduce the alarm threshold flow if necessary (for **E20**; for guideline values see Tab. 7-1 , page 128).
7. Take appropriate medical steps if necessary (e.g., volume substitution, checking the function of the right ventricle).
8. Change the position of the patient if necessary.
9. If **E20** occurs together with **E21**: activate pulsatility control if necessary (see section 6.6.3: Pulsatility control (PC), page 72). If **E20** occurs alone: check whether pulsatility control is activated and deactivate if necessary.

Persistent E20/E21:

Check the position and condition of the inflow cannula (echocardiography, X-ray, CT). If the cannula is suspected to be poorly positioned: take appropriate medical action.

If the offset of the rotor position was not configured during implantation:

HOTLINE

Contact the emergency hotline! +49 (0)30 81 87 27 72

10.22 E23 Control unit too hot

Message **E23 Control unit too hot** will appear if the control unit has become overheated due to direct warming or heat build-up – for example, if the control unit has

been placed under a blanket. Overheating due to a fault within the control unit is possible, but very rare.

WARNING

Never use water or other fluids to cool the control unit! Otherwise there is a risk of short-circuit or failure of the system.

1. Check whether external factors could have resulted in overheating: direct heat (e.g., direct sunlight, high ambient temperature, heat build-up)?
2. Modify the surrounding conditions: remove the control unit from the heat source, or ensure adequate ventilation. Acknowledge the message repeatedly if necessary.

If the surrounding conditions are not the cause:

1. Replace the control unit. See section 11.6.1: Replacing the control unit, page 170

When replacing the control unit: connect the batteries! Check the speed and adjust if necessary.

HOTLINE

Contact the emergency hotline! +49 (0)30 81 87 27 72

10.23 E24 Control unit too cold

Because the control unit itself produces heat, the message **E24 Control unit too cold** will only appear if the ambient temperatures are extremely low (approx. -30°C) or if a very cold (approx. -10°C) replacement control unit is connected.

WARNING

Never heat the control unit by applying heat directly (lighter, heating, etc.)! Otherwise the control unit may fail to function correctly.

Cautionary measure

If the control unit is covered with textiles, listen for an acoustic alarm, which warns of overheating due to heat build-up!

1. Protect the control unit against cold, moisture, drafts (e.g., conceal under a jacket, move to a warmer environment).
2. Acknowledge the message (repeatedly if necessary).

If the surrounding conditions are not the cause:

HOTLINE

Contact the emergency hotline! +49 (0)30 81 87 27 72

10.24 EF30 Control unit malfunctioning

Possible causes for the message **EF30 Control unit malfunctioning**:

- Plug coupling not closed correctly
- Fault in the control unit
- High bearing power

IMPORTANT: If the bearing power exceeds 5 W, the pump will stop. In this case, message **H40 Temporary pump stop** will appear; however, it will be overlaid by message **EF30**. The pump restarts automatically once the bearing power falls below 3.5 W. This can sometimes take 30 to 60 seconds.

If the pump stops for more than 10 seconds, message **EF40 Pump stop** will appear.

1. Acknowledge the message.
2. Ensure that the plug coupling is closed correctly, and check that the arrow markings on the plug and socket are aligned. See Fig. 7-55 , page 126.
3. Briefly press the button on the control unit to determine whether message **H40** has appeared.

If message H40 Temporary pump stop has appeared:

1. Take appropriate medical action. See section 10.14: H40 Temporary pump stop, page 152.
2. First wait approx. 10 seconds to see whether **EF40** appears. If EF40 appears: See section 10.25: EF40 Pump stop, page 161.

If message H40 does not appear or disappears after 10 seconds (without EF40!):

1. Connect the operator terminal, start the monitor program, and check for messages and bearing power.
2. Bearing power > 3.5 W: Replace the control unit. See section 11.6.1: Replacing the control unit, page 170

If the bearing power permanently exceeds the usual value by more than 1 W:

HOTLINE	**Contact the emergency hotline! +49 (0)30 81 87 27 72**

If EF30/EF40 persist:

If messages **EF30** and **EF40** still appear despite having taken all other corrective action (including replacing the control unit), the bearing power is still very high, or the pump is inactive, the pump may need to be replaced. See section 11.6.3: Replacing the pump, page 173.

In all cases:

HOTLINE	**Contact the emergency hotline! +49 (0)30 81 87 27 72**

10.25 EF40 Pump stop

Message **EF40 Pump stop** will appear if the pump stops for more than 10 seconds.

Possible causes of this message:

- Plug coupling not closed correctly
- Fault in the control unit
- Defect in the pump or driveline
- Continuously high bearing power (> 5 W)

1. Acknowledge the message.
2. Ensure that the plug coupling is closed correctly, and check that the arrow markings on the plug and socket are aligned. See Fig. 7-55 , page 126.
3. Auscultate to check whether the pump is active. Take appropriate medical action if necessary.

If message EF40 persists:

1. Replace the control unit. See section 11.6.1: Replacing the control unit, page 170
2. Auscultate to check whether the pump is active. Take appropriate medical action if necessary.

HOTLINE	**Contact the emergency hotline! +49 (0)30 81 87 27 72**

IMPORTANT: If messages **EF30** and **EF40** still appear despite having taken all other corrective action (including replacing the control unit), the bearing power is still very high, or the pump is inactive, the pump may need to be replaced. See section 11.6.3: Replacing the pump, page 173.

10.26 EF50 Pump cable disconnected

Message **EF50 Pump cable disconnected** will appear if the plug coupling is open while the control unit is being supplied with power.

WARNING

Check that the driveline is not twisted. The blue longitudinal marking on the driveline helps to ensure that the cable is aligned. Otherwise the driveline may be damaged.

NOTICE

Check that the driveline is not twisted. The blue longitudinal marking on the driveline helps to ensure that the cable is aligned. Otherwise the control unit may be damaged.

During replacement of the control unit:

1. Proceed with replacement: disconnect the power source (battery, power supply unit) from the control unit by gripping the safety plug's ribbed sleeve with marking.

During normal operation:

1. Ensure that the plug coupling is closed correctly, and check that the arrow markings on the plug and socket are aligned. See Fig. 7-55 , page 126.
2. If necessary, open and reclose the plug coupling, and check that the arrow markings on the plug and socket are aligned. The pump will operate at the speed set previously.
3. Check for any current messages after 10 seconds. If any messages have appeared, take the appropriate action immediately!

If EF50 reappears:

1. Replace the control unit. See section 11.6.1: Replacing the control unit, page 170.

10.27 EF60 Pump too hot

Possible causes of this message:

- Plug coupling not closed correctly
- Control unit malfunctioning
- Break in the driveline

1. Ensure that the plug coupling is closed correctly, and check that the arrow markings on the plug and socket are aligned. See Fig. 7-55 , page 126.
2. In mains operation: disconnect the power supply unit from the control unit.

3. Check whether the pump is active (by auscultation or via the operator terminal).
4. Check whether message EF60 is still present after 10 minutes.

HOTLINE **Contact the emergency hotline! +49 (0)30 81 87 27 72**

If message EF60 has not disappeared after 10 minutes:

1. Replace the control unit. See section 11.6.1: Replacing the control unit, page 170.
2. If message **EF60** persists after replacing the control unit, the pump may need to be replaced. See section 11.6.3: Replacing the pump, page 173.

HOTLINE **Contact the emergency hotline! +49 (0)30 81 87 27 72**

11 Detecting and Eliminating Errors

As a rule, immediately replace any external components which are visibly damaged. In such a case:

HOTLINE **Contact the emergency hotline! +49 (0)30 81 87 27 72**

11.1 Control unit

Possible error scenarios:

- On connection of a charged battery, the control unit will display **A01** or **A11**. See section 11.1.1, page 165.
- The display indicates unlikely or impossible values (e.g.: battery operating time > 20 h, mean flow > 20 L/min or < 0 L/min); see section 11.1.2, page 165.
- A buzzer on the control unit is faulty; see section 11.1.3, page 166.
- Individual segments of the display are faulty, see section 11.1.4, page 166.
- Slow tone sequence (. . .); see section 11.1.5, page 166.

11.1.1 On connection of a charged battery, the control unit displays A01 or A11

➢

1. Check the position of the plug.
2. If the plug is loose in the socket: the battery plug is faulty. Replace the battery. Contact the emergency hotline.
3. If the plug is firmly positioned in the socket: press the button on the battery to check the charge level. If the battery LEDs illuminate: the control unit is faulty. Replace the control unit. See section 11.6.1: Replacing the control unit, page 170

HOTLINE **Contact the emergency hotline! +49 (0)30 81 87 27 72**

11.1.2 The display indicates unlikely or impossible values

Examples of unlikely or impossible values are a battery operating time > 20 h, mean flow > 20 L/min or < 0 L/min.

➢

1. Connect the operator terminal and check the values.

HOTLINE **Contact the emergency hotline! +49 (0)30 81 87 27 72**

11.1.3 A buzzer on the control unit is faulty

➢

1. Replace the control unit. See section 11.6.1: Replacing the control unit, page 170

HOTLINE **Contact the emergency hotline! +49 (0)30 81 87 27 72**

11.1.4 Individual segments of the display are faulty

➢

1. Replace the control unit. See section 11.6.1: Replacing the control unit, page 170

HOTLINE **Contact the emergency hotline! +49 (0)30 81 87 27 72**

11.1.5 Slow tone sequence (. . .)

Possible causes for a slow tone sequence:

The slow interval tone (. . .) may have various causes:

- **Interruption of power supply:** INCOR stops. The display disappears. For 3 to 5 minutes, an interval tone sounds and fades. If the power supply is restored, the pump resumes operation at the previously set speed.
- **Severe malfunction of control unit:** Communication to the operator terminal is interrupted. The display disappears or shows the information most recently visible. An interval tone sounds. Depending on the type of malfunction, INCOR continues working at the previously set speed or the pump stops.

➢

1. Auscultate to check whether the pump is active.
2. **If the pump is not active:** replace the control unit. See section 11.6.1: Replacing the control unit, page 170.

If the pump is active:

HOTLINE **Contact the emergency hotline! +49 (0)30 81 87 27 72**

11.2 Power supply unit

Power supply unit connected to the mains: indicator LED not illuminated

1. Disconnect the power supply unit from the control unit. Disconnect the power supply unit from the mains.
2. Connect the power supply unit to the mains. The indicator LED must be illuminated.
3. Connect the power supply unit to the control unit. The indicator LED must remain illuminated. If not: order a new power supply unit. If this is the case:

@ SERVICE	**service@berlinheart.de**

IMPORTANT: Until the new power supply unit arrives, use the compatible power supply unit from the charging unit for mains operation!

11.3 Batteries

LEDs not indicating the charge level when charging

1. Check: is the power supply unit connected to the charging unit? Is the power supply unit connected to the mains?
2. Press the button on the battery. If no LED lights up, the battery is faulty and must be replaced. If this is the case:

HOTLINE	**Contact the emergency hotline! +49 (0)30 81 87 27 72**

11.4 Charging unit

11.4.1 Error LED flashing

1. Remove the battery from the charging unit.
2. Disconnect the charging unit from the mains power supply and reconnect. The charging unit will perform a self-test: the LEDs are briefly illuminated. The fan briefly switches on and then off. Wait for the self-test to finish.

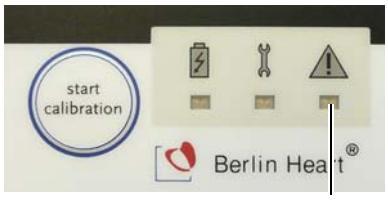


Fig. 11-1 Control panel of charging unit: Error LED

3. Reconnect the battery to the charging unit.
4. If the **error LED (1)** is no longer flashing, resume use of the battery and charging unit as normal. If the **error LED** continues to flash:

HOTLINE **Contact the emergency hotline! +49 (0)30 81 87 27 72**

11.4.2 Error LED illuminated

1. Remove the battery from the charging unit.
2. Disconnect the charging unit from the mains power supply and reconnect. The charging unit will perform a self-test: the LEDs are briefly illuminated. The fan briefly switches on and then off. Wait for the self-test to finish.

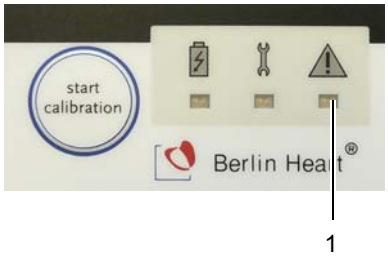


Fig. 11-2 Control panel of charging unit: Error LED

3. If the **error LED (1)** is no longer illuminated, proceed with step 4. If the **error LED** is still illuminated: inform the emergency hotline.
4. Reconnect the battery to the charging unit.
5. If the **error LED (1)**is no longer illuminated, resume use of the battery and charging unit as normal. If the **error LED** is still illuminated:

HOTLINE **Contact the emergency hotline! +49 (0)30 81 87 27 72**

11.5 Monitor program

Possible error scenarios:

- The curve display freezes. See section 11.5.1, page 169.
- A message is displayed in the monitor program, but not on the control unit. See section 11.5.2, page 169
- The monitor program and control unit display different values. See section 11.5.3, page 169.
- The monitor program indicates unlikely or impossible values (e.g., mean flow < 0 L/min). See section 11.5.4, page 169.
- The set and actual values differ from each other (either during the operation **Send settings and patient data** or when replacing the control unit while the monitor program is running). See section 11.5.5, page 169.
- Message: **Communication to the control unit is interrupted, please check connection!** See section 11.5.6, page 169.
- Monitor is black, operator terminal cannot be started. See section 11.5.7, page 170.
- Program crash: monitor program not running. See section 11.5.8, page 170.

11.5.1 Curve display frozen

➢

1. Menu selection **Display** > **Start**.

Curve display remains frozen:

See section 11.5.8: Program crash, monitor program not running, page 170.

11.5.2 Message displayed in the monitor program, but not on the control unit

➢

1. End the monitor program by selecting **End**; restart the operator terminal.

11.5.3 Different values in the monitor program and control unit

➢

1. End the monitor program by selecting **End**; restart the operator terminal.

Different values still displayed in the monitor program and control unit:

➢

1. Replace the operator terminal and check the values again.

Different values still displayed in the monitor program and control unit:

➢

1. Replace the control unit. See section 11.6.1: Replacing the control unit, page 170

11.5.4 Monitor program indicating unlikely or impossible values

Examples of unlikely or impossible values: battery operating time > 20 h, mean flow > 20 L/min or < 0 L/min.

HOTLINE	**Contact the emergency hotline! +49 (0)30 81 87 27 72**

11.5.5 Set and actual values differ

This may be the case either during the operation **Send settings and patient data** or when replacing the control unit while the monitor program is running.

➢

1. Check: is pulsatility control activated? If not, end the monitor program with **End**, then restart the operator terminal to retrieve the current set values.

11.5.6 Message: Communication to the control unit is interrupted

The full text of the message reads: **Communication to the control unit is interrupted, please check connection!** Instead of the measured values, question marks are displayed.

1. Check the plug of the communication cable. If necessary, insert it correctly.
2. Check the power supply of the control unit and restore if necessary.

Message still visible:

See section 11.5.8: Program crash, monitor program not running, page 170.

11.5.7 Monitor black, operator terminal cannot be started

1. Check the power supply.

11.5.8 Program crash, monitor program not running

1. Turn the operator terminal off and on again.

HOTLINE

Contact the emergency hotline! +49 (0)30 81 87 27 72

11.6 Emergency measures

11.6.1 Replacing the control unit

WARNING

If the hemodynamic status of the patient is found to be critical, the control unit must be replaced within 30 seconds! Otherwise, support may be inadequate.

Before using an external defibrillator: disconnect the pump from the control unit (open the plug coupling). Otherwise the control unit may fail.
IMPORTANT: Such action causes the pump to stop!

Only use a pump and control unit with the same AP number! In any other circumstances the smooth operation of INCOR cannot be guaranteed.

Whenever a control unit is to be used/replaced: connect the batteries! It is not possible to activate the pump with the power supply unit only.

Whenever a control unit is to be used/replaced: check the speed and adjust as necessary. If the settings and patient information have not first been transferred from the active control unit, the pump will not start automatically. The operator terminal must then be used to start the pump.

Check that the driveline is not twisted. The blue longitudinal marking on the driveline helps to ensure that the cable is aligned. Otherwise the driveline may be damaged.

IMPORTANT: If replacement of the control unit causes the pump to stop temporarily, medical measures for maintaining the circulation may be necessary.

Replacement of the control unit is necessary in the following cases:

- Continuous tone, which cannot be eliminated by pressing the button on the control unit
- Messages **EF30 Control unit malfunctioning**, **EF40 Pump stop**, and possibly **EF60 Pump too hot**, if there are no clinical reasons for such messages. See section 10.24: EF30 Control unit malfunctioning, page 160, section 10.25: EF40 Pump stop, page 161 and section 10.27: EF60 Pump too hot, page 162. IMPORTANT: The pump may have stopped! Check by auscultation!
- Message **H27 Event memory not readable**
- The control unit reacts to connection of a fully charged battery with message **A01** or **A11** (**Replace main/backup battery**)
- Individual segments in the display defective
- The acoustic signal in the control unit is faulty (2 audible alarms missing when button is pressed)

Preparation

1. Prepare the replacement control unit and extra battery. The indicator on the control unit points towards the left, the button towards the right.
2. Place the closed plug coupling of the malfunctioning control unit next to the control unit plug of the intact control unit.

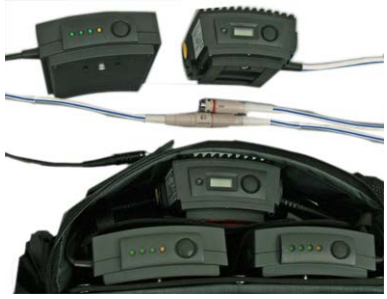


Fig. 11-3 Prepared components

3. Connect the extra battery to the replacement control unit. The set speed will be displayed for a few seconds.

Fig. 11-4 Replacement control unit displaying the speed

Replacement

1. Disconnect the pump from the malfunctioning control unit. To do so, retract the **sleeve marked with a double arrow** on the control unit plug **(1)**, allowing the plug coupling to be opened.
   The pump will stop.

Fig. 11-5 Plug coupling closed

2. Connect the pump to the replacement control unit by inserting the **control unit plug (1)** into the **pump socket (4)**. IMPORTANT: The **arrows** (**2** and **3**) must be aligned!
   The pump will start operating at the speed set in the control unit.

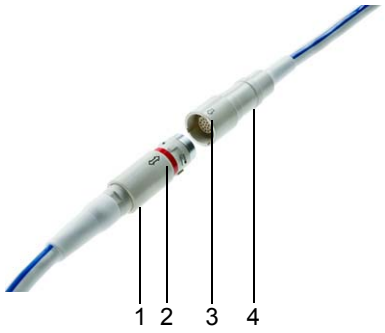


Fig. 11-6 Plug coupling open

Subsequent adjustment

1. Remove the batteries from the malfunctioning control unit and connect the missing battery to the intact control unit.
2. If the speed displayed differs considerably from the previously set speed: Adjust the speed. See section 11.6.2: Adjusting the speed on the control unit, page 172. If the pressure difference curves and/or the flow deviate considerably from the values last obtained, manual offset correction may be necessary. Please contact the emergency hotline!
3. Next: Remove the defective control unit and batteries that are not connected from the INCOR smart bag. Place the intact control unit and connected battery in the INCOR smart bag.

IMPORTANT: For **EF30**, **EF40**, **EF60**: if the pump does not function after replacing the control unit, the pump may need to be replaced. See section 11.6.3: Replacing the pump, page 173

11.6.2 Adjusting the speed on the control unit

This should be done if, after restarting, the control unit displays a speed that differs significantly from the previously set speed.

This can only be done within 60 seconds of connecting the new control unit to a battery! Thereafter, the speed can only be adjusted via the operator terminal.

1. Press the button on the control unit for a few seconds. The indicated speed will flash.
2. By pressing the button again, the speed can be changed in increments of 500. It first increases up to 9000 with every press of the button, then decreases with every press of the button to 6000. Then it increases again.
3. If the button is not pressed in the next 10 seconds, the pump will continue to operate at the modified speed.
4. Check the system via the monitor program; if necessary, continue to adjust the speed.
5. If a previously active control unit is restarted: check the speed of the replacement control unit and adjust as necessary.

11.6.3 Replacing the pump

The pump may need to be replaced if

- messages **EF30**, **EF40**, **EF60** persist even after undertaking all the other described corrective action, including replacement of the control unit, and there is a justified suspicion that the control unit did not cause the pump to stop.
- the bearing power remains above 3.5 W, even after replacing the control unit.

For the general sequence of operations, see chapter 7: Implantation, page 95.

WARNING

Replace the pump during battery operation!

Before using an external defibrillator: disconnect the pump from the control unit (open the plug coupling). Otherwise the control unit may fail.
IMPORTANT: Such action causes the pump to stop!

Before cutting through the driveline, remove it from the control unit! Otherwise there is a risk of electric shock.

When using a cauterization knife, the current must not flow directly through the pump. Therefore, do not attach the electrode of the cauterization knife to the back of the patient! Avoid contact between the cauterization knife and pump! Otherwise there is a risk of electric shock.

Check that the driveline is not twisted. The blue longitudinal marking on the driveline helps to ensure that the cable is aligned. Otherwise the driveline may be damaged.

EF30 and **EF40**: If messages persist after undertaking all the other measures described: determine by auscultation whether the pump has actually stopped before replacing it. Only replace the pump if it has actually stopped. Otherwise it does not need to be replaced.

HOTLINE

Contact the emergency hotline! +49 (0)30 81 87 27 72

NOTICE

Check that the driveline is not twisted. The blue longitudinal marking on the driveline helps to ensure that the cable is aligned. Otherwise the control unit may be damaged.

ADVICE

We recommend deactivating PC, PFC, and SP prior to further surgical procedures.

IMPORTANT: During the several minutes of interruption to circulatory support caused by replacement of the pump, medical steps may need to be taken. Introduction of ECC must be possible at short notice.

Removing a defective pump

1. Prepare the control units belonging to the new pump. Ensure that the pump and control unit have identical AP numbers.
2. Perform an appropriate surgical procedure to expose the pump.
3. Clamp off the inflow and outflow cannulae.
4. Open the snap-in connectors on the inflow and outflow sides of the pump to separate the pump from the cannulae. To do so, retract the silicone cover; rotate the guide ring against the resistance towards the detent ring until it can be removed. Put the old pump aside.
5. Remove the guide ring and silicone cover from the inflow cannula.

Connecting an intact pump

1. Attach the new guide ring with silicone cover to the inflow cannula.
2. Connect the new pump to the inflow cannula, close the snap-in connector and turn back the silicone cover of the guide ring. de-air the system. by puncturing the seal cap and briefly stopping the vent.
3. Remove the guide ring and silicone cover from the outflow angle section (if not being used: outflow cannula).
4. Place the new guide ring and silicone cover on the outflow angle section (if not being used: outflow cannula).
5. Connect the new pump to the outflow angle section (if not being used: outflow cannula), close the snap-in connector and turn back the silicone cover of the guide ring.
6. de-air the system. If required: puncture the cannulae at the designated site.
7. Tunnel the new driveline subcutaneously in the direction of the right iliac wing. Select the site for transcutaneous exit of the driveline. The transcutaneous exit site should be lateral to the medioclavicular line at the level of the umbilicus. Make the skin incision here and pull the driveline through. IMPORTANT: A distance of at least 10 cm is required subcutaneously to prevent ascending infections. IMPORTANT: It is essential to make a new skin incision!

8. Connect the driveline to the new control unit 1. To do so, insert the control unit plug of control unit 1 into the pump socket (close plug coupling).
9. Align the two control units with the pump to which they belong (perform offset correction; see section 7.5.1: Aligning the control units with the pump: offset correction, page 125).

12 EMC Tables

12.1 Electromagnetic emissions

Guidelines and manufacturer's declaration – electromagnetic interference emission measurement		
The INCOR system is intended for use in an environment as described below. The customer or user of the INCOR system should ensure that it is used in such an environment.		
Interference emission measurements	**Compliance**	**Electromagnetic environment - guidelines**
RF emissions as per CISPR 11	Group 1	The INCOR system uses RF energy exclusively for its internal operation. Its RF emissions are therefore very low, and are not likely to cause any interference in nearby electronic equipment.
RF emissions as per CISPR 11	Class B	The INCOR system is suitable for use in all facilities, including residential buildings and those connected directly to a public supply system which is also used for supplying residential buildings.
Harmonic emissions in accordance with IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions according to IEC 61000-3-3	Complies	

Tab. 12-1 Electromagnetic emissions

12.2 Electromagnetic immunity - part 1

Guidelines and manufacturer's declaration – electromagnetic immunity			
The INCOR system is intended for use in an electromagnetic environment as described below. The customer or user of the INCOR system must ensure that it is used in such an environment.			
Immunity tests	**IEC 60601 Test level**	**Level of compliance**	**Electromagnetic environment – guidelines**
Electrostatic discharge (ESD) according to IEC 61000-4-2	±6 kV contact discharge ±8 kV air discharge	±6 kV contact discharge ±8 kV air discharge	Floors should be made of wood or concrete, or be covered with ceramic tiles. If the floor is covered with synthetic material, the relative humidity must be at least 30%.
Fast transient electrical interference/bursts in accordance with IEC 61000-4-4	±2 kV power lines ±1 kV for input and output lines	±2 kV power lines ±1 kV for input and output lines	The quality of the supply voltage should be consistent with a typical commercial or hospital environment.
Surges in accordance with IEC 61000-4-5	±1 kV differential mode voltage ±2 kV common mode voltage	±1 kV differential mode voltage ±2 kV common mode voltage	The quality of the supply voltage should be consistent with a typical commercial or hospital environment.
Voltage dips, short-term interruptions and fluctuations of the power supply according to IEC 61000-4-11	< 5% UT (> 95% dip in UT) for ½ cycle 40% UT (60% dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles < 5% UT (> 95% dip in UT) for 5 seconds	< 5% UT (> 95% dip in UT) for ½ cycle 40% UT (60% dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles < 5% UT (> 95% dip in UT) for 5 seconds	The quality of the supply voltage should be consistent with a typical commercial or hospital environment. If the user of the INCOR system requires continued operation in the event of interruption to the power supply, it is advisable to power the INCOR system from an uninterrupted power source or battery.
Magnetic field from the supply frequency (50/60 Hz) according to IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be consistent with the typical values found in a commercial or hospital environment.
NOTE: UT is the AC supply voltage prior to application of the test level.			

Tab. 12-2 Electromagnetic immunity - part 1

12.3 Electromagnetic immunity - part 2

Guidelines and manufacturer's declaration – electromagnetic immunity			
The INCOR system is intended for use in an electromagnetic environment as described below. The customer or user of the INCOR system must ensure that it is used in such an environment.			
Immunity tests	**IEC 60601 - Test level**	**Level of compliance**	**Electromagnetic environment – guidelines**
			Portable and mobile radio devices should not be used any closer to the INCOR system or its cables than the recommended safety distance calculated from the equation applicable to transmission frequencies.
Conducted RF interference in accordance with IEC 61000-4-6	3 V [e] 150 kHz to 80 MHz outside of the ISM bands[a] 10 V [e] 150 kHz to 80 MHz inside the ISM bands[a]	3 V 10 V	Recommended safety distance d=0.35√P d=1.2√P
Conducted HF interference according to IEC 61000-4-3	10 V/m 80 MHz to 2.5 GHz	10 V/m	d=1.2√P 80 MHz to 800 MHz d=2.3√P 800 MHz to 2.5 GHz
			P is the maximum nominal power of the transmitter in watts (W) according to the transmitter manufacturer, and d the recommended safety distance in meters (m)[b]. The field strengths of stationary radio transmitters, as determined by an appropriate site[c] survey, should be lower than the compliance level in each frequency range[d]. Interference may occur in the vicinity of equipment bearing the following symbol. 

Tab. 12-3 Electromagnetic immunity - part 2

a) The ISM frequency bands (for industrial, scientific and medical applications) between 150 kHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz and 40.66 MHz to 40.70 MHz.

b) The conformance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range of 80 MHz to 2.5 GHz are aimed at reducing the probability of mobile/portable communication devices generating interference when they are unintentionally brought within the vicinity of the patient. For this reason, the additional factor of 10/3 is applied when calculating the recommended safety distances in these frequency ranges.

c) The field strengths of stationary transmitters, such as base stations for mobile phones and land mobile radio devices, amateur radios, AM and FM radio and television broadcasters, cannot be theoretically predicted with accuracy. In order to determine the electromagnetic environment in relation to stationary transmitters, a study of the location should be taken into consideration. If the measured field strength at the location in which the device is to be used exceeds the compliance level mentioned above, the INCOR system must be monitored in order to verify normal operation. If the performance is found to be abnormal, additional measures may be necessary, such as realigning or relocating the INCOR system.

d) Above a frequency range of 150 kHz to 80 MHz, the field strength should be less than 10 V/m.

e root mean square

12.4 Recommended safety distances between portable and mobile RF telecommunications devices and INCOR

Recommended safety distances between portable and mobile RF telecommunications devices and INCOR

The INCOR system is intended for use in an electromagnetic environment in which RF interference is controlled. The customer or user of the INCOR system can help to prevent electromagnetic interference by ensuring a minimum distance between portable and mobile RF telecommunications devices (transmitters) and the INCOR system, depending on the power output of the communications device as indicated below.

	Safety distance depending on transmission frequency [m]			
Nominal power of the transmitter in W	**150 kHz to 80 MHz outside of the ISM bands** **$d=0.35\sqrt{P}$**	**150 kHz to 80 MHz inside the ISM bands** **$d=1.2\sqrt{P}$**	**80 MHz to 800 MHz** **$d=1.2\sqrt{P}$**	**800 MHz to 2.5 GHz** **$d=2.3\sqrt{P}$**
0.01	0.04	0.12	0.12	0.23
0.1	0.11	0.38	0.38	0.73
1	0.35	1.20	1.20	2.30
10	1.11	3.79	3.79	7.27
100	3.50	12.00	12.00	23.00

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2: The ISM frequency bands (for industrial, scientific and medical applications) between 150 kHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz and 40.66 MHz to 40.70 MHz.

NOTE 3: The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range of 80 MHz to 2.5 GHz are intended to reduce the probability of mobile/portable communication devices generating interference when they are unintentionally brought within the vicinity of the patient. For this reason, the additional factor of 10/3 is applied when calculating the recommended safety distances in these frequency ranges.

NOTE 4: These guidelines may not be applicable in all cases. The propagation of electromagnetic variables is influenced by the absorption and reflection of buildings, objects and people.

Tab. 12-4 Safety distance depending on transmission frequency

In the case of transmitters with a maximum nominal power not indicated in the above table, the distance can be determined using the equation in the respective column, whereby P is the maximum nominal power of the transmitter in watts [W] according to the transmitter manufacturer.

13 Checklists and Sample Copies

13.1 Checklist: implantation (silicone outflow cannula)

IMPORTANT: This checklist is intended as a working aid only. It by no means replaces the detailed descriptions provided in the specific chapter on implantation. See chapter 7: Implantation, page 95. Take note in particular of the safety information detailed therein!

Procedure	Done?
Preoperative preparations (section 7.1, page 95)	
Preparing and checking the components (section 7.1.1, page 95)	
1. Prepare:	
• Case 1; check the temperature indicator on the box of implantation set 1.	
• Case 2; check the charge level by pressing the button on the INCOR batteries. If not all the LEDs illuminate: charge the battery in the charging unit. Observe the battery LED of the charging unit for a few minutes. If the battery LED does not flash green after a few minutes: do not use the battery. Use the battery of the replacement system instead.	
2. Check the charge level of the battery in the operator terminal, and charge the battery if necessary.	
3. Allow the systems to acclimatize for 2 hours.	
4. Prepare a roll table with:	
• Inner compartment of INCOR Smart Bag with 2 charged batteries and control unit 1 (do not yet insert the battery plug into the control unit!)	
• Operator terminal with accompanying power supply unit and communication cable	
• Charging unit with batteries (one main battery, one backup battery)	
• 2 x power supply unit (for charging unit and control unit)	
• Control unit 2	
• Outer compartment of INCOR Smart Bag	
• Boxes with sterile INCOR components	

Tab. 13-1 Implantation checklist

Procedure	Done?
• Instructions for clinical use and OR accompanying documentation (including Latest News, if applicable)	
Preparing the control units and operator terminal (section 7.1.2, page 96)	
5. Connect the operator terminal to the mains using the power supply unit, then boot.	
6. Take the password envelope out of the OR accompanying documentation.	
7. Log in with the **OP** user profile.	
8. Set the correct date and time, if necessary.	
9. Do not turn the operator terminal off.	
Preparing the unsterile components (section 7.1.3, page 98)	
10. Use the communication cable to connect control unit 1 with the operator terminal.	
Entering the patient's information into the control units	
11. Connect the backup battery to control unit 1. This is acknowledged by a short audible alarm on the control unit. The control unit displays very high battery operating times (> 10:00 h). Messages **A02 Main battery not connected** and **H50 No pump connected** appear. IMPORTANT: Do not yet acknowledge the messages.	
12. Connect control unit 1 to the operator terminal. Log in as an OR user.	
13. Acknowledge messages **A02** and **H50**.	
14. Enter the patient's information (**Service** menu item) and apply. The patient's information is now stored in control unit 1.	
15. Remove the plug of the operator terminal from the control unit. Do not turn the computer off!	
16. Disconnect the battery from the control unit. The control unit emits a non-acknowledgeable interval tone, which ceases after approx. 5 minutes.	
17. Repeat step 11 to step 13 with control unit 2.	
18. Transfer the patient data from the hard disk of the operator terminal to the control unit (**Service** menu item, option **Send patient data/settings**).	
19. Repeat step 15 and step 16 with control unit 2.	

Tab. 13-1 Implantation checklist

Procedure	Done?
Intraoperative preparations (section 7.2, page 98)	
Securing the inner compartment of the INCOR Smart Bag to the operating table.	
Unpacking, checking and laying out the sterile components (section 7.2.1, page 98)	
20. Check the temperature indicator of the unsterile outer packaging. Do not use the pump if its temperature indicator has turned black.	
21. Ensure that the pump and control unit have identical AP numbers.	
22. Have a non-sterile person open the aluminum-coated outer packaging and remove the components in the sterile packaging.	
23. The inner sterile packaging should be opened by a sterile person and the components laid out ready for use.	
24. Ring set: remove and lay out the seal rings and guide rings. Take care when handling the guide rings: do not grip the ring by the claws, but rather by the section covered in silicone. The silicone cover must remain intact on the ring. Do not bend the claws by applying pressure.	
25. The suture ring from implantation set 2 is secured on the suture ring holder by a protective ring. Remove the protective ring from the suture ring holder.	
Preparing the inflow cannula (section 7.2.2, page 99)	
26. Moisten the cannula.	
27. Attach the guide ring to the pump end of the cannula. The claws should be pointing toward the pump. The silicone cover should remain retracted. It must completely enclose the smooth side of the guide ring.	
28. Attach the seal ring to the pump end of the cannula. The seal ring should sit perfectly in the groove.	
29. Pick up the protection balloon and remove the protective cap from the end of the tube.	
30. Insert the free end of the tube into the inflow cannula from the inflow side. The entire protection balloon should still be protruding from the cannula.	

Tab. 13-1 Implantation checklist

Procedure	Done?
31. Fill the single-use syringe with 10 mL NaCl solution, attach to the three-way stop cock, and de-air. Screw the three-way stop cock onto the free end of the tube. In doing so, ensure that the tube is not twisted.	
32. Fill and de-air the protection balloon and tube.	
33. Bring the protection balloon into position. Around half of the protection balloon must protrude above the crown of the cannula.	
34. Build up the pressure in the protection balloon. The protection balloon must not slip into the cannula due to pulling on the tube or pressure on the balloon. If the protection balloon is too large, it will not easily glide into the ventricle and may lift the sealing lip on the suture ring. If it is too small, it will slide back into the cannula when pushed.	
Connecting the pump to the outflow angle section (not applicable if the outflow angle section is not being used) (section 7.2.3, page 100)	
35. Moisten the outflow angle section.	
36. Attach the guide ring with silicone cover to the inflow side of the outflow angle section. The claws should be pointing toward the pump. The silicone cover should remain retracted. It must completely enclose the smooth side of the guide ring.	
37. Attach the seal ring to the inflow side of the outflow angle section. The seal ring should sit perfectly in the groove.	
38. Attach the outflow angle section to the outflow side of the pump. Note in this case: the arrow on the pump body is pointing in the direction of blood flow. The collar of the outflow angle section must be flush with the detent ring of the pump.	
39. Allow the guide ring of the outflow angle section to snap into place. All the claws of the guide ring must be fully engaged.	
40. Ensure that the snap-in connector is correctly engaged: a correctly engaged snap-in connector can easily be turned back and forth within the snap-in position!	
41. Turn back the silicone cover of the guide ring. Ensure that the silicone cover is concealing the entire guide ring.	
Surgery (section 7.4, page 115)	
Anastomosis of the suture ring to the ventricle (section 7.4.1, page 115)	
42. Start extracorporeal circulation.	

Tab. 13-1 Implantation checklist

Procedure	Done?
43. If necessary, place a vent in the pulmonary artery or in the left atrium.	
44. If indicated, start fibrillation.	
45. Opening the left ventricle **46.** (LV) using the apex coring knife.	
47. Inspection of the LV. The opening to the LV should be free from potential inflow impediments, e.g. trabeculae and thrombi.	
48. Apply 10-12 felt-underlaid, double-reinforced sutures (non-absorbable suture material, e.g. prolene(R) 3-0 SH-1) circularly around the apical incision. Do not tie.	
49. Place the applied sutures synchronously on the suture ring. The suture ring is held by the ring holder.	
50. Push the holder with the suture ring down and tie all the sutures. Do not tie four sutures with 90° spacing. Ensure that the ring is sitting smoothly and is free of creases, and that the sealing lip is not damaged.	
51. To vent, insert the free end of the vent tube into the ring holder (minimum inner diameter: 7 mm, outer diameter: approx. 12 mm)	
52. Remove the ring holder. To do so, cut through the retention stitches and ensure that they have all been removed.	
Fastening the inflow cannula to the suture ring (section 7.4.2, page 116)	
53. Insert the prepared inflow cannula together with the protection balloon into the apex of the ventricle.	
54. Rotate the inflow cannula to the optimal position so that the pump can be placed in the anterior lower mediastinum. IMPORTANT: Following anastomosis of the inflow cannula, the position of the cannula can no longer be adjusted.	
55. Suture the four threads left on the suture ring with the suture edge of the inflow cannula and tie. Check the sufficiency of the anastomosis.	
56. Empty and remove the protection balloon.	
Connecting the pump to the inflow cannula (section 7.4.3, page 117)	
57. Pick up the pump.	

Tab. 13-1 Implantation checklist

Procedure	Done?
58. Connect the pump to the inflow cannula using the snap-in connector: Proceed in a similar way to connecting the outflow angle section and pump. See step 35 to step 41. The collar of the inflow cannula must be flush with the detent ring of the pump! Take care with the direction: the arrow on the pump body points in the direction of blood flow!	
59. Allow the guide ring to snap into place. All the claws of the guide ring must be fully engaged.	
60. Ensure that the snap-in connector is correctly engaged: a correctly engaged snap-in connector can easily be turned back and forth within the snap-in position!	
61. Turn back the silicone cover of the guide ring. Ensure that the silicone cover is concealing the entire guide ring.	
De-airing the systemsection 7.4.3, page 117	
62. Stop the vent in order to fill and de-air the pump and outflow angle section. Then reactivate the vent.	
63. Defibrillate, if indicated.	
64. Attach seal caps to the outflow angle section or use a vent tube adapter.	
If required: de-airing the pump and outflow angle section with the vent	
65. Attach the supplied vent tube adapter to the outflow side of the pump or outflow angle section.	
66. Connect the vent tube to the vent tube adapter.	
Tunneling the driveline (section 7.4.4, page 119)	
67. Screw the trocar onto the trocar adapter of the driveline.	
68. Moisten the driveline including the velour and trocar adapter with NaCl solution.	
69. Tunnel the driveline subcutaneously in the direction of the right iliac wing. Select the site for transcutaneous exit of the driveline. The transcutaneous exit site should be lateral to the medioclavicular line at the level of the umbilicus. Make the skin incision here and pull the driveline through. IMPORTANT: A distance of at least 10 cm is required subcutaneously to prevent ascending infections.	
70. Unscrew the trocar from the trocar adapter.	

Tab. 13-1 Implantation checklist

Procedure	Done?
Anastomosis and length adaptation (section 7.4.5.1, page 120)	
71. Clamp the ascending aorta tangentially and make a longitudinal incision. In doing so, use the head of the outflow cannula as a gage: the length of the incision should be approx. 25 mm, i.e., about 5 mm shorter than the compressed head of the outflow cannula (length: approx. 30 mm). IMPORTANT: If the incision is too short, bleeding may occur at the site of anastomosis.	
72. Perform end-to-side anastomosis of the outflow cannula with the ascending aorta. Running or interrupted sutures (with felt pledget) can be used.	
73. Determine the required length of the outflow cannula.	
74. Adapt the length of the outflow cannula. To do so, cut off the necessary number of collars. Cut immediately before the front surface. The cut should be a maximum of 0.5 mm away from the front surface. IMPORTANT: The excess on the cut surface may not be more than 0.5 mm! Make sure that the cut is straight. IMPORTANT: At least one collar must remain on the cannula!	
Connecting the outflow cannula to the system (section 7.4.5.2, page 121)	
75. First attach the guide ring, then the seal ring to the inflow side of the outflow cannula. The claws should be pointing toward the pump. De-air the outflow cannula in a retrograde direction.	
76. Remove the seal cap or vent tube adapter from the outflow angle section or pump.	
77. Connect the outflow cannula to the outflow angle section or pump. In doing so, carefully de-air the cannula and the pump (feed in NaCl solution or fill the cannula and pump with blood). The front side of the cannula must be flush with the detent ring of the pump. Allow the guide ring to snap into place. All the claws of the guide ring must be fully engaged.	
78. Check the position of the snap-in connector: a correctly engaged snap-in connector can easily be turned back and forth within the snap-in position!	
79. Turn back the silicone cover of the guide ring. Ensure that the silicone cover is concealing the entire guide ring.	

Tab. 13-1 Implantation checklist

Procedure	Done?
80. If there is still air in the system: de-air the system. To do so, puncture the outflow angle section. If the outflow angle section is not being used, only the felt pledget of the outflow cannula may be punctured. Size of the puncture cannula 21G. Ensure that the puncture is made at a 90° angle to the felt pledget. Keep the number of punctures to the minimum.	
If the snap-in connector of the outflow angle section/outflow cannula has to be opened	
81. Retract the silicone cover between the outflow angle section and outflow cannula to expose the detent ring of the outflow angle section.	
82. Push the angle section key onto the outflow angle section. The key surfaces of the angle section key enclose the detent ring on the side, and the contact surface of the key presses from below against the detent ring. Hold the key and outflow angle section firmly in this position. Note: the angle section key can be affixed to all surfaces of the detent ring.	
83. Grip the guide ring. Twist the guide ring slightly towards the detent ring, then tighten. Do not compress the guide ring.	
84. Remove the key.	
85. Grip the detent ring and outflow cannula, then remove the outflow cannula.	
86. Inspect before reconnecting: is the silicone edge of the outflow angle section flush with the edge of the detent ring? If not: replace the outflow angle section.	
Mounting the pump socket ready for connection (section 7.4.7, page 124)	
Removing the trocar adapter from the pump socket	
87. Baseline situation: the trocar adapter and pump socket are still connected to each other and covered with a silicone tube. Remove the silicone tube by rolling it back as far as possible, but at least as far as the metal section of the pump socket. If the resistance to this action is too great, the silicone tube can be cut carefully with a scalpel. IMPORTANT: Do not bring the scalpel into contact with the kink protection sleeve at the point where the socket and cable meet!	
88. Grip the trocar adapter and pull back the closing sleeve as far as the end of the slit.	

Tab. 13-1 Implantation checklist

Procedure	Done?
89. Now grip the pump socket and exposed section of the trocar adapter and pull gently to separate one from the other. In doing so, gently maneuver the trocar adapter from side to side as necessary. The core of the pump socket is now exposed.	
Affix sleeve to pump socket	
90. Guide the sleeve, narrow end first, onto the pump socket in such a way that the markings on the sleeve and the pump socket are perfectly aligned. IMPORTANT: The sleeve can only be positioned on the pump socket if the markings on the pump socket and sleeve are precisely aligned.	
91. Now apply force to push the sleeve onto the pump socket so that it is aligned. After overcoming initial, palpable resistance, continue to push until it engages, i.e., as far as the end mark. Rather than twisting the sleeve against the pump socket or cable, make sure that the markings are constantly aligned. Otherwise, the sleeve cannot be brought into the snap-in position.	
92. Pull on the sleeve to check it. The sleeve is now inextricably connected to the pump socket, and the socket is ready to be plugged in.	
Activating and configuring the pump (section 7.5, page 125)	
Aligning the control units with the pump: Offset correction (section 7.5.1, page 125)	
Connecting the pump to the control unit	
93. Prepare the INCOR Smart Bag with control unit 1 and batteries.	
94. The outflow cannula must be clamped by the surgeon.	
95. Connect the pump and control unit 1 to each other by means of the plug coupling. To do so, insert the control unit plug into the pump socket. IMPORTANT: The arrow markings on the control unit plug and the pump socket must be aligned!	
Performing offset correction on control unit 1	
96. Connect the operator terminal to control unit 1.	
97. Connect the backup battery to control unit 1. Once the pump and backup battery are connected to the control unit, do not pull on the plug or cable! Auto-calibration of the control unit commences; wait 30 seconds.	

Tab. 13-1 Implantation checklist

Procedure	Done?
98. Log in as an OR user.	
99. Ensure that the system is in halt mode (displayed speed = 0).	
100. Select **Offset of rotor position** from the **Settings** menu. The **Offset of rotor position** window opens. The pressure difference curve will most likely not coincide with the zero line (see section 7.5.1, page 125).	
101. To adjust the displayed pressure difference, press **<↑>** / **<↓>** until the pressure difference curve coincides with the zero line. Every step corresponds to 2 mmHg.	
102. After adjustment: select **Close**. The configured value is applied.	
103. Prepare control unit 2.	
104. Firstly, disconnect the battery from control unit 1, then pull the safety plug of the communication cable of control unit 1 out of the pump socket (plug coupling open). To open the plug coupling, pull back the sleeve of the safety plug of the communication cable marked with a double arrow. Only then can the safety plug of the communication cable be removed from the pump socket by pulling.	
105. Remove control unit 1 from the bag and put to one side. The control unit will emit an acoustic alarm for about 5 minutes.	
Performing offset correction on control unit 2	
106. Take control unit 2 and place it in the bag.	
107. Connect control unit 2 to the pump by means of the plug coupling.	
108. Repeat step 96 to step 102 for control unit 2, as described for control unit 1.	
109. Remove the clamp from the outflow cannula. The pump is now sufficiently prepared that it can be activated. Control unit 2 remains connected to the pump as the active control unit. Control unit 1 serves as the replacement control unit.	
Starting the system via the monitor program, setting the parameters (section 7.5.2, page 128)	
Perfusion	
110. Select Constant mode. The pump will operate at 5000 rpm.	

Tab. 13-1 Implantation checklist

Procedure	Done?
111. In agreement with the surgeon: adjust the speed to the requirements, while simultaneously weaning from ECC. Avoid myocardial suction!	
112. Enter alarm threshold flow.	
113. Enter the pressure difference alarm threshold	
114. If necessary, the alarm thresholds for flow and pressure difference must again be checked and readjusted in the intensive care unit.	
Surgery	
115. Before switching to continuous pumping mode: insert a left atrial pressure measurement line, if necessary.	
116. Switch to continuous pumping mode. The pump will operate at 5000 rpm. Adjust the speed.	
117. Slowly reduce and wean from ECC.	

Tab. 13-1 Implantation checklist

For further details, See section 7.6: Postoperative care on the intensive care unit, page 129.

13.2 Implantation record form

Berlin Heart®

IMPLANTATION RECORD FORM

INCOR® DATABASE

PLEASE FILL OUT THE FORM AND **SEND IT BY FAX IMMEDIATELY AFTER IMPLANTATION TO: + 49 – 30 – 81 87 27 37**

PATIENT INFORMATION

Hospital			**City**		**Country**
Patient Initials	**ID-No.**	**Gender** m ☐ f ☐	**Date of birth** [dd/mm/yy]	**Size** [cm]	**Weight** [kg]
Indication	idiopathic CMP ☐	ischemic CMP ☐	congenital ☐	postcardiotomy ☐	
	acute myocardial infarction ☐	myocarditis ☐	other ☐	.....	
Intention to treat	bridge to recovery ☐	destination therapy ☐	bridge to transplantation ☐		

IMPLANTATION DETAILS (Legal requirement for device tracking)

Implantation date [dd/mm/yy]	**INCOR® Pump Number [AP-No.]**	**If INCOR® Graft Outflow Cannula was used:**
		Solely one single Implantation Set Part 2 used?
Surgeon [name]	**INCOR® Suture Ring [Lot-No.]**	**yes** ☐ **no** ☐
		If yes: Implantation Set Part 2 [Lot-No.]
CPB time [min]	**INCOR® Inflow Cannula [Lot-No.]**	**If no, please specify component lot numbers:**
Access ☐ medial ☐ lateral	**If INCOR® Silicone Outflow Cannula was used:**	Graft Connector:
		Screw Clamp:
☐ minimal-invasive	**INCOR® Outflow Cannula [Lot-No.]**	Prosthetic Vascular Graft:
		Kink Protection Sleeve:
	INCOR® Outflow Angle Section [Lot-No.]	Outflow Angle Section, Graft:

PRE- IMPLANTATION CONDITION

Urgency of implantation elective ☐ urgent ☐ emergency ☐

INTERMACS level

1 ☐	Critical cardiogenic shock despite escalating support	
2 ☐	Progressive decline with inotropic dependence	
3 ☐	Clinically stable with mild to moderate inotropic dependence	
4 ☐	Recurrent, no refractory, advanced heart failure that can be stabilized with intervention	
5 ☐	Exertion intolerant but is comfortable at rest and able to perform activities of daily living with slight difficulty	
6 ☐	Exertion limited; is able to perform mild activity, but fatigue results within a few minutes of any meaningful physical exertion	
7 ☐	Advanced NYHA functional class III	

On ventilation	no ☐	yes ☐	..... days	
Other MCS	no ☐	yes ☐		
		IABP ☐	..... days	
		ECMO ☐	..... days	
		Others ☐	..... days	
CPR within 24h (pre-implantation)	no ☐	yes ☐	unknown ☐	
Dialysis/Hemofiltration within 72h (pre-implantation)	no ☐	yes ☐	unknown ☐	
History of stroke	no ☐	yes ☐	unknown ☐	
History of prev. thor. surg.	no ☐	yes ☐	unknown ☐	

PRE- IMPLANTATION HEMODYNAMICS (most recent – if any parameter is not available please mark)

MAP [mmHg]	**CVP** [mmHg]	**PAP mean** [mmHg]	**LVEDP / PCWP** [mmHg]	**LVEF** [%]
FS [%]	**Cardiac Output** [l/min]	**Cardiac Index** [l/min/sqm]	**LVEDD** [mm]	

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13.3 Follow-up form

Berlin Heart®

FOLLOW-UP FORM

INCOR® DATABASE

PLEASE COMPLETE THE DATA IN THIS FORM AS IT OCCURS AND **SEND IT BY FAX EVERYTIME YOU HAVE ADDED INFORMATION TO: + 49 – 30 – 81 87 27 37**

INCOR® Pump Number [AP-No.]	**INCOR® Pump AP-No. and date of implantation is the identifier for the patient**	**Hospital** **Date of implantation (dd/mm/yy)**

POSTOPERATIVE COURSE

First time extubated [dd/mm/yy]	**Cumulative units of blood within 7 days** [units]

ANTICOAGULATION / ANTIAGGREGATION

Heparin start [dd/mm/yy]	**ASA start** [dd/mm/yy]	**Other** [dd/mm/yy] / **Which**?
LMWH start [dd/mm/yy]	**Dipyridamole start** [dd/mm/yy]	**Other** [dd/mm/yy] / **Which**?
Vit.-K-Antag. start [dd/mm/yy]	**Clopidogrel start** [dd/mm/yy]	**HIT** no ☐ yes ☐

TRANSFER NOTIFICATION

From **To**	**Date** [dd/mm/yy]	**1 = Intensive Care Unit** **2 = Step Down Unit** **3 = Rehab Centre** **4 = Home**
From **To**	**Date** [dd/mm/yy]	
From **To**	**Date** [dd/mm/yy]	
From **To**	**Date** [dd/mm/yy]	

ADVERSE EVENTS

Date [dd/mm/yy] **Type**	01 = Major Bleeding 02 = Cardiac Arrhythmias 03 = Pericardial Fluid Collection 04 = Device Malfunction 05 = Hemolysis 06 = Hepatic Dysfunction 07 = Hypertension 08 = Major Infection 09 = Myocardial Infarction 10 = Neurological Dysfunction 10a = TIA 10b = Ischemic CVA 10c = Hemorrhagic CVA 11 = Psychiatric Episode	12 = Renal Dysfunction 13 = Respiratory Failure 14 = Right Heart Failure 15 = Arterial Non-CNS Thromboembolism 16 = Venous Thromboembolism Event 17 = Wound Dehiscence 18 = Other (please specify)
Date [dd/mm/yy] **Type**		
Date [dd/mm/yy] **Type**		
Date [dd/mm/yy] **Type**		
Date [dd/mm/yy] **Type**		

DEVICE EXPLANT

Date [dd/mm/yy]	**HTx** ☐ **weaned** ☐ → **Lot-No. of weaning set** ……
Remarks: ……	**died** ☐ →**primary cause of death** ……

In case of questions clinical contact person for follow-up: _____ **Tel.:** _____ **Email:** _____

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Appendix

1. INTERMACS Levels

1 = Critical cardiogenic shock despite escalating support

2 = Progressive decline with inotropic dependence

3 = Clinically stable with mild to moderate inotropic dependence

4 = Recurrent, no refractory, advanced heart failure which can be stabilized with intervention

5 = Exertion intolerant but is comfortable at rest and able to perform activities of daily life with slight difficulty

6 = Exertion limited; is able to perform mild activity, but fatigue occurs within a few minutes of any meaningful physical exertion

7 = Advanced NYHA functional class III

2. Adverse Events Definitions

The INCOR® DATABASE Adverse Events Definitions are geared to the INTERMACS AE's to facilitate more transparency and comparability.

01 = Major Bleeding:

Internal or external bleeding that results in death, the need for re-operation, hospitalization or necessitates transfusion of ≥ 4 U packed red blood cells (PRBC) within any 24 hour period during the first 7 days post-implantation or ≥ 2 U PRBC within any 24 hour period after 7 days post-implantation.

Note: Hemorrhagic stroke is considered a neurological event and not as a separate bleeding event.

02 = Cardiac Arrhythmias:

Any documented arrhythmia that results in clinical compromise (e.g., diminished LVAD flow, oliguria, pre-syncope or syncope) that requires hospitalization or occurs during a hospital stay.

Cardiac arrhythmias are classified as 1 of 2 types:

1) Sustained ventricular arrhythmia requiring defibrillation or cardioversion.

2) Sustained supraventricular arrhythmia requiring drug treatment or cardioversion.

03 = Pericardial Fluid Collection:

Accumulation of fluid or clot in the pericardial space that requires surgical intervention or percutaneous catheter drainage.

04 = Device Malfunction:

Device malfunction denotes a failure of one or more of the components of the INCOR® VAD which either directly causes or could potentially induce a state of inadequate circulatory support (low cardiac output state) or death. Berlin Heart GmbH must confirm device failure. A failure that was iatrogenic or recipient-induced will be classified as an Iatrogenic/Recipient-Induced Failure.

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Device failure should be classified according to which components fail as follows:

1) Pump failure (blood contacting components of pump and any motor or other pump actuating mechanism that is housed with the blood contacting components). In the special situation of pump thrombosis, thrombus is documented to be present within the device or its conduits that results in or could potentially induce circulatory failure.

2) Non-pump failure (e.g. electric power supply unit, batteries, controller, cables)

05 = Hemolysis:

A plasma-free hemoglobin value that is greater than 40 mg/dl, in association with clinical signs associated with hemolysis (e.g. anemia, low hematocrit, hyperbilirubinemia) occurring after the first 72 hours post-implantation. Hemolysis related to documented non-device-related causes (e.g. transfusion or drug) is excluded from this definition.

06 = Hepatic Dysfunction:

An increase in any two of the following hepatic laboratory values (total bilirubin, aspartate aminotransferase/AST and alanine aminotranferease/ALT) to a level greater than three times the upper limit of normal for the hospital, beyond 14 days post-implantation (or if hepatic dysfunction is the primary cause of death).

07 = Hypertension:

New onset blood pressure elevation ≥ 110 mmHg mean pressure.

08 = Major Infection:

A clinical infection accompanied by pain, fever, drainage and/or leucocytosis that is treated by anti-microbial agents (non-prophylactic). A positive culture from the infected site or organ should be present unless strong clinical evidence indicates the need for treatment despite negative cultures. The general categories of infection are listed below:

Localized Non-Device Infection

Infection localized to any organ system or region (e.g. mediastinitis) without evidence of systemic involvement (see sepsis definition), ascertained by standard clinical methods and either associated with evidence of bacterial, viral, fungal or protozoal infection, and/or requiring empirical treatment.

Percutaneous Site and/or Drive Line Infection

A positive culture from the skin and/or tissue surrounding the drive line or from the tissue surrounding the external housing of the pump, coupled with the need to treat with antimicrobial therapy, when there is clinical evidence of infection such as pain, fever, drainage, or leucocytosis.

Internal Pump Component, Inflow or Outflow Tract Infection

Infection of blood-contacting surfaces of the LVAD/RVAD documented by positive site culture.

Sepsis

Evidence of systemic involvement by infection, manifested by positive blood cultures and/or hypotension.

09 = Myocardial Infarction:

Two categories of myocardial infarction will be identified:

Peri-Operative Myocardial Infarction

The clinical suspicion of myocardial infarction together with CK-MB or Troponin > 10 times the local hospital upper limits of normal, found within 7 days following VAD implantation together with ECG findings consistent with acute myocardial infarction.

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Non-Perioperative Myocardial Infarction

The presence at > 7 days post-implantation of two of the following three criteria:

a) chest pain which is characteristic of myocardial ischemia,

b) ECG with a pattern or changes consistent with a myocardial infarction, and

c) Troponin or CK (measured by standard clinical pathology/laboratory medicine methods) greater than the normal range for the local hospital with positive MB fraction (≥ 3% total CK). This should be accompanied by a new regional LV or RV wall motion abnormality on a myocardial imaging study.

10 = Neurological Dysfunction:

Any new, temporary or permanent, focal or global neurological deficit ascertained by a standard neurological examination (administered by a neurologist or other qualified physician and documented with appropriate diagnostic tests and consultation note). The examining physician will distinguish between a transient ischemic attack (TIA), which is fully reversible within 24 hours (and without evidence of infarction), and a stroke, which lasts longer than 24 hours (or less than 24 hours if there is evidence of infarction). Each neurological event must be subcategorized as:

10a = TIA:

Transient Ischemic Attack (acute event that resolves completely within 24 hours with no evidence of infarction)

10b = Ischemic CVA:

Ischemic Cerebrovascular Accident (event that persists beyond 24 hours or less than 24 hours associated with infarction on an imaging study.

10c = Hemorrhagic CVA:

Hemorrhagic Cerebrovascular Accident (event that persists beyond 24 hours or less than 24 hours associated with positive findings on an imaging study.

11 = Psychiatric Episode:

Disturbance in thinking, emotion or behaviour that causes substantial impairment in functioning or marked subjective distress requiring intervention. Intervention is the addition of new psychiatric medication, hospitalization or referral to a mental health professional for treatment. Suicide is included in this definition.

12 = Renal Dysfunction:

Two categories of renal dysfunction will be identified:

Acute Renal Dysfunction

Abnormal kidney function requiring dialysis (including hemofiltration) in patients who did not require this procedure prior to implantation, or a rise in serum creatinine of greater than 3 times baseline or greater than 5 mg/dl sustained for over 48 hours.

Chronic Renal Dysfunction

An increase in serum creatinine of 2 mg/dl or greater above baseline, or requirement for hemodialysis sustained for at least 90 days.

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13 = Respiratory Failure:

Impairment of respiratory function requiring re-intubation, tracheostomy or the inability to discontinue ventilatory support within six days (144 hours) post-VAD implantation. This excludes intubation for re-operation or temporary intubation for diagnostic or therapeutic procedures.

14 = Right Heart Failure:

Symptoms and signs of persistent right ventricular dysfunction (central venous pressure (CVP) > 18 mmHg with a cardiac index < 2.0 l/min/m^2 in the absence of elevated left atrial/pulmonary capillary wedge pressure (greater than 18 mmHg), tamponade, ventricular arrhythmias or pneumothorax) requiring either RVAD implantation or inotropic therapy, fourteen days or more after LVAD implantation.

15 = Arterial Non-CNS Thromboembolism:

An acute systemic arterial perfusion deficit in any non-cerebrovascular organ system due to thromboembolism confirmed by one or more of the following:

1) standard clinical and laboratory testing
2) operative findings
3) autopsy findings

This definition excludes neurological events.

16 = Venous Thromboembolism Event:

Evidence of venous thromboembolic event (e.g. deep vein thrombosis, pulmonary embolism) by standard clinical and laboratory testing.

17 = Wound Dehiscence:

Disruption of the apposed surfaces of a surgical incision, excluding infectious etiology, and requiring surgical repair.

18 = Other:

An event that cause

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13.4 Sample copy: Outpatient data recording

Name	AP number

Date	Speed	Flow
Pressure difference min./ max.	INR	
PC on [ ] off [ ]	PFC on [ ] off [ ]	SP on [ ] off [ ]
Messages		
Comments		

Date	Speed	Flow
Pressure difference min./ max.	INR	
PC on [ ] off [ ]	PFC on [ ] off [ ]	SP on [ ] off [ ]
Messages		
Comments		

Date	Speed	Flow
Pressure difference min./ max.	INR	
PC on [ ] off [ ]	PFC on [ ] off [ ]	SP on [ ] off [ ]
Messages		
Comments		

13.5 Checklists: Transferral to outpatient care

13.5.1 Preparatory measures for outpatient care

The following preparatory measures were taken before discharging the patient to outpatient care:	Done
Replacement control unit aligned to the pump (offset correction)	
Settings (speed, pressure difference alarm threshold, flow alarm threshold) checked and adjusted as necessary	
PC, PFC and SP settings checked and adjusted as necessary (Activated? Parameters?)	
Patient data, user data and current settings entered into the replacement control unit	
The patient has been trained, especially on how to replace the control unit	
Anticoagulation checked and adjusted as necessary	
The patient has confirmed that he/she has received training as well as all the components, accessories and documents	
The telephone number of the hospital contact person has been noted in the patient's instructions for use, on the patient's ID card and short instructions for the patient	
The current speed has been entered in the patient's instructions for use	
Domestic electrical installations have been discussed with the patient and adjusted as necessary (see section 2.1, page 13 and section 3.9, page 23)	
The charging unit, operator terminal and power supply unit have been securely installed in the patient's home, and cable ducts confirmed as safe	
I hereby affirm that I have received the above-cited components and documents.	
Patient's name:	Date, signature:
I hereby affirm that I have handed over the above-cited components and documents to my patient.	
Name of attending physician:	Date, signature:

Tab. 13-2 Preparatory measures

13.5.2 Familiarization of the patient with the INCOR system

Familiarization of the patient with the INCOR system	Done
Permanently active components • INCOR control unit, including an explanation of all values and displays • INCOR batteries, including an explanation of the battery LEDs	
Non-permanently active components • INCOR power supply unit • INCOR charging unit including power supply unit • INCOR operator terminal with accompanying power supply unit and communication cable	
• INCOR Smart Bag including how to position the belt strap	
Power supply • When operated from the power supply unit • When operated from the batteries: duration of battery operation	
Safety concept • Operating principle of the safety plugs • Operating principle of the plug coupling • Messages	
Appropriate use of INCOR, especially • Cautionary measures and safety information • Protection of all components from electromagnetic fields	
Consequences of incorrect use of INCOR • Wound infections • Failure of power supply • Damage to and failure of components	
I hereby affirm that I have received instruction from my physician in all of the actions described above, and that I have a firm command of all of these concepts.	
Patient's name:	Date, signature:
I affirm that my patient has been instructed in all of the actions described above, and has a firm command of all of these concepts.	
Name of attending physician:	Date, signature:

Tab. 13-3 Familiarization of the patient with the INCOR system

13.5.3 Patient training

Patient training	Done
Inserting and removing the safety plug, opening and closing the plug coupling	
Power supply • Mains operation: connecting the power supply unit to the mains power supply and control unit • Battery operation • Switching between mains and battery operation • Connecting the charging unit to the mains power supply • Replacing discharged batteries and charging them in the charging unit • Calibrating the battery in the charging unit, if necessary	
Operator terminal • Connecting the operator terminal to the control unit, starting the monitor program • Reading the values • Ending the monitor program	
Exchanging the control unit for the replacement control unit	
Wound care	
Cautionary measures • When washing • When sleeping • When selecting clothing • When coming into contact with (domestic) animals • During wound care • When mobile	
All measures for resolving messages according to the patient's instructions for use	
Cleaning the components	
I hereby affirm that I have received instruction from my physician in all of the actions described above, and that I have a firm command of all of these concepts.	
Patient's name:	Date, signature:
I affirm that my patient has been instructed in all of the actions described above, and has a firm command of all of these concepts.	
Name of attending physician:	Date, signature:

Tab. 13-4 Patient training

13.5.4 Handover of all components and documents

The following components and documents were given to the patient before being discharged to outpatient care:	Received
Components	
• 1 active control unit	
• 1 replacement control unit	
• 2 main batteries	
• 2 backup batteries	
• 2 power supply units, each with a mains power cable	
• 1 charging unit	
• 1 Control & Monitoring Station (operator terminal) with accompanying power supply unit and communication cable	
• 1 INCOR Smart Bag	
Documents	
• 1 set of instructions for use for the patient	
• 1 set of short instructions for the patient	
• 1 patient ID card	
• Copies of the *Outpatient data recording* form	
I hereby affirm that I have received the above-cited components and documents.	
Patient's name:	Date, signature:
I hereby affirm that I have handed over the above-cited components and documents to my patient.	
Name of attending physician:	Date, signature:

Tab. 13-5 Components and documents for the patient

14 Appendix

14.1 Scope of delivery

NOTE: Case 1 comes in 2 designs. The designs vary in that the outflow cannula and contents of the sets differ.

Case 1: Sterile components - REF: 5100210

Components		REF
1 x implantation set 1		5100207
	1 x axial pump, sterile in aluminum-coated outer packaging	5100206
	1 x seal cap, sterile	5100116
	1 x outflow angle section, sterile in aluminum-coated outer packaging	5200613
	1 x angle section key, sterile	5100023
	1 x apex coring knife, sterile	5100141
	1 x protection balloon, sterile	5100178
	1 x vent tube adapter, sterile	5100154
	1 x trocar, sterile	5100149
	2 x pump socket sleeve, sterile	5100077
1 x implantation set 2		5200040
	1 x inflow cannula, sterile	5200034
	1 x suture ring on holder, sterile	5200016
	1 x outflow cannula, sterile	5200004
	1 x 10 mL single-use syringe, sterile	5100146
	1 x three-way stop cock, sterile	5100144
	1 x ring set, sterile	5100175
1 x explantation set		5100400
	1 x scraper, sterile	5100143
	1 x cutting tool	5100118
	2 x seal cap, sterile	5100116

Tab. 14-1 Case 1: Sterile items

Case 1 sterile components, graft - REF: 5100128

Components	REF
1 x implantation set part 1, inflow side	5100123
1 x axial pump, sterile	5100206
1 x inflow cannula, sterile	5200034
1 x suture ring on holder, sterile	5200016
2 x pump socket sleeve, sterile	5100077
1 x ring set 2, sterile	5100122
1 x implantation set part 2, outflow side	5200124
1 x outflow angle section, sterile	5200301
1 x graft connector, sterile	5200302
1 x screw clamp, sterile	5200303
1 x vascular graft prosthesis, sterile	5200304
1 x kink protection sleeve, sterile	5200305
1 x surgical set	5100127
1 x apex coring knife with protecting cap, sterile	5100141
1 x vent tube adapter, sterile	5100154
1 x angle section key, sterile	5100023
1 x trocar, sterile	5100149
1 x protection balloon with tube, sterile	5100178
1 x 10mL single-use syringe, sterile	5100146
1 x three-way stop cock, sterile	5100144
1 x seal cap for blood pump, sterile	5100116
1 x expanding mandrel, sterile	5200306
1 x torque screwdriver, sterile; incl. instructions for use	5200370
1 x explantation set	5100126
1 x scraper, sterile	5100143
1 x cutting tool	5100118
2 x seal cap, sterile	5100116

Tab. 14-2 Case 1 sterile components, graft

Case 2: Unsterile components

Components		REF
	2 x INCOR control unit	5400102
	2 x INCOR main battery	5500008
	2 x INCOR backup battery	5500028
	1 x INCOR charging unit	5800682
	2 x INCOR power supply unit (for control unit and charging unit), each with a mains power cable	5700004
	1 x INCOR control & monitoring station (operator terminal), including stand, software, power supply unit and mains power cable	5600033
	1 x communication cable	5600007
	1 x INCOR Smart Bag, including 1 x short instructions for the patient	5300489
	Cable protector set, short polyester velour	5100235
Instructions for use		
	1 x instructions for clinical use	
	1 x patient's instructions for use	
	1 x short instructions for clinical use	
	1 x patient ID card	
	1 x OR accompanying documentation	
	1 x password envelope	
	1 x implantation record form	

Tab. 14-3 Unsterile items

14.2 Accessories

Components		REF
Weaning set (1x seal plug, 1x insertion tool, position spacers 32 mm and 37 mm)		W00I-002-00
Explantation set		5100400
	1 x scraper, sterile	5100143
	1 x cutting tool	5100118

Tab. 14-4 Accessories

Components		REF
	2 x seal cap, sterile	5100116
1 x cable protector set for short polyester velour		5100235

Tab. 14-4 Accessories

14.3 Technical specifications

Product	Value
Manufacturer and distributor	Berlin Heart GmbH Wiesenweg 10 12247 Berlin, Germany
Classification	Active, implantable medical device compliant with Directive 90/385/EEC
Overall system	
Operating voltage (Power supply unit)	AC 100 to 240 V, 240VA 50/60 Hz
Ambient temperature (control unit and batteries)	-10°C to +40°C
Air pressure	700 hPa to 1060 hPa
Battery operating time	7 h
Max. ambient magnetic field strength	3 A/m
Max. high-frequency electromagnetic alternating field strength	10 V/m
Lifetime	
INCOR pump with cannulae	5 years, single use
External INCOR components: control unit with plug coupling, operator terminal, power supply unit, charging unit, and all cables	5 years

Tab. 14-5 Technical specifications

Product	Value
Maintenance	
INCOR does not require maintenance. The charging unit is also designed to be maintenance-free when used as intended. The infiltration of dust may lead to wear on the fan, possibly causing an increase in fan noise. If you notice anything unusual about the charging unit, e.g., defective casing or an increase in fan noise, inform the emergency hotline (+49 (0)30 8187 2772)	
Blood pump	
Inner diameter (pump tube)	16 mm
Minimum inner diameter (passage width) of pump in the area of the olives	11.3 mm
Outer diameter of blood pump body	31.7 mm (37 mm)
Pump length (stub-stub)	123 mm
Largest axial extension (corresponds to installation length)	184 mm
Weight (including driveline and cannulae)	Approx. 350 g
Volume of blood pump body	Approx. 60 cm^3
Design speed	7500 rpm
Delivery capacity at design point	4.5 L/min. at 75 mm Hg
Potential speed	5000 - 10 000 rpm
Power consumption of bearing	0.5 W
Power consumption of motor	4 W at design point
Material	Titanium
Coating of blood-contacting surfaces	Carmeda BioActive Surface
Application component	CF

Tab. 14-5 Technical specifications

Product	Value
Cannulae	
Minimum inner diameter (passage width) of cannulae	12.7 mm
Material	Silicone; partially reinforced with plastic, partially surrounded by suturable polyester velour; inflow cannula with titanium stub
Dimensions of inflow cannula	Length: 75 mm Inner diameter: inflow side 16 mm outflow side 12.7 mm
Dimensions of outflow cannula	Length: 125 mm Inner diameter: 12.7 mm
Dimensions of outflow angle section	Length: 61.5 mm Inner diameter: inflow side 12.7 mm outflow side 11.3 mm
Tensile forces of snap-in connectors	> 10 N (corresponding to requirements of DIN EN 45502-1)
Control unit	
Dimensions	106 mm x 106 mm x 65 mm
Weight	740 g
Operating voltage	18 V DC to 28 V DC (powered by power supply unit and batteries)
Protection type	IP54 (protection against dust and splash water)
Application component	CF
Volume of acoustic alarm	approx. 69 dB(A)
Batteries	
Type	Lithium-ion batteries in plastic casing
Dimensions	132 mm x 115 mm x 55 mm

Tab. 14-5 Technical specifications

Product	Value
Weight	800 g
Output voltage	20.5 V DC to 24.6 V DC
Capacity	2.3 Ah
Operating time	Approx. 3.5 h (depending on speed)
Charging time	Approx. 2 h to 4 h
Protection type	IP54 (protection against dust and splash water)
Power supply unit	
Dimensions (L x W x H)	165 mm x 95 mm x 55 mm
Weight	Without mains power cable: 740 g Mains power cable: 220 g
Input voltage	AC 100-240 V, 240 VA, 50/60 Hz
Power consumption (design point)	Control unit: 32 - 50 VA
Output voltage	DC 28 V, max. 3.6 A
Ambient temperature	0°C - 40°C
Protection type	IP22 (protected against access with a finger, protection against falling dripping water if the casing is tilted up to 15°)
Protection class	II
Charging unit	
Dimensions (L x W x H)	270 mm x 150 mm x 325 mm (10.63 in. x 5.91 in. x 12.80 in.) without batteries 270 mm x 170 mm x 325 mm (with batteries)
Weight	2300 g
Operating voltage	DC 28 V, max 2.5 A (powered by power supply unit)
Power consumption	Max. 72 VA
Ambient temperature	0°C - 40°C

Tab. 14-5 Technical specifications

Product	Value
Protection type	IP30 (protection against contact, but not water)
Operator terminal with monitor program	
Weight (incl. accompanying power supply unit and stand)	3.75 kg
Operating voltage	DC 19 V, 3 A
Accompanying power supply unit	AC input: 100-240 V, 1.5-0.7 A, 47-63 Hz DC output: 19 V, 3.15 A
Ambient temperature	0°C - 35 °C
Accuracy of display	
Flow	At 8000 rpm: ± 0.4 L/min.
Pressure difference	At 100 mm Hg and 5 L flow: ±5 mm Hg At 20 mm Hg and 8 L flow: ±5 mm Hg At 170 mm Hg and 0 L flow: ±5 mm Hg
Speed	±100 rpm
Motor current	±10%
Motor power	±10%
Bearing power	(+0.5 W to +1.2 W) ±0.4 W
Temperature	±5°C

Tab. 14-5 Technical specifications

14.4 Control unit displays

Display	Description
Numerals, with 2 digits after the colon (e.g.: 7:42 AM)	Normal display: operating time of the active battery in hours: minutes
Normal display permanent	Battery operation
normal display flashes	Mains operation

Tab. 14-6 Overview: Control unit displays

Display	Description
Numerals, with one digit after the period (e.g.: 4.9)	Mean flow in L/min, displayed at the press of the button
Letter(s) and number (e.g., A02)	Messages
Without colon (e.g., A02)	Current message
With colon (e.g., EA:00)	Resolved message, appears at the press of the button

Tab. 14-6 Overview: Control unit displays

14.5 Configurable parameters: default settings and ranges

Parameter	Default	Possible range
General		
Alarm threshold flow [l/min.]	0	0 to 9
Alarm threshold pressure difference [mm Hg]	0	- 50 to 90
Offset of rotor position	-	1.5 to 3.5
Set speed (constant/max.) [rpm]	0	5000 to 10,000
PC		
Degree of pulsatility [mm Hg]	5	1 to 10
PFC		
Duration of speed reduction [ms]	2000	500 to 2000
Fall time [ms]	100	0 to 500
Rise time [ms]	500	0 to 500
reduced speed [rpm]	3000	3000 to 5000
Interval [min]	1	1 to 30
SP		
Pressure threshold [mm Hg]	120	90 to 140
Speed reduction [rpm]	1500	0 to 1500

Tab. 14-7 Overview: adjustable parameters

Parameter	Default	Possible range
Duration of speed reduction [ms]	1000	500 to 3000
Rise time [ms]	2500	500 to 5000

Tab. 14-7 Overview: adjustable parameters

14.6 Overview: messages, acoustic alarms, measures

IMPORTANT: This short overview is solely for the purposes of quick reference. It by no means replaces the detailed descriptions given in the relevant chapter. See chapter 10: Messages and Measures, page 145. Take note in particular of the safety information detailed therein!

Message	Sound	Corrective action
A01/ A11: Change main/backup battery	. . .	Acknowledge. **If A11 appears:** Mains operation. **In all cases:** disconnect the empty battery from the control unit and connect a fully charged battery. Charge the empty battery. **A01 appears when connecting a charged battery:** ensure that the battery plug is positioned correctly.
A02/ A12: Main/backup battery not connected	. . .	Acknowledge. Check the position of the battery plug and correct it if necessary. Connect the battery.
HA01: Main battery remaining run time < 20 minutes	. . .	Acknowledge. Ensure that a charged main battery is available. **HA01 appears when connecting a charged battery:** ensure that the battery plug is positioned correctly.
HA04/ HA14: Main battery/Backup battery calibration cycle required	____	Acknowledge. **If HA14 appears:** Mains operation. **Always:** Replace battery and calibrate in the charging station.
HA05/HA15: Main battery/Backup battery old	____	Acknowledge. Leave the battery connected for the time being. Contact the Sales Team: sales@berlinheart.de
H26: Pump is in halt mode	____	Acknowledge.
H27: Event memory not readable	____	Acknowledge. Repeat the read-out. **H27 reappears**: HOTLINE
H30: Temporary malfunction of control unit	____	Acknowledge. Press the button on the control unit: further messages? Take the appropriate action. Evaluate the curves in the monitor program. Note the circumstances in which H30 appeared. **If H30 reappears:** HOTLINE
H31: Reset due to internal error	____	Acknowledge. Evaluate the curves in the monitor program. If necessary, take corrective action. Start data recording; transfer data to manufacturer. Note the circumstances in which H31 appeared (Handling of INCOR? Electromagnetic radiation? etc.)
H40: Temporary pump stop	____	Acknowledge. Press the button on the control unit: further messages? Take the appropriate action. Evaluate the curves in the monitor program. Read the event memory; transfer data to manufacturer. Note the circumstances in which H40 appeared (Where was the patient? Mains/battery operation? Were there any other messages? etc.)

Tab. 14-8 messages, acoustic alarms, measures

Message	Sound	Corrective action
H50: No pump connected	____	**For data administration:** Acknowledge the message. After data entry/transfer: end the monitor program, then disconnect the batteries from the control unit. **When replacing the control unit:** Connect the driveline to the control unit using the plug coupling. Proceed with replacement of the control unit.
EA03/ EA13: Main battery/Backup battery too hot	. . .	Acknowledge. Check the surrounding conditions. Remove the battery from the heat source. **If the surrounding conditions are not the cause for the message:** Replace the battery.
EA10: Backup battery malfunctioning	. . .	Acknowledge. Connect the power supply unit to the control unit. Connect the power supply unit to the mains. Remove the plug of the backup battery from the control unit, then reinsert. If the message reappears within 20 minutes: replace the backup battery. If the message again reappears within 20 minutes: Replace the control unit. **In all cases:** HOTLINE
E00: Power supply unreliable	. . .	Acknowledge. **During battery operation:** Connect the power supply unit to the control unit. Connect the power supply unit to the mains. Replace the main battery. Change the backup battery. **In mains operation:** Replace the main battery. Change the backup battery. disconnect the power supply unit from the control unit.
E20/E21: Mean flow too low/Pressure difference too high	. . .	Acknowledge. Press the button on the control unit: further messages? Take the appropriate action. Evaluate the circulatory status of the patient and the curves in the monitor program. If necessary, reduce the speed and alarm threshold flow. Take appropriate medical action if necessary. Change the position of the patient if necessary. **If E20 occurs together with E21:** activate pulsatility control, if necessary. **If E20 appears alone:** Deactivate pulsatility control, if necessary. **Persistent E20/E21:** check the position and condition of the inflow cannula. **If offset has not been configured:** HOTLINE
E22: Pressure difference too low	. . .	Acknowledge. Press the button on the control unit: further messages? Take the appropriate action. Evaluate the circulatory status of the patient and the curves in the monitor program. Take appropriate medical action if necessary. Reconsider anticoagulation therapy if necessary. if necessary, increase the speed. Reduce the pressure difference alarm threshold, if necessary. Deactivate pulsatility control, if necessary.
E23: Control unit too hot	. . .	Acknowledge. Check the surrounding conditions. Remove the control unit from the heat source or ensure that it is adequately ventilated. **If the surrounding conditions are not the cause for the message:** Replace the control unit. HOTLINE

Tab. 14-8 messages, acoustic alarms, measures

Message	Sound	Corrective action
E24: Control unit too cold	. . .	Acknowledge. Protect the control unit against cold, moisture, and drafts. Acknowledge the message, repeatedly if necessary.
EF30: Control unit malfunctioning	. . .	Acknowledge. Verify that the plug coupling is closed. Further messages? **If H40 appears:** Take appropriate medical action. Wait 10 seconds: does EF40 appear? **If EF40 appears:** Take the appropriate action. **H40 does not appear or is extinguished**: start the monitor program, check the bearing power. **Bearing power > 3.5 W:** Replace the control unit. **Bearing power permanently exceeds the usual value by more than 1 W:** HOTLINE
EF40: Pump stop	. . .	Acknowledge. Verify that the plug coupling is closed. **If the plug coupling is not the cause:** Replace the control unit. HOTLINE. In all cases: auscultate to check whether the pump is active.
EF50: Driveline disconnected	. . .	**During replacement of the control unit:** continue with replacement. **During normal operation:** Verify that the plug coupling is closed. After 10 seconds, check are there any other messages? Take the appropriate action. **If EF50 reappears:** Replace the control unit.
EF60: Pump too hot	. . .	Acknowledge. Verify that the plug coupling is closed. **In mains operation:** disconnect the power supply unit from the control unit. Check: is the pump active? HOTLINE. **If EF60 still persists after 10 min:** Replace the control unit. **If message EF60 persists further:** the pump may need to be replaced.

Tab. 14-8 messages, acoustic alarms, measures

14.7 Symbols

	Order number		Use by
	Lot number		Manufacturer
	Serial number		Date of manufacture
	Not for reuse		Patient number
	Sterilized with ethylene oxide		Do not use if package is damaged.
	Temperature restriction		Do not resterilize
	Humidity limit		Keep dry
	Type CF application component		Protection class II device
	Conforms to RoHS		Recycle Lithium-ion battery
	Instructions for use must be followed!		Do not dispose of in household waste
	Instructions for use must be followed!		Green Dot Scope of application: Germany Packaging can be disposed of (empty) with general waste.

Fig. 14-1 Symbols

Index

D

E

F

G

H

I

K

L

M

N

O

P

R

S

T

U

V

W

X

Print Control

A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P	Q	R	S	T	U	V	W	X	Y	Z		Ä	Ö	Ü
a	b	c	d	e	f	g	h	i	j	k	l	m	n	o	p	q	r	s	t	u	v	w	x	y	z		ä	ö	ü
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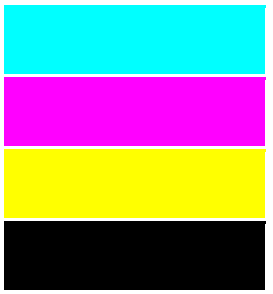

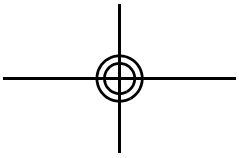

en

GA Klinik Marker außen
GA Patient Marker innen