INCOR®
Superior Pump
Implantable
Ventricular Assist Device

Patient's Instructions for Use
Edition 6
Your hospital contact person:

These instructions for use apply to:

- 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

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. INCOR has carried the CE mark since 2003.

Berlin Heart GmbH
Wiesenweg 10
12247 Berlin
Germany

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Your INCOR works at the following speed:

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Previous versions of these Patient's Instructions for Use are superseded by the publication of this revision.

All translations of these Patient's Instructions for Use have been prepared and checked to the best of our knowledge. However, only the German edition of these Patient's Instructions for Use is considered to be legally binding.

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Chapter 1 Introduction

1 Introduction

You and your physician have agreed on the use of the implantable ventricular assist device known as the INCOR® Superior Pump (referred to below as: INCOR).

These instructions for use will help you to use your INCOR safely and comfortably.

For your own safety, please read these instructions for use very carefully. Heed all the safety information and practice all the actions described here thoroughly. Only use the INCOR components as described in these instructions for use.

Your hospital contact person in the cardiac center can provide additional assistance. You can find his/her telephone number on the first page of these instructions for use.

The following symbols are used in these instructions for use:

**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 will not result in 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.
Chapter 1 Introduction

**HOTLINE**

Notify the hospital contact person!

You can find the telephone number of your hospital contact person on the first page of these instructions for use.

**INSTRUCTION**

1. The instructions are numbered incrementally.

**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

The INCOR is an electrically operated, implantable ventricular assist device. As with all electrically operated systems, safe and smooth operation of INCOR is only possible if its proper usage is ensured.

Incorrect use of INCOR can result in damage or breakdown of components or failure of the power supply.

To ensure your safety and the correct operation of your pump, it is therefore essential that you heed the following instructions on using and living with the INCOR device. You will receive comprehensive training from your hospital contact person early on for this purpose. Upon completion of training, you will need to sign the Patient training checklist to confirm that you can safely perform all relevant actions and measures when using INCOR.

If you have any questions on the correct use of INCOR, e.g. relating to wound care, selection of clothing, behavior in public or when traveling, handling animals, etc., you can consult your hospital contact person at any time.

---

**WARNING**

Only use intact components! Do not use components that are visibly damaged. Only then can it be guaranteed that INCOR will function perfectly.

---

2.1 Conditions of use

**WARNING**

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.
Chapter 2  Important Safety Information

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.
Chapter 2  Important Safety Information

WARNING

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 10: EMC Tables, page 103.

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

INTEGRITY

INCOR must only be operated with the components mentioned here.

Only use components which belong with the device! The pump and control unit must have 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.

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

2.4 Handling

**Daily routine**

**WARNING**

Only use intact components! Only then can it be guaranteed that INCOR will function perfectly.

Ensure that the replacement control unit is within reach at all times! Otherwise, in the event of an error, the pump may stop.

Ensure that both buzzers on the control unit are functioning correctly! Otherwise messages may not be properly recognized. Check the buzzers on a daily basis. See section 6.1: Buzzer checks, page 34.

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, wire brushes, etc.)! Otherwise there is a risk of electric shock or failure of the system.

---

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

---

Before washing or taking a shower, 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.

---

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.
Chapter 2  Important Safety Information

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 8.

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.

Protect the driveline against damage! Keep pets away from the driveline! 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!
Chapter 2  Important Safety Information

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 cut may cause the pump to stop. Only when changing the batteries, restarting and replacing the control unit is one or no battery connected.

**INCOR Smart Bag**

**WARNING** Always ensure that the INCOR Smart Bag is firmly attached to the body. 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 could 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 could be injured as a result.

### 2.5 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.

Replacing the control unit

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.
2.6 Combination with other products/procedures

**WARNING**

Notify the hospital contact person!

### Unfeasible combinations

- Mechanical heart valve prostheses
- Magnetic resonance imaging
- Radiotherapy
- Nuclear diagnostics/nuclear therapy
- Electro-stimulation therapy
- Therapeutic ultrasound (e.g. lithotripsy)
- Diathermy
- High-frequency surgery (cauterization); exception: implantation or explantation

### 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**

For X-ray and CT: we recommend placing the control unit next to you, on your lap or between your thighs.

IMPORTANT: Once the INCOR device has been implanted, there is a relative contraindication to the use of an intra-aortic balloon pump (IABP).
Chapter 2  Important Safety Information

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

Feasible combinations

• Cardiac pacemaker
• Implantable defibrillator
• Stents
• Diagnostic ultrasound
3 General Product Information

3.1 Risks and side effects

The following complications are known to be possible:

- Bleeding
- Thromboembolic complications
- Infections
- Hemolysis

3.2 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.

3.3 Maintenance

INCOR does not require maintenance.

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 this case notify your hospital contact person:

Notify the hospital contact person!
The human circulatory system

All muscles, nerves and organs of the human body require oxygen. The oxygen is transported by the blood to all parts of the body.

The heart, a large hollow muscle, first pumps the blood to the lungs, where it is enriched with oxygen (right side of the heart, pulmonary circulation), and then to the entire body (left side of the heart, systemic circulation).

Each half of the heart consists of an atrium in which the blood first accumulates, and a ventricle into which the blood then flows. The ventricle then contracts and pushes the blood out of the heart into the blood vessels.

When the left ventricle contracts, it causes the blood to flow through the vessels in a pressure wave. This pressure wave can be felt as a pulse.
Chapter 4 Your blood circulation with INCOR

**The implanted INCOR components**

Ventricular assist devices such as INCOR relieve the heart of some of this pumping action.

With INCOR, the blood flows out of the left ventricle through the inflow cannula into an electrically operated pump, and from there through the outflow cannula into the systemic circulation.

Pump construction: the visible outer casing contains the pump tube. Inside the pump tube there is an electrically powered impeller that transports the blood. The impeller is magnetically supported.

The impeller rotates at a constant speed, continually transporting the blood. Unlike the human heart, INCOR does not create a pressure wave.
Depending on the strength with which your own left ventricle contracts, a stronger or weaker residual pulse will be noticeable. However, a weak residual pulse does not indicate a low blood flow, but rather that INCOR is performing most of the pumping action.

A driveline leads out through the skin from the pump and is connected to the control unit by the plug coupling and control unit cable. The control unit is carried externally. See fig. 4-1, page 16.

The external INCOR components

The control unit controls and monitors the entire system. The main and backup batteries are connected to the control unit. They supply the system with power and must remain connected at all times. Always carry the control unit and batteries with you. See fig. 4-2, page 17.

INCOR also includes:

- A power supply unit, which is also used to supply power and is connected as needed
- A charging unit in which empty batteries can be charged
- An operator terminal which can be connected to the control unit as needed

![Fig. 4-2 Components you always carry with you](image)

1. Inflow cannula
2. Axial 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
Chapter 4  Your blood circulation with INCOR
Chapter 5  Description

5 Description

5.1 INCOR control unit

The control unit controls and monitors the entire system. It regulates the power supply and indicates when a battery needs replacing or if there are any malfunctions.

The pump, main battery and backup battery must always be connected to the control unit. A power supply unit, and an operator terminal for checkups, are also required.

You have been given two identical control units by your hospital: an active control unit and a replacement control unit.

![Control unit with control unit cable and control unit plug](image)

**Fig. 5-1**  Control unit with control unit cable and control unit plug

The control unit cable is permanently connected to the control unit. The blue longitudinal markings on the driveline and control unit cable help to prevent any twisting when the two are connected.

The **pump socket** is the socket on the driveline.

The **control unit plug** is the plug on the control unit cable.

Together, the pump socket and control unit plug are referred to as the plug coupling.

The **plug coupling** is the connection between the pump and the control unit.
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.

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

User and display elements of the control unit

Fig. 5-2  Connection sockets of the control unit (I)

1  Socket for power supply unit
2  Socket for backup battery

Fig. 5-3  Connection sockets of the control unit (II)

1  Socket for operator terminal
2  Socket for main battery
3  Logo: here, main battery
4  Control unit cable with control unit plug
Chapter 5 Description

Fig. 5-4   Indicator, display and button on control unit

Possible displays

Normal display: remaining operating time of active battery in hours : minutes (e. g. 2:30).

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

Messages (e. g. A01). 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 on the control unit; acoustic alarm check

- 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)
Chapter 5  Description

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.

5.2 INCOR batteries

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

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.

![Diagram of Main Battery and Backup Battery]

**Fig. 5-5** Main battery and backup battery
Chapter 5  Description

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.

Typical application scenarios for battery operation:

- When you want to move about
- Personal hygiene (washing, showering)
- In humid areas (bathrooms, etc.)
- Outdoors

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.
### Charge Level vs. Display

<table>
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<tr>
<th>Charge Level</th>
<th>Display</th>
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<tr>
<td>&gt; 75%</td>
<td>4 LEDs illuminated</td>
</tr>
<tr>
<td>&gt; 50%</td>
<td>3 LEDs illuminated</td>
</tr>
<tr>
<td>&gt; 25%</td>
<td>2 LEDs illuminated</td>
</tr>
<tr>
<td>&gt; 8%</td>
<td>1 LED illuminated</td>
</tr>
<tr>
<td>&lt; 8%</td>
<td>1 LED flashes</td>
</tr>
</tbody>
</table>

**Tab. 5-1**  LED display depending on charge level

**Fig. 5-7**  View of battery from above
5.3 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. There is an indicator LED on the top panel of the power supply unit. If the power supply unit is providing the correct output voltage, the indicator LED will be green. If the charge level of one of the batteries connected to the control unit is less than 85 %, the power supply unit will charge the battery. In doing so, its LEDs will constantly indicate the charge level.

Typical application scenarios for mains operation:
- When 2 empty batteries are being replaced or if the backup battery is disconnected from the control unit
- When sleeping
- When residing somewhere with a mains power supply that fulfills the requirements

![Diagram of Power Supply Unit](Fig. 5-8)

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

![Diagram of Mains Power Cable](Fig. 5-9)

1. Mains plug (shaped plug without earthing contact)
2. Cable
3. Plug for power supply unit (2-pin, compliant with IEC60320 C17)
5.4 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. 5-2, page 27. 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.

Fig. 5-10 Charging unit with 2 batteries
Fig. 5-11  Detailed view of control panel

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
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<tr>
<td><img src="image" alt="Battery" /></td>
<td>Battery</td>
<td><img src="image" alt="Green" /> / <img src="image" alt="Orange" /></td>
</tr>
<tr>
<td><img src="image" alt="Wrench" /></td>
<td>Wrench</td>
<td><img src="image" alt="Orange" /></td>
</tr>
<tr>
<td><img src="image" alt="Warning triangle" /></td>
<td>Warning triangle</td>
<td><img src="image" alt="Orange" /></td>
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Tab. 5-2  LEDs of the charging unit
<table>
<thead>
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<th>Status</th>
<th>Action</th>
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<tr>
<td>Flasing orange</td>
<td>OFF</td>
</tr>
<tr>
<td>ON</td>
<td>Calibrating, battery discharging</td>
</tr>
<tr>
<td>Flasing green</td>
<td>OFF</td>
</tr>
<tr>
<td>Flashing</td>
<td>Battery charging, calibration required</td>
</tr>
<tr>
<td>ON</td>
<td>Battery charging, calibrating</td>
</tr>
<tr>
<td>Green</td>
<td>OFF</td>
</tr>
<tr>
<td>ON</td>
<td>Battery fully charged, calibration required</td>
</tr>
<tr>
<td>OFF</td>
<td>OFF</td>
</tr>
<tr>
<td>Flashing</td>
<td>Battery charging error</td>
</tr>
<tr>
<td>ON</td>
<td>Charging unit error</td>
</tr>
</tbody>
</table>

**Tab. 5-3** LED displays – status and actions
Chapter 5  Description

5.5  **INCOR Smart Bag**

INCOR Smart Bag is used for secure storage and safe transportation of the control unit and batteries.

The cover flap of the INCOR Smart Bag can be released by opening the all-round zipper. The INCOR Smart Bag can also be opened from the front with 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.
5.6 INCOR cable protector set

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

Overview

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

Fig. 5-12  Cable protection - full view

Fig. 5-13  Close-up - ends of cable protector

Fig. 5-14  Close-up - cable protection
5.7 INCOR Control & Monitoring Station

The monitor program is installed on the INCOR Control & Monitoring Station (operator terminal for short). You can use the operator terminal to obtain information on the status and operation of INCOR. Your physician can use the operator terminal to adjust the INCOR settings. See chapter 7: Using the Operator Terminal, page 59.

Fig. 5-15 Operator terminal with stand
Chapter 5 Description
Chapter 6 Routine Use

6 Routine Use

This chapter describes the everyday handling of INCOR.

For your own safety, please perform all the actions as they are described here. Practice all of these actions carefully!

For information on how to use the operator terminal, see chapter 7: Using the Operator Terminal, page 59.

---

**WARNING**

Refer to the conditions of use! See section 2.1: Conditions of use, page 3.

---

Ensure that both buzzers on the control unit are functioning correctly! Otherwise messages may not be properly recognized. Check the buzzers on a daily basis. See section 6.1: Buzzer checks, page 34.

---

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 8.

---

**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 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!

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

6.1 Buzzer checks

**INSTRUCTION**

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 such a case: replace the control unit. See section 9.6: Emergency measures, page 99.

6.2 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.
INSTRUCTION

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: disconnect the power supply unit from the mains.

6.3 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.

INSTRUCTION

1. Insert the plug (2) into the socket so that the markings on the plug and the socket (3) are aligned. Push the plug firmly into the socket as far as it will go. If positioned correctly, 3/4 of the marking on the plug (3) will be concealed.

2. Check the position of the plug by gently pulling on the kink protection sleeve (1). The plug must not loosen from the socket. Adjust as necessary.
Fig. 6-1 Inserting the safety plug (here: main battery plug)

Removing the plug from the socket

INSTRUCTION

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

For information on how to use the plug coupling, see section 9.6: Emergency measures, page 99.

6.4 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.
6.4.1 Carrying strap and click fastener

**WARNING**

Always ensure that the INCOR Smart Bag is firmly attached to the body. 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 could 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 could be injured as a result.

![INCOR Smart Bag worn over the shoulder or on the hip](image)

Fig. 6-2 INCOR Smart Bag worn over the shoulder or on the hip
Wearing the INCOR Smart Bag over the shoulder

**INSTRUCTION**

1. If necessary, 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 necessary, readjust the length of the carrying strap. See below.

Wearing the INCOR Smart Bag on the hip

**INSTRUCTION**

1. If necessary, shorten the carrying strap. See below.
2. Open the click fastener by pressing on the centre 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. 6-4.
5. If necessary, readjust the length of the carrying strap. See below.

---

**Fig. 6-3** Click fastener open
Adjusting the length of the carrying strap

1. If necessary, 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. See fig. 6-5.

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. See fig. 6-6.

3. If necessary, reattach the padding to the carrying strap.
6.4.2 Securing the batteries

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. Change the battery. See section 6.6: Changing a battery, page 42. Close the cover flap and front flap.

6.5 Switching between battery and mains operation

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 cut 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 to mains operation**

1. Connect the power supply unit to the mains. 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. 5-2, page 20. 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 to battery operation

INSTRUCTION

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.

6.6 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!

Cautionary measures

- Immediately after removing a discharged battery: connect a fully charged battery!
- Recharge any discharged batteries immediately!
- If you have 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!

### INSTRUCTION

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 registered 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 fig.6-1, page36. The plug must not loosen from the socket. Adjust as necessary.

5. Recharge the empty main battery in the charging unit.

**Changing the backup battery**

### INSTRUCTION

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: when pressing the button on the battery, all 4 battery LEDs must light up.
3. Disconnect the empty backup battery from the control unit. This is registered 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 fig. 6-1, page 36. The plug must not loosen from the socket. Adjust as 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.

### 6.7 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!
6.7.1 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.
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 in fig. 6-7)** of the charging unit flashes green. The battery is charging.
5. The **wrench LED (3 in fig. 6-7)** of the charging unit may flash orange: the battery must be calibrated. See 6.7, page 44.
6. Once the battery is fully charged, the battery **LED (2 in fig. 6-7)** 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.

![Fig. 6-7 Control panel of charging unit: charging](image_url)
If the battery LED flashes green: the battery is charging. If the battery LED is permanently green: the battery is fully charged. See table 5-2, “LEDs of the charging unit,” on page 27.

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.

### 6.7.2 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 wrench LED of the charging unit flashes.

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


#### INSTRUCTION

1. If the battery is not yet positioned in the charging unit: perform steps 1 to 4 as described in section 6.7.1: Charging a battery in the charging unit, page 45.

2. Press the **Start Calibration** (1 in fig. 6-8) key. The **battery LED** (2 in fig. 6-8) will flash green, and the **wrench LED** (3 in fig. 6-8) will turn orange. The battery is calibrating.

3. Once the battery is fully calibrated, the **battery LED** remains green and the **wrench LED** is extinguished. Pull the battery plug out of the socket of the charging unit. If the **battery LED** is permanently green and the **wrench 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.
If two batteries need to be calibrated, we recommend calibrating one battery after the other using only one charging slot. Hence, the second charging slot remains available for standard battery charging.

If further calibration is required

1. Either: press the Start Calibration key to start the second calibration process immediately. On completion of the second calibration process, disconnect the charging unit from the mains power supply. Or: remove the battery and disconnect the charging unit from the mains power supply in order to start the second calibration process at a later point. Then proceed with steps 1 to 4 as described above.
6.8 Exercise particular caution when...

6.8.1 ... washing or taking a shower

**WARNING**
Before washing or taking a shower, 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 cable protector against moisture!

Cautionary measures

- 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 bag with the components and/or control unit and batteries in watertight packaging (plastic bag) when taking a shower, but for no longer than about 20 minutes (heat build-up).
- 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!

6.8.2 ... sleeping

**INSTRUCTION**

1. If possible, connect the operator terminal to the control unit for data recording.
Chapter 6 Routine Use

Cautionary measures

- Switch the system to mains operation.
- Suspend the bag containing the batteries and the control unit on a suitable bracket beside or above 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.

6.8.3 ... relying on battery operation for a prolonged period of time

Cautionary measures

- Always carry the replacement control unit with you.
- Check the charge level by pressing the button on the batteries. Allow for an operating time of one hour as a safety reserve. If necessary, change the batteries and carry a further power source (fully charged battery or power supply unit).
- Check the charge level of the batteries at regular intervals.
- If you feel unsure with INCOR: carry these instructions for use with you.

6.9 Using the INCOR cable protector set

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.

IMPORTANT: Safeguard the cable protector against moisture.
6.9.1 Attaching the cable protector

**INSTRUCTION**

1. Attach the cable protector. See fig. 6-9, page 50 to fig. 6-11, page 50.

2. Use adhesive tape (e.g. Leukoplast®) to affix the cable protector (fig. 5-14, page 30) to the kink protection sleeve of the cable.

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. 6-9** Cable protector on the kink protection sleeve

**Fig. 6-10** Attaching the cable protector

**Fig. 6-11** Close-up - cable protector in place
6.9.2 Cleaning the cable protector

**ADVICE**
Peel back the cable protector from the cable only as far as the fixation point. Do not loosen the fixation material every time disinfection is carried out. If the fixation material loosens: remove any residual adhesive.

**IMPORTANT:** During wound care: disinfect the exposed cable and cable protector at least once a week. See section 6.11: Wound care and dressing changes, page 54.

**INSTRUCTION**

1. Peel back the cable protector from the cable as far as the fixation point, or remove (fig. 6-13). To do so, loosen the fixation material and remove any residual adhesive.

Fig. 6-12

Fig. 6-13
2. Spray the cable with disinfectant until it is moistened completely.

Fig. 6-14

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

Fig. 6-15

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. 6-16

6. Attach the disinfected cable protector to the disinfected cable. See section 6.9.1: Attaching the cable protector, page 50.

Fig. 6-17
### 6.10 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, wire brushes, 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, 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. Only clean the **driveline** with water or alcohol (e.g. a 70 % alcohol solution).

**Cautionary measure**

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

- All components: dry cloth.
- Driveline in the area of the transcutaneous exit site: additional cleaning as part of wound care. See section 6.11: Wound care and dressing changes, page 54.
- INCOR Smart Bag: clean the empty bag with water, using a brush.
- Control unit and batteries: wiping disinfection with an alcohol-based solution is possible.

6.11 Wound care and dressing changes

**WARNING**

Attach the driveline to the body, close to the wound, using drain fixation tape (e.g. Secutape®). 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. Only clean the driveline with water or alcohol (e.g. a 70 % alcohol solution).

**ADVICE**

We recommend that sterile disposable gloves, a cap, and face mask be worn during wound care.

We advise against the use of tape for adhesion of the driveline. Over time, residues of adhesive lead to contamination of the cable and an increased risk of infection.
Chapter 6 Routine Use

IMPORTANT: Include the cable protector in wound care procedures. See section 6.9.2: Cleaning the cable protector, page 51.

The exit site should be treated as an open wound. At the point where the driveline exits the skin, pathogens can enter the body and cause harmful inflammations. Thorough wound care can help to avoid this.

Tend to the wound exactly as you have practiced with your physician and the nursing staff at the hospital.

Frequency of dressing changes:

- When the wound is dry and free of infection: wound care and dressing change once daily to begin with, then every two days after 10 to 14 days if the wound conditions are normal
- If the wound is infected: wound care and dressing change twice daily

Material:

- 1 cap
- 1 face mask
- 1 pair of disposable gloves
- 1 pair of sterile disposable gloves
- 1 sterile drape (75 cm x 90 cm)
- Disinfectant according to prescription in a sterile bowl
- 1 sterile packaged band-aid (approx. 7 cm x 5 cm)
- 2 sterile packaged band-aids (approx. 10 cm 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

INSTRUCTION

1. Put on the disposable gloves.
2. Remove the old dressing in a non-sterile environment.
3. Unpack all the materials required for wound care in a sterile environment and lay them out on the sterile drape.
4. Remove the disposable gloves. Put on the cap, face mask and sterile disposable gloves.
5. Examine the transcutaneous exit site and, if there are any changes, take the appropriate action as necessary. Seek medical advice as appropriate.
6. Clean the driveline at the transcutaneous exit site using a sterile compress soaked with disinfectant.
7. 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.

Applying a new dressing and fixation tape

INSTRUCTION

1. Place the slit compress around the driveline, with the slit at the top. Fix the compress with a band-aid above the driveline.

Fig. 6-18
Chapter 6  Routine Use

2. Place a folded compress beneath the driveline for padding and positioning.

3. Position 3 folded compresses around the driveline, each at a 90° angle to the other.

4. Place a compress over the driveline and padding.

5. Affix the upper half of the compress extensively with tape.
6. Attach the driveline to the body, close to the wound, using drain fixation tape. In doing so, heed the manufacturer's instructions. The fixation tape should be directly adjacent to the compress.

7. Affix the lower half of the compress extensively with slit tape, with the slit at the top. The driveline is positioned on the tape. Tape over the upper section of the fixation tape.
Chapter 7 Using the Operator Terminal

7 Using the Operator Terminal

This chapter explains how to work with the operator terminal and monitor program. The monitor program gives you detailed information on the status of your INCOR device. The information obtained in this way can be made available to your hospital contact person, as needed.

7.1 Overview

![Overview of operator terminal](INC_0000200x00_en)

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

**Fig. 7-1** Overview of operator terminal
Chapter 7  Using the Operator Terminal

Fig. 7-2  Overview of monitor program

**Menu bar**

The menu options you can select are displayed in blue font
Display window

Information on the status of your INCOR device:
- Mains/battery operation
- Remaining operating time of main battery
- Heart rate
- Implant date
- Number of postoperative days (POD)
- Your name
- Information on whether the functions PC, PFC und SP are activated.

The functions PC und SP help to prevent myocardial suction of the interventricular septum (wall dividing the left and right halves of the heart) on the inflow cannula. Suction phenomena occur when the selected speed is too high for the volume supplied in the ventricle and the ventricle is at risk of collapsing.

If PFC is activated, the speed of your INCOR will be reduced at regular intervals. This will result in regular opening of the aortic valve.

Speed and flow

The current values for speed and flow are continually displayed here. The window will have a red background if a message has appeared.

Alarm display and window with current messages

If a battery or error message is active, the alarm display appears and a window opens displaying all current messages.

Curve diagram

Your physician can configure the monitor program to display either one diagram (primary diagram) or two diagrams (primary
and secondary diagram). He or she can also configure which of the aforementioned curves should be visible.

- **Pressure difference** (primary diagram; [mmHg]): the pressure difference is the difference between the pressure before the pump and the pressure after the pump.
- **Flow** (primary diagram; [L/min]): volume of blood delivered per minute by INCOR.
- **Diastolic level** (primary diagram): average level of the diastolic plateau over several cycles. Diastole: relaxation and filling phase of the heart.
- **Rotational speed** (secondary diagram): actual speed in rpm.

**Status bar**

- Login status
- Version number of firmware, motor software and interface software
- Pump ID (AP number)
- Time

### 7.2 Functions of the monitor program

Your physician will use the monitor program to

- start the pump
- adjust the settings
- transfer data to the replacement control unit

You can use the monitor program to monitor the system (measurements, messages) and read data.

All functions of the monitor program that change your system settings are password-protected to prevent unintentional manipulation.
7.3 Basic instructions

**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.

**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!

**ADVICE**

We recommend leaving the activated operator terminal connected to your INCOR overnight. A file containing detailed information is then created each day at midnight, which in certain circumstances can provide your hospital contact person with important information.

**IMPORTANT:** Always end the monitor program in order to shut down the operator terminal!
7.3.1 Switching the operator terminal on: starting the monitor program

**INSTRUCTION**

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 **USB plug of the communication cable** (2 in fig. 7-3, page 64) into the lower USB port of the operator terminal.

5. 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.

7.3.2 Switching the operator terminal off: ending the monitor program

**INSTRUCTION**

1. Select **End**.

2. Confirm the **End program?** query. The monitor program ends and the operator terminal switches itself off.
7.3.3 Entering information into 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.
- **Alphanumeric inputs**: using the virtual alphanumerical keyboard.

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

![Alphanumerical keyboard](image1)

**Fig. 7-4** Alphanumerical keyboard

![Numerical keypad](image2)

**Fig. 7-5** Numerical keypad

Some entries (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.
7.4 Menu item: Messages

If there is a battery or error message,

- the Messages menu item is displayed in red font.
- the alarm display appears.
- the Current messages window appears. See fig. 7-2, page 60.

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

Fig. 7-6 Messages

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.
Chapter 7  Using the Operator Terminal

The Messages submenu also contains 3 buttons:

- **Ackn. alarm**: 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.

### 7.5 Menu item: Current values

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

![Current values](image)

**Fig. 7-7**  Current values
Chapter 7 Using the Operator Terminal

Current values (actual values)

- **Current speed [rpm]**: speed at which your INCOR is working right now
- **Flow [L/min]**: volume of blood delivered by INCOR per minute
- **Actual degree of pulsatility**: the average deviation of the pressure curve from its average value (similar to standard deviation)
- **Calculated heart rate [1/min]**: your pulse as measured by INCOR
- **Motor power [W]**: the power required by the motor in your INCOR pump
- **Bearing power [W]**: the power required by the magnetic bearing in your INCOR pump
- **Battery operating time [h:min]**: the remaining operating time of the main battery

Current settings

- **Set speed or max. speed [rpm]**: the speed set as the target value by your physician. If pulsatility control is activated, this value is displayed as the maximum achievable speed.
- **Degree of pulsatility**: the default value set by your physician as the degree of pulsatility (see above).
- **Alarm threshold flow [L/min]**: if this value is not reached, message E20 (Mean flow too low) is triggered. The triggered flow alarm is only canceled when the mean value is at least one liter per minute above the set threshold value.
- **Alarm threshold pressure difference [mmHg]**: the pressure difference is the difference between the pressures before and after the pump. The alarm threshold pressure difference describes the value below which message E22 (Pressure difference too low) is triggered.
7.6 **Menu item: Service**

The menu item *Service* contains the following options:

- Start data recording
- Save data to USB memory stick
- Select language
- **Set date and time**

![Service Menu](image)

**Fig. 7-8** Service

**Submenu item: Start data recording**

The monitor program saves the current curve data every 9 milliseconds. These data are normally overwritten every 3 minutes. If events occur (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.

Your hospital contact person can read these data, if necessary.

**INSTRUCTION**

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.

### 7.7 Menu item: End

See section 7.3.2: Switching the operator terminal off: ending the monitor program, page 64.
8  Messages and Measures

- Carefully practice all the measures described here!
- If a message appears: do exactly as described in this chapter.
- Remain calm!
- If you have any urgent questions about INCOR, call your hospital contact person! You can find his/her telephone number on the first page of these instructions for use.

If INCOR is working perfectly,
- the normal display will appear on the control unit (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 9: Detecting and Eliminating Errors, page 91.

Message and message code

INCOR will generate a message to inform you that a specific measure must be carried out. A corresponding 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.
### Types of messages

<table>
<thead>
<tr>
<th>Type and acoustic alarm</th>
<th>Description</th>
<th>Unresolved, acknowledged messages...</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>A:</strong> Battery message</td>
<td>No malfunction. Battery empty or not connected. Take action immediately!</td>
<td>... recur after 30 s, and if re-acknowledged will recur after double the amount of time in each case (max. 8 min).</td>
</tr>
<tr>
<td>Battery message</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Short audible alarms in rapid succession</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(- - -)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>H, HA:</strong> Notification message</td>
<td>Faulty status, breakdown not imminent, take action as soon as possible.</td>
<td>... do not recur.</td>
</tr>
<tr>
<td>Notification message</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Continuous tone</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(____)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Tab. 8-1 Types of messages
Chapter 8  Messages and Measures

What to do when a message appears

Respond to each message exactly as described in this chapter. Carry out the appropriate measures and acknowledge the message. Ask your hospital contact person if you have any queries relating to a message.

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 acknowledgement. Then take the necessary action.

<table>
<thead>
<tr>
<th>Type and acoustic alarm</th>
<th>Description</th>
<th>Unresolved, acknowledged messages...</th>
</tr>
</thead>
<tbody>
<tr>
<td>E, EA: Error message</td>
<td>Malfunction. Take action immediately!</td>
<td>... recur after 30 s, and if re-acknowledged will recur after double the amount of time in each case (max. 8 min).</td>
</tr>
<tr>
<td>Short audible alarms in rapid succession (- - -)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>EF: Fatal error message</td>
<td>Faulty control unit or pump stop imminent/pump has stopped - take IMMEDIATE action!</td>
<td>... recur after 30 s.</td>
</tr>
<tr>
<td>Short audible alarms in rapid succession (- - -)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Tab. 8-1  Types of messages
8.1 **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.

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.
If a message appears when connecting a charged battery:
see section 9.1.1: On connection of a charged battery, the control unit displays A01 or A11, page 91.

If a message appears when the power supply unit is connected:
see section 6.2: Connecting the power supply unit to the mains power supply, page 34.

8.2 A11 Change backup battery

Message A11 Change backup battery appears if the remaining operating time of the active backup battery is less than about 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.

Never disconnect both batteries from the control unit simultaneously! Otherwise the pump may stop.

Always replace the backup battery under mains operation! If the backup battery is empty, the main battery will also be empty!

INSTRUCTION

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 backup battery.
Chapter 8 Messages and Measures

3. Check: is the main battery also empty? If any messages have appeared, also replace it with a fully charged battery.

4. Charge the empty battery/batteries in the charging unit. See section 6.7: Charging and calibrating a battery, page 44.

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 9.1.1: On connection of a charged battery, the control unit displays A01 or A11, page 91.

If a message appears when the power supply unit is connected:
see section 6.2: Connecting the power supply unit to the mains power supply, page 34.

8.3 A02 Main battery not connected

When changing a battery:
The message will disappear once the new battery is connected.

When not changing a battery:

[INSTRUCTION]

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. To do so:

[HOTLINE]

Notify the hospital contact person!
Chapter 8  Messages and Measures

8.4  A12 Backup battery not connected

When changing a battery:
The message will disappear once the new battery is connected.

When not changing a battery:

INSTRUCTION

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. To do so:

HOTLINE  Notify the hospital contact person!

8.5  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.

INSTRUCTION

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:

INSTRUCTION

1. Check the position of the battery plug and rectify if necessary.
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.

### 8.6 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 6.7: Charging and calibrating a battery, page 44.

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. connecting it to the charging unit and pressing the *Start Calibration* key. 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.

### 8.7 HA14 Backup battery calibration cycle required

The message **HA14 Backup battery calibration cycle required** appears if a battery has frequently 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 6.7: Charging and calibrating a battery, page 44.
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!

INSTRUCTION
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 connecting it to the charging unit and pressing the Start Calibration key. 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.

8.8 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.

INSTRUCTION
1. Acknowledge the message. Leave the battery connected for the time being.
2. Order a new battery. To do so:

HOTLINE
Notify the hospital contact person!
8.9 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.

**INSTRUCTION**

1. Acknowledge the message. Leave the battery connected for the time being.
2. Order a new battery. To do so:

**HOTLINE**

Notify the hospital contact person!

8.10 H30 Temporary malfunction of control unit

Message **H30 Temporary malfunction of control unit** appears if there is a temporary fault 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 8.21: EF30 Control unit malfunctioning, page 88.

**INSTRUCTION**

1. Briefly press the button on the control unit to determine whether there are any further messages (in particular: **H40**; see section 8.12: H40 Temporary pump stop, page 81): take action in accordance with these messages.
2. Note the circumstances in which the message occurred.

If the message appears repeatedly:

**HOTLINE**

Notify the hospital contact person!

8.11 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 stops for a short time (1 to 2 seconds).
INSTRUCTION

1. Acknowledge the message.
2. Note the circumstances in which the message occurred (Handling of INCOR? Electromagnetic radiation? etc.).

HOTLINE

Notify the hospital contact person!

8.12 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 temporary pump overload). The message then disappears.
- the pump will stop for longer (e.g. due to a defect 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.

INSTRUCTION

1. Check for further messages and take the appropriate action.
2. Connect the operator terminal to the control unit and turn on.
3. Note the circumstances in which the message occurred (Where were you? Mains/battery operation? Were there any other messages? etc.).

HOTLINE

Notify the hospital contact person!
Chapter 8  Messages and Measures

8.13  H50 No pump connected

The message **H50 No pump connected** appears if batteries are connected to a control unit to which no pump is connected. 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.

**When replacing the control unit**

<table>
<thead>
<tr>
<th>WARNING</th>
</tr>
</thead>
<tbody>
<tr>
<td>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.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>NOTICE</th>
</tr>
</thead>
<tbody>
<tr>
<td>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.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>INSTRUCTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Connect the driveline to the control unit using the plug coupling.</td>
</tr>
</tbody>
</table>

**When not replacing the control unit (e.g., testing the replacement control unit)**

<table>
<thead>
<tr>
<th>INSTRUCTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Acknowledge the message.</td>
</tr>
<tr>
<td>2. After data entry/transfer: disconnect the batteries from the control unit.</td>
</tr>
</tbody>
</table>

8.14  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.

**INSTRUCTION**

1. Check the surrounding 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:

**INSTRUCTION**

1. Disconnect the main battery from the control unit and connect the other main battery to the control unit. See section 6.6: Changing a battery, page 42.

**HOTLINE**

Notify the hospital contact person!

### 8.15 EA10 Backup battery malfunctioning

Message **EA10 Backup battery malfunctioning** appears if either the backup battery is actually faulty or the control unit is erroneously displaying a fault in the backup battery.

**INSTRUCTION**

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 20 minutes.
If the message reappears after 20 minutes:

**INSTRUCTION**

1. Disconnect the backup battery from the control unit and connect the other backup battery to the control unit. See section 6.6: Changing a battery, page 42.

2. Wait 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, the control unit is faulty. In such a case, replace the control unit. See section 9.6: Emergency measures, page 99.

**HOTLINE**

Notify the hospital contact person!

---

### 8.16 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.

**INSTRUCTION**

1. Check the surrounding 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:

INSTRUCTION

1. Disconnect the backup battery from the control unit and connect the other backup battery to the control unit. See section 6.6: Changing a battery, page 42.

8.17 E00 Power supply unreliable

Message E00 Power supply unreliable appears 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

INSTRUCTION

1. Connect the power supply unit to the mains. Connect the power supply unit to the control unit.
2. Change the main battery. See section 6.6: Changing a battery, page 42.
3. Change the backup battery. See section 6.6: Changing a battery, page 42.

During mains operation

INSTRUCTION

1. Change the main battery. See section 6.6: Changing a battery, page 42.
2. Change the backup battery. See section 6.6: Changing a battery, page 42.
3. Disconnect the power supply unit from the control unit; disconnect the power supply unit from the mains.
8.18 E20/E21/E22 Adjustment required

INCOR cannot achieve the optimal supply for your body with the current settings. Your circulatory status has very likely changed.

Meaning of each message:

• **E20**: Mean flow too low
• **E21**: Pressure difference too high
• **E22**: Pressure difference too low

Notify the hospital contact person!

8.19 E23 Control unit too hot

Message **E23 Control unit too hot** appears 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.

**INSTRUCTION**

1. Check whether external factors may have caused overheating: direct warming (e.g. due to 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:

[HOTLINE] Notify the hospital contact person!

8.20 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!

**INSTRUCTION**

1. Protect the control unit against cold, moisture, drafts (e.g. conceal under a jacket, go inside).
2. Acknowledge the message (repeatedly if necessary).

If the surrounding conditions are not the cause:

[HOTLINE] Notify the hospital contact person!
8.21 EF30 Control unit malfunctioning

**INSTRUCTION**

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. 9-5, page 101.
3. Briefly press the button on the control unit to determine whether message H40 or EF40 has appeared.

**HOTLINE** Notify the hospital contact person!

8.22 EF40 Pump stop

Message **EF40 Pump stop** will appear if the pump stops for more than 10 seconds.

**INSTRUCTION**

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. 9-5, page 101.

**INSTRUCTION**

If message EF40 persists:


**HOTLINE** Notify the hospital contact person!

8.23 EF50 Driveline disconnected

Message **EF50 Driveline disconnected** will appear if the plug coupling is open while the control unit is being supplied with power.
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.

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. 9-5, page 101.

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:

Chapter 8  Messages and Measures

8.24  EF60 Pump too hot

INSTRUCTION

1. Ensure that the plug coupling is closed correctly, and check that the arrow markings on the plug and socket are aligned. See fig. 9-5, page 101.

2. In mains operation: disconnect the power supply unit from the control unit.

3. Check whether message EF60 is still present after 10 minutes.

INSTRUCTION


HOTLINE Notify the hospital contact person!
Chapter 9  Detecting and Eliminating Errors

9 Detecting and Eliminating Errors

As a rule, immediately replace any external components that are visibly damaged. In such a case:

.Notify the hospital contact person!

9.1 Control unit

Possible error scenarios:

- On connection of a charged battery, the control unit displays A01 or A11. See Section 9.1.1, page 91.
- 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 9.1.2, page 92.
- A buzzer on the control unit is faulty; see Section 9.1.3, page 92.
- Individual segments of the display are faulty: see Section 9.1.4, page 92.
- Slow tone sequence (. . .); see Section 9.1.5, page 93.

9.1.1 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 9.6: Emergency measures, page 99.
9.1.2 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.

9.1.3 A buzzer on the control unit is faulty


9.1.4 Individual segments of the display are faulty

9.1.5 Slow tone sequence (....)

Possible causes for a slow tone sequence:

- **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.

### INSTRUCTION


### HOTLINE

Notify the hospital contact person!

9.2 Power supply unit

Power supply unit connected to the mains: indicator LED not illuminated

### INSTRUCTION

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. To do so:

### HOTLINE

Notify the hospital contact person!
IMPORTANT: Until the new power supply unit arrives, use the compatible power supply unit from the charging unit for mains operation!

9.3 Batteries

LEDs not indicating the charge level when charging

INSTRUCTION

1. Check: is the mains power cable connected to the charging unit? Is the charging unit activated?

2. Press the button on the battery. If no LED is illuminated, the battery is faulty and must be replaced. If this is the case:

HOTLINE Notify the hospital contact person!

9.4 Charging unit

9.4.1 Warning triangle LED flashing

INSTRUCTION

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.

3. Reconnect the battery to the charging unit.

Fig. 9-1 Control panel of charging unit: warning triangle LED
4. If the **warning triangle LED (1)** no longer flashes: resume use of the battery and charging unit as normal. If the **warning triangle LED** continues to flash:

---

**HOTLINE**

Notify the hospital contact person!

9.4.2 Warning triangle 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.

3. If the **warning triangle LED (1)** is no longer illuminated: proceed with step 4. If the **warning triangle LED** is still illuminated: inform the emergency hotline.

4. Reconnect the battery to the charging unit.
5. If the **warning triangle LED (1)** is no longer illuminated: resume use of the battery and charging unit as normal. If the **warning triangle LED** is still illuminated:

---

**HOTLINE**

Notify the hospital contact person!

![Fig. 9-2 Control panel of charging unit: warning triangle LED](image)
9.5 Monitor program

Possible error scenarios:

- The curve display freezes. See Section 9.5.1, page 96.
- A message is displayed in the monitor program, but not on the control unit. See Section 9.5.2, page 96.
- The monitor program and control unit display different values. See Section 9.5.3, page 97.
- The monitor program indicates unlikely or impossible values (e.g.: mean flow < 0 L/min). See Section 9.5.4, page 97.
- Message: Communication to the control unit is interrupted, please check connection! See Section 9.5.5, page 97.
- Monitor is black, operator terminal cannot be started. See Section 9.5.6, page 98.
- Program crash: monitor program not running. See Section 9.5.7, page 98.

9.5.1 Curve display frozen

1. Menu selection Display > Start.

Curve display remains frozen:

see section 9.5.7: Program crash, monitor program not running, page 98.

9.5.2 Message displayed in the monitor program, but not on the control unit

1. End the monitor program by selecting End; restart the operator terminal.
9.5.3 Different values in the monitor program and control unit

**INSTRUCTION**

1. End the monitor program by selecting **End**; restart the operator terminal.

Different values still displayed in the monitor program and control unit:

**INSTRUCTION**

1. Replace the operator terminal and check the values again.

Different values still displayed in the monitor program and control unit:

**INSTRUCTION**


9.5.4 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** Notify the hospital contact person!

9.5.5 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.
Chapter 9 Detecting and Eliminating Errors

INSTRUCTION

1. Check the plug of the communication cable. If necessary, plug in correctly.

2. Check the power supply of the control unit and restore if necessary.

Message still visible:
see section 9.5.7: Program crash, monitor program not running, page 98.

9.5.6 Monitor black, operator terminal cannot be started

INSTRUCTION

1. Turn the operator terminal off and on again.

If the power supply is not the cause:

HOTLINE Notify the hospital contact person!

9.5.7 Program crash, monitor program not running

INSTRUCTION

1. Turn the operator terminal off and on again.

HOTLINE Notify the hospital contact person!
9.6 Emergency measures

9.6.1 Replacing the control unit

**WARNING**

Only use components which belong with the device! 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 the AP number of the control unit is located on the identification plate of the control unit.

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.

**ADVICE**

We recommend sitting at a table when replacing the control unit.

**HOTLINE**

Notify the hospital contact person!

IMPORTANT: To ensure safe operation of INCOR, you must be able to replace the control unit with speed and confidence. Practice replacing the control unit with your hospital contact person until you feel truly confident. Replacement of the control unit is an emergency measure, however. Hence this is not a routine procedure with INCOR and is only necessary in the event that INCOR seriously malfunctions.
Replace the control unit in the following circumstances:

- if a continuous tone cannot be eliminated by pressing the button on the control unit
- **EF30 Control unit malfunctioning** (8.21, page 88)
  **EF40 Pump stop** (8.22, page 88)
  **EF60 Pump too hot** (8.24, page 90)
- if the control unit reacts to connection of a fully charged battery with message **A01** or **A11** (Replace main/backup battery).

IMPORTANT: Always follow the instructions for the appropriate error scenario!

Also replace the control unit if:

- individual segments in the display are defective
- the acoustic signal in the control unit is faulty (2 audible alarms missing when button pressed)

IMPORTANT: In such error scenarios, the INCOR pump function is not impaired. There is a risk, however, of messages going unnoticed or not being clearly identified.

Preparation

INSTRUCTION

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.

![Prepared components](Fig. 9-3)
Chapter 9 Detecting and Eliminating Errors

3. Connect the extra battery to the replacement control unit. The set speed will be displayed for a few seconds.

![Replacement control unit displaying the speed](image)

Replacement

<table>
<thead>
<tr>
<th>INSTRUCTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Disconnect the pump from the malfunctioning control unit. To do so, retract the <strong>sleeve of the control unit plug marked with a double arrow</strong> (1), allowing the plug coupling to be opened. The pump will stop.</td>
</tr>
</tbody>
</table>

![Plug coupling closed](image)

| 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 to operate at the speed set in the control unit. |

![Plug coupling open](image)
Subsequent adjustment

**INSTRUCTION**

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 9.6.2: Adjusting the speed on the control unit, page 102.

3. Next: remove the malfunctioning control unit and batteries that are not connected from the INCOR Smart Bag. Place the intact control unit and connected batteries in the INCOR Smart Bag.

**9.6.2 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.

**INSTRUCTION**

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 ten seconds, the pump will continue to operate at the modified speed.
10 EMC Tables

10.1 Electromagnetic emissions

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.

<table>
<thead>
<tr>
<th>Interference emission measurement(s)</th>
<th>Compliance</th>
<th>Electromagnetic environment - guidelines</th>
</tr>
</thead>
<tbody>
<tr>
<td>RF emissions in accordance with CISPR 11</td>
<td>Group 1</td>
<td>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.</td>
</tr>
<tr>
<td>RF emissions in accordance with CISPR 11</td>
<td>Class B</td>
<td>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.</td>
</tr>
<tr>
<td>Harmonic emissions in accordance with IEC 61000-3-2</td>
<td>Class A</td>
<td>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.</td>
</tr>
<tr>
<td>Voltage fluctuations/flicker emissions in accordance with IEC 61000-3-3</td>
<td>Complies</td>
<td>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.</td>
</tr>
</tbody>
</table>

Tab. 10-1 Electromagnetic emissions
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.

<table>
<thead>
<tr>
<th>Immunity tests</th>
<th>IEC 60601 test level</th>
<th>Level of compliance</th>
<th>Electromagnetic environment - guidelines</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electrostatic discharge (ESD) in accordance with IEC 61000-4-2</td>
<td>±6 kV contact discharge</td>
<td>±6 kV contact discharge</td>
<td>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%.</td>
</tr>
<tr>
<td></td>
<td>±8 kV air discharge</td>
<td>±8 kV air discharge</td>
<td></td>
</tr>
<tr>
<td>Fast transient electrical interference/ bursts in accordance with IEC 61000-4-4</td>
<td>±2 kV power lines</td>
<td>±2 kV power lines</td>
<td>The quality of the supply voltage should correspond to a typical business and hospital environment.</td>
</tr>
<tr>
<td></td>
<td>±1 kV for input and output lines</td>
<td>±1 kV for input and output lines</td>
<td></td>
</tr>
<tr>
<td>Surges in accordance with IEC 61000-4-5</td>
<td>±1 kV differential mode voltage</td>
<td>±1 kV differential mode voltage</td>
<td>The quality of the supply voltage should correspond to a typical business and hospital environment.</td>
</tr>
<tr>
<td></td>
<td>±2 kV common mode voltage</td>
<td>±2 kV common mode voltage</td>
<td></td>
</tr>
</tbody>
</table>

**Tab. 10-2**  Electromagnetic immunity, part 1
### Chapter 10  EMC Tables

<table>
<thead>
<tr>
<th>Immunity tests</th>
<th>IEC 60601 test level</th>
<th>Level of compliance</th>
<th>Electromagnetic environment - guidelines</th>
</tr>
</thead>
<tbody>
<tr>
<td>Voltage dips, short interruptions and fluctuations in the power supply in accordance with IEC 61000-4-11</td>
<td>&lt; 5 % UT (&gt; 95 % dip in UT) for ½ cycle&lt;br&gt;40 % UT (60 % dip in UT) for 5 cycles&lt;br&gt;70 % UT (30 % dip in UT) for 25 cycles&lt;br&gt; &lt; 5 % UT (&gt; 95 % dip in UT) for 5 seconds</td>
<td>&lt; 5 % UT (&gt; 95 % dip in UT) for ½ cycle&lt;br&gt;40 % UT (60 % dip in UT) for 5 cycles&lt;br&gt;70 % UT (30 % dip in UT) for 25 cycles&lt;br&gt; &lt; 5 % UT (&gt; 95 % dip in UT) for 5 seconds</td>
<td>The quality of the supply voltage should correspond to a typical business and 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.</td>
</tr>
<tr>
<td>Magnetic field at supply frequency (50/60 Hz) in accordance with IEC 61000-4-8</td>
<td>3 A/m</td>
<td>3 A/m</td>
<td>Magnetic fields at mains frequency should correspond to the typical values found in a business or hospital environment.</td>
</tr>
</tbody>
</table>

**NOTE:** UT is the AC supply voltage prior to application of the test level.

**Tab. 10-2**  Electromagnetic immunity, part 1
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.

<table>
<thead>
<tr>
<th>Immunity tests</th>
<th>IEC 60601 - test level</th>
<th>Level of compliance</th>
<th>Electromagnetic environment - guidelines</th>
</tr>
</thead>
</table>
| Conducted RF interference in accordance with IEC 61000-4-6 | 3 Vrms  
150 kHz to 80 MHz outside the ISM bands\(^a\)  
10 Vrms  
150 kHz to 80 MHz inside the ISM bands\(^a\) | [\(V_1\)] 10 V  
[\(V_2\)] 10 V | 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. |

Recommended safety distance  
d=0.35 \(\sqrt{P}\)  
d=1.2 \(\sqrt{P}\)

\(^a\) ISM bands refer to Industrial, Scientific, and Medical frequency bands.

Tab. 10-3  Electromagnetic immunity, part 2
Chapter 10  EMC Tables

<table>
<thead>
<tr>
<th>Immunity tests</th>
<th>IEC 60601 - test level</th>
<th>Level of compliance</th>
<th>Electromagnetic environment - guidelines</th>
</tr>
</thead>
</table>
| Radiated RF interference in accordance with IEC 61000-4-3 | 10 V/m  
80 MHz to 2.5 GHz | [E₁] 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]. The field strengths of stationary radio transmitters, as determined by an appropriate site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment bearing the following symbol.

Tab. 10-3   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 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 designed to reduce the probability of mobile/portable communication devices generating interference when they are unintentionally brought into 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 survey of the location should be considered. 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.
10.4 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.

<table>
<thead>
<tr>
<th>Nominal power of the transmitter in W</th>
<th>Safety distance depending on transmission frequency [m]</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>150 kHz to 80 MHz outside the ISM bands d=0.35√P</td>
</tr>
<tr>
<td>0.01</td>
<td>0.04</td>
</tr>
<tr>
<td>0.1</td>
<td>0.11</td>
</tr>
<tr>
<td>1</td>
<td>0.35</td>
</tr>
<tr>
<td>10</td>
<td>1.11</td>
</tr>
</tbody>
</table>

Tab. 10-4 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.

<table>
<thead>
<tr>
<th>Nominal power of the transmitter in W</th>
<th>150 kHz to 80 MHz outside the ISM bands $d=0.35\sqrt{P}$</th>
<th>150 kHz to 80 MHz inside the ISM bands $d=1.2\sqrt{P}$</th>
<th>80 MHz to 800 MHz $d=1.2\sqrt{P}$</th>
<th>800 MHz to 2.5 GHz $d=2.3\sqrt{P}$</th>
</tr>
</thead>
<tbody>
<tr>
<td>100</td>
<td>3,50</td>
<td>12,00</td>
<td>12,00</td>
<td>23,00</td>
</tr>
</tbody>
</table>

**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 designed to reduce the probability of mobile/portable communication devices generating interference when they are unintentionally brought into 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 situations. The propagation of electromagnetic variables is influenced by the absorption and reflection of buildings, objects and people.
11 Appendix

11.1 You have received the following components and documents from your hospital

- 2 x control unit
- 2 x main battery
- 2 x backup battery
- 1 x charging unit
- 2 x INCOR power supply unit (for control unit and charging unit), each with a mains power cable
- 1 x INCOR Control & Monitoring Station (operator terminal), including stand, software, power supply unit and mains power cable
- 1 x communication cable
- 1 x INCOR Smart Bag (incl. 1 x Short Instructions for the Patient)
- 1 x Patient’s Instructions for Use
- 1 x patient ID card
- If necessary, 1 x Latest News on further developments to INCOR that have not yet been included in the instructions for use
11.2 Technical specifications

<table>
<thead>
<tr>
<th>Product</th>
<th>INCOR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manufacturer and distributor</td>
<td>Berlin Heart GmbH</td>
</tr>
<tr>
<td></td>
<td>Wiesenweg 10</td>
</tr>
<tr>
<td></td>
<td>12247 Berlin, Germany</td>
</tr>
<tr>
<td>Classification</td>
<td>Active, implantable medical</td>
</tr>
<tr>
<td></td>
<td>device compliant with Directive</td>
</tr>
<tr>
<td></td>
<td>90/385/EEC</td>
</tr>
<tr>
<td><strong>Overall system</strong></td>
<td></td>
</tr>
<tr>
<td>Largest axial extension</td>
<td>184 mm</td>
</tr>
<tr>
<td>(corresponds to installation</td>
<td></td>
</tr>
<tr>
<td>length)</td>
<td></td>
</tr>
<tr>
<td>Operating voltage (power</td>
<td>AC 100 to 240 V, 1.6 - 0.8 A</td>
</tr>
<tr>
<td>supply unit)</td>
<td>47 - 63 Hz</td>
</tr>
<tr>
<td>Ambient temperature (control</td>
<td>- 10 °C to + 40 °C</td>
</tr>
<tr>
<td>unit and batteries)</td>
<td></td>
</tr>
<tr>
<td>Battery operating time</td>
<td>7 h</td>
</tr>
<tr>
<td>Max. ambient magnetic field</td>
<td>3 A/m</td>
</tr>
<tr>
<td>strength</td>
<td></td>
</tr>
<tr>
<td>Max. alternating, high-</td>
<td>10 V/m</td>
</tr>
<tr>
<td>frequency electromagnetic</td>
<td></td>
</tr>
<tr>
<td>field strength</td>
<td></td>
</tr>
<tr>
<td><strong>Lifetime</strong></td>
<td></td>
</tr>
<tr>
<td>INCOR pump with cannulae</td>
<td>5 years, single use</td>
</tr>
</tbody>
</table>

**Tab. 11-1** Technical specifications
External INCOR components: control unit with plug coupling, operator terminal, power supply unit, charging unit, and all cables | 5 years

### 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, 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 your hospital contact person!

### Pump

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inner diameter (pump tube)</td>
<td>16 mm</td>
</tr>
<tr>
<td>Minimum inner diameter (passage width) of pump in the area of the olives</td>
<td>11.3 mm</td>
</tr>
<tr>
<td>Outer diameter of blood pump body (diameter incl. cable bead)</td>
<td>31.7 mm (37 mm)</td>
</tr>
<tr>
<td>Pump length (stub - stub)</td>
<td>123 mm</td>
</tr>
<tr>
<td>Weight (including driveline and cannulae)</td>
<td>Approx. 350 g</td>
</tr>
<tr>
<td>Volume of blood pump body</td>
<td>Approx. 60 cm$^3$</td>
</tr>
<tr>
<td>Design speed</td>
<td>7500 rpm</td>
</tr>
</tbody>
</table>

**Tab. 11-1  Technical specifications**
| **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 |

**Cannulae**

| **Minimum inner diameter (passage width) of cannulae** | 12,7 mm |
| **Material** | Silicone; partially reinforced with plastic, partially surrounded by sutureble 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 |

**Tab. 11-1** Technical specifications
### Dimensions of outflow angle section

<table>
<thead>
<tr>
<th></th>
<th>Length: 61,5 mm</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Inner diameter:</td>
</tr>
<tr>
<td></td>
<td>inflow side 12.7 mm</td>
</tr>
<tr>
<td></td>
<td>outflow side 11.3 mm</td>
</tr>
</tbody>
</table>

### Tensile forces of snap-in connectors

- > 10 N (corresponding to requirements of DIN EN 45502-1)

### Control unit

<table>
<thead>
<tr>
<th></th>
<th>106 mm x 106 mm x 65 mm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weight</td>
<td>740 g</td>
</tr>
<tr>
<td>Operating voltage</td>
<td>DC 18 V to DC 28 V</td>
</tr>
<tr>
<td></td>
<td>(powered by power supply unit and batteries)</td>
</tr>
<tr>
<td>Protection class</td>
<td>IP54 (protection against dust and splash water)</td>
</tr>
</tbody>
</table>

### Batteries

<table>
<thead>
<tr>
<th></th>
<th>Lithium-ion batteries in plastic casing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dimensions</td>
<td>132 mm x 115 mm x 55 mm</td>
</tr>
<tr>
<td>Weight</td>
<td>800 g</td>
</tr>
<tr>
<td>Output voltage</td>
<td>DC 20.5 V to DC 24.6 V</td>
</tr>
<tr>
<td>Capacity</td>
<td>2,3 Ah</td>
</tr>
<tr>
<td>Operating time</td>
<td>Approx. 3.5 h (depending on speed)</td>
</tr>
<tr>
<td>Charging time</td>
<td>Approx. 2 h to 4 h</td>
</tr>
</tbody>
</table>

**Tab. 11-1** Technical specifications
<table>
<thead>
<tr>
<th><strong>Protection class</strong></th>
<th><strong>IP54 (protection against dust and splash water)</strong></th>
</tr>
</thead>
</table>

**Power supply unit**

<table>
<thead>
<tr>
<th><strong>Dimensions (L x W x H)</strong></th>
<th>171 mm x 72 mm x 42 mm</th>
</tr>
</thead>
</table>
| **Weight**                | Without mains power cable: 740 g  
Mains power cable: 220 g |
| **Input voltage**         | AC 100 - 240 V, 1.6-0.8 A, 47-63 Hz |
| **Power consumption**     | Control unit: 32 - 50 VA |
| (design point)            |                       |
| **Output voltage**        | DC 28 V, max. 4.83 A |
| **Ambient temperature**   | 0 - 40 °C             |
| **Protection class**      | IP40 (protection against contact, but not water) |

**Charging unit**

| **Dimensions (L x W x H)** | 270 mm x 150 mm x 325 mm (without batteries)  
270 mm x 170 mm x 325 mm (with batteries) |
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Weight</strong></td>
<td>2300 g</td>
</tr>
<tr>
<td><strong>Operating voltage</strong></td>
<td>DC 28 V, max 2.5 A (powered by power supply unit)</td>
</tr>
<tr>
<td><strong>Power consumption</strong></td>
<td>Max. 72 VA</td>
</tr>
</tbody>
</table>

**Tab. 11-1** Technical specifications
<table>
<thead>
<tr>
<th><strong>Ambient temperature</strong></th>
<th>0 - 40 °C</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Protection class</strong></td>
<td>IP30 (protection against contact, but not water)</td>
</tr>
<tr>
<td><strong>Operator terminal with monitor program</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Weight (incl. accompanying power supply unit and stand)</strong></td>
<td>3,75 kg</td>
</tr>
<tr>
<td><strong>Operating voltage</strong></td>
<td>DC 19 V, 3 A</td>
</tr>
</tbody>
</table>
| **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 - 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 % |

**Tab. 11-1** Technical specifications
11.3 Control unit displays

<table>
<thead>
<tr>
<th>Display</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Numerals, with 2 digits after the colon (e.g. 7:42)</td>
<td>Normal display: operating time of the active battery in hours : minutes</td>
</tr>
<tr>
<td>Normal display permanent</td>
<td>Battery operation</td>
</tr>
<tr>
<td>Normal display flashing</td>
<td>Mains operation</td>
</tr>
<tr>
<td>Numerals, with one digit after the period (e.g. 4.9)</td>
<td>Mean flow in L/min, displayed at the press of the button</td>
</tr>
<tr>
<td>Letter(s) number (e.g.: A02)</td>
<td>Messages</td>
</tr>
<tr>
<td>Without colon (e.g.: A02)</td>
<td>Current message</td>
</tr>
<tr>
<td>With colon (e.g.: EA:00)</td>
<td>Resolved message, appears at the press of the button</td>
</tr>
</tbody>
</table>

Tab. 11-1 Technical specifications

Tab. 11-2 Overview: control unit displays
11.4 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 8: Messages and Measures, page 71. Take note in particular of the safety information detailed therein!

<table>
<thead>
<tr>
<th>Message</th>
<th>Measure</th>
</tr>
</thead>
<tbody>
<tr>
<td>A01/A11: Main/backup battery</td>
<td>Acknowledge. <strong>If A11 appears:</strong> mains operation. <strong>Always:</strong> disconnect the empty battery from the control unit and connect a fully charged battery. Charge the empty battery. <strong>A01/A11 appears when connecting a charged battery:</strong> ensure that the battery plug is positioned correctly.</td>
</tr>
<tr>
<td>A02/A12: Main/ Backup battery not connected</td>
<td>Acknowledge. Check the position of the battery plug and correct if necessary. Connect battery.</td>
</tr>
<tr>
<td>HA01: Main battery remaining run time &lt; 20 minutes</td>
<td>Acknowledge. Ensure that a charged main battery is available. <strong>HA01 appears when connecting a charged battery:</strong> ensure that the battery plug is positioned correctly.</td>
</tr>
</tbody>
</table>

Tab. 11-3 Messages, acoustic alarms, measures
<table>
<thead>
<tr>
<th>Message</th>
<th>Measure</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>HA04/HA14:</strong> Main battery/Backup battery calibration cycle required</td>
<td>Acknowledge. <strong>If HA14 appears:</strong> mains operation. <strong>Always:</strong> replace and calibrate the battery in the charging unit. Sound: ___</td>
</tr>
<tr>
<td><strong>HA05/HA15:</strong> Main battery/Backup battery old</td>
<td>Acknowledge. Leave the battery connected for the time being. HOTLINE. Sound: ___</td>
</tr>
<tr>
<td><strong>H30:</strong> Temporary malfunction of control unit</td>
<td>Acknowledge. Press the button on the control unit: further messages? Take the appropriate action. Note the circumstances in which H30 appeared. <strong>If H30 reappears:</strong> HOTLINE. Sound: ___</td>
</tr>
<tr>
<td><strong>H31:</strong> Reset due to internal error</td>
<td>Acknowledge. Note the circumstances in which H31 appeared (Handling of INCOR? Electromagnetic radiation? etc.). HOTLINE. Sound: ___</td>
</tr>
<tr>
<td><strong>H40:</strong> Temporary pump stop</td>
<td>Acknowledge. Press the button on the control unit: further messages? Take the appropriate action. Note the circumstances in which H40 appeared (Where were you? Mains/battery operation? Were there any other messages? etc.) Sound: ___</td>
</tr>
</tbody>
</table>

**Tab. 11-3** Messages, acoustic alarms, measures
<table>
<thead>
<tr>
<th>Message</th>
<th>Measure</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>H50:</strong> No pump connected  &lt;br&gt; Sound: ____</td>
<td><strong>For data administration:</strong> acknowledge the message. Disconnect the batteries from the control unit.  &lt;br&gt; <strong>When replacing the control unit:</strong> connect the driveline to the control unit using the plug coupling. Proceed with replacement of the control unit.</td>
</tr>
<tr>
<td><strong>EA03/EA13:</strong> Main battery/Backup battery too hot  &lt;br&gt; Sound: . . .</td>
<td>Acknowledge. Check the surrounding conditions. Remove the battery from the heat source. <strong>If the surrounding conditions are not the cause for the message:</strong> change the battery. HOTLINE.</td>
</tr>
<tr>
<td><strong>EA10:</strong> Backup battery malfunctioning  &lt;br&gt; Sound: . . .</td>
<td>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 reappears within 20 minutes: replace the control unit. <strong>In all events:</strong> HOTLINE.</td>
</tr>
<tr>
<td><strong>E00:</strong> Power supply unreliable  &lt;br&gt; Sound: . . .</td>
<td>Acknowledge.  &lt;br&gt; <strong>In battery operation:</strong> connect the power supply unit to the control unit. Connect the power supply unit to the mains. Change the main battery. Change the backup battery.  &lt;br&gt; <strong>In mains operation:</strong> change the main battery. Change the backup battery. Disconnect the power supply unit from the control unit.</td>
</tr>
<tr>
<td>Message</td>
<td>Measure</td>
</tr>
<tr>
<td>------------------------------</td>
<td>-------------------------------------------------------------------------</td>
</tr>
<tr>
<td><strong>E20/E21/E22:</strong> Adjustment required</td>
<td>HOTLINE.</td>
</tr>
<tr>
<td><strong>E23:</strong> Control unit too hot</td>
<td>Acknowledge. Check the surrounding conditions. Remove the control unit from the heat source, or ensure adequate ventilation. <strong>If the surrounding conditions are not the cause for the message:</strong> replace the control unit. HOTLINE.</td>
</tr>
<tr>
<td><strong>E24:</strong> Control unit too cold</td>
<td>Acknowledge. Protect the control unit against cold, moisture, and drafts. Acknowledge the message, repeatedly if necessary.</td>
</tr>
<tr>
<td><strong>EF30:</strong> Control unit malfunctioning</td>
<td>Acknowledge. Ensure that the plug coupling is closed. Further messages? HOTLINE.</td>
</tr>
<tr>
<td><strong>EF40:</strong> Pump stop</td>
<td>Acknowledge. Ensure that the plug coupling is closed. <strong>If message EF40 persists:</strong> replace the control unit. HOTLINE.</td>
</tr>
</tbody>
</table>

Tab. 11-3  Messages, acoustic alarms, measures
<table>
<thead>
<tr>
<th>Message</th>
<th>Measure</th>
</tr>
</thead>
</table>
| **EF50:** Driveline disconnected | During replacement of the control unit: proceed with replacement.  
 **During normal operation:** ensure that the plug coupling is closed. After 10 seconds, check whether there are any other messages. Take the appropriate action. **If EF50 reappears:** replace the control unit. HOTLINE. |
| **EF60:** Pump too hot | Acknowledge. Ensure that the plug coupling is closed. **In mains operation:** disconnect the power supply unit from the control unit. HOTLINE. **If EF60 persists after 10 min:** replace the control unit. |

**Tab. 11-3** Messages, acoustic alarms, measures
# 11.5 Symbols

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image1.png" alt="Image" /></td>
<td>Heed the instructions for use!</td>
</tr>
<tr>
<td><img src="image2.png" alt="Image" /></td>
<td>Order number</td>
</tr>
<tr>
<td><img src="image3.png" alt="Image" /></td>
<td>Serial number</td>
</tr>
<tr>
<td><img src="image4.png" alt="Image" /></td>
<td>Manufacturer</td>
</tr>
<tr>
<td><img src="image5.png" alt="Image" /></td>
<td>Application component BF</td>
</tr>
<tr>
<td><img src="image6.png" alt="Image" /></td>
<td>Protection class II</td>
</tr>
<tr>
<td><img src="image7.png" alt="Image" /></td>
<td>Only store or use in a dry environment</td>
</tr>
<tr>
<td><img src="image8.png" alt="Image" /></td>
<td>Special waste</td>
</tr>
<tr>
<td><img src="image9.png" alt="Image" /></td>
<td>Special waste (RoHS)</td>
</tr>
</tbody>
</table>

**Fig. 11-1** Explanation of symbols
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This document provides information about changes that have not yet been included in the instructions for use.

This document replaces all previous editions.

**Product:** INCOR®
Superior Pump Implantable Ventricular Assist Device

**Accompanying documents:**
- Clinical Instructions for Use Edition 6 / 6.1 (IFU Clinic)
- Patient’s Instructions for Use Edition 6 / 6.1 (IFU Patient)

This document applies exclusively in connection with the above named instructions for use.

It is essential to read the accompanying documents!

The safety notes detailed therein must be observed in particular!

The numbering of the sections in this Latest News refers to the relevant chapters or sections of the accompanying documents.
Important Safety Information

2.9  Ambulatory care (new section in IFU Clinic)

WARNING

For patients who are not physically or mentally able to operate INCOR correctly: make sure that therapy is monitored in an ongoing manner by a person trained in the INCOR system. Otherwise, there is no guarantee that the patient is receiving proper care.

Operator requirements

3.9.1 General (IFU Clinic)

Change:

• neue Information

Before an INCOR is implanted, the patient must be clinically evaluated in accordance with the current version of the ISHLT Guidelines.¹

Safety plugs

5.3 / 6.3 Inserting and removing the safety plug

Changes:

• new Warning
• new information

Inserting the plug into the socket

WARNING

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. A replacement of the control unit may be necessary.

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.

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

1. Insert 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 plug must not loosen from the socket. Adjust as necessary.

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