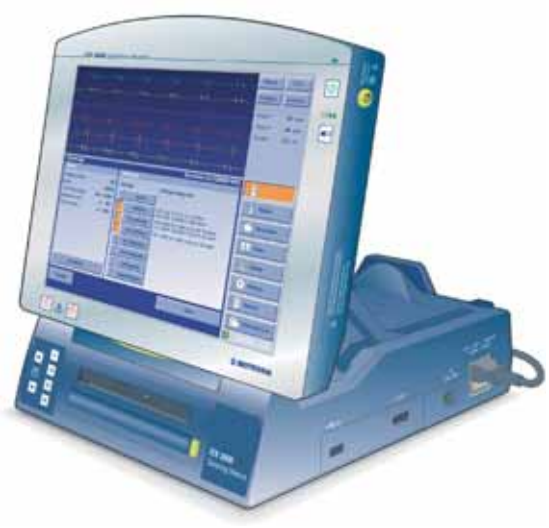
Technical Manual

ICS 3000

Cardiac Rhythm Management

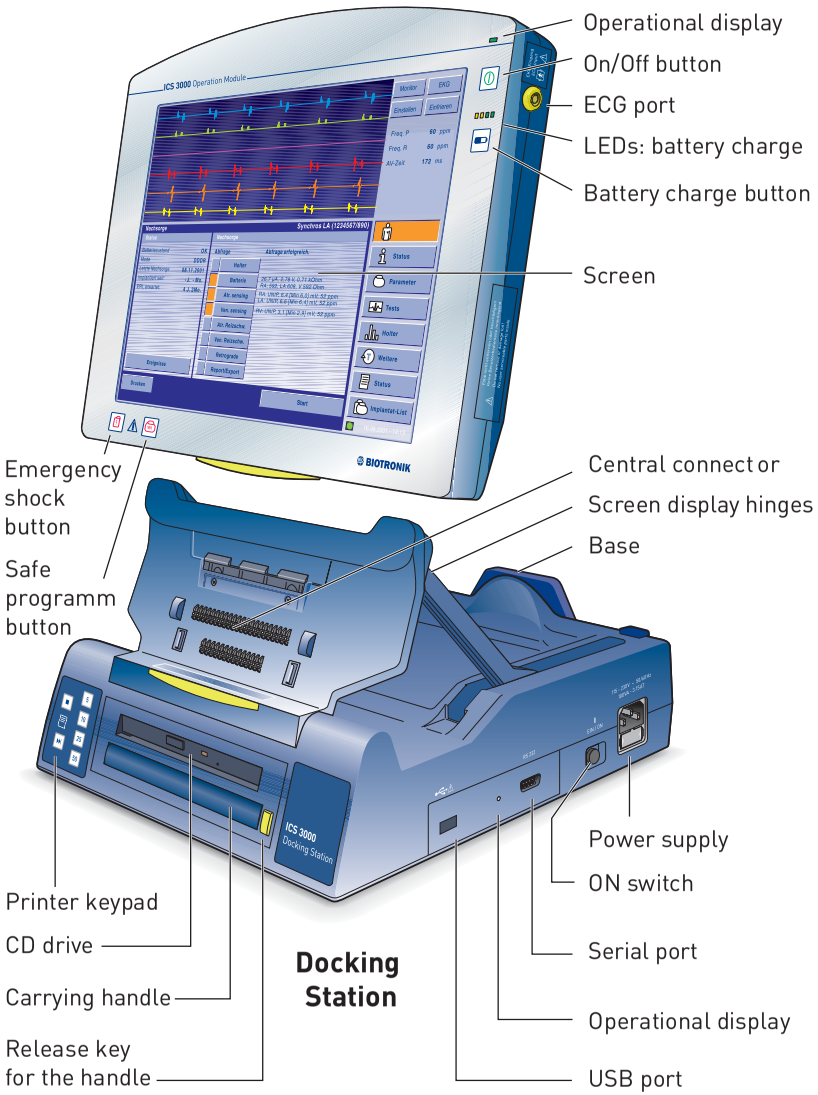
Implant Control System 3000

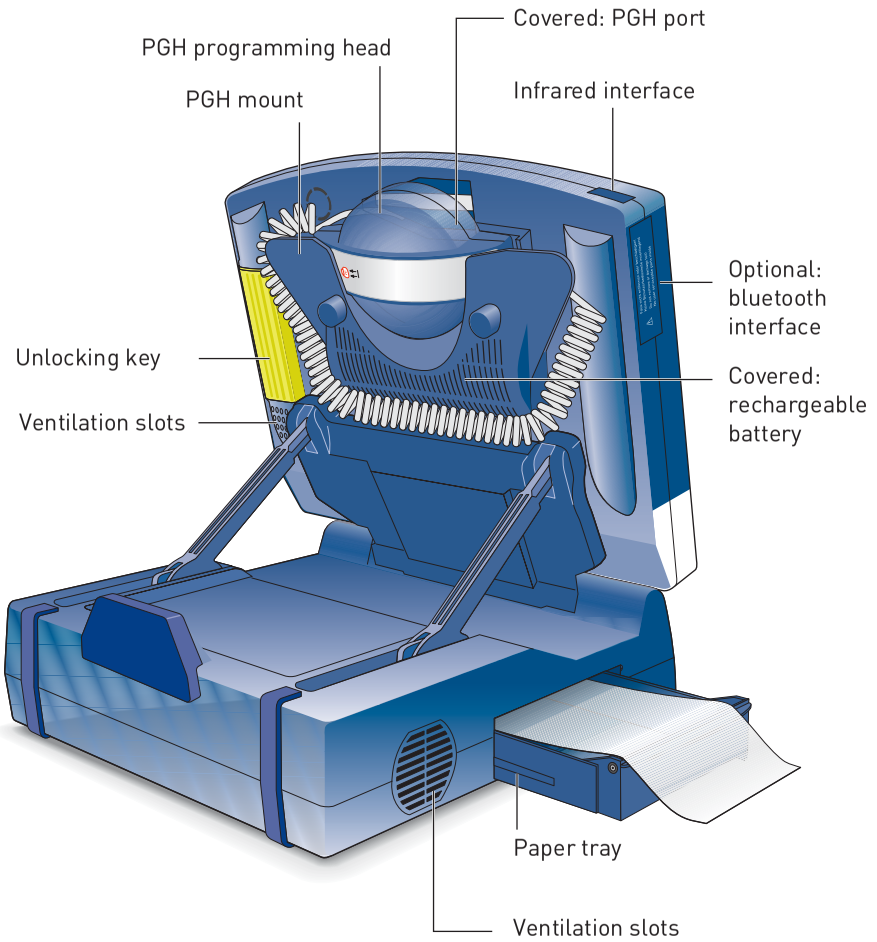


BIOTRONIK

Implant Control System ICS 3000

Operation Module





This product conforms with the directives 90/385/EEC relating to active implantable medical devices and 99/5/EC on radio equipment and telecommunication terminal equipment. It was approved by independent Notified Bodies and is therefore designated with the CE mark. The product can be used in all European Union countries as well as in countries that recognize the above-mentioned directives.

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Introduction

The portable Implant Control System ICS 3000 is intended for use as a programming and monitoring system in the implantation and follow-up of electrotherapeutic implants.

It is a compact unit with numerous functions:

Programmer ≙ for clinical follow up of pacemakers, ICD, and CRT devices manufactured by BIOTRONIK.

Miniclinic ≙ for monitoring the pacing function of pacemakers made by other manufacturers.

ECG printer and ECG monitor ≙ for real-time display and printing out up to 3 ECG derivations – surface ECG (Einthoven) – esophageal lead and up to 3 intracardiac leads.

Data transfer ≙ for transferring program data and the contents of the diagnostic memory for the purposes of computerized archiving and evaluation with the CDM 3000 Cardiac Data Manager.

Documentation ≙ for generating follow-up reports using the integrated system printer and/or an external printer.

The system is modular and can be configured and expanded as required. The basic configuration consists of the following modules:

ICS 3000 DS Docking Station

ICS 3000 OM Operation Module

ICS 3000 PGH Programming Head

ICS 3000 SW Software for programmer, implant programs

Note: Please comply with the technical manuals for the software and the connected devices.

Warranty

Improper use of the equipment will cause the warranty for the ICS 3000 and accessories to become invalid.

Safe Handling of the ICS 3000

Intended Use

The ICS 3000 is intended for use by physicians and trained medical personnel. To use the system, individuals must have a fundamental medical understanding of the respective therapy and detailed knowledge of how the implant functions and the conditions for its use. The operator should be present at all times when the ICS 3000 is in use.

Residual risk No risks are associated with the programming system if it is used correctly and has been serviced and inspected according to BIOTRONIK specifications. The risk evaluation by the Risk Management Team has determined that the residual risk is as low as reasonably possible.

Safety Instructions

Note: The ECG connection makes electrical contact with the patient via the electrodes. It is an applied BF-type part and is defibrillation-proof when the approved patient cable is used.

Caution! Never simultaneously touch the patient and connector components that conduct safety extra-low voltage.

Note: When working with the software, maintain minimum amplitudes or values of physiologic patient signals. If these values are not met, inaccurate results may be produced.

WARNING! Do not use the ICS 3000 on the patient in conjunction with RF-surgical equipment.

WARNING! During diagnosis, therapy or implantation with the ICS 3000, keep emergency equipment ready: external defibrillator and external stimulator, devices for monitoring cardiac activity.

Device Combinations

Caution! When using devices in combinations, it is absolutely essential that all the devices are connected to permanently installed outlets of the same power supply destined for medical use. Do not use any outlets that can be moved (such as extension cables, multiple outlets, etc.).

- Connect only devices of Safety Class I which meet the standards EN 60950 or IEC 950 and are at least 1.50 m away from the patient. Before starting the devices, check the overall leakage currents in accordance with EN 60601-1-1.
- Ensure that the leakage currents do not exceed the following maximum values when operating the device within the patient's vicinity (* NC Normal Condition / ** SFC Single Fault Condition):

	NC*	**SFC****
Housing leakage current	0.1 mA	0.5 mA
Ground leakage current	0.5 mA	1.0 mA
Patient leakage current	0.01 mA =	0.05 mA =
	0.1 mA ~	0.5 mA ~
Patient auxiliary current	0.01 mA =	0.05 mA =
	0.1 mA ~	0.5 mA ~

Caution! Connecting additional devices to the ICS (monitor, CDM 3000, external printer) may cause leakage current limits to be exceeded. Combine only devices that comply with the standards EN 60950 or IEC 950 and that are set up outside of the patient environment at a distance of at least 1.50 meters. For each device combination, compliance with the overall leakage currents must be established and documented before putting it into operation. However, the test must be repeated in accordance with legal requirements and at least once a year.

Accessories

- Use only accessories that have been approved by BIOTRONIK. BIOTRONIK-approved device combinations can be used if the device to be connected complies with the IEC 601 / EN 60601 / VDE 0750 standards series and this conformity is substantiated by CE certification conducted by an independent, Notified Body.

Caution! Using unapproved accessories can impair the electromagnetic compatibility, cause leakage currents to exceed permissible levels, reduce the dielectric strength, and cause functional disturbances in both the hardware and software.

Cables

Caution! The plugs of the patient cable may not touch any conductive or grounded components! Secure any unused patient cable connectors. Never simultaneously touch the patient and connector components that conduct safety extra-low voltage.

PK-222

Device: Redel, P series, 14-pin, 40° coded
- — Defibrillation protection: 5 kV, according to EN 60601-2-25 voltage limitation to nominal 15 V nominal, 100 V maximum
- — Maximum energy consumption: ≤ 10%; based on defibrillation energy
- — Contact resistance: 10 kΩ
- — Weight 0.2 kg

Patient: 4 color-coded banana plugs

PK-199 Oesophagus

Patient: 4-pin Redel plug for the esophageal lead and four 4 mm- banana plugs for the surface leads

Device: Redel, P series, 14-pin, 40° coded

NK-3

Device: Right-angle cold device socket

Power supply: Shockproof right-angle plug 422U/311

Operating conditions

Caution! The ICS may be operated only in areas used for medical purposes (in accordance with DIN VDE 0107:1994). Do NOT operate the ICS 3000 in areas where there is a risk of explosion.

Note: The ICS 3000 is designed to be operated and stored in an enclosed area.

- Operate the ICS 3000 and its individual components only after placing it on a stable, level surface (e.g., a table).

Caution! Connect only the BIOTRONIK power supply cable to the power supply; never use any other cables for the ICS 3000.

WARNING! Never connect the ICS 3000 to the patient at the same time you are using electrosurgical instruments (such as an electrocautery). This might harm the patient and/or cause improper or unpredictable functioning of the device.

WARNING! Under no circumstances should you attempt to change settings by selecting the parameter(s) several times in rapid succession. This could produce unintended results.

Caution! The ICS 3000 has a touch screen for all input. Exercise care in configuring the settings, so that you do not activate an undesired function unintentionally.

WARNING! Use the safe program function only under the direct supervision of a physician.

WARNING! Keep an external defibrillator available when using the NIPS function.

Electromagnetic Compatibility

Note: The ICS 3000 is protected against interference due to electromagnetic radiation, electrostatic discharge, and other disturbances, including those associated with electric power lines. Interference from the ICS 3000 has also been minimized. Thus, the ICS 3000 meets the requirements of EN 60601-1-2 in every respect.

Note: The electromagnetic compatibility of the device meets the requirements specified in the standards. Avoid strong electrical, magnetic, or electromagnetic fields. However, strong electromagnetic fields can be generated by electrical devices and lines (e.g. power lines, electric motors, PCs, monitors, etc.) in the immediate vicinity of ICS 3000, which impair the functioning of ICS 3000. This could lead to an interruption in the telemetric connection to the implant, to an erroneous display of the ECG or IEGM, to malfunctions in operating procedures or similar problems. If it is not possible to switch off the interfering device, maintain a minimum distance to the electromagnetic environment as specified in the appendix of this manual (see page 42).

Caution! Pay attention to the following device disturbances:

- An unexpected power-down of the device;
- Detection of spontaneous cardiac events not displayed on the ECG/IEGM screen;
- Interference from an indeterminate source.

Action to take

- Turn off the electrical device causing the interference.
- Remove the source of the interference from the vicinity of the ICS 3000.
- Move the ICS 3000 away from the vicinity of the source of interference.
- Switch the ICS 3000 off and then on again.
- If the interference persists, contact BIOTRONIK or an authorized representative.

Instructions for use

Caution! The ICS 3000 programming and monitoring system is a sophisticated precision instrument and must therefore be handled with care. The ICS 3000 can be damaged by improper handling. Transport it carefully. Mechanical impact (if, for example, the ICS 3000 or the programming head is put down hard or dropped) can impair functioning. In this case, have the device checked by BIOTRONIK or an authorized representative.

Note: The ICS 3000 with its OM, DS, and PGH components may be operated in the vicinity of the patient.

Note: System error messages are generated optically and/or acoustically.

Note: The ICS 3000 may NOT be used as a life support system.

Note: The ICS 3000 is portable. The Docking Station and Operation Module can be used while plugged into the power supply. The Operation Module can also be used in wireless mode (with its rechargeable battery pack).

Caution! Detach the Operation Module only by using the release button on the back of the Operation Module; otherwise the locking mechanism will be damaged. Follow the instructions in the software user manual.

Note: The device contains measurement functions that indirectly serve specific diagnostic purposes.

Caution! Do not operate or store the ICS 3000 in direct sunlight or under similar heat sources (e.g., halogen lighting). Also, do not operate it near heaters or other sources of heat. Exposure to high heat can cause damage.

Caution! Never close or block the ventilation slots on the back of the device.

Caution! Never remove the label from the housing of the ICS 3000.

Caution! Never use organic solvents such as ether or acetone to clean the device. Always ensure that no liquids can penetrate the device.

Caution! Never sterilize the ICS 3000.

Caution! Do not operate the ICS 3000 near flammable or explosive materials.

Caution! The ICS 3000 may be used only in spaces suited for medical purposes and equipped with grounded alternating current.

Connecting the programmer to the patient

- When used in the operating room, cover the programming head and the cable connecting it to the ICS 3000 with a sterile cover.

Caution! Use the safe program function only under the direct supervision of a physician.

Caution! The ICS 3000 stores programming and diagnostic data in its memory. In the event of a loss of power or power-down during operation, all data in the memory could be lost.

External Defibrillation

Caution! During defibrillation, do not touch the programmer and its accessories that are attached to the patient.

Caution! The ICS 3000 is protected against defibrillation current. However, damage to devices connected to intracardiac leads cannot be ruled out.

- Place the electrodes of an external defibrillator at least 10 cm away from the implanted electrodes.
- Set the energy level no higher than that required to achieve defibrillation.
- After external defibrillation, check all the functions of the ICS 3000; see Inspection B.

Storage and shipping

- Use the provided packaging when returning devices to the manufacturer. The same environmental conditions apply to both storage and shipping (see „Technical Data“ on page 35).
- The thermal paper printouts are moisture-sensitive and fade when exposed to strong sunlight. Make copies for permanent documentation.

Self-test

After it has been turned on, the device carries out self-tests for approximately 1 minute.

WARNING! The ICS 3000 cannot be used during the self-test. To ensure the device is always ready for operation, do not switch it off during an examination.

Power Supply

The ICS 3000 has an internal 9.6 V NiMH rechargeable battery. Nickel metal hydride rechargeable batteries have a service life of 500 to 700 charging cycles.

Under optimal conditions, the capacity of 3800 mAh suffices for an uninterrupted system operating time in modular mode of approximately 1.5 hours.

The power unit supplies all components and additional modules with electricity. Automatic power monitoring protects the device from electrical overload.

Switching On the System

Battery level indicator

Before switching on the system, you can check the current battery level with the detached and powered-down Operation Module.

With more than 130 mA battery power, the LEDs light up independently.

- If the LEDs do not light up, press the battery level indicator button: The LEDs that indicate the respective battery level will light up for 4 seconds.

2 yellow, 2 green	Battery level 75% – 100%
2 yellow, 1 green	Battery level 50% – 75%
2 yellow	Battery level 25% – 50%
1 yellow, flashing	Battery level < 25%

Note: The Operation Module sends a report when the battery level is low (see technical manual for the software). Save all data and connect the Operation Module to the Docking Station to recharge the battery pack. If you fail to connect the Operation Module to the Docking Station before the battery is completely discharged, the Operation Module automatically saves the current data and powers down.

On/Off button

Use the On/Off button on the Operation Module to switch on both components if they are connected to each other for stationary operation and connected to the power supply.

When the Docking Station is switched on, the green LED on the right side of the housing will be illuminated.

System does not switch on

If the Operation Module cannot be turned on with its On/Off button, its battery is completely depleted. In this case, the Operation Module must be operated on the Docking Station and must be turned on with the Docking Station's On/Off button.

- In emergencies, switch on the docking station as well as the complete system using the ON switch next to the power connection socket.

Modular operation

If you remove the Operation Module from the Docking Station, the battery pack will provide power for the continued uninterrupted operation of the Operation Module.

The green LED on the Docking Station goes out.

On the Operation Module, an illuminated green LED and the display illumination indicates readiness for operation.

Switching Off the System

Normal shut-down

When you press the On/Off button quickly, the Operation Module switches to standby mode within a few seconds.

— The data are saved.

— The screen goes black.

— The battery level of the rechargeable battery is checked; if it is fully charged, the Operation Module and Docking Station will switch off automatically after 30 seconds.

If the Operation Module is connected, the system connected to the power supply and the battery is no longer fully charged, it will be automatically recharged (see also „Automatic Battery Recharge“ on page 15).

— The screen goes black and the fan continues to run.

— The system shuts down completely only after the battery has been recharged.

Note: After a normal shut-down, the ICS is quickly ready for operation again: Depending on the pre-defined setting, a restart takes 30 or 60 seconds.

Forced shut-down

If the software does not respond to brief pressure on the button for normal shut-down, you can force the system to shut down.

When you press the On/Off button for 3 seconds, the Operation Module switches itself off immediately.

— Any unsaved data will be lost.

— The battery will not be automatically recharged.

— The subsequent restart takes about 60 seconds.

WARNING! To switch off the device in an emergency, unplug the device. In an emergency, the device cannot be switched off effectively using the On/Off button on the Operation Module, because there is a delay in switching off. The ON switch on the Docking Station is used only for switching on the device.

Automatic Battery Recharge

Automatic battery recharging begins after a normal shut-down. The recharging status is shown graphically on the Operation Module display as a percentage. The LEDs light up in reverse sequence; see „Battery level indicator“ on page 12.

Depending on the battery level, recharging may take up to 4 hours. When recharging is completed, the LEDs go out.

Battery is not recharged

— The Operation Module and Docking Station are not connected to each other.

— The battery is of poor quality: for example, it is too old or has been poorly maintained.

— The ICS underwent a forced shut-down (On/Off button was pressed longer than 3 seconds).

— The internal operating temperature after switching on or during operation is too high.

— No power supply

Battery Maintenance

The rechargeable battery is automatically serviced every 4 weeks after normal shut-down, if the ICS is configured to do this (see technical manual for the software).

The maintenance cycle lasts approximately 12 hours, and includes battery charging, complete discharge and recharge.

Charging status

The charging status – either "Charging" or "Discharging" – is indicated graphically on the display.

Battery maintenance: Charging > Discharging > Charging

Note:

Do not switch off the system during battery maintenance: otherwise the battery will not be completely charged or discharged. If necessary, operate the system in stationary mode.

Switching off automatic battery recharge

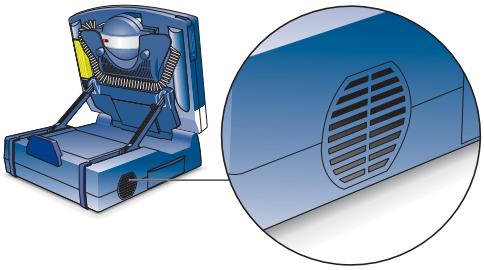
In the program under "More" > "Preferences" > "System", set "Automatic Battery Maintenance" to "OFF".

Docking Station

The Docking Station is the power-driven base unit of the system, which is used only in conjunction with the Operation Module. Additional modules can be connected to the expanded versions.

Ventilation slots

A temperature-controlled fan ensures optimal cooling.



- The ventilation slits must remain clear.

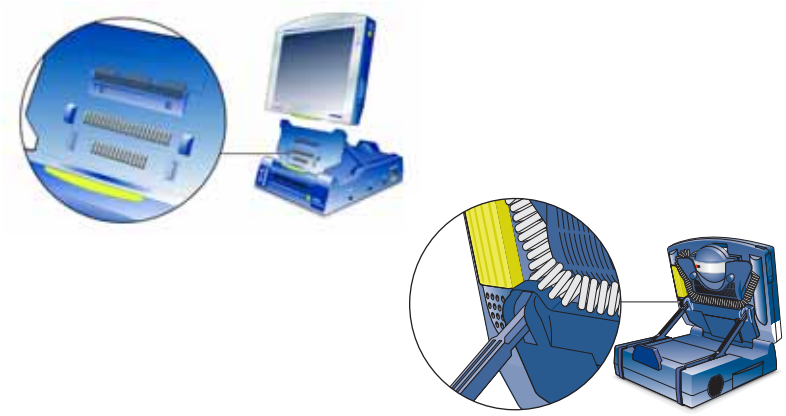
Carrying handle

Note: When you press the handle release key, the handle is immediately fully extended.

Caution! To lift the ICS 3000 by its handle, fold the Operation Module down completely; otherwise the programming head could fall out of its holder.

Connecting and Disconnecting the Operation Module

A central connector connects the Docking Station to the Operation Module.



- Use only the unlocking key on the back of the Operation Module to disconnect it; otherwise the release mechanism can be damaged (see also the technical manual for the software).

CD Drive

The CD drive is used for updating ICS software, the installation of the CD supplied by BIOTRONIK with instructions for use, and – if a CD writer is available – data back-up.

- When you press the black button on the drive itself, the CD holder extends.

Internal Printer

The ICS 3000 includes a high-resolution, graphics-capable thermal printer. The device prints on ICS 3000 thermal folding paper (see „Scope of Delivery“ on page 39).

Note: The thermal paper printouts are moisture-sensitive and fade when exposed to strong sunlight. Make copies for permanent documentation.

- To open the paper tray, lift the lever below the recessed handle on the paper tray and pull out the tray.
- To insert paper: Cut a triangle from the top sheet of the new paper, and push the cut sheet into the feed slot of the printer until it comes completely out of the paper discharge slot. Close the paper tray cover.
- Insert the paper tray.

Note: The printer is ready for operation only when the paper tray has been inserted.

- Using the numbered buttons, switch on the printer and select the printing speed in mm/s.
- Pressing the button at the top left stops the printout of the ECG.
- Press the button with the triangles to advance the paper to the beginning of the next page.

  The feed mechanism automatically advances the paper to the next tear-off edge.

Ports on the Docking Station

Caution! Never simultaneously touch the patient and connector components that conduct safety extra-low voltage.

USB Port for USB data stick, mouse or printer – with the Operation Module connected.

Caution! Connect only devices which do not have their own power supply; with regard to external printers, you must comply with the specifications listed on page 26.

Serial port This port can be used, for example, to connect the BIOTRONIK CDM 3000 Cardiac Data Manager.

- Connect a standard 9-pin RS-232 interface connector. All the connector pins must be fully assigned and connected 1:1.

Note: Do not use cables with a metal plug.

Operation Module

PC based

The Operation Module is the central operating, control and data storage unit for the entire system. For information on the power supply, see page 12.

See also „Connecting and Disconnecting the Operation Module“ on page 18.

— A system clock guarantees precision of ±10 minutes per year.

— The system battery lasts for 10 years.

— The system is equipped with a sound chip and a loudspeaker for acoustic signals.

Note: Important messages are signalled visually and acoustically.

Screen

The 12" color TFT screen is a touch screen. It is used for displaying information and is operated by touching the screen with your finger or a pen.

Caution! Do not use pointed or metal objects when selecting screen elements.

Angle adjustment

Two screen display hinges permit the screen to be adjusted to eight different fixed angles.

Ventilation slots

Together with temperature monitoring, the automatic ventilation system ensures optimal cooling.

- The ventilation slits must remain clear.

Ports on the Operation Module

Note: The ECG and PGH ports are mechanically coded; it is not possible to connect the cables incorrectly.

ECG port The ECG module is used with extremity leads: 3-channel ECG (Einthoven) and a miniclinic to monitor the functioning of implants.

⚠ • 14-pin port for PK-222 or PK-199

Caution! The plugs of the patient cables may not touch any conductive or grounded components!

Note: For information regarding approved adhesive and clip electrodes for surface leads, see page 40

PGH The 14-pin port for the programming head (see fold-out page) is located at the back of the Operation Module.

Infrared Normal IrDA standard (infrared interface, see fold-out page) with transfer rates of up to 115 kbps.

Bluetooth interface Bluetooth is an industry standard for wireless networking of devices over a short distance. It can be used to connect an external printer; see page 26.

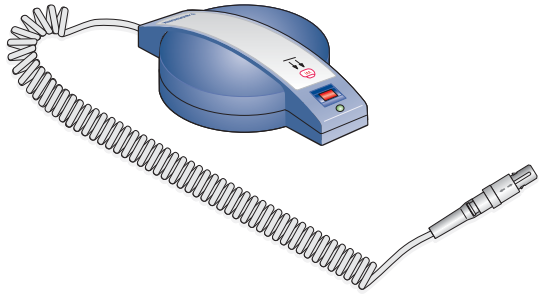
PGH Programming Head

ICS 3000 PGH (Programming head)

Communication between the programmer and the implant takes place by means of telemetry via the ICS 3000 PGH (programming head). The output data from the implant (digital and analog) are converted into digitally coded impulses and transmitted over an inductive coupling between the coils of the programming head and those of the implant.

Note: Connect the programming head to the Operation Module before you turn it on.

The programming head port is located on the back of the Operation Module, behind the mount for the programming head (see the fold-out page).



With some implants, telemetry cannot be carried out until a reed switch in the implant has been closed. For this reason, a strong permanent magnet has been integrated into the programming head. Before the programming head and the implant can exchange data, the reed switch in the implant is closed.

When the reed switch is open, telemetry is blocked. This protects the implant from unintentional reprogramming. With some implants, closing the reed switch also switches the device over to an asynchronous pacing program (see the technical manual of the respective implant).

Note: Each programming head features a diagram of the implant to assist in positioning the head. Silicone nubs on the underside prevent the head from slipping.

Caution! To program and interrogate the implant, the programming head is brought into physical contact with the patient. The programming head contains a strong magnet. Do not place it close to magnetically sensitive objects such as computer diskettes or wristwatches.

- If you are programming the implant under sterile conditions, operate the programming head with a sterile cover (see „Optional Accessories“ on page 40).

The LED at the front of the programming head indicates the telemetry contact to the implant:

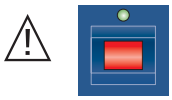
Green LED Telemetry contact optimal

Yellow LED Telemetry contact in limit value range (implant dependent)

Red LED Telemetry contact disturbed

LED off No telemetry contact

[Safe Program]



The PGH 3000 programming head is equipped with its own safe program button. This function can be started directly with top priority from any application if the programming head is positioned above the implant; the button has the same function as the safe program button on the Operation Module. See „Emergency Programs“ on page 29.

WARNING! Use the safe program function only under the direct supervision of a physician.

Conductor to ICS: PGH with straight cable

The ICS 3000 is operated with the PGH programming head, which may have a spiral cable or a straight cable as a conductor.

If the Operation Module is used in portable fashion, there is a danger of tripping if there is a straight cable hanging down loose.

- When transporting the unit, wind a straight PGH cable around the mount on the back of the operation module as shown below.

Note: If you wish to fold down the Operation Module completely onto the Docking Station, please make sure that the cable does not get pinched.

Using Basic Functions

External Printer

You can connect an external printer to the programmer under the following electrical safety conditions:

With the exception of the wireless connection, after the system has been installed in the hospital, compliance with the leakage current limit values according to EN 60601-1-1, Paragraph 19 must be demonstrated.

The following devices can be configured:

- The printer is connected via a wireless connection; see „Bluetooth interface“ on page 22.
- The printer is battery-operated and is connected to the USB port of the ICS 3000 Docking Station.
- The printer is powered via the mains supply and is connected to the USB port of the ICS 3000 via an isolating separator (EN 60601-1-1, Paragraph 17.201) with a dielectric strength of at least 1.5 kV (e.g. an isolating USB-hub model UISOHUB4 by B&B electronics).
- The printer is supplied directly from the mains by a medical device power pack and connected to the USB port of the ICS 3000.

Note: The printer must be set up outside the patient's vicinity (at least 1.5 meters away from the patient). Any printer that supports the PCL5 printer language and is compatible with a generic HP driver can be used.

ICS 3000 Software

Software updates are performed by authorized persons using a CD-ROM.

Installing the CD

Technical manuals for the implant programs are supplied on an additional CD. The CD contains technical manuals in PDF format for printing and in HTML format for help.

- Please follow the installation instructions on the CD.

Languages

Language settings are found under "More" > "Preferences" > "Language".

- To apply changes, the system must be restarted using the "Restart Now" button at the left of the dialog.

Programmer

The available functions depend on the individual implant:

— Identify the implant
— Interrogate the program
— Read out the memory
— Real-time test
— Transmit IEGM and event markers
— Adjust and transmit the program
— Memory functions

ECG Recorder and ECG Monitor

All ECGs can be displayed in real time in recorder or trigger mode and printed on the internal printer.

- Record 3-channel ECGs using PK-222; for approved adhesive and clip electrodes, see page 40.

  — Up to 3 leads for the Einthoven ECGs
  — Up to 3 IEGMs, depending on the implant
  — Event markers (depending on the implant)

- Record esophageal lead with PK-199; for an approved temporary esophageal lead, see page 40.

Note: Comply with the technical manual for PK-199.

Recording ECGs and IEGMs

The intracardiac electrograms received from the implant as well as the surface ECG and the esophageal lead can be simultaneously displayed and printed. The recording of the surface ECG does not depend on other functions, so that the implant can be interrogated and programmed during the ongoing ECG display. The recorded electrograms can be saved and measured with electronic calipers.

Overmodulation When the ECG input is overmodulated, the signal is displayed only as a solid line on the upper frame of the ECG window.

1. Test the electrode contacts.
2. Remove other devices from the patient.
3. Turn off sources of interference.

Miniclinic

The pacing pulses delivered by the implant are continually recorded and evaluated along with the surface ECG. The values for rates, pulse width, and AV delay (for multi-chamber pacing only) are automatically calculated and displayed based on this information. This recognition software, the system's Miniclinic, can monitor all single- and dual-chamber pacemakers, regardless of the brand or manufacturer of the pacemaker. If only one pulse is detected, this is assigned to the ventricle. If two pulses are detected, these are interpreted as atrial and ventricular pulses.

Note: When working with the software, maintain minimum amplitudes or values of physiologic patient signals. If these values are not met, inaccurate results may be produced.

The M 50 magnet can be used to check the pacing function of the implanted pacemaker.

Data Transfer

The follow-up data can be saved, sorted and exported.

— Connection of an external PC system for data processing (e.g., CDM 3000 Cardiac Data Manager)
— Connection of an external printer for printing out all the data with the exception of real-time ECGs
— Connection of a USB data stick

Documentation

Internal printer for the complete documentation of:

— all follow-up reports (e.g., program and test data, saved data)
— all real-time ECGs (ECG, IEGM, event markers)

Interrogating and Programming the Implant

The BIOTRONIK implants can communicate bidirectionally with the ICS 3000 via the programming head. As soon as the programming head is correctly positioned over the implant, the program data and all data stored in the implant can be transmitted to the ICS 3000.

Depending on the implant, a large number of adjustable sets of parameters are available. These parameter sets are combined and saved in the program that is currently in use. The ICS 3000 detects obvious programming errors and requires these to be corrected before the program is transferred to the implant.

Emergency Programs

Both the safe program as well as the emergency shock can be triggered at any time using the respective buttons. Contact with the implant is crucial. The current programming is then immediately turned off and the respective parameters are deactivated.

WARNING! Trigger the safe program or an emergency shock only under the supervision of a physician.

Calling up and Triggering the Safe Program

1 Position the programming head over the implant.

The safe program switches on the pacemaker, and paces it at 10 V and 70 ppm.

2 Press the safe program button on the Operation Module or the programming head (see page 23).

Calling up and Triggering an Emergency Shock

In the ICS 3000, the emergency shock command is issued by the hardware button; the emergency shock is always generated by the implant according to the preset implant program.

Note: The emergency shock button on the predecessor model TMS 1000 plus is used to immediately trigger a self-generated emergency shock during the intraoperative phase.

1 Position the programming head over the implant.

The emergency shock is a biphasic defibrillation shock, which can stop an unexpected tachyarrythmia with 30 J (high energy implants: 36 J).

2 To call up the command: Press the emergency shock button on the Operation Module.

For safety reasons, a dialog also gives you the option of canceling the action.

3 To execute the command: Press the emergency shock button a second time.

Non-invasive Programmed Stimulation

WARNING! Keep an external defibrillator available while using the NIPS function.

The pulse delivery of implanted BIOTRONIK pacemakers can be externally controlled through the ICS 3000 via the properly positioned programming head. In such instances, the pacemaker is operating in a temporary standby mode. This type of stimulation is called non-invasive programmed stimulation (NIPS); how it functions depends on the respective implant and software.

Analog Telemetry

Transmitting real-time measurement data from the implant to the ICS 3000 is known as analog telemetry. This includes the battery and electrode measurement data as well as intracardiac electrograms with event markers.

The EMI Test

The telemetry between the programming head and the implant can be adversely affected by electromagnetic interference (EMI). This can make it difficult or even impossible to interrogate or program the implant. This is the reason for the EMI test, a feature you can use to locate the sources of the electromagnetic interference. This test lets you locate and eliminate the source of interference.

Care and Maintenance

WARNING! Perform maintenance tasks only when the device is unplugged.

Changing the rechargeable battery Depleted rechargeable batteries can be replaced; contact BIOTRONIK.

Caution! After a battery change, a complete battery maintenance cycle must be carried out so that the rechargeable battery reaches its full capacity and this can be displayed. Even if a full or partially charged battery is used, the maintenance cycle must be carried out (see the technical manual for the software).

Cleaning and Disinfection

To clean the device and the programming head, use a cloth moistened with a mild soap solution, alcohol, or other sterile solution (comply with the manufacturer's recommendations concerning dilution before use).

Caution! Never use organic solvents such as ether or acetone to clean the device. Always ensure that no liquids can penetrate the device.

- Be careful not to allow any liquid to enter the housing during cleaning.
- Do not exert any pressure on the screen. Even slight pressure over a large area can irreparably damage the touch screen.
- Disinfect the device with a mixture of 70% isopropanol and 30% water, or use Lysoformin 3000 (concentration = 2% , application time = 15 min).

Sterilization

Caution! Do not sterilize the ICS 3000!

- If you are conducting pacemaker programming under sterile conditions, operate the programming head with a sterile cover (see „Optional Accessories“ on page 40).

Maintenance

The ICS 3000 requires no maintenance. The following inspections must be carried out:

Inspection A Before each use, check the following:

- Visually examine the ICS 3000 and the programming head.
- Check the housing and cables for mechanical damage.
- Check the system time and date and adjust if necessary.
- Check if a replacement pen is available? (If not, order one.)
- Check accessories, particularly the patient cables.

Inspection B As part of the safety checks every year and if malfunctions are suspected:

- First, conduct Inspection A.
- Check all mechanical and electrical functions according to the BIOTRONIK test specification.
- Check the accessories, particularly PK-222 and PK-199, and send them with the unit to the manufacturer if necessary.

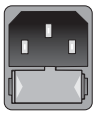
Note: The devices used for the electrical function test are usually not readily available in hospitals. Therefore, it is recommended that the ICS 3000 be checked by BIOTRONIK or by a test center authorized by BIOTRONIK.

- Contact BIOTRONIK with any problems you may have: describe the problem, have program printouts or ECGs available, note error messages.

Changing a Fuse

The fuses are located in a fuse drawer below the connection for the power supply.

Caution! Before changing the fuses, you must turn off the ICS 3000 and unplug the power supply cable.



- To unlock the drawer, push the latches at the right and left of the drawer inwards together.
- Pull the drawer out.
- Replace the old fuses with new ones of the same type. The type of fuse is marked on the fuse itself; see also „Power Supply“ on page 38.

Caution! Defective fuses may indicate a technical defect in the device. Conduct a type B inspection.

Disposal

This device contains materials that must be correctly disposed of in accordance with environmental protection regulations. European Directive 2002/96/EC regarding waste electrical and electronic equipment (WEEE) applies to this device.

- Send the devices you are no longer using to the local BIOTRONIK representative. This ensures that disposal will be carried out in accordance with the national versions of the WEEE directive.

  This device contains a crossed-out garbage can symbol on its label. This requires the device to be collected and disposed of in accordance with the WEEE directive. The black bar underneath the garbage can symbol indicates that the device was sold after the national version of the WEEE directive in your country was implemented in your country.
- Should you have any questions, please contact BIOTRONIK.

Technical Data

ICS 3000: General Information

Dimensions [mm]	322*168*332 (W*H*D)
Safety class	I (DIN EN 60601-1, Section 5.1
Protection degree	IP 20, IEC 60529
Protection degree for anesthetics	None; DIN EN 60601-1, Section 39
Operating mode	Continuous operation

Permissible Environmental Conditions

	Operation	Storage
Temperature [°C]	10 – 40	0 – 50
Relative Humidity [%]	25 – 95	35 – 75
	No condensation	
Air pressure [hPa]	700 – 1060	

Operation Module: General Information

Dimensions [mm]	318*85*270 (W*H*D)
Weight [kg]	3,2
Operating voltage [V]	9.6; DC
Max. power [W]	30, not including the battery charge
Average power [W]	20, not including the battery charge
Serial port	1; includes IrDA
USB port	1

Rechargeable Battery

Type	NiMH (HHR-380AB L2x2+L2x2)
Voltage [V]	9,6
Capacity [Ah]	3,8
Operating time [hrs]	1,5
Battery monitoring	Gas gauge, battery level monitoring

LCD screen

Type	TFT; color
Size ["]	12.1; active diagonal
Resolution [dpi]	800*600; SVGA
Brightness (programmable)	80 cd/m^2; with battery operation (software-dependent)
	200 cd/m^2; with battery operation (software-dependent)

ECG module: General Information

Protection degree	BF, EN 60601-1, Section 5.2
Power consumption [W]	0.7; maximum
More	Defibrillation-proof

ECG module: ECG Functions

Leads	3, Einthoven
dB	Common-mode rejection and crosstalk attenuation 60; at 50 Hz and input resistance <100 kΩ
Input alternating current [mV]	±25
Permissible DC offset [mV]	±300
Amplitude tolerance [%]	±5; in a frequency range of 5 to 50 Hz; further requirements as specified in AAMI EC 11 1991
A/D converter	12 bit
Scan rate [Hz]	500 ... 1000, for ECG data (software-dependent)
Resolution [µV]	1,5
Noise [µV]	< 20
Frequency range [Hz]	0,6 ... 150; +0/-3 dB for the leads
Overmodulation display	Continuous signal line at the upper or lower limit of the ECG field
ECG port	Redel plug, 14-pin

	Miniclinic
Stimulation modes	Single- and multi-chamber
Pacing rate [ppm]	30 ≙ 180; ±2
Period [ms]	333 ≙ 2000; 2 ±4
Pulse width (A+V) [ms]	0,1 ≙ 2,5; 0,05 ±0,05
AV conduction time [ms]	50 ≙ 300; 2 ±4
Miniclinic Trigger level [mV]	2 ≙ 150; 2 ±4
	PGH Programming Head
ICS 3000PGH	Spiral cable, extendable to approx. 2.30 meters
ICS 3000PGH	Straight cable, 2.1 meters Straight cable, 2.9 meters
Dimensions [mm]	142*97*42 (W*H*D)
Weight [kg]	0,5
PGH connection	Redel plug, 14-pin
Protection degree	IP 30
Protection degree for application part	Type B
Magnetic flux density [mT]	>2.0 at 60 mm distance >20.0 at 10 mm distance 30.0 at 0 mm distance
	Docking Station: General Information
Dimensions [mm]	284*103*322 (W*H*D)
Weight [kg]	3,8
Cooling	with fan
Fan control	temperature-controlled

Power Supply

Type	Primary clocked broadband power supply
Mains voltage [V], Frequency [Hz]	100 – 115 V ± 10% / 60 Hz / 1.2 A / AC 220 – 230 V ± 10% / 50 Hz / 0.6 A / AC
Safety class	I, DIN EN 60601-1, Sec. 5.1
Fuse [A]	3.15 surge-proof
Power [W]	Continuous power: 100 Short-term maximum: 140

Charging Circuit

Type	Switch mode charging circuit corresponding to battery type
Safety switch	To prevent overloading and excessive temperature
Recharging time [hrs]	4; charging with 1/3 C

Internal Printer

Power [W]	Controller and on standby: 1 Thermoline and motor: 50
Type of printer	Thermal printer
Resolution [dots/mm]	8
Paper width [mm]	112
Printing width [mm]	104
Feed rate [mm/s]	5, 10, 25, 50, for graphics as well
Feed rate tolerance [%]	±2,5; Maximum absolute error over 100 mm printout

Scope of Delivery

Note: The software must be ordered separately.

Standard

		Order number
ICS 3000 Complete	Complete system with accessories	336828
	Complete system with accessories, with exclusively UL-certified components	349528
ICS 3000 Pen	Stylus and holder	340295
ICS 3000PGH	Spiral cable, extendable to approx. 2.30 meters	340 296
ICS 3000 Paper	Printer paper for ICS, PMS, and TMS	348728
ICS 3000 SoftCase	Carrying case	342349
PK Electrode clip	Clip adapter for adhesive electrodes	340293
User Manual en	Technical Manual, Software	345885
Technical Manual en	Technical Manual, Hardware	336831
NK-3 / 2.5 m	Power supply cord	107526
PK-222-EU / 2.8 m	3-channel patient cable for ECG or IEGM leads	335284

Optional Accessories

		Order number
M 50	Permanent magnet Magnetic flux density: 12.5 min. [mT] Dimensions: 60*17*26 (W*H*D) [mm] Weight: 0.185 kg	112149
ICS 3000PGH	Straight cable, 2.1 meters	350103
	Straight cable, 2.9 meters	355547
NK-11 / 3 m	Power supply cord for the US; A PE conductor compliant with UL 2601-1; Device: Right-angle socket Power supply: Right-angle plug	128865
NK-16-GB / 2 meters	Power supply cord for the United Kingdom	330705
NK-21-AU,UY / 2.5 meters	Power supply cord for Australia and Uruguay	339035
NK-22-AR / 2.5 meters	Power supply cord for Argentina	339039
NK-26-CL, IT / 2.5 meters	Power supply cord for Chile and Italy	339043
PK-199 Oesophagus/ 2.8 meters	Patient cable for the esophageal lead	355373
PK-222-US / 2.8 m	Same as the PK-222-EU with country-specific color coding of the banana plugs	335281
Sterile cover 1	Sterile cover for ICS 3000 PGH; single-use, cannot be re-sterilized	340287
Rechargeable battery, NiMH 9.6 V	Replaceable rechargeable battery for the Operation Module	336549

Approved ECG Electrodes

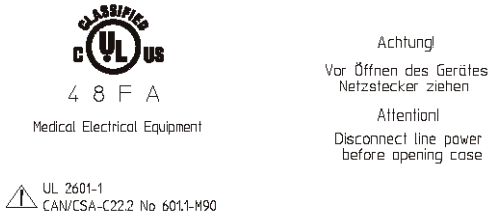
Adhesive electrodes	Kendall ARBO H34 SG
	Kendall ARBO H68
	SKINTACT T 60
	Dahlhausen Type 454
	Dahlhausen Type 460
Clip electrode	GOLMED G 502
Esophageallead	Osypka TO 4, 10.5 F

Country-Related Information

UL Certification

The ICS 3000 US (order number: 349 528, ICS 3000 with Implant Module: 354 877) has been certified by Underwriters Laboratories Inc. in accordance with UL 2601-1 and CAN/CSAC22.2 No 601.1-M90.

UL-certified devices are identified as follows:



Distribution in the USA and Canada

In the US and Canada, the device must be connected to a center-tapped power outlet if the voltage network carries 230 V at 60 Hz.

Programming Head

Industry Canada

The programming head is registered with Industry Canada under the following identification:

IC: 4708A-ICSPGH

The code IC in front of the certification/registration number only indicates that the technical requirements for Industry Canada are met.

United States of America

The programming head is registered with FCC under the following number: FCC ID: QRIICSPGH

This device complies with part 15 of the FCC rules. Operation is subject to the following two conditions:

This device may not cause harmful interference

This device must accept any interference received, including interferences that may cause undesired operation.

Modifications not expressly approved by this company could void the user's authority to operate the equipment.

Electromagnetic Compatibility in Compliance with EN 60601-1-2:2002

- As the user, you must ensure that the ICS 3000 is operated in a suitable electromagnetic environment.

  The following guidelines may not be applicable in all cases. The propagation of electromagnetic values is, for example, affected by absorption and reflection by structures, objects and people. This data is for your personal information.

- The ICS 3000 should not be operated in the vicinity of devices that display the symbol "Beware of non-ionizing radiation." Interference is possible in the vicinity of such devices.

Electromagnetic Emissions (Table 201)

Measuring the Emitted Interference	Compliance	Guidelines for the Electromagnetic Environment
High-frequency emitted interference According to CISPR 11	Group 1	The device uses RF energy only for its internal function. Therefore, the emitted interference of high-frequency waves is very low and not likely to cause any interference in nearby electronic equipment.
High-frequency emitted interference According to CISPR 11	Class B	The device is suitable for use in all establishments. This includes residences and facilities directly connected to the public power supply network that supplies buildings used for domestic purposes.
Emitted interference of harmonic oscillations According to IEC 61000-3-2	Class A	
Emitted interference of voltage fluctuations According to IEC 61000-3-3	Complies	

Recommended Safety Distances (Table 206)

- Safety distances help prevent interference if you maintain a minimum distance between transmitters such as mobile RF telecommunication devices and the ICS 3000. The necessary distance depends on the respective power output of the transmitter.

Note: At 80 MHz and at 800 MHz, the higher frequency range applies.

Transmission Frequency	**150 kHz to 80 MHz**	**80 MHz up to 800 MHz**	**800 MHz to 2.5 GHz**
Maximum output power of the transmitter [W]	Safety distance [m]		
0,01	0,12	0,12	0,24
0,1	0,37	0,37	0,74
1	1,17	1,17	2,34
10	3,70	3,70	7,40
100	11,7	11,7	23,4

- For transmitters whose maximum output power is not indicated in the table, the recommended safety distance d can be calculated in meters using an equation that is suitable for the respective transmission frequency range. P is the maximum output power of the transmitter in watts [W] according to the specification of the transmitter's manufacturer.

Transmission Frequency	**150 kHz to 80 MHz**	**80 MHz up to 800 MHz**	**800 MHz to 2.5 GHz**
Equation	$d = 1,17\sqrt{P}$	$d = 1,17\sqrt{P}$	$d = 2,34\sqrt{P}$

Resistance to Electromagnetic Interference (Tables 202 and 204)

- When the measured field strength exceeds the specified compliance level at the operating location of the ICS 3000, observe the device in order to determine whether it is functioning properly.
- If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the device. In the frequency range of 150 kHz to 80 MHz, ensure that field strengths are lower than 3 V/m.

Note: U_T is the mains alternating voltage before applying the test levels.

Test of Interference Resistance	Test Level According to IEC 60601-1-2	Compliance	Guidelines for the Electromagnetic Environment
Electrostatic discharge (ESD) According to IEC 61000-4-2	±6 kV contact discharge ±8 kV air discharge	Same as test level	• Operate the devices on floors made of wood, concrete, or ceramic tile. If the floor is covered with synthetic material, the relative humidity must be at least 30%.
Fast transient electric interference (bursts) According to IEC 61000-4-4	±2 kV for power lines ±1 kV for input and output lines	Same as test level	• Ensure that the power supply quality is that of a typical commercial and/ or hospital environment.
Surges According to IEC 61000-4-5	±1 kV push-pull voltage ±2 kV push-push voltage		
Voltage drops, brief interruptions, and supply voltage fluctuations According to IEC 61000-4-11	<5% U_T for 1/2 period >95% drop 40% U_T for 5 periods 60% drop 70% U_T for 25 periods 30% drop <5% U_T for 5 s >95% drop	Same as test level	• Ensure that the power supply quality is that of a typical commercial and/ or hospital environment. • If you require continued operation during power supply interruptions, connect the device to an uninterruptible power supply or use a battery for operation.

Test of Interference Resistance	Test Level According to IEC 60601-1-2	Compliance	Guidelines for the Electromagnetic Environment
Magnetic field at the supply frequencies (50/60 Hz) According to IEC 61000-4-8	3 A/m	Same as test level	• Ensure that the magnetic field strengths are at levels characteristic of a location in a typical commercial and/or hospital environment.

Note: At 80 MHz and at 800 MHz, the higher frequency range applies.

Test of Interference Resistance	Test Level According to IEC 60601-1-2	Compliance	Guidelines for the Electromagnetic Environment
Conducted RF interference According to IEC 61000-4-6	3 V_{eff}	3 V	• Maintain safety distance of mobile radio equipment to the ICS 3000; see page 5 • The field strength of stationary transmitting devices must be measured on site and must be lower than the compliance level at all frequencies: consider any studies done on site. • The field strength must be lower than 3 V/m over the frequency range of 150 kHz to 80 MHz.
Radiated RF interference According to IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	

Symbol Index

Follow the instructions for use!

Operation Module

On/Off button

Button for displaying the battery level

Safe program button

Emergency shock button

ECG input with a BF degree of protection, defibrillation-proof

Connection for the PGH 3000 programming head with a B degree of protection

Programming Head

Safe program button on the PGH 3000 programming head

Position indicator on the PGH 3000 programming head

Docking Station

USB port, only for devices approved by BIOTRONIK

RS 232

Serial port

I
EIN / ON

ON switch, for switching on the system even when the battery is fully depleted

Mains

100-115 V~; 60 Hz; 1.2 A
220-230 V~; 50 Hz; 0.6 A
 3.51 A-T

Mains voltage; mains frequency; power consumption

Mains current for the fuse (surge-proof)

Housing covers

Labeling on protective port covers:

Folie nicht entfernen oder beschädigen!
Keine Benutzerbedienteile innenliegend

Do not remove or damage foil!
No user serviceable parts inside

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