Edora 8

ProMRI®

Pacemaker | Bradyarrhythmia Therapy |
Cardiac Resynchronization Therapy

Technical Manual

417803

Revision: B (2016-03-23)

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CE 0123 2016

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1 Product Description

Intended Medical Use

Intended use

Edora is a family of implantable pacemakers that can be implanted for all bradycardia arrhythmia indications. The primary objective of the therapy consists of improving patients' symptoms that can be clinically manifested. The implantation of the pacemaker is a symptomatic therapy with the following objective:

- Compensation of bradycardia by atrial, ventricular, or AV sequential pacing
- Additional triple-chamber features: Resynchronization of ventricular chamber contraction via biventricular pacing

Diagnosis and therapy forms

The cardiac rhythm is automatically monitored and bradycardia arrhythmias are treated. All major therapeutic approaches from the field of cardiology and electrophysiology are unified in this pacemaker family. BIOTRONIK Home Monitoring® enables physicians to perform therapy management at any time.

Required expertise

In addition to having basic medical knowledge, the user must be thoroughly familiar with the operation of a device system.

- Only qualified medical specialists having the special knowledge required for the proper use of implanted devices are permitted to use them.
- If users do not possess this knowledge, they must be trained accordingly.

Indications

Guidelines of cardiological societies

Generally approved differential diagnostic methods, indications, and recommendations for pacemaker therapy apply to BIOTRONIK devices.

The guidelines provided by cardiology associations offer decisive information:

- We recommend observing the indications published by the German Cardiac Society (Deutsche Gesellschaft für Kardiologie, Herz- und Kreislaufforschung) and the ESC (European Society of Cardiology).
- This also applies to the guidelines published by the Heart Rhythm Society (HRS), the American College of Cardiology (ACC), the American Heart Association (AHA), and other national cardiology associations.

Device types

For the following symptoms/expectations, the following device types are indicated:

Symptom/expectation	SR	DR	HF
Disorientation due to bradycardia	x	x	x
Presyncope	x	x	x
Benefit from resynchronization of the right and left ventricles			x
Syncope	x	x	x

Pacing modes

For the following symptomatic, the following pacing modes are indicated:

Symptom/expectation	Pacing mode
Sick sinus syndrome	Dual-chamber pacing
Chronic, symptomatic second and third-degree AV block	Dual-chamber pacing
Adams-Stokes syndrome	Dual-chamber pacing
Symptomatic bilateral bundle branch block when tachyarrhythmia and other causes have been ruled out	Dual-chamber pacing
• Chronotropic incompetence • Benefit from increased pacing rate with physical activity	R mode or CLS
Sinus node dysfunction in the presence of normal AV and intraventricular conduction	Atrial pacing
Bradycardia in conjunction with the following: • Normal sinus rhythms with only rare episodes of AV block or sinus arrest • Chronic atrial fibrillation • Severe physical disability	Ventricular pacing

MR conditional

ProMRI® labeled MRI conditional pacemakers are safe for use in the MRI environment when used in conjunction with a complete MRI conditional pacing system and according to the instructions given in the ProMRI® manual.

Contraindications

Guidelines

No contraindications are known for the implantation of multifunctional single-chamber, dual-chamber, or triple-chamber pacemakers, provided differential diagnostics precedes implantation according to the appropriate guidelines and no modes or parameter combinations are configured that pose a risk to the patient.

Pacing modes and parameters

The compatibility and effectiveness of parameter combinations must be checked and, as the case may be, adapted after programming.

Set of facts	Contraindicated pacing mode
Additionally implanted ICD	Unipolar pacing

Set of facts	Inappropriate pacing mode
Chronic atrial tachycardia, chronic atrial fibrillation or flutter	Atrial-controlled modes (DDD, VDD, AAI)
Poor tolerance of pacing rates above the basic rate, e.g., angina pectoris	
AV conduction disorder	Atrial single-chamber pacing
Failing AV conduction	

Set of facts	Adapt parameters
Slow retrograde conduction after ventricular pacing: Risk of pacemaker-mediated tachycardia	• Extend atrial refractory period (ARP) and/or: • Shorten AV delay • Rarely: Program to DDI, DVI or VVI
Poor tolerance of pacing rates above the basic rate, e.g., angina pectoris	• Lower atrial upper rate • Lower maximum sensor rate • Deploy atrial overdrive pacing

System Overview

Device family

This device family consists of single-chamber, dual-chamber and triple-chamber devices with or without Home Monitoring. Not all device types are available in every country.

The following device variants are available:

Device type	Variant with Home Monitoring	Variant without Home Monitoring
Single-chamber	Edora 8 SR-T	Edora 8 SR
Dual-chamber	Edora 8 DR-T	Edora 8 DR
Triple-chamber	Edora 8 HF-T, Edora 8 HF-T QP	—

Device

The device's housing is made of biocompatible titanium, welded from the outside and therefore hermetically sealed. The ellipsoid shape facilitates ingrowth into the pectoral muscle area. The housing serves as an antipole in the case of unipolar lead configuration.

Lead connections

BIOTRONIK provides pacemakers with headers for different standardized lead connections:

- IS-1
- IS-1/IS4

Note: Suitable leads must comply with the norms:

- A device's IS-1 connector port must only be used for connecting leads with an IS-1 connector that conform to ISO 5841-3.
- A device's IS4 connector port must only be used for connecting leads with an IS4 connector that conform to ISO 27186.

Note: The device and leads have to match.

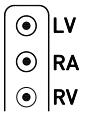
- Only quadripolar leads must be connected to the IS4 connector on device type HF QP with IS4.

Note: Use only adapters approved by BIOTRONIK for leads with different connections.

- If you have any questions concerning the compatibility of other manufacturers' leads, please contact BIOTRONIK.

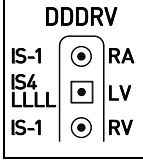
IS-1

The device labeling provides information pertaining to the connection assignment:

SR	DR	HF
VVIR/AAIR IS-1	DDDR  IS-1	DDDRV  IS-1

Connector port	Lead connector	Configuration	Implantation site	Device type
A/RA	IS-1	Unipolar, bipolar	Atrium	DR, HF
V/RV	IS-1	Unipolar, bipolar	Right ventricle	SR, DR, HF
LV	IS-1	Unipolar, bipolar	Left ventricle	HF

IS-1/IS4 The device labeling provides information pertaining to the connection assignment:

HF QP


Connector port	Lead connector	Configuration	Implantation site	Device type
RA	IS-1	Unipolar, bipolar	Atrium	HF QP
RV	IS-1	Unipolar, bipolar	Right ventricle	HF QP
LV	IS4	Unipolar, bipolar	Left ventricle	HF QP

Leads BIOTRONIK leads are sheathed in biocompatible silicone. They can be flexibly maneuvered, are stable long-term, and are equipped for active or passive fixation. They are implanted using a lead introducer set. Some leads are coated with polyurethane which is known to increase the gliding properties for the lead. Leads with steroids reduce inflammatory processes. The fractal design of the leads allows for low pacing thresholds, high pacing impedance, and a low risk of oversensing.

BIOTRONIK provides adapters to connect already implanted leads to new devices.

Telemetry Telemetric communication between the device and the programmer can be carried out following initialization either by applying the programming head (PGH) to the device or by using wireless wandless telemetry in the programmer.

Programmer Using the programmer, the pacing thresholds can be determined and all tests can be performed during implantation and in-office follow-up. In addition to this, the programmer is used to set mode and parameter combinations, as well as for interrogation and saving of data from the device. Leadless ECG, IEGM, markers and functions are displayed simultaneously on the color display.

Modes The mode setting depends on the individual diagnosis:

Device type	Modes	Standard
SR	• VVI-CLS • VVIR, V00R, AAIR, A00R • VVI, VVT, V00, AAI, AAT, A00 • OFF	VVIR
DR	• VVI-CLS; DDD-CLS • DDD-ADI, DDDR-ADIR • DDDR, DDIR, DVIR, D00R, VDDR, VDIR • VVIR, V00R, AAIR, A00R • DDD, DDT, DDI, DVI, D00, VDD, VDI • VVI, VVT, V00, AAI, AAT, A00 • OFF	DDDR
HF (QP)	• VVI-CLS, DDD-CLS • DDD-ADI, DDDR-ADIR • DDDR, DDIR, DVIR, D00R, VDDR, VDIR • VVIR, V00R, AAIR, A00R • DDD, DDT, DDI, DVI, D00, VDD, VDI • VVI, VVT, V00, AAI, AAT, A00 • OFF	DDDR

Note: Home Monitoring is possible in all modes.
The OFF mode only functions temporary, i.e. during a test.

NBG codes

AAIR or VVIR is the NBG code for the antibradycardia mode of the single-chamber device:

A/V	Pacing in the atrium or ventricle
A/V	Sensing in the atrium or ventricle
I	Pulse inhibition in the atrium and ventricle
R	Rate adaptation

DDDR is the NBG code for the antibradycardia mode of the dual-chamber device:

D	Pacing in the atrium and ventricle
D	Sensing in the atrium and ventricle
D	Pulse inhibition and pulse triggering
R	Rate adaptation

DDDRV is the NBG code for the antibradycardia mode of the triple-chamber device:

D	Pacing in the atrium and ventricle
D	Sensing in the atrium and ventricle
D	Pulse inhibition and pulse triggering
R	Rate adaptation
V	Multisite pacing in both ventricles

BIOTRONIK Home Monitoring®

In addition to effective pacing therapy, BIOTRONIK provides a complete therapy management system:

- With Home Monitoring, diagnostic and therapeutic information and technical data are automatically sent to a stationary or mobile transmitter via an antenna in the device header. The data are encrypted and sent from the transmitter to the BIOTRONIK Service Center via the cellular phone network.
- The received data are deciphered and evaluated. Each physician can set the criteria for evaluation to be used for each patient and can configure the time of notification via e-mail, SMS or fax.
- A clear overview of the results of this analysis is displayed for the attending physicians on the protected internet platform Home Monitoring Service Center (HMSC).
- Data transmission from the device is performed with a daily device message.
- Device messages, which indicate special events in the patient's heart or in the device, are forwarded with the following message.
- A test message can be initiated at any time using the programmer to immediately check the Home Monitoring function.

Order numbers for Edora

The devices can be obtained as follows:

Edora 8 SR	407164	Edora 8 DR-T	407145
Edora 8 SR-T	407157	Edora 8 HF-T	407138
Edora 8 DR	407152	Edora 8 HF-T QP	407137

Package contents

The storage package includes the following:

- Sterile packaging with device
- Serial number label
- Patient ID card
- Warranty booklet

Note: The technical manual pertaining to the device is either included in hard copy form in the storage package or in digital form on the internet.

The sterile packaging includes the following:

- Device
- Screwdriver

Diagnostic and Therapy Functions

General overview

All the systems have extensive features that allow quick diagnosis and delivery of safe therapy for bradycardia conditions.

- Automatic functions make it easy and fast to implant, configure, and check the pacemaker.
- Auto-initialization after implantation: The device recognizes the implanted leads autonomously and sets the polarity. The automatic functions of the software are activated after 10 min.

Diagnostics functions

- Data from the last interrogations and follow-ups are recorded as well as arrhythmia episodes; they are stored together with other data to assess the state of both the patient and the device at any time.
- Continuous automatic below-threshold impedance measurements are performed in the device independent of the pacing pulse in order to check the lead for proper functioning.
- Once a telemetry connection has been established during a test procedure in an in-office follow-up, the IEGM is displayed with markers.

Antibradycardia pacing

- Sensing: The amplitudes of the P and R waves are measured in the implanted device fully automatically and permanently to record varying amplitudes. The sensitivity for the atrium and ventricle is adapted automatically on an ongoing basis. The measurement data are averaged and the trend can be displayed.
- Pacing thresholds: Pacing thresholds are automatically identified in the device, in single and dual-chamber devices the right ventricular, in triple-chamber devices the right and left ventricular pacing thresholds. Capture control adjusts the pulse amplitudes in such a way that every change of the pacing threshold results in the patient being paced at an optimal amplitude.
- Timing: Pacing in the atrium is checked particularly carefully in dual and triple-chamber devices by an automatic adaptation of the atrial refractory period in order to avoid pacemaker-mediated tachycardia (Auto PVARP function: the postventricular atrial refractory period is adapted automatically).
- Additional, special form of rate adaptation: An increased cardiac output requirement is detected using physiological impedance measurement. The measuring principle is based on contractile changes (ionotropy) of the myocardium (CLS function: Closed Loop Stimulation). Rate adaptation is automatically initialized and optimized in CLS mode.
- Ventricular pacing suppression with devices from the 8 series: Unnecessary ventricular pacing is avoided by promoting intrinsic conduction (Vp suppression function). The device can adapt itself to conduction changes. In the case of intrinsic conduction, the device switches from a DDD(R) to an ADI(R) mode.
- In the course of the follow-up, an automatic test of the AV delay is performed to improve the heart performance. AV delays are calculated; the optimum values can be applied.

Resynchronisation therapy

Triple-chamber devices have functions to configure different VV delays in order to resynchronize the ventricles.

- Capture Control is also available for the left ventricle with automated tracking of the pacing threshold or automatic threshold monitoring (ATM) for trend analysis.
- To ensure that no additional surgery is necessary in case of a left-sided increase of pacing threshold or undesired phrenic nerve stimulation, different pacing polarities can be set for the left ventricular lead with a triple-chamber device. Up to 13 vectors can be used with the HF QP device type.
- With the QP device type, the LV vector test provides a fast measurement of the pacing threshold, the phrenic nerve pacing threshold and the pacing impedance. The relative influence on the service time is also displayed. The measurement results are evaluated automatically so that the optimal pacing polarity can be set.

  The short RV-LV conduction test supports also the selection.
- An additional diagnostic function with biventricular pacing: Variability of the heart rate, patient activity, and thoracic impedance are monitored on a continual basis.

Programs

There are two types of therapy programs:

- Default parameters are offered for the most common indications (ProgramConsult function).
- Individual settings can be saved in 3 individual therapy programs.

ProMRI devices recognize magnetic resonance imaging devices

The static magnetic field of magnetic resonance imaging devices is reliably recognized with the aid of a sensor. This sensor can be activated for a maximum of 14 days using the MRI AutoDetect function during an interrogation.

If the patient comes near a magnetic resonance imaging device within the time set, the implanted device recognizes the static magnetic field and automatically activates the preset MRI program. Reprogramming to the permanent program occurs also automatically after leaving the imaging device.

Home Monitoring functions

The device automatically sends information to the transmitter once a day. In addition to this, test messages can be initiated using the programmer. Important medical information includes, among others, the following:

- Ongoing atrial and ventricular arrhythmia
- Parameters relevant to leads in the atrium and ventricle: thresholds, sensing amplitudes, impedances
- Current statistics on bradycardia therapy
- Individually adjustable timing interval for device messages which provide additional information pertaining to the device messages
- IEGM online HD® with up to 3 high definition channels
- Transmission of these IEGM recordings with device messages

2 General Safety Instructions

CAUTION
Safety information Cardiac electrotherapy is subject to special operating conditions and possible complications and risks. • Please take all precautionary measures carefully into account.

Operating Conditions

Technical manuals

The following technical manuals provide information about usage of the device systems:

— Technical manual for the device

— Technical manual for the HMSC

— Technical manuals for leads

— Technical manuals for the programmer and its accessories

— Technical manuals for the user interface

— Technical manuals for cables, adapters and accessories

- Technical manuals are either included in hard copy form in the storage package or in digital form on the internet:
  manuals.biotronik.com
- Follow all relevant technical manuals.
- Keep technical manuals for later use.

Care during shipping and storage

- Devices are not to be stored close to magnets or sources of electromagnetic interference.
- Note the effects of the storage period; see Battery Data.

Temperature

Extremely low and high temperatures affect the service time of the battery in the device.

- Permitted for shipping and storage:
  –10°C to +45°C

Sterile delivery

The device and the screwdriver have been gas-sterilized. Sterility is guaranteed only if the blister and quality control seal have not been damaged.

Sterile packaging

The device and screwdriver are each packaged in 2 separately sealed blisters. The inner blister is also sterile on the outside so that it can be transferred in a sterile state during implantation.

Single use only

The device and screwdriver are intended for single use only.

- Do not use the device if the package is damaged.
- The device must not be resterilized and reused.

Possible Complications

General information on medical complications

Complications for patients and device systems generally recognized among practitioners also apply to BIOTRONIK devices.

- Normal complications may include fluid accumulation within the device pocket, infections, or tissue reactions. Primary sources of complication information include current scientific and technological knowledge.
- It is not possible to guarantee the efficacy of antiarrythmia therapy, even if the programs have proven successful during tests or subsequent electrophysiological examinations. In rare cases the set parameters can become ineffective. In particular it is inevitable that tachyarrhythmias may be induced.

Skeletal myopotentials

Bipolar sensing and control of sensitivity are adapted by the device to the rate range of intrinsic events so that skeletal myopotentials are usually not sensed. Skeletal myopotentials can nonetheless be classified as intrinsic events especially with a unipolar configuration and/or very high sensitivity and, depending on the interference, may cause inhibition or antiarrhythmia therapy.

Nerve and muscle stimulation

A device system consisting of a unipolar lead and an uncoated device may result in undesirable pacing of the diaphragm in the case of an initial or permanent high setting of the pulse amplitude.

Possible technical failures

Technical failure of a device system cannot be entirely ruled out. Possible causes may include the following:

- Lead dislodgement
- Lead fracture
- Insulation defects
- Device component failures
- Battery depletion

Electromagnetic interference (EMI)

Any device can be sensitive to interference, for example, when external signals are sensed as intrinsic rhythm.

- BIOTRONIK devices have been designed so that their susceptibility to EMI is minimal.
- Due to the intensity and variety of EMI, there is no guarantee for safety. It is generally assumed that EMI produces only minor symptoms in patients - if any.
- Depending on the pacing mode and the type of interference, sources of interference may lead to pulse inhibition or triggering, an increase in the sensor-dependent pacing rate or asynchronous pacing.
- Under unfavorable conditions, for example during diagnostic or therapeutic procedures, interference sources may induce such a high level of energy into the pacing system that the cardiac tissue surrounding the lead tip is damaged.

Device behavior in case of EMI

In the case of electromagnetic interference or undesired myopotentials, the device paces asynchronously for the duration of the time that the interference rate is exceeded.

Static magnetic fields

The pacemaker switches to magnet response from a field strength > 1.0 mT.

Possible Risks

Procedures to avoid

The following procedures must be avoided as they may cause harm to the patient or damage the device and, as a result, put the system functionality at risk:

- Therapeutic ultrasound
- Transcutaneous electrical nerve stimulation
- Hyperbaric oxygen therapy
- Applied pressures higher than normal pressure

Potentially risky therapeutic and diagnostic procedures

If electrical current from an external source is conducted through the body for diagnostic or therapeutic purposes, then the device can be subjected to interference and the patient placed at risk.

Arrhythmia or ventricular fibrillation can be induced during diathermic procedures such as electrocautery, HF ablation or HF surgery. For example, damaging pressure levels may arise during lithotripsy. Influences on the device are not always immediately clear.

If potentially risky procedures cannot be avoided, the following should be observed at all times:

- Electrically insulate patients.
- Switch the pacemaker function to asynchronous modes if needed.
- Do not introduce energy near the device system.
- Check the peripheral pulse of the patient.
- Monitor the patient during and after every intervention.

External defibrillation

The device is protected against the energy that is normally induced by external defibrillation. Nevertheless, any implanted device may be damaged by external defibrillation. Specifically, the current induced in the implanted leads may result in necrotic tissue formation close to the electrode/tissue interface. As a result, sensing properties and pacing thresholds may change.

- Place adhesive electrodes anterior-posterior or perpendicular to the axis formed by the device to the heart at least 10 cm away from the device and from implanted leads.

Radiation therapy

The use of radiation therapy must be avoided due to possible damage to the device and the resulting impaired functional safety. If this type of therapy is to be used anyway, prior risk/benefit analysis is absolutely necessary. The complexity of influencing factors such as different sources of radiation, a variety of devices and therapy conditions makes it impossible to issue directives that guarantee radiation therapy without an impact on the device. The EN 45502 standard pertaining to active implantable medical devices requires the following measures during the administration of therapeutic ionizing radiation:

- Adhere to instructions for potentially risky therapeutic and diagnostic procedures.
- Shield device against radiation.
- After applying radiation, double-check the device system to make sure it is functioning properly.

Note: Please contact BIOTRONIK with questions on the risk/benefit analysis.

Magnetic resonance imaging

Magnetic resonance imaging must be avoided due to the associated high frequency fields and magnetic flux density: Damage or destruction of the device system by strong magnetic interaction and damage to the patient by excessive warming of the body tissue in the area surrounding the device system.

Under certain conditions and when maintaining mandatory measures to protect the patient and the device system, magnetic resonance imaging can be performed. BIOTRONIK devices with the "MR conditional" function bear the identification ProMRI.

- The ProMRI manual – MR conditional device systems – contains detailed information on safely conducting an MRI.
  - Download the digital manual from the web site: manuals.biotronik.com
  - Order the printed manual at BIOTRONIK.
- Does approval as "MR conditional" apply in your country or region? Ask for current information at BIOTRONIK.

3 Implantation

Implantation Procedure

Having parts ready

The following parts that correspond to the requirements of the EC Directive 90/385/EEC are required:

- Device with screwdriver from BIOTRONIK
- BIOTRONIK leads and lead introducer set
  - Single-chamber device: unipolar or bipolar lead for the right ventricle
  - Dual-chamber device: one unipolar or bipolar lead each for the atrium and for the right ventricle
  - Triple-chamber device: an additional unipolar, bipolar, or quadripolar LV lead
- Approved connections are IS-1 and IS4: Use only adapters approved by BIOTRONIK for leads with different connections or leads from other manufacturers.
- BIOTRONIK programmer (with integrated wandless telemetry or with separate SafeSync Module) and approved cables
- External multi-channel ECG device
- Keep spare parts for all sterile components.

Keeping an external defibrillator ready

In order to be able to respond to unforeseeable emergencies or possible technical failures of the device:

- Keep an external defibrillator and paddles or adhesive electrodes ready.

Unpacking the device

WARNING
Inadequate therapy due to defective device If an unpacked device is dropped on a hard surface during handling, electronic parts could be damaged. • Use a replacement device. • Return the damaged device to BIOTRONIK.

- Peel the sealing paper off of the outer blister at the marked position in the direction indicated by the arrow. The inner blister must not come into contact with persons who have not sterilized their hands or gloves, nor with non-sterile instruments.
- Use the gripping tab on the inner blister to remove it from the outer blister.
- Peel the sealing paper off of the sterile inner blister at the marked position in the direction indicated by the arrow.

Note: The device is disabled on delivery and can be implanted immediately after unpacking without manual activation.

Checking parts

Damage to any of the parts can result in complications or technical failures.

- Check for damage before and after unpacking all parts.
- Replace damaged parts.

Implantation site

In general, the pacemaker is implanted subcutaneously or subpectorally, depending on the lead configuration as well as the anatomy of the patient.

Overview: Implanting

1	Shape the device pocket and prepare the vein.
2	Implant the leads and perform measurements.
3	Connect device and leads.
4	Insert the device. The device starts auto-initialization on its own.
5	Guide the fixation suture through the opening in the header and fixate the device in the prepared device pocket.
6	Close the device pocket.
7	Prior to testing and configuration, wait for the successful completion of automatic device initialization.

Note: If necessary, the device can also be programmed before or during auto-initialization.

Avoid damage to the header

Set screws must be tightened or loosened with care.

- Loosen set screws with the supplied screwdriver. Use only BIOTRONIK screwdrivers with torque control!
- If lead revision is necessary, re-order sterile screwdrivers from BIOTRONIK.

Preventing short circuits in the header

WARNING

Short circuit due to open lead connector ports

Connector ports in the header which are open and thus not electrolyte-proof may cause undesired current flows to the body and penetration of body fluid into the device.

- Close unused connector ports with blind plugs.

Keeping distance between leads

WARNING

Inadequate therapy

Insufficient lead spacing or inappropriate lead positioning may lead to far-field sensing.

- Leads must not contact each other. Position the tip and ring of newly implanted leads with a sufficient distance from old implanted leads.

Connecting the lead connector to the device

1	Remove stylets and stylet guides.
2	• Connect the unipolar or bipolar IS-1 lead connector for the right ventricle to RV. • Connect the unipolar or bipolar IS-1 lead connector atrium to A. • Connect the unipolar or bipolar IS-1 or the quadripolar IS4 lead connector for the left ventricle to LV.
3	Push the lead connector into the header without bending the conductor until the connector tip becomes visible behind the set screw block.
4	If the lead connector cannot be inserted completely, the set screw may be protruding into the drill hole of the set screw block. Carefully loosen the set screw without completely unscrewing it, so that it does not become tilted upon retightening.
5	Use the screwdriver to perpendicularly pierce through the slitting in the center of the silicone plug until it reaches the set screw.
6	Turn the set screw clockwise until the torque control starts (you will hear a clicking sound).
7	Carefully withdraw the screwdriver without retracting the set screw. • When the screwdriver is withdrawn, the silicone plug automatically seals the lead connection safely.

Applying the programming head

The programming head (PGH) features a diagram of the device. This is used to assist in positioning the head to ensure proper telemetry.

- Make sure the PGH is positioned correctly.

Establishing wandless telemetry

The programmer must be no less than 20 cm and no more than 3 m from the device; ideally there should be no hindrances between the patient and the programmer.

- Switch on wandless telemetry on the programmer.
- Apply the programming head for about 2 s until successful initialization is displayed on the programmer:

  The wandless telemetry symbol is displayed in the navigator and the signal strength is displayed in the status line.

- Remove the programming head.

Auto-initialization

Auto-initialization begins automatically once the first connected lead is sensed.

Auto-initialization is usually terminated 10 minutes after connection of the first lead. If no other program has been transferred in the meantime, the device subsequently works with active automatic functions in the factory settings or with the preset program of the user.

Manual setting of the lead polarity or measurement of lead impedances is not necessary.

Note: After auto-initialization, all parameters are activated as in the standard program.

Behavior during auto-initialization

- During transmission of a permanent program:
  Auto-initialization is terminated and the transferred program is active.
- During testing:
  Tests cannot be performed during auto-initialization; stop it beforehand. Auto-initialization will not be continued upon completion of the test.

Precautionary Measures while Programming

CAUTION
Safety information
The programming of device systems requires special precautions. • Please carefully take all precautionary measures into account.

Checking the device system

- After auto-initialization, perform a follow-up to see if the device system is functioning properly.
- Perform a pacing threshold test to determine the pacing threshold.

Performing standard tests and monitoring the patient

Critical conditions can occur for the patient even during standard tests due to inadequate parameter settings or interrupted telemetry.

- Ensure sufficient patient care even during tests.
- After the threshold test, check to determine whether the threshold is clinically and technically justifiable.
- Continuously monitor the ECG and the patient's condition.
- Cancel testing if necessary.

Do not interrupt wandless telemetry during a treatment

Disconnecting the SafeSync Module from the programmer can result in interference with or termination of the SafeSync wandless telemetry.

- Do not disconnect the SafeSync Module from the programmer.
- Do not take the Operation Module off the ICS 3000.

Cancelling telemetry

Programmer interference or interrupted telemetry during performance of temporary programs (follow-up tests) can result in inadequate pacing of the patient. This is the case if the programmer can no longer be operated due to a program error or a defective touch screen and therefore the temporary program cannot be terminated. Under these circumstances, it is helpful to cancel telemetry, in which case the device automatically switches to the permanent program.

- In the case of telemetry with PGH: lift the programming head by at least 30 cm.
- In the case of wandless telemetry: switch off and reposition the programmer.
- Turn off possible sources of interference.

Avoiding critical parameter settings

No modes and parameter combinations that pose a risk to the patient should be set.

- Prior to setting rate adaptation, determine the patient's capacity for strain.
- Check compatibility and effectiveness of parameter combinations after making settings.

Manually setting lead polarity

Due to the risk of an entrance/exit block, bipolar lead polarity (sensing/pacing) should only be set if bipolar leads are implanted.

Setting sensing

Manually set parameters can be unsafe. For example, unsuitable far-field protection may impede sensing of intrinsic pulses.

- Use automatic sensitivity control.

Setting the sensitivity

A value set to < 2.5 mV/unipolar for device sensitivity may result in noise caused by electromagnetic fields.

- Therefore, it is recommended that a value of ≥ 2.5 mV/unipolar be set according to paragraph 28.22.1 of the EN 45502-2-1 standard. Setting sensitivity values < 2.5 mV/unipolar requires explicit clinical need. Values like this must only be set and retained with physician supervision.

Preventing device-induced complications

BIOTRONIK devices are equipped with several functions to prevent device-induced complications to the greatest extent possible:

- Measure the retrograde conduction time.
- If the function is not yet automatically set: activate PMT protection.
- Set the VA criterion: The aim is to set a VA criterion that is longer than the longest measured retrograde conduction time.

Preventing conduction of atrial tachycardia

BIOTRONIK devices are equipped with several functions to prevent conduction of atrial tachycardia to the ventricle(s):

- Set Mode Switching for indicated patients.
- Set the upper rate and the refractory periods to prevent abrupt ventricular rate switching.
- Prefer Wenckebach response and avoid 2:1 behavior.
- Set all parameters so as to prevent constant changing between atrial and ventricular-controlled modes.

Phrenic nerve stimulation that cannot be terminated

With LV pacing, chronic phrenic nerve stimulation can in rare cases not be terminated by reprogramming the available left ventricular pacing configurations or by other measures.

- Possibly set a right ventricular mode both in the permanent program and for Mode Switching.

Avoiding risks in the case of exclusive left ventricular pacing

Lead dislodgement in the case of exclusive left ventricular pacing could pose the following risks: loss of ventricular pacing as well as induction of atrial arrhythmia.

- Consider sensing and pacing parameters with reference to loss of therapy.
- Exclusive left ventricular pacing is not recommended for patients who depend on the device.
- Take possible interruption of automatic Active Capture Control into consideration.
- In the case of follow-ups and threshold tests, take loss of synchronized ventricular pacing into consideration.
- Mode Switching does not allow exclusive left ventricular pacing; consider the consequences when setting Mode Switching parameters.

If an ICD is implanted at the same time, do not permit unipolar pacing

If an ICD is implanted in addition to a pacemaker and a lead failure occurs, it is possible to switch to unipolar pacing after resetting the pacemaker or using the automatic lead check. As a result, the ICD could falsely inhibit or trigger tachyarrhythmiatherapy activity.

- Unipolar leads are not permitted in this configuration.

Recognizing lead failure

Automatic impedance measurement is always switched on.

- Impedance values that indicate technical failure of a lead are documented in the event list.

Consider power consumption and service time

The pacemaker permits programming of high pulse amplitudes with long pulse widths at high rates to be able to adequately treat even rare diagnoses. In combination with low lead impedance, this results in a very high level of power consumption.

- When programming large parameter values, take into account that the replacement indication ERI will be reached very early because the service time of the battery may be reduced to less than 1 year.

Home Monitoring: The CardioMessenger should be relatively close to the patient; if it is too far away, the device constantly seeks and consumes more power than necessary.

- Home Monitoring ON reduces the service time by approximately 15% in single- and dual-chamber devices and by approximately 10% in triple-chamber devices.

Wandless telemetry: 15 minutes of usage reduces the service time by approximately 7 days.

- Do not establish unnecessary wandless telemetry.
- After 5 min without input, the device switches to the economy mode.
- Check the battery capacity of the device at regular intervals.

Magnet Response

Programming head application

When the programming head is applied, time remains for device interrogation before the device switches back to the previously set permanent therapy mode. The same applies to programming head application to establish wandless telemetry contact.

Magnet response in standard program

Applying a magnet or the programming head can result in an unphysiological rhythm change and asynchronous pacing. The magnet response is set as follows in the standard program of BIOTRONIK pacemakers:

- Asynchronous:
  For the duration of the magnet application – mode D00 (where applicable V00 / A00) without rate adaptation;
  Magnet rate: 90 bpm
- Automatic:
  For 10 cycles – mode D00, subsequently mode DDI without rate adaptation;
  Magnet rate: 10 cycles with 90 bpm, subsequently set basic rate
- Synchronous:
  Mode DDD (where applicable: VVI) without rate adaptation;
  Magnet rate: set basic rate

Note: See also the replacement indication information for magnet response at ERI.

Magnet application by patients

If patients are performing their own magnet application, the synchronous magnet response must have been programmed. Patients should also know the following:

- When may the magnet be used?
  In cases of severe dizziness and indisposition.
- How long is the magnet placed on the pacemaker?
  1 to 2 s.
- What happens when the magnet is applied?
  The IEGM of the last 10 seconds is stored.
- What has to happen after magnet application?
  The patient has to contact the physician for a follow-up.

Follow-up

Follow-up intervals

Follow-ups must be performed at regular, agreed intervals.

- Following the lead ingrowth phase, approximately 3 months after implantation, the first follow-up should be carried out by the physician using the programmer (in-office follow-up).
- The next in-office follow-up should be carried out once a year and no later than 12 months after the last in-office follow-up.

Follow-up with BIOTRONIK Home Monitoring®

Monitoring using the Home Monitoring function does not serve to replace regular in-office appointments with the physician required for other medical reasons.

Follow-up supported by Home Monitoring can be used to functionally replace in-office follow-up under the following conditions:

- The patient was informed that the physician must be contacted if symptoms worsen or if new symptoms arise despite the use of the Home Monitoring function.
- Device messages are transmitted regularly.
- The physician decides whether the data transmitted via Home Monitoring with regard to the patient's clinical condition as well as the technical state of the device system are sufficient. If not, an in-office follow-up has to be carried out.

Possible early detection due to information gained via Home Monitoring may necessitate an additional in-office follow-up. For example, the data may indicate at an early stage lead problems or a foreseeable end of service time (ERI). Furthermore, the data could provide indications of previously unrecognized arrhythmias or regarding modification of therapy by reprogramming the device.

Follow-up with the programmer

Use the following procedure for in-house follow-up:

1	Record and evaluate the ECG.
2	Interrogate the device.
3	Evaluate the status and automatically measured follow-up data.
4	Check the sensing and pacing functions.
5	Manually perform standard tests if necessary.
6	Possibly evaluate statistics and IEGM recordings.
7	Possibly adjust program functions and parameters.
8	Transmit the program permanently to the device.
9	Print and document follow-up data (print report).
10	Finish the follow-up for this patient.

Patient Information

Patient ID card

A patient ID card is included in delivery.

- Provide the patient with the patient ID card.
- Request that patients contact the physician in case of uncertainties.

Prohibitive signs

Premises with prohibitive signs must be avoided.

- Draw the patient's attention to prohibitory signs.

Possible sources of interference

Electromagnetic interference should be avoided in daily activities. Sources of interference should not be brought into close proximity of the device.

- Draw the patient's attention to special household appliances, security checkpoints, anti-theft alarm systems, strong electromagnetic fields, cellular phones, and transmitters among other things.
- Request patients to do the following:
  - Use cellular phones on the opposite side of their body from the device.
  - Keep the cellular phone at least 15 cm away from the device both during use and when stowing.

Replacement Indications

Possible charging status

The time span from the beginning of service (BOS) to elective replacement indication (ERI) is determined by, among others, the following:

- Battery capacity
- Lead impedance
- Pacing program
- Pacing to inhibition ratio
- Pacemaker circuit properties

The following are the defined pacemaker operational statuses:

- BOS: Beginning of Service: > 90%
- ERI: Elective Replacement Indication (i.e., RRT: Recommended Replacement Time)
- EOS: End of Service

ERI activation

ERI detection is automatically activated after the following events:

- Successful auto-initialization

ERI display

ERI is displayed as follows:

- On the programmer after interrogation of the pacemaker
- By a defined decrease in the basic rate as well as the magnet rate

Rate decrease

The decrease of basic rate and magnet rate is defined as follows:

- In the following modes, the pacing rate decreases by 11%:
  DDD(R); DDT; D00(R); VDD(R); VDI(R); VVI(R); VVT; AAI(R); AAT; A00(R)
- In the modes DDI(R) and DVI(R), only the VA interval is extended by 11%. This reduces the pacing rate by up to 11%, depending on the configured AV delay.

Change of the mode with ERI

This change depends on the mode which is set. It is displayed on the programmer.

- Single-chamber modes: VVI
- Dual-chamber modes: VDD
- Triple-chamber modes: Dual-chamber pacing, one biventricular setting is kept

Deactivated functions with ERI

The following functions are deactivated:

- Atrial pacing
- Night program
- Rate adaptation
- Atrial and ventricular capture control
- Rate fading
- Atrial overdrive pacing
- IEGM recordings
- Statistics
- Home Monitoring
- Rate hysteresis
- Ventricular pacing suppression

Magnet response at ERI

After reaching ERI, pacing is performed as follows after applying the magnet or programming head:

Magnet response	Cycles 1 to 10	After 10th cycle
Automatic	Asynchronous with 80 bpm	Synchronous with basic rate reduced by 11%
Asynchronous	Asynchronous with 80 bpm	Asynchronous with 80 bpm
Synchronous	Synchronous with basic rate reduced by 11%	Synchronous with basic rate reduced by 11%

Expected service times after ERI

The information is based on the following:

- Lead impedance of 500 Ω or 600 Ω
- 100% pacing
- Interval from ERI to EOS for the single-chamber device in AAI(R)/VVI(R) mode, for the dual and triple-chamber device in DDD(R) mode
- Standard program with both high and low pacing energy
- Data of the battery manufacturer (see the battery data)

110 bpm **4.6 V** **1.5 ms** **500 Ω**	**30 bpm** **0.2 V** **0.1 ms** **500 Ω**	**70 bpm** **2.5 V** **0.4 ms** **500 Ω**	**70 bpm** **5.0 V** **0.4 ms** **500 Ω**	**60 bpm** **2.5 V** **0.4 ms** **600 Ω**	**60 bpm** **5 V** **0.4 ms** **600 Ω**
Mean value: 8 months Minimum value: 6 months		— Minimum value: 6 months		— Minimum value: 6 months	

Explantation and Device Replacement

Explantation

- Disconnect the leads from the header.
- Remove the device and, if necessary, leads using state-of-the-art technology.
- Explants are biologically contaminated and must be disposed of safely due to risk of infection.

Device replacement

The following applies to leads from a previous device that are intended for further use:

- Check the leads prior to connecting to the new device.

If, upon replacing the device, already implanted leads are no longer used but left in the patient, then an additional uncontrolled current path to the heart can result.

- Isolate unused lead connectors and close unused connector ports.

Basic principles:

- The device must not be resterilized and reused.

Cremation

Devices should not be cremated.

- Explant the device before the cremation of a deceased patient.

Disposal

BIOTRONIK takes back used products for the purpose of environmentally safe disposal.

- Clean the explant with a solution of at least 1% sodium hypochlorite.
- Rinse with water.
- Fill out explantation form and send to BIOTRONIK together with the cleaned device.

4 Parameters

Note: Unless described separately, information for device type HF also applies to device type HF QP.

Timing

Basic rate day/night

Parameter	Range of values	Standard	SR	DR	HF
Basic rate	30 ... (5) ... 100 ... (10) ... 200 bpm	60 bpm	x	x	
		50 bpm			x
Night rate	OFF; 30 ... (5) ... 100 ... (10) ... 200 bpm	OFF	x	x	x
Night begins	00:00 ... (10 min) ... 23:50 hh:mm	—	x	x	x
Night ends					

Rate hystereses

Parameter	Range of values	Standard	SR	DR	HF
Hysteresis	OFF; -5 ... (-5) ... -25 ... (-20) ... -65 bpm	OFF	x	x	x
Repetitive/ search cycles	OFF; ON	OFF	x	x	x

AV delay

Parameter	Range of values	Standard	SR	DR	HF
AV delay	Low; Medium; High; Fixed; Individual	Low		x	x
	20 ... (5) ... 350 ms (in 6 rate ranges)	180-170-160-150-140 ms		x	
	CLS and all HF modes: 20 ... (5) ... 350 ms (in 6 rate ranges)	150-140-130-120-120 ms		x	x
Sense compensation	OFF; -10 ... (-5) ... -120 ms	-45 ms		x	x

AV hystereses

Parameter	Range of values	Standard	SR	DR	HF
AV hysteresis mode	OFF; Positive; Negative HF when setting RV: IRSplus	OFF		x	x
Positive modes: AV hysteresis	70; 110; 150; 200 ms	70 ms CLS modes: 110 ms		x	x
Negative modes: AV hysteresis	10 ... (10) ... 150 ms	50 ms		x	x
AV repetetive / scan cyles	OFF; ON	ON		x	x

Ventricular pacing

Parameter	Range of values	Standard	SR	DR	HF
Ventricular pacing	BiV, RV; LV	BiV			x
Triggering	OFF; RVs; RVs + PVC	RVs			x
LV T-wave protection	ON; OFF	ON			x
Maximum trigger rate	AUTO; 90 ... (10) ... 160 bpm	AUTO			x
Initially paced chamber	RV; LV	LV			x
VV delay after Vp	0 ... (5) ... 80 ... (10) ... 100 ms	0 ms			x
VV delay after Vs	0 ms	0 ms			x

Upper rate

Parameter	Range of values	Standard	SR	DR	HF
Upper rate SR: in VVT mode	90 ... (10) ... 200 bpm	130 bpm	x	x	x
Wenckebach response/ 2:1 rate	Automatically set	—		x	x
Atrial upper rate	OFF; 175; 200; 240 bpm	240 bpm		x	x

Mode switching

Parameter	Range of values	Standard	SR	DR	HF
Mode switching	OFF; ON	ON		x	x
Intervention rate	100 ... (10) ... 250 bpm	160 bpm		x	x
Switch to mode	DDI; DDI(R) when permanent DDD(R) VDI; VDI(R) when permanent VDD(R)	DDI(R)		x	x
Ventricular pacing	RV; BiV	BiV			x
Onset criterion	3 ... (1) ... 8 (out of 8)	5		x	x
Resolution criterion				x	x
Change of the basic rate with mode switching	OFF; +5 ... (5) ... +30 bpm	+10 bpm			
Rate stabilization with mode switching	OFF; ON	OFF		x	x
2:1 lock-in protection	OFF; ON	ON		x	
	When setting RV: OFF; ON	ON			x

Ventricular pacing suppression

Parameters valid for devices in DDD-ADI or DDDR-ADIR modes:

Parameter	Range of values	Standard	SR	DR	HF
Vp suppression	OFF; ON	OFF		x	x
Pacing suppression after consecutive Vs	1 ... (1) ... 8	6		x	x
Pacing support after x cycles	1 ... (1) ... 4 (out of 8)	3		x	x

Refractory periods

Parameter	Range of values	Standard	SR	DR	HF
RV refractory period	200 ... (25) ... 500 ms	250 ms	x	x	x
Atrial refractory period	AUTO	AUTO		x	x
Atrial refractory period in the modes AAI(R); AAT(R); DDT	300 ... (25) ... 775 ms	350 ms		x	x
LV refractory period	200 ms	200 ms			x
AUTO PVARP	OFF; ON	ON		x	x
PVARP	175 ... (25) ... 600 ms	225 ms		x	x
PVARP after PVC	PVARP + 150 ms (max: 600 ms)	Automatically set		x	x

Blanking periods

Parameter	Range of values	Standard	SR	DR	HF
Far-field protection after Vs	100 ... (10) ... 220 ms	100 ms		x	x
Far-field protection after Vp	100 ... (10) ... 220 ms	150 ms		x	x
Ventricular blanking period after Ap	30 ... (5) ... 70 ms	30 ms		x	x

PMT protection

Parameter	Range of values	Standard	SR	DR	HF
PMT protection	OFF; ON	ON		x	x
VA criterion	250 ... (25) ... 500 ms	350 ms		x	x

Pacing and Sensing

Pulse amplitude and pulse width

Parameter	Range of values	Standard	SR	DR	HF
Pulse amplitude A/RV/LV	0.2 ... (0.2) ... 6.0 ... (0.5) ... 7.5 V	3.0 V	x	x	x
Pulse width A/RV/LV	0.1 ...(0.1) ... 0.5 ... (0.25) ... 1.5 ms	0.4 ms	x	x	x

Sensitivity

Parameter	Range of values	Standard	SR	DR	HF
Sensitivity	AUTO; 0.5 ... (0.5) ... 7.5 mV	AUTO	x		
Sensitivity A	AUTO; 0.1 ... (0.1) ... 1.5 ... (0.5) ... 7.5 mV	AUTO		x	x
RV sensitivity	AUTO; 0.5 ... (0.5) ... 7.5 mV	AUTO	x	x	x
LV sensitivity	OFF; AUTO; 0.5 ... (0.5) ... 7.5 mV	AUTO			x

Atrial capture control

Parameter	Range of values	Standard	SR	DR	HF
Atrial capture control	ATM (monitoring only); ON; OFF	ON		x	x
Minimum amplitude	0.5 ... (0.1) ... 4.8 V	1.0 V		x	x
Threshold test start	2.4 ... (0.6) ... 4.8 V	3.0 V		x	x
Safety margin	0.5 ... (0.1) ... 1.2 V	1.0 V		x	x
Search type	Interval; time of day	Time of day		x	x
Interval	0.1; 0.3; 1; 3; 6; 12; 24 h	24 h		x	x
Time of day	00:00 ... (00:10) ... 23:50 hh:mm	00:30 hh:mm		x	x

Ventricular capture control

Parameter	Range of values	Standard	SR	DR	HF
Capture control RV	ATM (monitoring only); ON; OFF	ON	x	x	x
Capture control LV					x
Minimum amplitude RV	0.7 V	0.7 V	x	x	x
Minimum amplitude LV					x
Threshold test start	2.4 ... (0.6) ... 4.8 V	3.0 V	x	x	x
RV safety margin	0.3 ... (0.1) ... 1.2 V	0.5 V	x	x	
LV safety margin	1.0; 1.2 V	1.0 V			x
Search type	Interval; time of day	Time of day	x	x	x
Interval	0.1; 0.3; 1; 3; 6; 12; 24 h	24 h	x	x	x
Time of day	00:00 ... (00:10) ... 23:50 hh:mm	00:30 hh:mm	x	x	x

Atrial overdrive pacing

Parameter	Range of values	Standard	SR	DR	HF
Atrial overdrive pacing	OFF; ON With ON: maximum over-pacing rate 120 bpm, mean rate increase approximately 8 bpm, rate decrease after 20 cycles	OFF		x	x

Lead configuration

Parameter	Range of values	Standard	SR	DR	HF
Sensing polarity A	Unipolar; bipolar	Unipolar	x	x	x
Sensing polarity RV	Unipolar; bipolar	Unipolar	x	x	x
Sensing polarity LV	Unipolar; bipolar	Unipolar			x
Pacing polarity A	Unipolar; bipolar	Unipolar	x	x	x
Pacing polarity RV	Unipolar; bipolar	Unipolar	x	x	x
Pacing polarity LV	Device type HF: LV1 tip -> LV2 ring LV1 tip -> RV ring LV2 ring -> LV1 tip LV2 ring -> RV ring LV1 tip -> housing LV2 ring -> housing	LV1 tip –> housing			x
	Device type HF QP LV1 tip -> LV2 ring LV1 tip -> LV4 ring LV1 tip -> RV ring LV1 tip -> housing LV2 ring -> LV1 tip LV2 ring -> LV4 ring LV2 ring -> RV ring LV2 ring -> housing LV3 ring -> LV2 ring LV3 ring -> LV4 ring LV3 ring -> RV ring LV4 ring -> LV2 ring LV4 ring -> RV ring	LV1 tip –> LV2 ring			x

IEGM recordings

Parameter	Range of values	Standard	SR	DR	HF
Number of recordings (each max. 10 s)	12 20	—	x	x	x
High atrial rate (HAR)	OFF; AT; mode switching	AT	x	x	x
High ventricular rate (HVR)	OFF; ON	ON	x	x	x
Patient triggering (triggered by patient)	OFF; ON	OFF	x	x	x
Pre-trigger recording	0; 25; 50; 75; 100%	75%	x	x	x
IEGM signal	Filtered; Unfiltered	Filtered	x	x	x

Rates for statistics

Parameter	Range of values	Standard	SR	DR	HF
HAR limit	100 ... (10) ... 250 bpm	200 bpm		x	x
HVR limit	150 ... (5) ... 200 bpm	180 bpm	x	x	x
HVR counter	4; 8; 12; 16 events	8 events	x	x	x
Start resting period	00:00 ... (1:00 AM) ... 23:00 hh:mm	2:00 hh:mm	x	x	x
Duration of resting period	0.5 ... (0.5) ... 12 h	4 h	x	x	x
Enable lead check	OFF; ON	ON	x	x	x

Rate Adaptation

CLS modes: closed loop stimulation

Parameter	Range of values	Standard	SR	DR	HF
Maximum CLS rate	80 ... (10) ... 160 bpm	120 bpm	x	x	x
CLS response	Very low; Low; Medium; High; Very high	Medium	x	x	x
CLS resting rate control	OFF; +10 ... (10) ... +50 bpm	+20 bpm	x	x	x
Vp required	Yes; No	No When BiV is set: Yes	x	x	x

R modes: Accelerometer

Parameters valid for devices with R modes:

Parameter	Range of values	Standard	SR	DR	HF
Sensor gain	AUTO; Very low; Low; Medium; High; Very high	AUTO	x	x	x
Max. activity rate	80 ... (10) ... 180 bpm	120 bpm	x	x	x
Sensor threshold	Very low; Low; Medium; High; Very high	Medium	x	x	x
Rate fading	OFF; ON	OFF	x	x	x
Rate increase	1; 2; 4; 8 bpm/cycle	2 bpm/cycle	x	x	x
Rate decrease	0.1; 0.2; 0.5; 1.0 bpm/cycle	0.5 bpm/cycle	x	x	x

MRI Program

MRI modes Modes valid for devices marked ProMRI:

Mode	Range of values	Standard	SR	DR	HF
MRI program	ON; OFF; AUTO	OFF	x	x	x
Expiration date	Today's date ... (1 day) ... today's date + 14 days	Today's date + 14 days	x	x	x
MRI mode	OFF; A00; V00	Dependent on permanent program	x		
	OFF; D00; A00; V00			x	
	OFF; D00; A00; V00; D00-BiV; V00-BiV				x

MRI parameters Preset parameters in the MRI program:

Parameter	Range of values	Standard	SR	DR	HF
Basic rate	70 ... (10) ... 160 bpm	90 bpm	x	x	x
AV delay	110 ms	110 ms		x	x
VV delay	0 ms	0 ms			x
Pulse amplitude A/RV	4.8 V	—	x	x	x
Pulse width A/RV	1.0 ms				
Pulse amplitude LV	0.2 ... (0.2) ... 6.0 ... (0.5) ... 7.5 V	As in permanent program			x
Pulse width LV	0.1 ... (0.1) ... 0.5 ... (0.25) ... 1.5 ms				

Preset Programs

Standard and safe program

Mode after auto-initialization:

Parameter	Factory setting	Standard	Safe program	SR	DR	HF
Mode	VVI	VVIR	VVI In the AAI mode, the safe program is also AAI.	x		
Mode	DDD	DDDR	VVI		x	x

Lead configuration, determined and set immediately after connection (auto lead check)

Parameter	Factory setting	Standard	Safe program	SR	DR	HF
Pacing polarity A/RV	Unipolar	Unipolar	Unipolar	x	x	x
Pacing polarity LV	TCUP	TCUP	TCUP			x
Sensing polarity A/RV	Unipolar	Unipolar	Unipolar	x	x	x
Sensing polarity LV	Unipolar	Unipolar	Unipolar			x
Automatic lead check	ON	ON	—	x	x	x

Parameters after auto-initialization:

Parameter	Factory setting	Standard	Safe program	SR	DR	HF
Basic rate	60 bpm	60 bpm	70 bpm	x	x	
	50 bpm	50 bpm				x
Night rate	OFF	OFF	OFF	x	x	x
Rate hysteresis	OFF	OFF	OFF	x	x	x
Upper rate	130 bpm	130 bpm	—		x	x
AV dynamics	Low	Low	—		x	x
AV hysteresis mode	OFF	OFF	—		x	x
Sense compensation	-45 ms	-45 ms	—		x	x
AV safety delay	100 ms	100 ms	—		x	x
VV delay	0	0	0			x
LV T-wave protection	ON	ON	ON			x
Far-field protection after Vs	100 ms	100 ms	—		x	x
Far-field protection after Vp	150 ms	150 ms	—		x	x
Ventricular blanking period after Ap	30 ms	30 ms	—		x	x
PMT protection	ON	ON	—		x	x
VA criterion	350 ms	350 ms	—		x	x
Magnet response	AUTO	AUTO	AUTO	x	x	x
Pulse amplitude A	3.0 V	3.0 V	—		x	x
Pulse amplitude RV	3.0 V	3.0 V	4.8 V	x	x	x
Pulse amplitude LV	3.0 V	3.0 V	4.8 V			x
Pulse width A	0.4 ms	0.4 ms	—		x	x
Pulse width RV	0.4 ms	0.4 ms	1.0 ms	x	x	x
Pulse width LV	0.4 ms	0.4 ms	1.0 ms			x
Sensitivity A	AUTO	AUTO	—		x	x
Sensitivity RV	AUTO	AUTO	2.5 mV	x	x	x
Sensitivity LV	AUTO	AUTO	2.5 mV			x

Parameter	Factory setting	Standard	Safe program	SR	DR	HF
Refractory period A	AUTO	AUTO	—		x	x
Refractory period RV	250 ms	250 ms	300 ms	x	x	x
Refractory period LV	200 ms	200 ms	200 ms			x
Mode switching	ON	ON	—		x	x
Onset criterion	5-out-of 8	5-out-of 8	—		x	x
Resolution criterion	5-out-of 8	5-out-of 8	—		x	x
Intervention rate	160 bpm	160 bpm	—		x	x
Switches to	DDIR	DDIR	—		x	x
The basic rate with mode switching	+10 bpm	+10 bpm	—		x	x
Rate stabilization with mode switching	OFF	OFF	—		x	x
PVARP	AUTO (Start 250 ms)	225 ms)	—		x	x
PVARP after PVC	400 ms	Automati-cally set	—		x	x
Capture control A	ON	ON	OFF	x	x	x
Capture control RV	ON	ON	OFF		x	x
Capture control LV	ON	ON	OFF			x
Atrial overdrive pacing	OFF	OFF	—		x	x
Vp suppression	OFF	OFF	—			x
IEGM recording (HAR)	ON	AT	OFF	x	x	x
IEGM recording (HVR)	ON	ON	OFF	x	x	x
Home Monitoring	OFF	OFF	OFF	x	x	x

Tolerances of Parameter Values

Parameter	Range of values	Tolerance
Basic rate	30 ... (5) ... 100 ... (10) ... 200 bpm	± 20 ms
Basic interval	1000 ms	± 20 ms
Magnet rate (magnet interval)	90 bpm (664 ms)	± 20 ms
Pulse amplitude	0.2 ... 7.5 V	The greater value of ±50 mV or +20/-25%
Pulse width	0.1 ... 1.5 ms	±10%
Sensitivity A EN 45502-2-1 triangle pulse	0.1 ... 0.2 mV	±0,05 mV
	0.3 ... 7.5 mV	±20%
Sensitivity RV/LV EN 45502-2-1 triangle pulse	0.5 ... 7.5 mV	±20%
Refractory period	200 ... 500 ms	± 20 ms
Maximum activity rate	80 ... 180 bpm	± 20 ms
Lead impedance	100 ... 200 Ω	±50 Ω
	201 ... 2500 Ω	±10%

5 Technical Data

Mechanical Characteristics

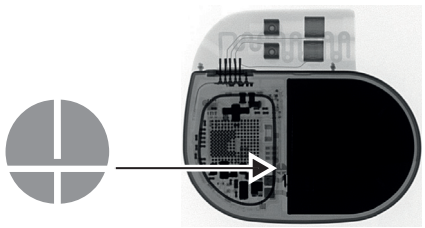
Measurements for the housing

Device	W x H x D [mm]	Volume [cm^3]	Mass [g]
Single-chamber SR(-T)	48 x 40 x 6.5	10	20.8
Dual-chamber DR(-T)	48 x 44 x 6.5	11	23.2
Triple-chamber HF-T	53 x 52 x 6.5	14	26.9
Triple-chamber HF-T QP	53 x 53 x 6.5	15	31.2

Note: D = housing without header

X-ray identification

All device types receive the BIOTRONIK logo for X-ray identification. It can be found centrally between the circuitry and the battery.



Materials in contact with body tissue

- Housing: Titanium
- Header: Epoxy, polysulfone; IS4 seal: Silastic
- Silicone plug: Silopren or silastic

Electrical Characteristics

Components and input values

Electrical characteristics determined at 37°C, 500 Ω:

Circuit technology	Dycostrate
Input impedance	> 10 kΩ
Pulse form	Biphasic, asymmetric
Polarity	Cathodic

Electrically conductive surface

The device housing has the form of a flattened ellipsoid. The electrically conductive area is for:

- Single and dual-chamber devices: 30 cm^2
- Triple-chamber devices: 33 cm^2

Telemetry data

- MICS frequency: 402 - 405 MHz
- Maximum power of transmission: < 25 µW (-16 dBm)

International radio certification

Devices with BIOTRONIK Home Monitoring® are equipped with an antenna for wireless communication.

- Telemetry information for Australia:

  This product is in compliance with the Australian "Radiocommuniations Act 1992" and therefore it is labelled according to the "Radiocommunications (Compliance Labelling - Devices) Notice."
- Telemetry information for Canada:

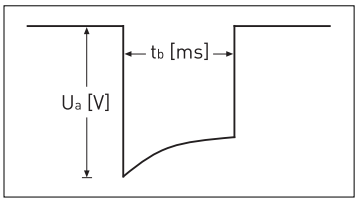
  This device must neither interfere with meteorological and earth resources technology satellites nor with meteorological stations working in the 400,150 to 406,000 MHZ band, and it must accept any interference received, including interference that may cause undesired operation.
  This device will be registered with Industry Canada under the following number:
  IC: 4708A-PNP
  The code IC in front of the certification/registration number only indicates that the technical requirements for Industry Canada are met.
- Telemetry information for Japan:

  In accordance with Japanese law, this device has been assigned an identification number under the "Ordinance concerning certification of conformity with technical regulations etc. of specified radio equipment", Article 2-1-8.
  R 202-LSE015
- Telemetry information for the USA:

  Telemetry data for the USA: This transmitter is authorized by rule under the Medical Device Radiocommunication Service (in part 95 of the FCC Rules) and must not cause harmful interference to stations operating in the 400.150-406.000 MHz band in the Meteorological Aids (i.e., transmitters and receivers used to communicate weather data), the Meteorological Satellite, or the Earth Exploration Satellite Services and must accept interference that may be caused by such stations, including interference that may cause undesired operation. This transmitter shall be used only in accordance with the FCC Rules governing the Medical Device Radiocommunication Service. Analog and digital voice communications are prohibited. Although this transmitter has been approved by the Federal Communications Commission, there is no guarantee that it will not receive interference or that any particular transmission from this transmitter will be free from interference.
  This device will be registered with Federal Communications Commission under the following number:
  FCC ID: QRIPNP

Pulse form

The pacing pulse has the following form:



The pulse amplitude reaches its maximum value at the beginning of the pulse (Ua). With increasing pacing duration (tb), the pulse amplitude is reduced dependent on the pacing impedance.

Resistance to interference

All variants of BIOTRONIK devices comply with the requirements of EN 45502-2-1: 2003, § 27.5.1 at the highest sensitivity.

Battery Data

Battery characteristics

The following data is provided by the manufacturers:

Manufacturer	Wilson GREATBATCH, INC. Clarence, NY 14031	LITRONIK GmbH, 01796 Pirna, Germany	
Battery type	GB 3193	LiS 2650MK	LiS 3150MK
System	QMR	$LiMn0_2$	$LiMn0_2$
Device type	SR; DR		HF; HF QP
Battery voltage at BOS	3.3 V	3.1 V	3.1 V
Open-circuit voltage	3.3 V	3.1 V	3.1 V
Nominal capacity	1010 mAh	950 mAh	1200 mAh
Usable capacity until EOS	971 mAh	880 mAh	1066 Ah
Remaining capacity at ERI	39 mAh	70 mAh	134 mAh

Shortening of the service time after long storage period

In case of implantation after an average storage period – about 1 year before the end of the use by date – the average service time decreases by about 1%.

Power consumption

- BOS, inhibited: SR(-T), DR(-T) 6 µA; HF-T (QP) 7 µA
- BOS, 100% pacing: SR(-T) 8 µA; DR(-T) 11 µA; HF-T (QP) 14 µA

Calculation of service times

Mean service times pre-estimated from the following and other data:

- Storage for 6 months
- Technical data of the battery manufacturer
- Basic rate of 60 bpm in AAIR/VVIR modes (single-chamber devices) or DDDR modes (dual-chamber and triple-chamber devices)
- Home Monitoring configuration: OFF
- No wandless telemetry
- Configuration of different pulse amplitudes and lead impedances

Mean service times SR

For single-chamber devices the following times result when set to AAIR or VVIR, with a basic rate of 60 bpm and a pulse width of 0.4 ms at an impedance of 500 Ω:

Amplitude	Pacing	Average service time
2.5 V	100%	13 years
	50%	14 years, 9 months
3.0 V	100%	11 years, 3 months
	50%	13 years, 7 months
5.0 V	100%	5 years, 6 months

Mean service times DR

For dual-chamber devices the following times result when set to DDDR with a basic rate of 60 bpm and a pulse width of 0.4 ms at an impedance of 500 Ω:

Amplitude	Pacing	Average service time
A: 2.5 V RV: 2.5 V	100%	9 years, 4 months
	50%	11 years, 4 months
A: 3.0 V RV: 3.0 V	100%	7 years, 8 months
	50%	10 years
A: 5.0 V RV: 5.0 V	100%	3 years, 2 months

Mean service times HF

For triple-chamber devices the following times result when set to DDDR with a basic rate of 60 bpm, 100% biventricular pacing and a pulse width of 0.4 ms at an impedance of 500 Ω:

Amplitude	Pacing	Average service time
A: 2.5 V	10%	9 years, 8 months
RV: 2.5 V LV: 2.5 V	100%	
A: 3.0 V	10 %	8 years
RV: 3.0 V LV: 3.0 V	100%	
A: 5.0 V RV: 5.0 V LV: 5.0 V	100%	2 years, 6 months

Legend for the Label

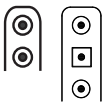
The label icons symbolize the following:

	Manufacturing date		Use by
	Storage temperature		Order number
	Serial number		Product identification number
	CE mark		
	Contents		Follow the instructions for use

 Sterilized with ethylene oxide			
	Do not resterilize		Single use only. Do not re-use!
	Do not use if packaging is damaged		Non-sterile

	Transmitter with non-ionizing radiation at designated frequency
Label icon on devices with ProMRI®: 	MR conditional: Patients having a device system implanted whose components are labeled with this symbol on the packaging can be examined using an MR scan under precisely defined conditions.

TP2	Compabiltiy with telemetry protocol version 2 of BIOTRONIK Home Monitoring

 Example	Uncoated device: NBG code and compatible leads
	Screwdriver
 Examples of the connector allocation: IS-1, IS-1/IS4	