Amvia Stellar

ProMRI

Pacemaker | Bradyarrhythmia Therapy | Cardiac Resynchronization Therapy

Technical Manual

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BIOTRONIK SE & Co. KG
Woermannkehre 1
12359 Berlin / Germany
Tel +49 (0) 30 68905-0
Fax +49 (0) 30 6852804
sales@biotronik.com
www.biotronik.com

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1 About this Technical Manual

Objective

In this technical manual, you will find information for physicians and medical professionals regarding the device, the implantation, programming, and follow-up of an implantable pacemaker as well as information on safe handling of the device.

Technical manuals

Technical manuals are either included in hard copy form in the storage package or available in digital form on the internet: https://manuals.biotronik.com.

1. Consult all relevant technical manuals.
2. Keep the technical manuals for future reference.

To ensure safe operation, in addition to this technical manual, please also consult the following manuals:

- Technical manual for the Home Monitoring Service Center
- Technical manuals for the leads
- Technical manuals for the programmer and its accessories
- Technical manuals for the programmer's software
- Technical manuals for cables, adapters, accessories
- "ProMRI – MR conditional device systems" manual

Conventions

Identification of Safety Warnings

The following symbol draws attention to potential hazards:

Follow all safety warnings indicated by this symbol to avoid possible serious or fatal injury or damage to the system.

Safety warnings are also indicated by a signal word.

- **DANGER:** Non-compliance may immediately lead to severe injury or death.
- **WARNING:** Non-compliance leads to a potentially dangerous situation that can cause severe injuries or death.
- **Caution:** Non-compliance leads to a potentially dangerous situation that can cause moderate injuries.
- **Attention:** Non-compliance leads to a potentially dangerous situation that can cause minor injuries and/or material damage.

Typographical Conventions

The following typographical conventions are used in this technical manual:

Instructions

The individual steps of an instruction are numbered. Prerequisites, intermediate results, and results may be specified.

Prerequisite

- This is a prerequisite.

1. Step
2. Step
   ▶ Intermediate result
3. Step

Result

This is the result.

Cross references

Cross references are indicated using "see" or "see also".

Highlights

Text that needs to be highlighted is shown in **bold**.

2 Product Description

Intended Medical Purpose

Intended purpose

Amvia Stellar are implantable pulse generators (IPG: DR-T) also called pacemakers and implantable cardiac resynchronization pacemakers (CRT-P: HF-T and HF-T QP).

An implantable pacemaker is part of an implantable pacemaker system comprising a pacemaker and leads. The primary function of the pacemaker is the ability, first, to sense the intrinsic heart rhythm/ rate and, second, to provide pacing by electrical pulses of low energy, as well as to provide antitachycardia pacing by electrical pulses of low energy when necessary to ensure a stable heart rate or to support the intrinsic heart rate when needed.

The implantation of a pacemaker is a symptomatic therapy with the following objectives:

- Sensing and recording the heart rhythm and automatically detecting bradycardia and atrial tachyarrhythmia (IPGs and CRT-Ps).
- Compensation of bradycardia through atrial or ventricular, or AV sequential pacing (IPGs and CRT-Ps).
- Physiological pacing (LBB(A)P or HBP) by stimulating the conducted system (IPGs and CRT-Ps).
- Termination of atrial tachycardia (AT/AF) through antitachycardia pacing (ATP) in the atrium (IPGs and CRT-Ps).
- Cardiac resynchronization through multisite ventricular pacing or through physiological pacing (CRT-Ps, e.g. biventricular pacing).

Diagnosis and therapy forms

The device monitors the heart rhythm and automatically detects and treats bradycardia and atrial tachycardia. BIOTRONIK Home Monitoring® enables physicians to supervise therapy management at any time.

Intended user group

In addition to having basic medical and cardiological knowledge, the user must be thoroughly familiar with the operation of a device system. Only qualified medical specialists who have this required special knowledge are permitted to use implantable devices.

If users do not possess this knowledge, they are not entitled to use the device system until they are trained accordingly.

BIOTRONIK offers user trainings for specific target groups.
Current information on training and education opportunities can be requested from:
education.training@biotronik.com

Intended clinical benefit

The clinical benefits for the patients inherent to the use of the implantable pacemakers are the detection of an unphysiological low heart rate (bradycardia) of a patient and subsequently the restoration of a physiological heart rate. The related performance outcome for this clinical benefit is defined as successful compensation of bradycardia by antibradycardia pacing.

Triple-chamber pacemakers provide the additional clinical benefit to improve the ejection fraction and / or cardiac output in patients with heart failure and interventricular dyssynchrony. The related performance outcome for this clinical benefit is defined as successful cardiac resynchronization through multisite ventricular or physiological pacing. Physiological pacing can prevent ventricular dyssynchrony and pacing-induced cardiomyophathy.

Atrial therapy provides the additional clinical benefit of terminating atrial stable tachyarrhythmia after detection. The associated performance outcome for this clinical benefit is defined as successful termination of atrial tachyarrhythmia using antitachycardia pacing.

Indications

Dual-chamber pacemakers are indicated to treat symptomatic bradycardia with antibradycardia pacing.

Triple-chamber pacemakers are indicated for patients

- who suffer from chronic heart failure with reduced left ventricular ejection fraction (LVEF ⩽ 35%) and dyssynchrony (defined as QRS duration ⩾130 ms).
- with heart failure and reduced LVEF (< 40%) who have a high-degree atrioventricular (AV) block with high ventricular pacing demand.
- with chronic heart failure and symptomatic atrial fibrillation with uncontrolled heart rate who are candidates for AV junctional ablation (irrespective of the QRS duration).

The most common indications for permanent pacemaker implantation are sinus node dysfunction (SND) and symptomatic high-grade atrioventricular (AV) block.

Beside the most common indications mentioned above the following conditions are included but are not limited to:

- Chronic bifascicular block
- Neurocardiogenic syncope and hypersensitive carotid sinus syndrome
- Hypertrophic cardiomyopathy
- Pacing to detect and terminate tachycardia
- Patients with congenital heart disease

Patients who demonstrate hemodynamic benefit through maintenance of AV synchrony should be considered for dual chamber pacing modes. Dual chamber modes are specifically indicated for treatment of conduction disorders that require both restoration of heart rate and AV synchrony such as AV nodal disease, diminished cardiac output or congestive heart failure associated with conduction disturbances, and tachyarrhythmias that are suppressed by chronic pacing.

In patients with bradycardia-tachycardia variant of SND programming of atrial ATP may be considered.

Rate-adaptive pacing with pacemakers is indicated for patients exhibiting chronotropic incompetence and who would benefit from increased pacing rates concurrent with physical activity.

Physiological pacing (e.g. HBP or LBB(A)P) is indicated to maintain or improve the cardiac hemodynamic function by optimizing the physiological cardiac contraction pattern in particular for patients with increased pacing demand.

Generally approved differential diagnostic methods, indications, and recommendations for pacemaker therapy apply to BIOTRONIK devices. See the current guidelines of cardiology associations for guidance. We recommend observing the indications published by the European Society of Cardiology (ESC). This also applies to the guidelines published by the Heart Rhythm Society (HRS), the American College of Cardiology (ACC), the American Heart Association (AHA), the German Cardiac Society (Deutsche Gesellschaft für Kardiologie, Herz- und Kreislaufforschung, (DGK)) and other national cardiology associations.

Depending on the patient`s anatomy, the pacemakers are implanted in the pectoral or abdominal region.

Intended Patient Group

The pacemakers are intended for adults (including immuno-compromised or elderly patients). The pacemakers are intended for pregnant patients but the need to limit fluoroscopy in pregnant women may complicate device implantation or the patient should be resorted to another imaging method. The pacemakers are intended for children who are suited to bear an implant of the physical dimensions of a pacemaker. Significant technical challenges may arise due to the growth of the patient and the size of the used leads.

The pacemakers are not intended for neonates or infants.
As there are no randomized clinical trials of bradycardia pacing in pediatric or pregnant patients, the level of evidence for guideline recommendations is consensus based.

Contraindications

- Sepsis
- Transient or reversible AV block/sinus bradycardia
- ATP therapy is contraindicated in patients with an accessory antegrade pathway.

No further contraindications apply to the implantation of multifunctional single-chamber, or dual-chamber pacemakers, provided differential diagnostics precedes implantation according to the current guidelines of cardiology published by the ESC and ACC/AHA/HRS and no modes or parameter combinations are configured that pose a risk to the patient (i.e. unipolar pacing in combination with an implantable cardioverter defibrillator).

System Overview

Device family

This device family comprises dual-chamber and triple-chamber devices. Not all device types are available in every country.

The following device variants are available:

Device type	Variants
Dual-chamber	Amvia Stellar DR-T
Triple-chamber	Amvia Stellar HF-T, Amvia Stellar HF-T QP

Note

Not all device types are approved in every country.
Not all functions and parameters mentioned in this technical manual are featured in every device type.

Product identification

Each product is identified by a so-called unique device identification (UDI). It enables products to be uniquely identified.

The first part of the UDI is the product-specific identifier UDI-DI (Unique Device Identification Device Identifier), which can be found next to the UDI symbol on the label.

In addition, a basic identifier called B-UDI-DI (Basic Unique Device Identification Device Identifier) is assigned to several products.

Using this B-UDI-DI, it will be possible to search the European Database on Medical Devices (EUDAMED) for additional information on the product.

Device type	UDI-DI	B-UDI-DI
Amvia Stellar DR-T	XXX	XXX
Amvia Stellar HF-T	XXX	XXX
Amvia Stellar HF-T QP	XXX	XXX

Device

The device's housing is made of biocompatible titanium, welded from the outside and is, 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 may only be used for connecting leads with IS-1 connectors that conform to ISO 5841-3.
- A device's IS4 connector port may only be used for connecting leads with IS4 connectors that conform to ISO 27186.

Note

The device and leads must match.

- Only quadripolar leads may be connected to the HF-T QP device type with IS4 connector port.

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 labeling on the device provides information pertaining to the connector port assignment in the header:

DR	HF

Connector port	Lead connector	Configuration	Implantation site	Device type
RA	IS-1	Unipolar, bipolar	Atrium	DR, HF
RV/His	IS-1	Unipolar, bipolar	Right ventricle, bundle of His, left bundle branch	DR, HF
LV/RV-Bckp	IS-1	Unipolar, bipolar	Left ventricle, right ventricle	HF

IS-1/IS4

The labeling on the device provides information pertaining to the connector port assignment in the header:

HF-T QP

Connector port	Lead connector	Configuration	Implantation site	Device type
RA	IS-1	Unipolar, bipolar	Atrium	HF-T QP
RV/His	IS-1	Unipolar, bipolar	Right ventricle, bundle of His, left bundle branch	HF-T QP
LV	IS4	Unipolar, bipolar	Left ventricle	HF-T QP

Leads

BIOTRONIK leads are insulated with 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. Steroid-eluting leads 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 a series of adapters to connect a variety of already implanted leads to new devices.

Telemetry

Telemetric communication between the device and the programmer is possible following initialization either by applying the programming head (PGH) to the device or by using wireless wandless telemetry in the programmer.

Programmer

Implantation and follow-ups are performed with the portable BIOTRONIK programmer using PSW software version 2204.A or higher.

The programmer contains an integrated module for RF telemetry.

Leadless ECG, IEGM, markers, and functions are displayed simultaneously on the color display.

The programmer allows for the determination of thresholds and the performance of all tests during an in-office follow-up. In addition, the permanent program can be changed and sent to the implanted device.

Furthermore, the programmer is used to set mode and parameter combinations, as well as for the interrogation and saving of data from the implanted device.

Pacing modes

Note

The pacing mode that should be programmed depends on the individual diagnosis. The possible modes that can be programmed specific to each device type are listed in the tables with the order numbers.

Device type	Pacing modes	Standard
DR-T	• DDD-CLS, DDI-CLS, VVI-CLS • DDDR-ADIR, DDD-ADI, VDDR • DDDR, DDIR, VDIR • VVIR, AAIR, • DDD, DDT, DDI, D00, VDD, VDI • VVI, VVT, V00, AAI • OFF	DDDR
HF-T (QP)	• DDD-CLS, DDI-CLS, VVI-CLS • DDDR-ADIR, DDD-ADI, VDDR • DDDR, DDIR, VDIR • VVIR, AAIR, • DDD, DDT, DDI, D00, VDD, VDI • VVI, VVT, V00, AAI • OFF	DDDR

Note

Home Monitoring is possible in all pacing modes.
The OFF mode only functions temporarily, i.e. during a test.

NBG codes

DDDR is the NBG code for the antibradycardia pacing 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 pacing 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 as well as technical data of the device are automatically and wirelessly sent to a transmitter via an antenna in the device header. The data is encrypted and sent from the transmitter to the BIOTRONIK Service Center via the cellular phone network.
- The received data is deciphered and evaluated. Each physician can individually set the criteria for evaluation and the time of notification via e-mail or SMS for each patient.
- A clear overview of the results of this analysis is displayed for the attending physician and clinical staff 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 regular message.
- A test message can be initiated at any time using the programmer to immediately check the Home Monitoring function.

Amvia Stellar order numbers

Amvia Stellar

Not all device types are available in every country:

	IS-1	IS-1/IS4
DR-T	460167	
HF-T	460166	
HF-T QP		460165

Package contents

The storage package includes the following:

- Sterile packaging with implantable device
- Serial number label
- Implant card
- Filling instructions for the implant card

Note

The technical manual pertaining to the device is either included in hard copy form in the storage package or is available in digital form on the internet: https://manuals.biotronik.com

Note

The warranty booklet for this device is either included in hard copy form in the storage package or is available in digital form on the internet: https://www.biotronik.com/warranty-booklet

The sterile packaging includes the following:

- Implantable device
- Torque wrench

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.

Diagnostic functions

- Data from the implantation and the most recent 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.
- Periodic automatic sub-threshold impedance measurements are performed in the device independent of the pacing pulse in order to check the lead for proper functioning.
- Leadless ECG function: For all device types, far-field derivation can be measured without external leads between ring electrode and housing.
- Once a telemetry connection has been established during a test procedure in an in-office follow-up, the leadless ECG and the IEGM are displayed with markers.

Antibradycardia pacing

- Sensing: P and R wave amplitudes are measured periodically and fully automatically by the device to record varying amplitudes. The sensitivity of the atrium and ventricle is also adjusted fully automatically on a regular basis. The measurement data is averaged and the trend can be displayed.
- Pacing thresholds: Pacing thresholds are automatically determined by the device: dual-chamber devices determine the atrial and right ventricular thresholds, and triple-chamber devices determine the atrial, and right and left ventricular 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. If His-bundle pacing is used, the threshold test is not available for all leads.
- 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: automatic post-ventricular atrial refractory period).
- Additional, specialized form of rate adaptation available: Increased demand for cardiac output is determined via physiological impedance measurement. The measuring principle is based on contractile changes (inotropy) of the myocardium (CLS function: closed loop stimulation). Rate adaptation is automatically initialized and optimized in CLS mode. If His-bundle pacing is used with an RV backup lead, CLS is not available.
- Ventricular pacing suppression: Unnecessary ventricular pacing is minimized 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. If His-bundle pacing is used, ventricular pacing suppression is not available.
- During an in-office follow-up, an automatic test of the AV delay is performed to improve the heart performance. The AV delays are calculated and the optimum values can be applied. If His-bundle pacing is used, AV-Opt is not available.

Physiological pacing

The device enables therapy through physiological stimulation, thereby improving the hemodynamic function of the heart.

- For His-bundle pacing, a lead can be implanted in the His bundle. In triple-chamber devices, an additional lead can be implanted in the left ventricle or as backup lead in the right ventricle.
- For left bundle branch pacing (LBBP), a lead can be implanted in the left bundle branch.

The programming of the device is adjusted to the implantation site of the lead.

Antitachycardia pacing

With the atrial ATP function, dual- and triple-chamber devices can treat atrial tachycardias with antitachycardia pacing (ATP) in case of stable heart rhythms. Two ATP sequences with up to 10 max. ATP attempts each can be programmed.
Before delivering the therapy, the lead check verifies the correct positioning of the atrial lead.
Depending on the programming, the delivery of the therapy can be repeated after a defined time interval or when there is a change in the atrial rhythm.
Additionally, a ventricular backup stimulation can be programmed.

If His-bundle pacing is used, ATP is not available.

Cardiac resynchronization therapy

For resynchronization of the ventricles, triple-chamber devices have functions for multisite ventricular pacing with possible VV delays in either direction.

- Capture Control is also available for the left ventricle with automated tracking of the pacing threshold or with automatic threshold monitoring (ATM) for trend analysis.
- To avoid the need for repeat surgery in case of a left-sided increase of pacing threshold or undesired phrenic nerve stimulation, different pacing polarities can be programmed for the left ventricular lead with a triple-chamber device. Up to 20 vectors are available with the HF-T QP device type.
- In the HF-T QP device type, the LV Vector Opt test provides a fast measurement of the pacing threshold, the phrenic nerve pacing threshold, and the pacing impedance. The impact on 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 also supports the selection.
- An additional diagnostic function with biventricular pacing: Heart rate variability, patient activity, and thoracic impedance are continuously monitored.
- The effectiveness of resynchronization can possibly be improved if there are intrinsic AV delays: The CRT AutoAdapt function measures the intracardiac conduction times every minute, sets up the pacing configuration to BiV or LV (with activated LV capture control), and adapts the AV delay automatically. If His-bundle pacing is used with an LV lead, CRT AutoAdapt is not available.

Storing programs

There are different therapy programs:

- Parameter settings effective for the most common pacemaker indications are offered in preconfigured programs (ProgramConsult).
- Up to 3 therapy programs can be stored for individual parameter settings.

ProMRI devices recognize magnetic resonance imaging scanners

The static magnetic field of an MRI scanner is reliably recognized with the aid of a sensor. The sensor can be activated after the implantation or during a follow-up using the MRI Guard 24/7 function.

If the patient is in the vicinity of an MRI scanner, the device recognizes the scanner's static magnetic field and automatically activates the preset MRI program. Reprogramming to the permanent program occurs automatically when the patient leaves the scanner.

Home Monitoring functions

- The device automatically sends information to the transmitter once a day. It also sends messages related to events, which are forwarded to the Home Monitoring Service Center (HMSC). In addition, test messages can be initiated using the programmer.
- Important medical information in the device messages include the following:
  - Atrial and ventricular arrhythmias
  - Parameters relevant to leads in the atrium and ventricle: pacing thresholds, sensing amplitudes, impedances
  - Current statistics
  - IEGM Online HD with up to 3 high-definition channels
- The following remote functions are possible via the Home Monitoring Service Center:
  - A schedule for Home Monitoring-supported follow-ups can be established.
- Current device data can be requested by the Home Monitoring Service Center using the QuickCheck function. If the patient is in the vicinity of the CardioMessenger transmitter, the usual data for a Home Monitoring-supported follow-up is compiled, an IEGM is added, and transmitted. This process is called interrogation-on-demand and usually runs within a maximum 15 minutes.
- The usual data for a Home Monitoring-supported follow-up is transmitted to the Home Monitoring Service Center immediately after the implantation using the EarlyCheck function. If capture control is activated, a threshold test is also carried out.

3 General Safety Instructions

General Information on Safe Handling of the Device

Observe notes and follow instructions

⚠ **WARNING**

Risk to patient, risk to physician and interferences of device

Cardiac electrotherapy is subject to specific conditions. From the transport to the storage, in terms of sterility, concerning technical complications, what requires special care during implantation or what needs to be observed regarding risky therapies with persons wearing a pacemaker: The device system is sensitive and must not be damaged, in order not to harm patients.

- It is always necessary to observe and follow all information in this manual, as well as related technical manuals.

Safety instructions and warnings in this technical manual

This technical manual provides safety-relevant information on several topics:

- On the one hand, there are safety warnings which are of a general nature. In this technical manual, these are mainly the following topics:
  - General information on the safe handling of the product
  - Operating conditions
  - Possible technical complications
  - Possible medical complications
- On the other hand, there are special and general warnings related to implantation, which educate about actions and provide instructions for safe operation. In this technical manual, these are mainly the following topics:
  - Implantation procedure
  - Precautionary measures while programming
  - Follow-up
  - Patient education
  - Replacement indications
  - Explantation and device replacement

Summary Report on Safety and Clinical Performance

The technical documentation of a device includes a brief report on safety and clinical performance (SSCP, Summary of safety and clinical performance). A current summary will be made available digitally on the internet by the European Commission: https://ec.europa.eu/tools/eudamed

Reporting of serious incidents

Serious incidents relating to the product must be reported to the manufacturer and the competent authority.

The competent authorities can be found at: https://ec.europa.eu

Operating Conditions

⚠ WARNING

Risk to patient and interferences of device

Cardiac electrotherapy is subject to special operating conditions. If these are not fulfilled, the functionality of the device may be impaired; if the functionality of the device is impaired, the patient may be at risk.

- Please observe the following operating conditions.

Care during shipping and storage

No electromagnetic interference should occur in the vicinity of devices.

- 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 during shipping and storage

Extremely low and extremely high temperatures can both affect the device's battery service time.

- Permissible temperature range: +5°C to +30°C
- Short-term permissible temperature range: -10°C to +45°C

Sterile delivery

The device and the torque wrench are delivered gas-sterilized. Sterility is guaranteed only if the blister and quality control seal are not damaged.

- Check the package for damage.
- Do not use parts from damaged package.

Sterile packaging

The device and torque wrench are each packaged in 2 separately sealed blisters. The inner blister is sterile on the outside so that it can be transferred and remain sterile during implantation.

Single use

The device and torque wrench are intended for single use only.

The device must not be used more than once or resterilized because of the following risks:

- Mechanical and electrical damage to the device, especially damage to the lead connections in the header
- Improper battery status
- Device-side infection risks

To ensure that the device is in perfect condition and can function properly:

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

The torque wrench is also intended for single use only.

Possible Complications

⚠ WARNING

Risk to patient and interferences with the device

Cardiac electrotherapy is subject to special complications. They must be considered so that the functionality of the device is not impaired and, as a result, put the patient at risk.

- Please take all the following safety information carefully into account.

General information on medical complications

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

It is impossible to guarantee the efficacy of antiarrhythmia therapy, even if the programs have proven successful during tests or subsequent electrophysiological studies. In some cases the set parameters may be ineffective. In particular, it cannot be excluded that tachyarrhythmias could be induced or accelerated by a therapy attempt, i.e., that long-lasting ventricular flutter or fibrillation occurs.

Primary sources of complication information include current scientific and technological knowledge.

Possible undesired side effects and adverse events

Possible residual risks are:

- Infection in blood circulation, infection of device pocket, peripheral infection by skin lesion
- Ongoing ventricular tachycardia, prolonged anesthesia or sedation, cardiac arrest, syncope in the presence of the attending physician, acute and serious heart failure, pulmonary embolism, arterial and venous embolism, acute and chronic toxic or allergic reaction
- Nausea/sickness/slight dizziness, pain, impairment of performance ability
- Muscle twitching, thermal tissue load, mechanical tissue irritation
- Prolonged undesired medical condition, prolonged psychological stress, physician misdiagnoses of patient medical condition, environmental impairment, repeated invasive intervention

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.

- Where appropriate, carry out a follow-up and evaluate the sensitivity and the pacing mode.

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 can include the following:

- Lead dislodgement, lead fracture
- Insulation defects
- Device component failures
- Battery depletion
- Interrupted telemetry

Electromagnetic interference (EMI)

Any device can be sensitive to electromagnetic 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, safety around sources of EMI cannot be guaranteed. In general, there are many sources of EMI that will produce minor or no symptoms in patients.
- 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, especially in the context of diagnostic or therapeutic procedures, sources of interference may induce such a high level of energy into the pacing system that the cardiac tissue surrounding the device or lead tip is damaged.
- Always evaluate the adjustment of sensing and triggered pacing mode.

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

⚠ WARNING

Risk to patient and interferences with the device

Cardiac electrotherapy is subject to special risks. They must be considered so that the functionality of the device is not impaired and, as a result, put the patient at risk.

- Please take all the following safety information carefully into account.

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

Risky therapeutic and diagnostic procedures

If electrical current from an external source is conducted through the body for diagnostic or therapeutic purposes, the device can be subjected to interference, which can put the patient 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. The effect on the device is not always immediately apparent.

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

- Have an external defibrillator ready.
- Electrically insulate the patient.
- Switch the pacemaker function to asynchronous modes if needed.
- Do not introduce energy near the device system.
- Additionally, 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. However, it is still possible for external defibrillation to damage the implanted device. 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 nevertheless to be used, 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 ISO 14708 standard pertaining to active implantable medical devices requires the following measures during the administration of therapeutic ionizing radiation:

- Adhere to instructions for risky therapeutic and diagnostic procedures.
- Shield device against radiation.
- After applying radiation, repeatedly verify proper function of the device system.

Note

Please contact BIOTRONIK with questions during the risk/benefit analysis.

Magnetic resonance imaging

Magnetic resonance imaging (MRI) should only be performed under certain conditions. Damage or destruction of the device system by strong magnetic interaction or harm to the patient by excessive warming of the body tissue in the area surrounding the device system must be avoided.

BIOTRONIK devices with the "MR conditional" function display the identification ProMRI. Magnetic resonance imaging (MRI) should only be performed while following mandatory precautions to protect the device system and the patient.

- The "ProMRI – MR conditional device systems" manual contains detailed information on safely conducting an MR scan.
  Download the digital manual from the website: https://manuals.biotronik.com
- Order the printed manual from BIOTRONIK.
- Does approval as "MR conditional" apply in your country or region? Request current information from BIOTRONIK.

4 Implantation

Implantation Procedure

WARNING

Risk to patient, risk to physician and interferences of device

Work preparations and implantation procedures require special measures.

- Please follow all procedures carefully.

Having parts ready

The following parts are required:

- Device with torque wrench from BIOTRONIK
- BIOTRONIK blind plugs
- BIOTRONIK leads and lead introducer set
  - Dual-chamber device: one unipolar or bipolar lead each for the atrium and for the right ventricle or the His bundle or the left bundle branch
  - Triple-chamber device: an additional unipolar, bipolar, or quadripolar LV lead or a unipolar or bipolar backup lead for the right ventricle
- Approved connections are IS-1 and IS4: Use only adapters approved by BIOTRONIK for leads with different connectors or leads from other manufacturers.
- BIOTRONIK programmer (with integrated RF telemetry) and approved cables
- External multi-channel ECG device
- Have additional quantities of sterile parts readily available

Check the operating environment for EMI

WARNING

Harmful effects of electromagnetic interference (EMI) on the functionality of the device

Even though the device is protected against EMI by the use of filters, the sensing functions may have such strong interference in medical environments that the device may no longer function correctly.

- Check the operating environment for the presence of electromagnetic interferences and eliminate them if necessary.
- Maintain adequate distance from electromagnetic sources.

Keeping an external defibrillator ready

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

- Have a properly working external defibrillator and paddles or adhesive electrodes available.

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 and as a result, the device might no longer function correctly.

- Use a replacement device.
- Return the damaged device to BIOTRONIK.

1. Peel off the sealing paper of the outer blister at the marked position in the direction of 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.
2. Use the gripping tab on the inner blister to remove it from the outer blister.
3. Peel off the sealing paper of the sterile inner blister at the marked position in the direction of 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.
- Do not use parts from damaged package.
- Replace damaged parts.
- Leads must not be shortened.

Implantation site

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

Avoiding damage to the header

Set screws must be tightened or loosened with care.

- Loosen set screws with the supplied torque wrench. Use only BIOTRONIK torque wrenches!
- If lead repositioning is necessary, reorder sterile torque wrenches from BIOTRONIK.

Ensure that connector ports are clean

In case of contamination during implantation:

- Clean lead connectors with a sterile cloth.
- Rinse connector port only with sterile water.

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.

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 bodily fluids 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 IS1 lead connector for the right ventricle or the left bundle branch to the RV connector port.
   Connect the unipolar or bipolar IS1 lead connector for the atrium to the RA connector port.
   Connect the unipolar or bipolar IS1 or the quadripolar IS4 lead connector for the left ventricle to the LV connector port.
3. **His bundle pacing:**
   Connect the unipolar or bipolar IS1 lead connector for the His bundle to the RV/His connector port.
   Connect the unipolar or bipolar IS1 lead connector for the atrium to the RA connector port.
   Connect the unipolar or bipolar IS1 lead connector for the left or the right ventricle to the LV/RV-Bckp connector port or the quadripolar IS4 lead connector for the left ventricle to the LV connector port.
   Left bundle branch pacing:
   Connect the unipolar or bipolar IS1 lead connector for the left bundle branch to the RV/His connector port.
   Connect the unipolar or bipolar IS1 lead connector for the atrium to the RA connector port.
   Connect the unipolar or bipolar IS1 or the quadripolar IS4 connector for the left ventricle to the LV/RV-Bckp connector port or the LV connector port.
   Conventional pacing:
   Connect the unipolar or bipolar IS1 lead connector for the right ventricle to the RV/His connector port.
   Connect the unipolar or bipolar IS1 lead connector for the atrium to the RA connector port.
   Connect the unipolar or bipolar IS1 or the quadripolar IS4 connector for the left ventricle to the LV/RV-Backp or the LV connector port.
4. Push the lead connector into the header without bending the conductor until the connector tip becomes visible behind the set screw block.

5. 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.
6. Use the torque wrench to perpendicularly pierce through the slitting in the center of the silicone plug until it reaches the set screw.
7. Turn the set screw clockwise until the torque control starts with a noticeable clicking sound.
8. Carefully withdraw the torque wrench without retracting the set screw.
   ▶ When the torque wrench 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 more than 3 m from the device; ideally there should be no obstructions between the patient and the programmer.

1. Turn on wandless telemetry on the programmer.
2. 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 bar.
3. 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

⚠ WARNING

Safety information

The programming of devices requires special precautionary measures.

- Please take all the following precautionary measures carefully 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.

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, canceling telemetry helps, whereby 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

Modes and parameter combinations that pose a risk to the patient should not be programmed.

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

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.
- In case of manual programming: Determine whether there is far-field sensing and, where appropriate, adapt the blanking period to the sensing setting.

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.

Note

Sensitivity in the atrium meets the requirements for electromagnetic compatibility as long as it is ≥ 0.3 mV/bipolar. Measures must be taken to assure interference-free therapy if more sensitive values < 0.3 mV/bipolar are set.

Preventing device-induced complications

BIOTRONIK devices feature several functions to prevent device-induced complications to the greatest extent possible:

- Measure the retrograde conduction time.
- In dual-chamber devices: Activate PMT protection and program it using the VA criterion, so that high pacing rates do not occur with retrograde conduction.
- Program 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 feature several functions to prevent conduction of atrial tachycardia to the ventricle(s):

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

Preventing device-induced ventricular tachycardia

If the atrial lead is not secure, when pacing using atrial ATP parameters, these pulses may be delivered to the ventricle. As a result, it is possible that the ventricle may be paced with a very high frequency and thus induce ventricular tachyarrhythmia.

- Activate therapy using atrial ATP parameters only when reliable, permanent fixation of the lead in the atrium is ensured.

Avoiding AV crosstalk

When pacing using atrial ATP parameters, atrial pacing pulses can either be conducted to the ventricle or be sensed so that ventricular pacing is prevented.

- Check the settings for the presence of crosstalk.
- If necessary, temporarily set VVI and a rate for backup stimulation so that ventricular pacing is not inhibited.

Preventing interferences from backup stimulation and intrinsic rhythm

If ventricular backup stimulation is set when pacing using atrial ATP parameters, interferences of the programmed rate with the ventricular intrinsic rhythm may occur.

- Adjust the rate of backup stimulation to prevent interference with ventricular intrinsic rhythm.

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 LV 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.
- Left ventricular only 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 tachyarrhythmia therapy 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 battery's service time 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 implanted 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.

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

- Do not establish unnecessary RF telemetry.
- After 5 min without input, the implanted 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 and for manual activation or deactivation of the therapy before the device switches back to the previously set permanent therapy mode. The same applies to the programming head application to establish RF 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, afterwards mode DDDR;

  Magnet rate: 10 cycles with 90 bpm, then the set basic rate
- Synchronous:

  Mode DDDR (where applicable VVIR);

  Magnet rate: the set basic rate

Note

For magnet response at ERI, see also Replacement Indications [Page 32].

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

⚠ WARNING

Risk to patient

The follow-up of device systems requires special measures.

- Please follow all procedures carefully.

Follow-up intervals

During follow-ups, proper functioning of the device system is also checked. This includes the set sensing amplitudes and the pacing thresholds, as well as the remaining service time. Follow-ups must be performed at regular, agreed upon intervals; longer intervals may lead to the loss of therapy.

- Following the lead ingrowth phase, approximately 3 months after implantation, the first follow-up must be carried out by the physician using the programmer (in-office follow-up).
- Subsequent in-office follow-up intervals may be extended up to 12 months, taking into account current medical guidelines and the use of BIOTRONIK Home Monitoring.

Follow-up with BIOTRONIK Home Monitoring

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

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

- The patient has been 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 needs to be performed.

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

Proceed as follows during an in-office 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. If applicable, evaluate statistics and IEGM recordings.
7. Customize program functions and parameters if necessary.
8. Transmit the permanent program to the device.
9. Print (print report) and document follow-up data.
10. Finish the follow-up for this patient.

Patient Information

WARNING

Risk to patient

The education of patients requires special information.

- Please share any of the following information carefully.

Patient information

Patient education also includes the following information:

- Information for patients is written in a language understandable to laypersons. Anatomy, technology, and living with an implanted device are the topics discussed here. This information is available in digital form on the internet: https://patients.biotronik.com.
- Request that patients contact their physician in case of uncertainties.
- Serious incidents relating to the product must be reported to the manufacturer and the competent authority. The competent authority can be found at: https://ec.europa.eu/

Patient implant card

A patient implant card is included in the package contents.

1. Fill in the patient implant card according to the enclosed instructions for completing.
2. Hand over the patient implant card to the patient after the implantation.

Possible sources of interference – prohibitive signs

Electromagnetic interference should be avoided during daily activities. Sources of interference should not be brought into close proximity of the device, in order to not impair the sensing functionality of device. There must be no electromagnetic interferences in the vicinity of the device, because tachycardia may not be detected and as a result the therapy might not be effective

- Educate the patient on sources of electromagnetic interference which include special household appliances, safety locks/anti-theft alarm systems, cell phones, and transmitters.
- Request patients to heed the following:
  - Use cell phones on the side of the body that is opposite of the device.
  - Keep the cell phone at least 15 cm away from the device both during use and during storage.
- Premises with prohibitive signs must be avoided. Educate the patient regarding prohibitive signs.

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 programmed pacing mode and is displayed on the programmer.

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

Deactivated functions with ERI

The following functions are deactivated:

- Night program
- Rate adaptation
- Closed loop stimulation
- IEGM recordings
- Rate hysteresis
- Ventricular pacing suppression
- Measurement of thoracic impedance
- CRT AutoAdapt
- Atrial ATP

- Home Monitoring
- MRI Guard 24/7
- Statistics
- Atrial and ventricular capture control

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
- Standard program with both high and low pacing energy
- Data of the battery manufacturer (see 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 5.0 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

⚠ WARNING

Risk to patient, risk to physician, environmental hazard

Explanations and device replacement require special measures.

- Please follow all procedures carefully.

Explantation

- Interrogate the device status.
- Remove the leads from the header. Do not simply cut them loose.
- Use state-of-the-art techniques to remove the device and, if necessary, the leads.

Note

Normal oxidation processes may cause housing discolorations. This is neither a device defect nor does it influence device functionality.

- Explanted devices are biologically contaminated: dispose of safely as there is 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 connector ports on the header with a blind plug.

Basic principles:

- The device must not be resterilized or 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 explanted device with an at least 1% sodium hypochlorite solution.
- Rinse off with water.
- Fill out the explantation form and send it to BIOTRONIK together with the cleaned device.

5 Parameter

Note

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

Bradycardia/CRT

Timing: basic rate day/night and rate hysteresis

Timing: Basic rate day/night and rate hysteresis

Parameter	Range of values	Standard	DR	HF
Basic rate	30 ... (5) ... 100 ... (10) ... 200 bpm	60 bpm	X	
		50 bpm		X
Rate hysteresis	OFF; -5 ... (-5) ... -25 ... (-20) ... -65 bpm	OFF	X	X
Scan/repetitive	OFF; ON	ON	X	X
Night rate	OFF; 30 ... (5) ... 100 bpm	OFF	X	X
Night begins	00:00 ... (00:01) ... 23:59 hh:mm	22:00 hh:mm	X	X
Night ends	00:00 ... (00:01) ... 23:59 hh:mm	06:00 hh:mm	X	X
Magnet response	ASYNC; SYNC; AUTO	AUTO	X	X

Timing: Rate adaptation via CLS

Note

Closed loop stimulation is not available if His-bundle pacing is used with an RV backup lead.

Parameter	Range of values	Standard	DR	HF
Maximum sensor rate	80 ... (10) ... 180 bpm	120 bpm	X	X
CLS response	Very low; Low; Medium; High; Very high	Medium	X	X
CLS resting rate control	OFF; +10 ... (10) ... +50 bpm	+20 bpm	X	X
Vp required	Yes; No	No	X	
		Yes		X

Timing: Rate adaptation via accelerometer

Parameter	Range of values	Standard	DR	HF
Max. sensor rate	80 ... (10) ... 180 bpm	120 bpm	X	X
Sensor gain	AUTO; Very low; Low; Medium; High; Very high	Medium	X	X
Sensor threshold	Very low; Low; Medium; High; Very high	Medium	X	X

Parameter	Range of values	Standard	DR	HF
Rate increase	1; 2; 4; 8 bpm/cycle	2 bpm/cycle	X	X
Rate decrease	0.1; 0.2; 0.5; 1.0 bpm/cycle	0.5 bpm/cycle	X	X
Rate fading	OFF; ON	OFF	X	X

Timing: Upper rate

Parameter	Range of values	Standard	DR	HF
Upper rate	90 ... (10) ... 200 bpm	130 bpm	X	X
Atrial upper rate	OFF; 175; 200; 240 bpm	200 bpm	X	X

Timing: Mode switching

Parameter	Range of values	Standard	DR	HF	QP
Intervention rate	OFF; 100 ... (10) ... 250 bpm	160 bpm	X	X	X
Mode	DDI, DDIR when permanent DDD(R), DDD-CLS and DDD(R)-ADI(R)	DDIR	X	X	X
	VDI, VDIR when permanent VDD(R)	VDIR	X	X	X
Modification of basic rate	OFF; +5 ... (5) ... +30 bpm	+10 bpm	X	X	X
After mode switching: Rate	OFF; +5 ... (5) ... +50 bpm	+10 bpm	X	X	X
After mode switching: Duration	1 ... (1) ... 30 min	1 min	X	X	X
Onset criterion	3 ... (1) ... 8 out of 8	5 out of 8	X	X	X
Resolution criterion	3 ... (1) ... 8 out of 8	5 out of 8	X	X	X
Rate stabilization with mode switching	OFF; ON	OFF	X	X	X
2:1 lock-in protection	OFF; ON	ON	X	X	X

Timing: Ventricular pacing suppression

Note

Ventricular pacing suppression is not available if His-bundle pacing is used.

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

Pacing: Ventricular pacing

Parameter	Range of values	Standard	DR	HF
Ventricular pacing	BiV; RV; LV	BiV		X
Triggering	OFF; RVs; RVs+PVC	RVs		X
LV T-wave protection	OFF; ON	ON		X
Maximum trigger rate: DDD-CLS, DDD(R), VDD(R)	UTR + 20, 90...(10)...160 bpm	UTR + 20		X
Maximum trigger rate: DDI(R), VDI(R), VVI-CLS, VVI(R), D00, V00	90...(10)...160 bpm	130 bpm		X
Initially paced chamber	RV; LV	LV		X
VV delay after Vp	0 ... (5) ... 100 ms	0 ms		X
VV delay after Vp at CLS	0...(5)...30 ms	0 ms		X
VV delay after Vp at V00/D00	0...(5)...100 ms	0 ms		X

Pacing: Right ventricular backup stimulation

Note

Programming is possible only if His-bundle pacing with RV backup lead is used.

Parameter	Range of values	Standard	DR	HF
RV backup stimulation	ON; OFF	ON		X
Triggering	OFF; RVs; RVs+PVC	RVs		X
RV T-wave protection	ON; OFF	ON		X
Maximum trigger rate: DDD(R), VDD(R)	UTR + 202, 90...(10)...160 bpm	UTR + 20		X
Maximum trigger rate: DDI(R), VDI(R), VVI(R), D00, V00	90...(10)...160 bpm	130 bpm		X
HV delay after pacing	0 ... (5) ... 0...(5)...100 ms	0 ms		X

Pacing: CRT AutoAdapt

Note

CRT AutoAdapt is not available if His-bundle pacing is used with an LV lead.

Parameter	Range of values	Standard	DR	HF
CRT AutoAdapt	OFF; AVadapt; ON	OFF		X
Adaptive AV reduction	0.5 ... (0.1) ... 0.9	0.7		X
Adaptive AV lower limit	50 ... (10) ... 150 ms	50 ms		X

Timing: AV delay

Note

If His-bundle pacing is used, the parameter names on the programmer change from AV to AH.

Parameter	Range of values	Standard	DR	HF	QP
AV dynamics	Low; Medium; High; Fixed	Low	X	X	
		With HBS: Fixed			
AV delay 1 after pacing	40...(5)...300 ms Only for Fixed, also: 15...(5)...35	180 ms (DR); 150 ms (HF (QP))	X	X	X
		With HBS: 110 ms			
AV delay 1 after sensing	Automatic: AV delay 1 after pacing + sense compensation	-	X	X	X
	Or: 40...(5)...300 ms Only for Fixed, also: 15...(5)...35	140 ms (DR); 110 ms (HF (QP))	X	X	X
		With HBS: 70 ms			
AV delay 1 at rate 1	50...(10)...130 bpm	60 bpm	X	X	X
		With HBS: -			
AV delay 2 after pacing	40...(5)...300 ms	140 (DR); 120 (HF (QP))	X	X	X
AV delay 2 after sensing	Automatic: AV delay 2 after pacing + sense compensation	-	X	X	X
	Or: 40...(5)...300 ms	100 (DR); 80 (HF (QP))	X	X	X
AV delay 2 at rate 2	60...(10)...140 bpm	130 bpm	X	X	X
Sense compensation	OFF; -5 ... (-5) ... -120 ms	-40 ms	X	X	X
AV hysteresis mode	OFF; Positive; Negative; IRSplus	OFF	X		
	OFF; Positive; Negative	OFF		X	X
AV hysteresis (positive)	70; 110; 150; 200 ms	-	X	X	X
CLS modes: AV hysteresis (positive)	70; 110; 150; 200 ms	-	X	X	X
AV hysteresis (negative)	10...(10)...150 ms	-	X	X	X
AV scan/repetitive (positive)	OFF; ON	ON	X	X	X

Timing: Pulse amplitude and pulse width

Parameter	Range of values	Standard	DR	HF
Pulse amplitude A	0.5...(0.25)...4.0...(0.5)...6.0; 7.5 VV	3.0 V	X	X
Pulse width A	0.1 ... (0.1) ... 0.5 ... (0.25) ... 1.5 ms	0.4 ms	X	X
Pulse amplitude RV	0.5...(0.25)...4.0...(0.5)...6.0; 7.5 V	3.0 V	X	X

Parameter	Range of values	Standard	DR	HF
Pulse width RV	0.1 ... (0.1) ... 0.5 ... (0.25) ... 1.5 ms	0.4 ms	X	X
Pulse amplitude LV	0.5...(0.25)...4.0...(0.5)...6.0; 7.5 V	3.0 V		X
Pulse width LV	0.1 ... (0.1) ... 0.5 ... (0.25) ... 1.5 ms	0.4 ms		X

Pacing: Atrial capture control

Parameter	Range of values	Standard	DR	HF
Atrial capture control	OFF; ATM; ON	ON	X	X
Threshold test start	2.5...(0.5)...5.0 V	3.5 V	X	X
Safety margin	0.5; 1.0; 1.2 V	1.0 V	X	X

Pacing: Ventricular capture control

Parameter	Range of values	Standard	DR	HF
Right ventricular capture control	OFF; ATM; ON	ON	X	X
Threshold test start	2.5 ... (0.5) ... 4.5; 4.8 V	3.0 V	X	X
Safety margin RV (ACC)	0.3...(0.1)...1.2 V	1.0 V	X	
Safety margin RV (ATT)	1.0; 1.2 V	1.0 V		X
Safety margin LV	0.5; 1.0; 1.2 V	1.0 V		X

Blanking periods and refractory periods

Parameter	Range of values	Standard	DR	HF	QP
Atrial refractory period	300 ... (25) ... 775 ms	350 ms	X	X	X
PVARP	AUTO; 175 ... (25) ... 600 ms	AUTO	X	X	X
PVARP extension	OFF; ON	ON	X	X	X
PVARP after Vs	OFF; ON	OFF	X	X	X
RV refractory period	200 ... (25) ... 500 ms	250 ms	X	X	X
Far-field protection after Vs	100 ... (25) ... 225 ms	100 ms	X	X	X
Far-field protection after Vp	100 ... (25) ... 225 ms	150 ms	X	X	X
PMT detection/termination	OFF; ON	ON	X	X	X
VA criterion	250 ... (10) ... 500 ms	350 ms	X	X	X

Lead configuration

Parameter	Range of values	Standard	DR	HF
Atr. pacing polarity	UNIP; BIPL	UNIP	X	X
Atr. sensing polarity	UNIP; BIPL	UNIP	X	X
Pacing polarity RV With HBS: Pacing polarity His	UNIP; BIPL	UNIP	X	X
Sensing polarity RV With HBS: Sensing polarity His	UNIP; BIPL	UNIP	X	X
Pacing polarity LV	LV1 → LV2; LV2 → LV1; LV1 → RV2; LV2 → RV2; LV1 → Can; LV2 → Can	LV1 → Can		X
Sensing polarity LV	LV1 → Can; LV1 → LV2	LV1 → Can		X

Tachycardia

AT/AF detection and termination

Parameter	Range of values	Standard	DR	HF
HAR limit	100 ... (10) ... 250 bpm	200 bpm	X	X

HVR detection and termination

Parameter	Range of values	Standard	DR	HF
HVR limit	150 ... (5) ... 200 bpm	180 bpm	X	X
HVR counter	4 ... (4) ... 20 ... (5) ... 60 Events	8 Events	X	X

Atrial therapy

Note

ATP is not available if His-bundle pacing is used.

Parameter	Range of values	Standard	DR	HF
1st ATP: Attempts	OFF; 1 ... (1) ... 10	OFF	X	X
ATP type	Burst; Ramp	Burst	X	X
Number S1	1 ... (1) ... 15	5	X	X
P-S1 interval	70 ... (5) ... 85; 88; 90; 95 %	80 %	X	X
S1 decrement	5 ... (5) ... 40 ms	10 ms	X	X
Backup stimulation	OFF; 70; 90 bpm	OFF	X	X

Atrial therapy: Delay and repetition

Parameter	Range of values	Standard	DR	HF
Therapy delay	OFF; 1 min; 2 min; 3 min; 4 min; 5 min; 6 min; 7 min; 8 min; 9 min; 10 min; 15 min; 20 min; 25 min; 30 min; 35 min; 40 min; 45 min; 50 min; 55 min; 1 h; 2 h; 3 h; 4 h; 5 h; 6 h; 7 h; 8 h; 9 h; 10 h; 11 h; 12 h; 13 h; 14 h; 15 h; 16 h; 17 h; 18 h; 19 h; 20 h; 21 h; 22 h; 23 h; 24 h	OFF	X	X
Repetition interval	OFF; 2; 4; 7; 12 ... (12) ... 36 h	OFF	X	X
Repetition due to rhythm change	OFF; ON	OFF	X	X

Sensing

Atrial sensing parameters

Parameter	Range of values	Standard	DR	HF
Sensing A	OFF; AUTO; 0.1 ... (0.1) ... 1.5 ... (0.5) ... 7.5 mV	AUTO	X	X
Detection hold-off period	121 ... (2) ... 145; 146 ... (2) ... 188; 189 ... (2) ... 229; 230 ... (2) ... 266 ms	121 ms	X	X
High-pass frequency	10; 18; 24; 32 Hz	18 Hz	X	X
Maximum sensitivity UNIP	0.5 ... (0.1) ... 6.7 mV	0.5 mV	X	X
Maximum sensitivity BIPL	0.2 ... (0.1) ... 6.7 mV	0.2 mV	X	X
Initial adaptation factor	37.5 ... (12.5) ... 87.5 %	50.0 %	X	X
Step duration after sensed event	OFF; ON	OFF	X	X

Right ventricular sensing parameters

Parameter	Range of values	Standard	DR	HF
Sensing RV	OFF; AUTO; 0.5 ... (0.5) ... 7.5 mV	AUTO	X	X
Blanking after atrial pacing RV	30 ... (5) ... 70 ms	30 ms	X	X
With HBS: Blanking after atrial sensing RV	OFF; 10 ... (5) ... 70 ms	OFF	X	X
Discrimination after As	250 ... (50) ... 800 ms	350 ms	X	X
Detection hold-off period	121 ... (2) ... 145; 146 ... (2) ... 188; 189 ... (2) ... 229; 230 ... (2) ... 266 ms	201 ms	X	X
High-pass frequency	10; 18; 24; 32 Hz	18 Hz	X	X

Left ventricular sensing parameters

Parameter	Range of values	Standard	DR	HF
Sensing LV	OFF; AUTO; 0.5 ... (0.5) ... 7.5 mV	AUTO		X
Detection hold-off period	121 ... (2) ... 145; 146 ... (2) ... 188; 189 ... (2) ... 229; 230 ... (2) ... 266 ms	201 ms		X
High-pass frequency	10; 18; 24; 32 Hz	18 Hz	X	X

Home Monitoring

Setting options on the programmer

Parameter	Range of values	Standard	DR	HF
Home Monitoring	OFF; ON	ON	X	X
Time of transmission	Std.; 00:00 ... (01:00) ... 23:00 hh:mm	Std.	X	X
Ongoing atrial episode	OFF; 6 h; 12 h; 18 h	12 h	X	X
Event-based IEGM	OFF; ON	ON	X	X
QuickCheck	OFF; ON	ON	X	X

Setting options in the Home Monitoring Service Center

Parameter	Range of values	Standard	DR	HF
Transmission on	XX.XX.XXXX	Follow-up + 91 days	X	X
Cycle duration	20 ... (1) ... 1096 days	91 days	X	X
HM follow-up dates (Remote Scheduling)	Any day; any day between Monday and Friday; Monday; Tuesday; Wednesday; Thursday; Friday; Saturday; Sunday	Any day	X	X

Diagnostics

Recording parameters

Parameter	Range of values	Standard	DR	HF
High atrial rate	OFF; ModeSw; AT	AT	X	X
High ventricular rate	OFF; ON	ON	X	X
For nsT	OFF; ON	ON	X	X
Patient trigger	OFF; ON	OFF	X	X
Pre-trigger recording	0 ... (25) ... 100 %	75 %	X	X
Periodic recording	When Home Monitoring is deactivated: OFF; 30 ... (30) ... 120; 180 days	90 days	X	X

Statistical parameters

Parameter	Range of values	Standard	DR	HF	QP
Resting period start	00:00 ... (01:00) ... 23:00 hh:mm	02:00 hh:mm	X	X	
Resting period duration	0.5 ... (0.5) ... 12.0 h	4.0 h	X	X	
AV delay adjustment sensing test	OFF; 300 ms	300 ms	X	X	
Thoracic impedance (TI)	OFF; ON	ON	X	X	

Lead check

Parameter	Range of values	Standard	DR	HF
Enable lead check	OFF; ON	ON	X	X

MRI program

Parameter	Range of values	Standard	DR	HF	QP
MRI program	ON; OFF; AUTO	OFF	X	X	
Expiration date	Today ... (1) ... Today + 14 days	Today + 14 days	X	X	X
	D00; V00; A00; AUTO	AUTO	X		
	D00/BiV; D00; V00/BiV; V00; A00; AUTO	AUTO		X	
Basic rate	Mean rate + 15 bpm; 70 ... (5) ... 100 ... (10) ... 160 bpm	Mean rate + 15 bpm	X	X	
LV pulse amplitude with MRI	0.5 ... (0.25) ... 4.0 ... (0.5) ... 6.0; 7.5 V	3.0 V		X	
LV pulse width with MRI	0.1 ... (0.1) ... 0.5 ... (0.25) ... 1.5 ms	0.4 ms		X	
Pacing polarity LV	LV1 → LV2 LV2 → LV1	Same as Permanent		X	
Pacing polarity LV	LV1 → LV2 LV1 → LV3 LV1 → LV4 LV2 → LV1 LV2 → LV3 LV2 → LV4 LV3 → LV1 LV3 → LV2 LV3 → LV4 LV4 → LV1 LV4 → LV2 LV4 → LV3	Same as Permanent			X

6 Technical Data

Mechanical Characteristics

Housing

Implanted device	W x H x D [mm]	Volume [cm^3]	Mass [g]
Dual-chamber DR-T	53 x 44 x 6.5	12	25.2
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

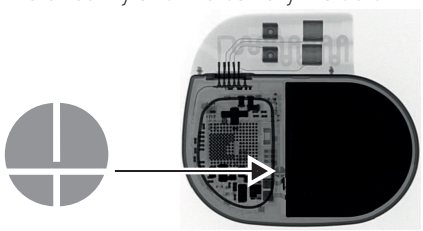
Materials in contact with body tissue

- Housing: Titanium
- Header: epoxy
  - Seal: IS4 connector port: silastic (0.14 cm^2 per connector port)
  - Cap IS4 connector port: polysulfone (0.14 cm^2 per connector port)
  - Front of the connector housing: Polysulfone (0.45 mm^2 per IS-1 connector port)
- Silicone plug: silicone (0.1 cm^2 per piece)

Device type	Contact surface titanium	Contact surface epoxy	Number of silicone plugs
DR-T	33.6 cm^2	11.6 cm^2	2
HF-T	33.3 cm^2	14.6 cm^2	3
HF-T QP	33.0 cm^2	19.8 cm^2	3

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 inside of the housing and is visible in an X-ray image.



Electrical Characteristics

Components and input values

Electrical characteristics determined at 37°C, 500 Ω:

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

Electrically conductive surface

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

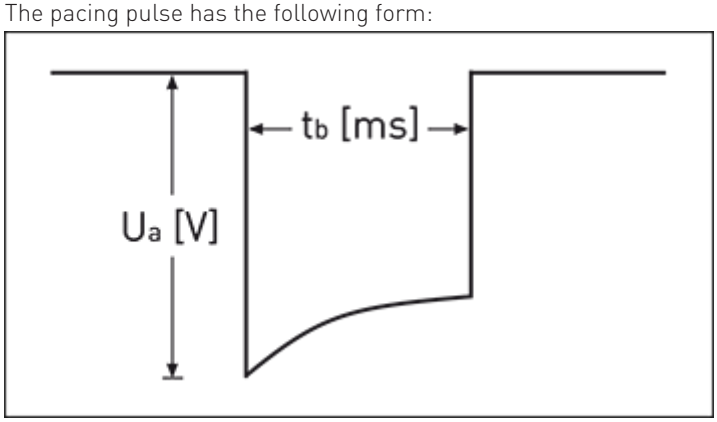
- For dual-chamber devices: 29.9 cm^2
- Triple-chamber devices: 33 cm^2

Telemetry data

- RF telemetry
  - MICS frequency: 402 ... 405 MHz
  - Maximum power of transmission: < 25 µW (-16 dBm)
- PGH telemetry
  - Operating frequency: 9 ... 90 kHz
  - Maximum magnetic field strength: < 30 dBµA/m (at 10 m)

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, Section 27.5.1 at the highest sensitivity.

Battery Data

Battery characteristics

The following data is provided by the manufacturers:

Manufacturer	LITRONIK Batterietechnologie GmbH Birkwitzer Strasse 79 01796 Pirna, Germany
Battery type	Li3150MK
System	$LiMnO_2$
Device type	DR-T; HF-T; HF-T QP
Battery voltage at BOS	3.1 V
Open-circuit voltage	3.1 V
Nominal capacity	1200 mAh
Usable capacity until EOS	1066 mAh
Remaining capacity at ERI	134 mAh

Storage period

The storage period affects the battery service time.

- The devices should be implanted before the use-by date indicated on the package.
- In case of implantation after an average storage period, approximately 1 year before the end of the use-by date, the average service time decreases by approximately 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 period of 6 months
- Technical data of the battery manufacturer
- No wandless telemetry
- Configuration of different pulse amplitudes and lead impedances

International radio certification

Telemetry information for Australia:

This device is in compliance with the Australian "Radiocommunications Act 1992" and, therefore, it is labeled according to the "Radiocommunications (Compliance labeling – Devices) Notice".

Telemetry information for Canada:

This device contains licence-exempt transmitter(s)/receiver(s) that comply with Innovation, Science and Economic Development Canada's licence-exempt RSS(s). Operation is subject to the following two conditions:

1. This device may not cause interference.
2. This device must accept any interference, including interference that may cause undesired operation of the device.

This device may not interfere with stations operating in the 400.150–406.000 MHz band in the meteorological aids, meteorological-satellite, and earth exploration-satellite services, and must accept any interference received, including interference that may cause undesired operation.

This device will be registered with Innovation, Science and Economic Development Canada under the following number:
IC: 4708A-IPG2267P2

Telemetry information for the USA:

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

1. This device may not cause harmful interference, and
2. This device must accept any interference received, including interference that may cause undesired operation

Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

This device complies with part 95 of the FCC Rules.
This device may not interfere with stations operating in the 400.150–406.000 MHz band in the Meteorological Aids, Meteorological-Satellite, and Earth Exploration Satellite Services, and must accept any interference received, including interference that may cause undesired operation.

This device will be registered with the Federal Communications Commission under the following number:
FCC-ID: QRI-IPG2267P2

Telemetry information for Japan:

This device is granted pursuant to the Japanese Radio Law.

R 202-SMK006

This device should not be modified (otherwise the granted designation number will become invalid).

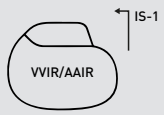
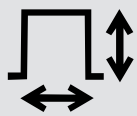
The device should be compliant to "Administrative Regulations on Low Power Radio Waves Radiated Devices":
Article 12
Without permission granted by the NCC, any company, enterprise, or user is not allowed to change frequency, enhance transmitting power or alter original characteristic as well as performance to a approved low power radio-frequency devices.
Article 14
The low power radio-frequency devices shall not influence aircraft security and interfere legal communications; If found, the user shall cease operating immediately until no interference is achieved.

The said legal communications means radio communications is operated in compliance with the Telecommunications Act. The low power radio-frequency devices must be susceptible with the interference from legal communications or ISM radio wave radiated devices.

Legend for the Label

The label icons symbolize the following:

Symbol	Meaning
	Manufacturing date
	Manufacturer
	Use by
	Temperature limit Observe the information on temperatures during shipping and storage in this technical manual.
MD	Medical device
REF	BIOTRONIK order number
SN	Serial number
PID	Product identification number
UDI	Unique device identifier
CE	CE mark
UK CA	UKCA mark
	Contents
	Device
	Torque wrench
manuals.biotronik.com 	Follow the instructions for use!
STERILE EO	Sterilized with ethylene oxide

Symbol	Meaning
	Single sterile barrier system with protective packaging inside
	Do not resterilize
	Do not reuse
	Do not use if packaging is damaged and consult the technical manual
	MR conditional
 Example	Uncoated device: NBG code and compatible leads
	Examples of the header configuration: IS-1, IS-1/IS4
	Shipping setting: Pulse amplitude and pulse width
	Shipping setting: Sensitivity
	Shipping setting: AV delay
	Shipping setting: VV delay
	Antitachycarida pacing in the right atrium