Acticor 7

ProMRI

ICD Family | Tachyarrhythmia Therapy |
Cardiac Resynchronization Therapy

Technical Manual

439128

Revision: C

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1 Product Description

Intended Medical Use

Intended use

Acticor belongs to a family of implantable cardioverter-defibrillators (ICDs). The primary objective of the therapy is to prevent sudden cardiac death. Furthermore, the device is capable of treating bradycardia arrhythmias and cardiac resynchronization therapy with multisite ventricular pacing.

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

- Termination of spontaneous ventricular fibrillation (VF) through shock delivery
- Termination of spontaneous ventricular tachycardia (VT) through antitachycardia pacing (ATP); in case of ineffective ATP or hemodynamically not tolerated VTs, with shock delivery
- Cardiac resynchronization through multisite ventricular pacing (triple-chamber devices)
- Compensation of bradycardia through ventricular (single-chamber devices) or AV sequential pacing (DX, dual- and triple-chamber devices).
  VR-T DX and HF-T/HF-T QP devices types with DX functionality are only indicated for patients not requiring atrial pacing.

Diagnosis and therapy forms

The device monitors the heart rhythm and automatically detects and treats cardiac arrest resulting from ventricular tachyarrhythmia. All major therapeutic approaches from the field of cardiology and electrophysiology are included. BIOTRONIK Home Monitoring enables physicians to perform therapy management at any time.

Indications

Acticor can treat life-threatening ventricular arrhythmias with antitachycardia pacing and defibrillation.

Generally approved differential diagnostics methods, indications, and recommendations for ICD therapy apply to BIOTRONIK devices. See the current guidelines of cardiology associations for guidance.

We recommend observing the indications published by the German Cardiac Society (Deutsche Gesellschaft für Kardiologie, Herz- und Kreislaufforschung, (DGK)) and 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), and other national cardiology associations.

Single-chamber and dual-chamber

Single-chamber and dual-chamber ICDs are indicated for patients with the following risk:

- Sudden cardiac death caused by ventricular arrhythmias

Triple-chamber

Triple-chamber ICDs are indicated for patients with the following risks:

- Sudden cardiac death caused by ventricular arrhythmias
- Congestive heart failure with ventricular asynchrony

Contraindications

Known contraindications:

- Tachyarrhythmia caused by temporary or reversible irritation, e.g. poisoning, electrolyte imbalance, hypoxia, sepsis or acute myocardial infarction
- Such frequent VT or VF that the therapies would cause an unacceptably rapid depletion of the device batteries
- VT with few or without clinically relevant symptoms
- VT or VF treatable by surgery
- Concomitant diseases that would substantially limit a positive prognosis
- Accelerated intrinsic rhythm

System Overview

Device family

The complete device family Acticor 7 consists of several device types with a DF4/IS-1 or DF4/IS-1/IS4 connection.

The following device variants are available:

Device type	Variant with Home Monitoring	
Single-chamber	Acticor 7 VR-T ProMRI Acticor 7 VR-T DX ProMRI	Device type with DF4 connection only
Dual-chamber	Acticor 7 DR-T ProMRI	
Triple-chamber	Acticor 7 HF-T ProMRI Acticor 7 HF-T QP ProMRI	

Note: Not all device types are included in every device family.

Note: Not all device types are available in every country.

Note: Not all device types are approved in every country.

Note: Not all functions and parameters mentioned in this technical manual are featured in each device type of each device family.

Device

The device's housing is made of biocompatible titanium, welded from outside and, therefore, hermetically sealed. The ellipsoid shape facilitates implantation in the pectoral muscle area.

The connections for bipolar pacing and sensing (and unipolar connections for the triple-chamber device) as well as for shock delivery are found in the device header.

The housing serves as a potential antipole during shock delivery or in the case of unipolar lead configuration.

Lead connectors

BIOTRONIK offers ICDs with headers for different standardized lead connections.

- DF4, DF4/IS-1 and DF4/IS4/IS-1

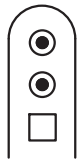
Note: Suitable leads must comply with the norms.

- A device's DF4 connector port may only be used for connecting leads with a DF4 connector that conform to ISO 27186.
- A device's IS4 connector port may only be used for connecting leads with a IS4 connector that conform to ISO 27186.
- A device's IS-1 connector port may only be used for connecting leads with an IS-1 connector that conform to ISO 5841-3.

Note: The device and leads have to match.

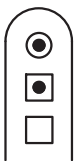
- Only DX leads for DF4 by BIOTRONIK may be connected to the device type VR DX with DF4.
- When working with DX functionality, DX leads for DF4 by BIOTRONIK may be connected to the device type HF and the device type HF QP with DF4.
- Only quadripolar leads may be connected to the device type HF QP with IS4.

DF4/IS-1 The labeling on each device provides information pertaining to the connector port location in the header:

VR	VR DX	DR	HF
RV: DF4-LLHH 	**RA:** IS-1 BI **RV:** DF4-LLHH 	**RA:** IS-1 BI **RV:** DF4-LLHH 	**RA:** IS-1 BI **LV:** IS-1 UNI/BI **RV:** DF4-LLHH 

Connector port	Lead connector	Configuration	Implantation site	Device type
RV	DF4	Bipolar and shock coil	Right ventricle	VR, DR, DX, HF
RA	IS-1	Bipolar	Atrium	DR, HF
LV	IS-1	Unipolar, bipolar	Left ventricle	HF

DF4/IS4/IS-1 The labeling on each device provides information pertaining to the connector port location in the header:

HF QP
RA: IS-1 BI **LV:** IS4-LLLL **RV:** DF4-LLHH 

Connector port	Lead connector	Configuration	Implantation site	Device type
RV	DF4	Bipolar and shock coil	Right ventricle	HF QP
LV	IS4	Unipolar, bipolar	Left ventricle	HF QP
RA	IS-1	Bipolar	Atrium	HF QP

Leads BIOTRONIK leads are sheathed 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 sliding properties for the lead. Steroid-eluting leads reduce inflammatory processes. The fractal design of the electrodes provides for low pacing thresholds.

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 intialized 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 the PSW software version 1801.A or higher.

The programmer contains an integrated module for wandless 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; furthermore, you can change the permanent program and send it to the implanted device.

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

Modes: overview

Note: Not all functions and parameters mentioned in this technical manual are featured in each device type of each device family.

Note: The mode that should be programmed depends on 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	Modes	Standard
VR	VVI-CLS; VVI; VVIR; V00; AUS	VVI
VR DX	VDD; VDDR; VDI; VDIR; VVI-CLS; VVI; VVIR; V00; AUS	VVI
DR, HF (QP)	DDD-CLS; DDD; DDDR; DDD-ADI; DDDR-ADIR; DDI; DDIR; D00; VDD; VDDR; VDI; VDIR; VVI-CLS; VVI; VVIR; V00; AAI; AAIR; OFF	DDD

NBD and NBG codes

VVE is the NBD code for the antitachycardia mode of the single-chamber, dual-chamber, and triple-chamber devices without atrial therapy:

V	Shock in the ventricle
V	Antitachycardia pacing (ATP) in the ventricle
E	Detection via IEGM analysis

VDE is the NBD code for the antitachycardia mode of the dual-chamber and triple-chamber devices with atrial therapy:

V	Shock in the ventricle
D	Antitachycardia pacing (ATP) in the atrium and ventricle
E	Detection via IEGM analysis

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

VDDR is the NBG code for the antibradycardia mode of the single-chamber type DX device:

V	Ventricular pacing
D	Sensing in the atrium and ventricle
D	Pulse inhibition and pulse triggering
R	Rate adaptation

VVIR is the NBG code for the antibradycardia modes of the single-chamber device:

V	Ventricular pacing
V	Sensing in the ventricle
I	Pulse inhibition in the ventricle
R	Rate adaptation

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 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 that indicate special cardiac or device related events are transmitted immediately.
- A test message can be initiated at any time using the programmer to immediately check the Home Monitoring function.

Acticor order numbers

Not all device types are available in every country:

Device type	Lead connection	Number of connector ports	Mode	Order number
Acticor series 7				
VR-T	DF4	1	VVE-VVIR	429526
VR-T DX	DF4/IS-1	2	VVE-VDDR	429525
DR-T	DF4/IS-1	2	VDE-DDDR	429524
HF-T	DF4/IS-1/IS-1	3	VDE-DDDRV	429523
HF-T QP	DF4/IS4/IS-1	3	VDE-DDDRV	429522

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 is available in digital form on the internet.

The sterile container includes the following:

- Device, blind plugs (if applicable)
- Screwdriver

Therapeutic and Diagnostic Functions

Diagnostic functions

- Data from 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 both the patients' and the device's state at any time.
- To check the lead for proper functioning, an automatic impedance measurement using subthreshold pacing pulses is performed in the device. Continuous impedance measurements of the shock paths and the pacing polarities of the RV lead improve the determination of lead failures.
- Leadless ECG function: For all device types, far-field derivation can be measured without external leads between the right ventricular distal shock coil and housing, which, depending on the implantation site, corresponds to ECG derivation II or III (Einthoven).
- 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.

Antitachycardia pacing

- The ICD can treat ventricular tachycardia with antitachycardia pacing (ATP); ATP can also be delivered in the VF zone (ATP One Shot) when the stability criterion (monomorphic rapid VTs) is met before shock delivery.
- The ICD can also respond to atrial tachycardia with antitachycardia pacing (ATP) in case of stable heart rates or with high-rate pacing (HF bursts) in case of unstable heart rates.
- Depending on the device type, the device software contains not only the ICD functions but also all pacemaker functions for 1, 2 or 3 chambers. The heart rhythm is continuously monitored; each arrhythmia is classified according to the heart rate and the adjustable detection criteria. Depending on the preset values, antibradycardia as well as antitachycardia therapy is inhibited or delivered.

Cardioversion, defibrillation

- The ICD can treat ventricular tachyarrhythmia with cardioversion and/or defibrillation. Shock polarity and energy can be programmed individually. Shock energies between 2.0 J and 40 J are possible. Before delivery of the shock, the ICD can be set to only deliver a shock when ongoing tachyarrhythmia is confirmed; during this time period the device can identify spontaneous conversion of the tachyarrhythmia and cancel the charging process if necessary.
- The shock paths can be set between the different shock coils (SVC/RV) and/or the housing.

Antibradycardia pacing

- Rate hystereses, automatic sensor functions, and a night program promote the patient's intrinsic rhythm, avoid overdrive pacing, and facilitate adaptation of the device to the individual needs of the patient.
- Both atrial and ventricular thresholds are determined automatically in the device. Additionally, capture control is used to set the pulse amplitudes so that pacing is performed with the optimum atrial and ventricular amplitude for the patients with each change of the pacing threshold.
- Setting an upper tracking rate for the atrium prevents unspecific atrial pacing, thus reducing the risk of pacemaker-mediated tachycardia.
- Positive AV hysteresis functions support intrinsic conduction and thus the natural contraction sequence. Negative AV hysteresis functions support the cardiac resynchronization therapy by maintaining pacing in stress situations.
- 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: unnecessary ventricular pacing is avoided by promoting intrinsic conduction (Vp suppression function). The device can

thereby adapt to conduction changes and switch between an ADI(R) and a DDD(R) mode.

Cardiac resynchronization therapy, CRT

- For resynchronization of the ventricles, triple-chamber devices have functions for multisite ventricular pacing with possible VV delays in either direction.
- 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 20 vectors can be used with the HF QP device type.
- With the HF QP device type: Two stimuli can be configured for the left ventricle to improve the resynchronization of the ventricles. The stimuli can be delivered sequentially or simultaneously.
- The effectiveness of resynchronization can be improved if intrinsic AV delays exist: The function CRT AutoAdapt measures the intracardiac conduction times every minute, sets up the pacing configuration on BiV or LV (with activated LV capture control) and adapts the AV delay automatically.

Storing programs

There are different therapy programs:

- Parameter settings effective for the most common pacemaker indications are offered in pre-configured programs (ProgramConsult).
- For individual programs, parameter settings can be stored in up to 3 therapy programs.

ProMRI devices recognize magnetic resonance imaging devices

The static magnetic field of an MRI scanner is reliably recognized with the aid of a sensor. The sensor can be activated for a maximum of 14 days using the MRI AutoDetect function during an in-office follow-up.

If the patient comes near an MRI scanner within the time set, the device recognizes the static magnetic field and automatically activates the preset MRI program. Reprogramming to the permanent program occurs also automatically when the imaging device is left.

Home Monitoring functions

- The device automatically sends information to the transmitter once a day. It also sends messages related to events, which are immediately forwarded to the Service Center. In addition to this, 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 HMSC:
  - Appointments for Home Monitoring-supported follow-ups can be scheduled.
  - Current device data can be requested by the HMSC using the QuickCheck function. Provided that the patient is in the vicinity of the transmitter (CardioMessenger), data usual for Home Monitoring-supported follow-up are compiled, an IEGM is added, and data transfer takes place in a timely manner; this process is called interrogation on demand and usually runs within a maximum of 15 minutes.

2 General Safety Instructions

General information on safe handling of the device

Follow notes and instructions

WARNING
Risk to patient, risk to doctor and interferences of device
Cardiac electrotherapy is subject to specific conditions. From the transport to the storage, what concerns sterility, what concerns technical complications, what requires special care while implanting or what to follow with regard to risky therapies in persons who have a pacemaker: The device system is sensitive and must not be damaged, in order not to harm patients. • It is always necessary that all information in this as well as related technical manuals must be taken note of and followed.

Safety instructions and warnings in this technical manual

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

- On the one hand, there are general safety warnings, which are basically valid. In this technical manual, the main topics are as below:
  - 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 regarding the implantation, which educate about actions and provide instructions for safe working. In this technical manual, the main topics are as below:
  - Implantation procedure
  - Precautionary measures while programming
  - Follow-up
  - Patient information
  - Replacement Indications
  - Explantation and device replacement

• Warnings have been particularly indicated in this technical manual with a symbol and a signal word: Non-compliance with the instructions can cause injury or even death to the patient.

Technical manuals

The following technical manuals provide information about safe 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 of the programmer

— Technical manuals for cables, adapters and accessories

— ProMRI - MR Manual Conditional device systems

- 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
- Follow all relevant technical manuals.
- Keep technical manuals for later use.

Required expertise

In addition to having basic medical knowledge, the user must be thoroughly familiar with the operation and the operation conditions 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 must be trained accordingly.

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 all operating conditions.

Care during shipping and storage

No electromagnetic interferences should occur in the vicinity of devices.

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

Delivery in shipment mode

The device is delivered in shipment mode to protect the battery; capacitor reforming required during storage could result in controlled extended charge times of the shock capacitors.

- The shipment mode is displayed on the programmer after the initial interrogation (it is deactivated during implantation – after transmission of the first program – by the first valid (in-range) measurement of the pacing impedance).

Temperature during shipping and storage

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

- Permitted for shipping and storage are +5°C to +45°C.

Sterile delivery

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

Sterile packaging

The device and screwdriver are packaged together in two 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

In order that infection risks are excluded, the device is intended for single use only.

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

Even the screwdriver is intended for single use only.

Possible Complications

WARNING

Risk to patient and interferences of device

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

- Please take all 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.

- 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 impossible to guarantee the efficacy of antitachycardia therapy, even if the programs have proven successful during tests or subsequent electrophysiological examinations. In rare cases the set parameters may become ineffective. It is possible for therapies to induce or accelerate tachycardia and cause sustained ventricular flutter or fibrillation.

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 recorded. Skeletal myopotentials can nonetheless be classified as intrinsic events especially at very high sensing sensitivity and, depending on the interference, may cause inhibition or antiarrhythmia therapy.

In the case of undesired myopotentials, the device switches to asynchronous pacing if the interference rate is exceeded.

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

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 interference if external signals are sensed as intrinsic rhythm or if measurements prevent rate adaptation:

- 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, if any, 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, for example during therapeutic or diagnostic 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.
- Always evaluate the setting of sensing and triggered pacing mode.

Device behavior in case of EMI In case of electromagnetic interference, the device switches to asynchronous pacing for as long as the interference rate is exceeded.

Static magnetic fields The magnetic sensor in the device detects magnetic fields starting at a magnetic flux density of approximately 1.5 mT. Magnetic fields below 1 mT do not affect the sensor.

Possible Risks

WARNING

Risk to patient and interferences of device

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

- Please take all safety 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:

- 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, then the device can be subjected to interference, which can place the patient at risk.

Arrhythmia or ventricular fibrillation can be induced during diathermic procedures such as electrocautery, RF ablation or RF surgery. For example, damaging pressure levels may arise during lithotripsy. Excessive warming of body tissue near the device system may occur during therapeutic ultrasound. Impact 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.
- Disable the ICD's detection function; the pacemaker function may remain active, but switch to asynchronous modes, if necessary.
- Do not introduce energy near the device system.
- Additionally check the peripheral pulse of the patient.
- Monitor the patient during and after any procedure.
- After each procedure, re-enable the detection function and verify normal device function.

During lithotripsy, the following also applies:

- Keep the focus of the lithotripter beam at least 2.5 cm away from the device.

For RF ablation or RF surgery, the following also applies:

- Set the pacing mode to reduce the effects of oversensing (for example, incorrect tracking or inhibition) as low as possible. For pacemaker-dependent patients, program an asynchronous mode. For non-pacemaker-dependent patients, program a non-pacing mode.
- Avoid direct contact between the ablation catheter and the device system.
- Position the grounding pad so that the current path does not pass through or near the device system; the current path must be at least 15 cm away from the device system.
- After completing the ablation procedure, restore the original settings.

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

Radiation therapy must be avoided due to possible damage to the device that could result in impaired device function. If it is determined that radiation therapy must be used, a 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 check proper fuction 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 damage 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. MRI should only be performed while following mandatory precautions to protect the device system and the patient.

- The ProMRI® manual – MR conditional device systems – contains detailed information on safely conducting an MR scan.
  - — Download the digital manual from the web site: 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.

3 Implantation

Implantation Procedure

WARNING
Risk to patient, risk to physician and interferences of device
Work preparation and implantation procedure require special measures.
• Please follow all procedures carefully.

Having parts ready

- Device with screwdriver from BIOTRONIK
- BIOTRONIK leads and lead introducer set
  - Single-chamber device: one bipolar ICD lead with 1 or 2 shock coils for the ventricle
    Single-chamber device DX: a pentapolar DX lead with wires for the atrium and a shock coil for the ventricle
  - Dual-chamber device: one bipolar lead for the atrium and one bipolar ICD lead for the ventricle with 1 or 2 shock coils
  - Triple chamber device: in addition a unipolar, bipolar or quadripolar LV lead; compatible leads of BIOTRONIK, see manual "ProMRI MR conditional device systems"
- The lead connections DF4, as well as IS4 and IS-1, are permitted. In order to prevent a contact problem and consequently deficient therapy, use only the adapters approved by BIOTRONIK for leads with different lead connections or leads from other manufacturers.
- BIOTRONIK programmer (with integrated wandless telemetry) and approved cables
- External multi-channel ECG device
- Keep spare parts for all sterile components.

Check the operating environment for EMI

WARNING
Harmful effects of electromagnetic interference (EMI) on the functionality of 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 opened device is dropped on a hard surface during handling, electronic parts could be damaged, and, as a result, it will no longer function correctly.

- 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, or with non-sterile instruments!
- Take hold of the inner blister by the gripping tab and take it out of the outer blister.
- Peel the sealing paper off of the sterile inner blister at the marked position in the direction indicated by the arrow.

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.
- Upon delivery, the tachyarrhythmia therapy function in the ICD is deactivated. The ICD must only be implanted in this state.
- Leads must not be shortened.

Implantation site

- Depending on lead configuration and the patient's anatomy, the ICD is generally implanted subpectorally on the left side.

Preventing leakage currents

Leakage currents between the tools and the device must be prevented during implantation.

- Electrically insulate the patient.

Preventing unintentional shock delivery

WARNING

Shock delivery with activated ICD

There is a risk of unintended shock delivery when handling an activated ICD.

- Deactivate ICD therapy before touching the device during implantation, device replacement and explantation.

Avoiding damage to the header

Set screws and blind plugs (if applicable) must be tightened or loosened with care.

- Loosen set screws with the supplied screwdriver. Use only BIOTRONIK screwdrivers with torque control!
- Do not forcibly pull out the blind plug!
- If lead repositioning 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 bodily fluids into the device. • Close unused connector ports with blind plugs.

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	Prepare the vein.
2	Implant the leads, perform the measurements, and fixate the leads.
3	Form the device pocket.
4	Connect the lead connector to the device.
5	Insert the device.
6	Guide the fixation suture through the opening in the header and fixate the device in the prepared device pocket.
7	Close the device pocket.
8	Check the device with standard tests.

Connecting the lead connector to the device

The lead connectors are connected to the ports in the header of the device:

1	Remove stylets and stylet guides.
2	Connect lead for defibrillation and sensing/pacing: DF4/IS-1 or DF4/IS4/IS-1 • Connect the DF4 connector to RV.
3	Connect lead for sensing/pacing: DF4/IS-1 or DF4/IS4/IS-1 • Connect the bipolar IS-1 connector for the atrium to RA. • Connect quadripolar IS4 connector left ventricle or unipolar or bipolar IS-1 connector left ventricle to LV.
4	Push the lead connector into the header without bending the conductor until the insertion indicator on the DF4 and the IS4 connector become visible behind the set screw block. This indicator can vary depending on the manufacturer of the lead used.
5	If you cannot easily plug the lead connector into the connection: • Use only sterile water as lubricant.
6	If the lead connector cannot be inserted completely, the set screw may be protruding into the drill hole of the set screw block. • Use the screwdriver to perpendicularly pierce through the slitted point in the center of the silicone plug until it reaches the set screw. • Carefully loosen the set screw without completely unscrewing it, so that it does not become tilted upon retightening.
7	Turn the set screw clockwise until torque control starts (you will hear a clicking sound).
8	Carefully withdraw the screwdriver without retracting the set screw. • The silicone plug automatically seals the access to the screw head safely when the screwdriver is withdrawn.

Keeping distance between leads

WARNING

Inadequate therapy

Leads that are not sufficiently spaced a distance apart or are positioned inappropriately can lead to far-field sensing or ineffective defibrillation.

- The distance between 2 shock coils must be greater than 6 cm.
- Tip and ring electrodes must not have contact with each other.

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.

- Turn 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.

Activating ICD therapy

- Load the software that is suitable for the device type in the programmer.
- Activate ICD therapy.
- Shipment mode is permanently deactivated once the leads have been connected, initial transmission of a program, and initial measurement of the pacing impedance have been performed successfully. The device data is saved.
- Take precautionary measures while programming.
- If the device induces tachycardia while programming ATPs or does not deliver adequate therapy during the DFT test, use emergency shock or an external defibrillator.

Recognizing lead failure

WARNING

Risk to patient and damage to the device because of lead failures

Technically, the following is prevented: Automatic impedance measurement is always switched on.

- Impedance values that indicate a technical failure of the leads are documented in the event list; review these measurements regularly.

Precautionary Measures while Programming

WARNING
Risk to patient
The programming of devices requires special precautionary measures.
• Please carry out all the following precautionary measures carefully.

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 feasible.
- 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 programming head: lift the PGH 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 compatibility and effectiveness of parameter combinations after programming.
- When setting atrial therapies after an AT or AF has been detected, note that no ventricular tachyarrhythmia can be detected for the duration of atrial therapy delivery.

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 and ATP therapy, undesired pacing of the phrenic nerve, as well as induction of atrial arrhythmias.

- Consider sensing and pacing parameters with reference to loss of therapy.
- Left ventricular only pacing must be avoided for patients who are pacemaker-dependent.
- Note that capture control is not available.
- During follow-ups and pacing threshold tests, note any loss of synchronized ventricular pacing, particularly in the case of triple chamber devices that have been implanted recently.
- Mode switching and post shock do not permit exclusive LV pacing. Please note the effects when programming mode switching and the post shock parameters.
- Use CRT Auto Adapt.

Monitoring the patient when setting asynchronous modes

The asynchronous modes V00 and D00 can only be set if tachyarrhythmia sensing is deactivated. This would leave the patient without detection and therefore, without ICD therapy.

- Continually monitor the patient.
- Have an external defibrillator ready.

Complying with the morphology criteria

To distinguish between ventricular and supraventricular tachyarrhythmia, QRS complexes, among other aspects, are compared to each other. You can set a MorphMatch threshold for the purpose of tachyarrhythmia discrimination, which is usually a standard value. Settings that differ, by utilizing a higher or lower threshold to discriminate the individual QRS complexes, may lead to a delayed/inhibited or unnecessary therapy.

- Set deviations from the standard with particular caution.

Setting sensing

Manually set parameters can be unsafe. For example, unsuitable far-field protection may impede sensing of intrinsic pulses and lead to inappropriate shock therapy.

- Note the automatic sensitivity control.
- In case of manual programming: Determine whether there is far-field sensing and, where appropriate, adjust the blanking time to the setting of sensing.

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 with the help of the VA criterion, so that high pacing rates do not occur with retrograde conduction.

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.

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 no ventricular pulses are prevented.

Observing the shock impedance limit

The implanted device could be damaged or the therapy delivery could be prevented, if the shock impedance is too low.

- The shock impedance must be > 25 Ω.

Preventing recurrence after therapy shock

After a therapy shock, pacing can be performed with a post-shock program if there is no intrinsic rhythm.

Permanent program	Post-shock program
DDD(R), DDD-CLS, DDD-ADI(R) DDI(R), AAI(R)	DDI
VDD(R), VDI(R)	VDI
VVI(R), VVI-CLS and OFF	VVI

- The following post-shock program parameters can be adjusted: Post-shock duration, basic rate, rate hysteresis, ventricular pacing, LV T-wave protection, triggering, AV delay (fixed, not dynamic)
- The default settings for the post-shock program are as follows:
  A and RV: 7.5 V and 1.5 ms
  LV: settings from the permanent program

Phrenic nerve stimulation that cannot be terminated

In rare cases, chronic phrenic nerve stimulation cannot be terminated by reprogramming the available left ventricular pacing configuration or using other measures.

- Program a right ventricular mode both in the permanent program as well as the ATP, in the post-shock program and for mode switching if needed.

Note the reduced pulse amplitude due to a battery voltage drop

If the rate and pulse amplitude are set very high and the pulse width is set too long at the same time, the battery voltage can temporarily drop so low that the actual pulse amplitude drops well below the programmed value level.

- Continuously check the pacing efficiency using ECG monitoring.

Observe when inducing short-term cardiac arrest

To permit TAVI (transcatheter aortic valve implantation), the pressure in the heart must be reduced so that the heart valve can be correctly positioned. Intentional cardiac arrest by high-rate pacing (rapid pacing) should be brief but must be tolerated by the patient and can trigger a life-threatening arrhythmia.

- Take all necessary precautionary measures and keep required emergency equipment ready.
- Continually monitor the patient by ECG.
- Complete the TAVI procedure before high-rate pacing ends. Extend the pacing duration if necessary.
- Abort the procedure if it is not successfully completed within the maximum pacing duration so that cardiac arrest can be stopped.
- Reactivate ICD therapy at a clinically indicated point in time when the TAVI procedure is completed.

Checking the settings of the DX lead

The triple-chamber device allows for a DX lead to be connected; for this, the DX functionality has to be programmed separately.

- DX sensing in the atrium requires a special setting in the programmer software which then has to be transmitted.

Checking for electrodes suitable for the shock path

Three different shock paths can be set. Two of these form an electrical path to the housing of the implanted device.

- For the RV -> SVC shock path, a second shock coil must be available (dual shock coil).

Considering power consumption and service time

Wandless telemetry requires slightly more power: Consumption during implantation corresponds to approximately 7 days of service time and consumption during a 20-minute follow-up corresponds to approximately 3 days.

- Do not establish unnecessary wandless telemetry.
- After 3 min without input, wandless telemetry switches to the economy mode.
- Check the battery capacity of the device at regular intervals.

The QuickCheck function, with which current device data can be requested at any time by the HMSC, slightly reduces the service time: For example, if QuickCheck is enabled for a whole year, the service time is reduced by 1 to 2 weeks, depending on the device type.

Note: Multi pole pacing also utilizes more power, which leads to variations in service time.

Magnet Response

Application of the programming head when ICD therapy is set

If a connected programming head is applied and is communicating with the programmer and ICD therapy is permanently set, detection and therapy remain intact, except during the diagnostic tests. If ICD therapy is not set as permanent, no therapy is delivered when the programming head is applied.

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 programming head application to establish RF telemetry contact.

Application of a permanent magnet

Applying a permanent magnet interrupts detection and therapy of tachycardia events. After 8 hours of this type of deactivation, the device automatically reactivates the therapy functions to prevent accidental permanent deactivation.

- If detection interruptions of longer than 8 hours are required, the magnet has to be briefly removed from the device. The 8 hour countdown restarts when the magnet is applied again.

Follow-up

WARNING
Risk to patient
The follow-up of device systems requires special measures. • Please carefully observe all measures.

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.

- The first follow-up should be carried out by the physician using the programmer (in-office follow-up) approximately 3 months after implantation following the lead ingrowth phase.
- 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 despite use of the Home Monitoring function if symptoms worsen or if new symptoms arise.
- 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 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 modification of the therapy by reprogramming the device.

Follow-up with the programmer

Use the following procedure for 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	Possibly evaluate statistics and IEGM recordings.
6	Manually perform standard tests if necessary.
7	Possibly customize program functions and parameters.
8	Transmit the permanent program to the implanted device.
9	Print and document follow-up data (print report).
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 ID card

A patient ID card is included in delivery.

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

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.

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

Draw the patient's attention to prohibitory signs.

Replacement Indications

Possible battery levels

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

Elective Replacement Indication (ERI)

Elective Replacement Indication can be detected by Home Monitoring.

CAUTION

Temporally limited therapy

If ERI occurs shortly after follow-up and is only detected during the subsequent follow-up, then the remaining service time can be much less than 3 months.

- Replace device soon.

- The device can monitor the heart rhythm for at least 3 more months.
- At least 6 maximum energy shocks can be delivered until EOS occurs.
- The set parameters in the device do not change.

EOS replacement indication

End of Service can be detected by Home Monitoring.

WARNING

Patient at risk of death

If EOS replacement indication occurs before replacement of the device, then the patient is without therapy.

- Replace device immediately.
- Monitor patient constantly until immediate replacement of the device!

- VT and VF detection and all therapies are deactivated!
- The antibradycardia function remains active in the VVI mode:
  - Ventricular pacing: RV; basic rate 50 bpm; without special pacemaker functions such as hysteresis, etc.
  - Pulse amplitude of 6 V; pulse width of 1.5 ms
  - Cycle duration for BIOTRONIK Home Monitoring: 90 days

Explantation and device replacement

WARNING

Risk to patient, risk to doctor, environmental hazard

Explanations and device replacement require special measures.

- Please carefully observe all measures.

Explantation

- Interrogate the device status.
- Deactivate VT and VF therapies prior to explantation.
- 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 ICD housing discolorations. This is neither a device defect nor does it influence device functionality.

- Explants are biologically contaminated and must be disposed of safely due to risk of infection.

Device replacement

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 and reduce the effect of a shock.

- Deactivate VT and VF therapies prior to device replacement.
- Isolate unused lead connectors with a blind cap and close connector ports on the header with a blind plug.

Basic principles:

- The device must not be resterilized and reused.

Cremation

Devices must 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 off with water.
- Fill out explantation form and send to BIOTRONIK together with the cleaned device.

4 Parameter

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

Tachycardia

General ICD therapy

Therapy readiness:

Parameter	Range of values	Standard	VR	DX	DR	HF
ICD therapy	OFF; ON	ON	x	x	x	x
Programs	Display standard program; Display safe program; Display first interrogated program; Individual 1, 2, 3; ProgramConsult	—	x	x	x	x

Detection

Note: Values can be set both in bpm, as well as in ms.

Interval rates

Parameter	Range of values	Standard	VR	DX	DR	HF
Interval AT/AF	240 ... 600 ms 100 ... (10) ... 250 bpm	300 ms 200 bpm		x	x	x
Interval VT1	OFF; 100 ... 222 bpm	OFF	x	x	x	x
Interval VT2	OFF; 120 ... 222 bpm					
Interval VF	OFF; 150 ... 250 bpm	200 bpm				

Detection counter and redetection counter:

Parameter	Range of values	Standard	VR	DX	DR	HF
Detection counter VT1	10 ... (2) ... 100	28	x	x	x	x
Detection counter VT2	10 ... (2) ... 80	20				
Detection counter VF	6 out of 8; 8 out of 12; 10 out of 14; 12 out of 16; 16 out of 20; 18 out of 24; 20 out of 26; 22 out of 30; 24 out of 30; 30 out of 40	18 out of 24				
Redetection counter VT1	10 ... (2) ... 50	20	x	x	x	x
Redetection counter VT2	10 ... (2) ... 40	14				
Redetection counter VF	6 out of 8; 8 out of 12; 10 out of 14; 12 out of 16; 16 out of 20; 18 out of 24; 20 out of 26; 22 out of 30; 24 out of 30	8 out of 12	x	x	x	x

Smart detection, onsets and stability criterion:

Parameter	Range of values	Standard	VR	DX	DR	HF
SMART detection VT1/VT2	OFF; ON	ON		x	x	x
SMART detection ON: Onset VT1/VT2	4 ... (4) ... 32 %	20 %		x	x	x
SMART detection ON: Stability VT1/VT2	8 ... (4) ... 48 %	12 %				
SMART detection OFF: Onset VT1/VT2	OFF; 4 ... (4) ... 32 %	20 %	x	x	x	x
SMART detection OFF: Stability VT1/VT2	OFF; 8 ... (4) ... 48 % 8 ... (4) ... 48 ms	48 ms				

Morphology criterion:

Parameter	Range of values	Standard	VR	DX	DR	HF
SMART detection OFF: MorphMatch VT1/VT2	OFF; Monitoring; ON	ON	x	x	x	x
MorphMatch threshold	Low (maximum value for threshold 58); STD (maximum value for threshold 76); High (maximum value for threshold 86)	STD	x	x	x	x

Sustained VT:

Parameter	Range of values	Standard	VR	DX	DR	HF
Sustained VT	OFF; 1; 2; 3; 5; 10; 20; 30 min	OFF	x	x	x	x

Therapy: Atrial therapy

Atrial therapy in the presence of stable atrial flutter:

Parameter	Range of values	Standard	VR	DX	DR	HF
ATP type	OFF; Burst; Ramp	OFF			x	x
Number S1	2 ... (1) ... 10	5			x	x
P-S1 interval	70 ... (5) ... 95 %	80 %			x	x
S1 decrement	5 ... (5) ... 40 ms	10 ms			x	x
Backup stimulation	OFF; 70; 90;	OFF			x	x

Atrial therapy in the presence of stable atrial fibrillation:

Parameter	Range of values	Standard	VR	DX	DR	HF
Therapy	OFF; HF (high frequency) burst	OFF			x	x
Rate	10 ... (5) ... 40 Hz	40 Hz			x	x
Duration	2 ... (1) ... 10	3 s			x	x
Backup stimulation	OFF; 70; 90;	OFF			x	x

Therapy: Ventricular ATP

ATP for V1 and V2:

Parameter	Range of values	Standard	VR	DX	DR	HF
Attempts	OFF; 1 ... (1) ... 10	OFF	x	x	x	x
ATP type	Burst; Ramp	Burst	x	x	x	x
Ventricular pacing	RV; LV; BiV	RV				x
S1 count	1 ... (1) ... 15	5	x	x	x	x
Add. S1	OFF; ON	ON	x	x	x	x
R-S1 interval	70 ... (5) ... 85; 88; 90; 95 %	80 %	x	x	x	x
S1 decrement	5 ... (5) ... 40 ms	10 ms	x	x	x	x
Scan decrement	OFF; 5 ... (5) ... 40 ms	OFF	x	x	x	x
ATP optimization	OFF; ON	OFF	x	x	x	x

ATP for VF:

Parameter	Range of values	Standard	VR	DX	DR	HF
ATP type	OFF; Burst; Ramp	Burst	x	x	x	x
Ventricular pacing	RV; LV; BiV	RV				x
S1 count	1 ... (1) ... 15	8	x	x	x	x
R-S1 interval	70 ... (5) ... 85; 88; 90; 95 %	88 %	x	x	x	x
ATP optimization	OFF; ON	OFF	x	x	x	x
ATP type ramp: S1 decrement	5 ... (5) ... 40 ms	10 ms	x	x	x	x
Early ATP delivery	OFF; ON	OFF	x	x	x	x

Therapy: Shock

Shock in VT1/VT2

Parameter	Range of values	Standard	VR	DX	DR	HF
Possible number of shocks	Not settable: 0; 1; 2; 6; 8	8	x	x	x	x
1st Shock	OFF; 2 ... (2) ... 20 ... (5) ... 40 J	40 J	x	x	x	x
2nd Shock	OFF; 4 ... (2) ... 20 ... (5) ... 40 J	40 J	x	x	x	x
3rd - nth shock	OFF; 4*40 J; 6*40 J	6*40 J	x	x	x	x

shock in VF

Parameter	Range of values	Standard	VR	DX	DR	HF
Possible number of shocks	Not settable: 6; 8	8	x	x	x	x
1st Shock	2 ... (2) ... 20 ... (5) ... 40 J	40 J	x	x	x	x
2nd Shock	4 ... (2) ... 20 ... (5) ... 40 J	40 J	x	x	x	x
3rd - nth shock	4*40 J; 6*40 J	6*40 J	x	x	x	x

Shock polarity, shock waveform, shock path:

Parameter	Range of values	Standard	VR	DX	DR	HF
Confirmation	OFF; ON	ON	x	x	x	x
Polarity	Normal; inverse; Normal -> alternating; Inverse -> alternating	Normal	x	x	x	x
Shock waveform	Biphasic; Biphasic 2; Biphasic -> alternating; biphasic 2 -> alternating	Biphasic	x	x	x	x
Shock path	RV -> housing + SVC RV -> housing RV -> SVC	RV-> housing + SVC	x		x	x
		RV -> housing		x		

Sensing

Sensitivity

Atrial sensing parameters

Parameter	Range of values	Standard	VR	DX	DR	HF
Sensing A	STD; OFF	STD		x	x	x
DX sensing	ON; OFF	OFF				x
Upper threshold RV	25; 50; 75 %	50 %			x	x
	In the case of DX sensing: 25, 50; 75%	75 %		x		x

Right ventricular sensing parameters

Parameter	Range of values	Standard	VR	DX	DR	HF
RV sensing	STD; TWS; VFS; IND	STD	x	x	x	x
Upper threshold	50; 75% With TWS: 75 %	50 %	x	x	x	x
Upper threshold duration RV after detection	110; 150 ... (50) ... 500 ms VFS: 110 ms	350 ms	x	x	x	x
Upper threshold duration RV after pace		400 ms				
Lower threshold RV	25; 50 %	25 %	x	x	x	x
T-wave suppression after pacing	OFF; ON	OFF	x	x	x	x

Left ventricular sensing parameters

Parameter	Range of values	Standard	VR	DX	DR	HF
LV sensing	STD; OFF; IND	STD				x
Upper threshold	50; 75%	50 %				x
Upper threshold duration LV after detection	110; 150 ... (50) ... 500 ms VFS: 110 ms	350 ms				x
Upper threshold duration LV after pacing		400 ms				
Lower threshold	25 %	25 %				x

Thresholds

Parameter	Range of values	Standard	VR	DX	DR	HF
Minimum threshold A	0.2 ... (0.1) ... 2.0 mV	0.4 mV		x	x	x
Minimum threshold RV	0.5 ... (0.1) ... 2.5 mV	0.8 mV	x	x	x	x
Minimum threshold LV	0.5 ... (0.1) ... 2.5 ... (0.5) ... 5.0 mV	1.6 mV				x

Bradycardia / CRT

Basic rate day/night and rate hystereses

Parameter	Range of values	Standard	VR	DX	DR	HF
Basic rate	30 ... (5) ... 100 ... (10) ... 160 bpm	40 bpm	x	x		
		60 bpm			x	x
Rate hysteresis	OFF; -5 ... (-5) ... -25 ... (-20) ... -65 bpm	OFF	x	x	x	x
Scan/repetitive	OFF; ON	ON	x	x	x	x
Night rate	OFF; 30 ... (5) ... 100 bpm	OFF	x	x	x	x
Night begins	00:00 ... (1 min) ... 23:59 hh:mm	10:00 PM hh:mm	x	x	x	x
Night ends		6:00 AM hh:mm				

Rate adaptation via accelerometer

Parameter	Range of values	Standard	VR	DX	DR	HF
Maximum sensor rate	80 ... (10) ... 160 bpm	120 bpm	x	x	x	x
Sensor gain	AUTO; Very low (1.3); Low (3); Medium (6); High (12); Very high (26)	Medium (6)	x	x	x	x
Sensor threshold	Very low (0); Low (3); Medium (7); High (11); Very high (15)	Medium (7)	x	x	x	x
Rate increase	1; 2; 4; 8 bpm/cycle	2 bpm/ cycle	x	x	x	x
Rate decrease	0.1; 0.2; 0.5; 1.0 bpm/cycle	0.5 bpm/ cycle	x	x	x	x
Rate fading	OFF; ON	OFF	x	x	x	x

Rate adaptation via CLS

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

Upper rate

Parameter	Range of values	Standard	VR	DX	DR	HF
Upper rate	90 ... (10) ... 170 bpm	130 bpm		x	x	x
Atrial upper rate	OFF; 175; 200; 240 bpm	200 bpm			x	x

Mode switching

Parameter	Range of values	Standard	VR	DX	DR	HF
Intervention rate	OFF; 120 ... (10) ... 200 bpm	160 bpm		x	x	x
Mode	After mode VDD(R): VDI(R)	VDIR		x	x	x
	After mode DDD(R), DDD-CLS, DDD-ADI(R): DDI(R)	DDIR			x	x
Modification of basic rate	OFF; 5 ... (5) ... 30 bpm	10 bpm		x	x	x
Onset criterion	3 ... (1) ... 8 (out of 8)	5		x	x	x
Resolution criterion						
After mode switching: Rate	OFF; 5 ... (5) ... 50 bpm	10 bpm		x	x	x
After mode switching: Duration	1 ... (1) ... 30 min	1 min				
Rate stabilization with mode switching	ON; OFF	OFF		x	x	x

Ventricular pacing suppression

Parameter	Range of values	Standard	VR	DX	DR	HF
Vp suppression	OFF; ON	OFF			x	x
Pacing suppression after consecutive Vs	1 ... (1) ... 8	6			x	x
Pacing support after X-out-of-8 cycles	1; 2; 3; 4	3			x	x

Ventricular pacing

Parameter	Range of values	Standard	VR	DX	DR	HF
Permanent	RV; BiV; 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)	90 ... (10) ... 160 bpm	130 bpm				
Initially paced chamber	RV; LV	LV				x
VV delay after Vp	0 ... (5) ... 100 ms	0 ms				x

Parameter	Range of values	Standard	VR	DX	DR	HF
CRT Auto Adapt	OFF; AVadapt; ON	OFF				x
Adaptive AV reduction	0.5 ... (0.1) ... 0.9	0.7				x
Lower limit adaptive AV delay	50 ... (10) ... 150 ms	50 ms				x

AV delay

Parameter	Range of values	Standard	VR	DX	DR	HF
AV dynamics	Low; Medium; High; Fixed; (Individual)	Low		x	x	x
AV delay 1 after pacing	40 ... (5) ... 350 ms Only for Fixed, also: 15	–			x	x
AV delay 1 after sensing	Either automatic: AV delay 1 after pacing + sense compensation	–			x	x
	Or: 15 (for Fixed); 40 ... (5) ... 350 ms	–		x		
AV delay 1 for rate 1	50 ... (10) ... 130 bpm	60 bpm		x	x	x
AV delay 2 after pacing	40 ... (5) ... 350 ms Only for Fixed, also: 15	–			x	x
AV delay 2 after sensing	Either automatic: AV delay 2 after pacing + sense compensation	–			x	x
	Or: 15 (for Fixed); 40 ... (5) ... 350 ms	–		x		
AV delay 2 for rate 2	60 ... (10) ... 140 bpm	130 bpm		x	x	x
Sense compensation	OFF; -5 ... (-5) ... -120 ms	-40 ms			x	x
AV hysteresis mode	OFF; Positive; Negative; IRSplus	OFF		x	x	
	OFF; Positive; Negative	OFF				x
AV hysteresis (positive)	70; 110; 150; 200 ms	70 ms		x	x	x
CLS modes: AV hysteresis (positive)	70; 110; 150 ms	110 ms		x	x	x
AV hysteresis (negative)	10 ... (10) ... 150 ms	50 ms		x	x	x
AV scan and repetitive (positive)	OFF; ON	ON		x	x	x

Post-shock pacing

Parameter	Range of values	Standard	VR	DX	DR	HF
Post-shock duration	OFF; 10 s; 30 s; 1 min; 2 min; 5 min; 10 min	10 s	x	x	x	x
Post-shock basic rate	30 ... (5) ... 100 ... (10) ... 160 bpm	60 bpm	x	x	x	x
AV delay post shock	50 ... (10) ... 350 ms	140 ms			x	x
Ventricular post-shock pacing	RV; BiV	RV				x
Post-shock LV T-wave protection	OFF; ON	OFF				x
Post-shock trigger	OFF; RVs; RVs+PVC	OFF				x

Atrial and ventricular pacing

Parameter	Range of values	Standard	VR	DX	DR	HF
Pulse amplitude A	0.5 ... (0.25) ... 4.0 ... (0.5) ... 6.0; 7.5 V	AUTO			x	x
Pulse amplitude V/RV			x	x	x	x
Pulse amplitude LV						x
Pulse width A	0.4; 0.5 ... (0.25) ... 1.5 ms	0.4 ms			x	x
Pulse width V/RV			x	x	x	x
Pulse width LV						x

Ventricular MultiPole pacing

Parameter	Range of values	Standard	QP
Pulse amplitude 1st and 2nd LV	0.5 ... (0.25) ... 4.0 ... (0.5) ... 6.0; 7.5 V	AUTO	x
Pulse width 1st and 2nd LV	0.4; 0.5 ... (0.25) ... 1.5 ms	0.4 ms	x
LV-LV delay	0 ... (5) ... 50 ms	0 ms	x

Pacing: Atrial capture control

Parameter	Range of values	Standard	VR	DX	DR	HF
Atrial capture control	OFF; ATM; ON	ON			x	x
Threshold test start	With ON: 2.5 ... (0.5) ... 5.0 V	3.5 V			x	x
Minimum amplitude	0.5 ... (0.25) ... 4.0 V	1.0 V			x	x
Safety margin	0.5; 1.0; 1.2 V	1.0 V			x	x

Ventricular capture control

Parameter	Range of values	Standard	VR	DX	DR	HF
Ventricular capture control RV + LV	OFF; ATM; ON	ON	x	x	x	x
Threshold test start	With ON: 2.5 ... (0.5) ... 5.0 V	3.5 V	x	x	x	x
Minimum amplitude	1.0 ... (0.25) ... 4.0 V	1.0 V	x	x	x	x
Safety margin RV	1.0; 1.2 V	1.0 V	x	x	x	x
Safety margin LV1 and LV2	0.5; 1.0; 1.2 V	1.0 V				x

Blanking and refractory periods

Parameter	Range of values	Standard	VR	DX	DR	HF
PVARP	AUTO; 175 ... (25) ... 600 ms	225 ms		x	x	x
PVARP extension	OFF; ON	ON		x	x	x
Blanking RV after atrial pacing	40 ... (10) ... 100 ms	50 ms			x	x
LV blanking after RV pacing	50 ... (10) ... 100 ms	80 ms				x
RV blanking after LV pacing						
Far-field protection after Vs	AUTO; OFF; 25 ... (25) ... 225 ms	AUTO		x	x	x
Far-field protection after Vp	50 ... (25) ... 225 ms	75 ms		x	x	x

PMT protection

Parameter	Range of values	Standard	VR	DX	DR	HF
PMT detection/termination	OFF; ON	ON		x	x	x
VA criterion	250 ... (10) ... 500 ms	350 ms		x	x	x

LV lead configuration

Parameter	Range of values	Standard	HF	QP
LV pacing polarity (IS-1)	LV1 -> LV2 LV1 -> RV LV1 -> housing LV2 -> LV1 LV2 -> RV	LV1 -> RV	x	
LV pacing polarity (IS-1)	LV1 -> LV2 LV1 -> LV3 LV1 -> LV4 LV1 -> RV LV1 -> housing LV2 -> LV1 LV2 -> LV3 LV2 -> LV4 LV2 -> RV LV2 -> housing LV3 -> LV1 LV3 -> LV2 LV3 -> LV4 LV3 -> RV LV3 -> housing LV4 -> LV1 LV4 -> LV2 LV4 -> LV3 LV4 -> RV LV4 -> housing	LV1 -> LV2		x
LV pacing polarity (IS4, MultiPole Pacing)	OFF LV1 -> LV2 LV1 -> LV3 LV1 -> LV4 LV1 -> RV LV1 -> housing LV2 -> LV1 LV2 -> LV3 LV2 -> LV4 LV2 -> RV LV2 -> housing LV3 -> LV1 LV3 -> LV2 LV3 -> LV4 LV3 -> RV LV3 -> housing LV4 -> LV1 LV4 -> LV2 LV4 -> LV3 LV4 -> RV LV4 -> housing	OFF		x
LV sensing polarity (IS-1)	LV1 -> housing LV1 -> LV2	LV1 -> housing	x	
Sensing polarity LV (IS4)	LV1 -> LV2 LV1 -> housing LV2 -> LV3 LV2 -> housing LV3 -> LV4 LV3 -> housing LV4 -> housing	LV1 -> LV2		x

Home Monitoring

Setting options on the programmer:

Parameter	Range of values	Standard	VR	DX	DR	HF
Home Monitoring	OFF; ON	OFF	x	x	x	x
Time of transmission	STD; 00:00 ... (1:00 AM) ... 11:00 PM hh:mm	STD	x	x	x	x
IEGM for therapy episodes	OFF; ON	ON	x	x	x	x
IEGM for monitoring episodes						
Ongoing atrial episode	OFF; 6; 12; 18 h	12 h		x	x	x
QuickCheck	OFF; ON	ON	x	x	x	x

Setting options in the Home Monitoring Service Center:

Parameter	Range of values	Standard	VR	DX	DR	HF
Transmission date	XX.XX.XXXX	Follow-up + 91 days	x	x	x	x
Cycle duration	20 ... (1) ... 366 days	91 days	x	x	x	x
HM follow-up visits (Remote Scheduling)	Any day; any day between Monday and Friday; Monday; Tuesday; Wednesday; Thursday; Friday; Saturday; Sunday	Any day	x	x	x	x

Diagnostics

The following recording parameters can be set:

Parameter	Range of values	Standard	VR	DX	DR	HF
For AT/AF	OFF; ON Extended ON Extended ON	ON		x	x	x
For SVT	OFF; ON	ON		x	x	x
For nsT	OFF; ON	ON	x	x	x	x
For CRT pacing interruption	OFF; ON	ON				x
Periodic recording	When Home Monitoring is deactivated: OFF; 30 ... (30) ... 180 days	90 days	x	x	x	x
IEGM configuration	RA, RV, LV RA, RV, FF FF; RV; LV	RA, RV, LV				x

The following statistical parameters can be set:

Parameter	Range of values	Standard	VR	DX	DR	HF
Start resting period	00:00 ... (1:00 AM) ... 11:00 PM hh:mm	2:00 AM hh:mm	x	x	x	x
Duration of resting period	0.5 ... (0.5) ... 12 h	4 h	x	x	x	x
AV delay adjustment in sensing test	OFF; 300 ms	300 ms		x	x	x
Thoracic impedance (TI)	OFF, ON	OFF	x	x	x	x

MRI program

MRI program

Parameter	Range of values	Standard	VR	DX	DR	HF
MRI program	OFF; AUTO; ON	OFF	x	x	x	x
Expiration date	Today ... (1) ... Today + 14 days	Today + 14 days	x	x	x	x
Mode	VOO; OFF	OFF	x	x		
	VOO; DOO; OFF				x	
	V00; V00-BiV; D00; D00-BiV; OFF					x
Basic rate	70 ... (5) ... 100 ... (10) ... 160 bpm	90 bpm	x	x	x	x
Pulse amplitude LV	As in permanent program; 0.5 ... (0.25) ... 4.0 ... (0.5) ... 6.0; 7.5 V	As in perma-nent program				x
Pulse width LV	As in permanent program; 0.4; 0.5 ... (0.25) ... 1.5 ms					x
Pacing polarity LV	IS-1: LV1 -> LV2 LV2 -> LV1 IS4: LV1 -> LV2 LV1 -> LV3 LV1 -> LV4 LV2 -> LV1 LV2 -> LV3 LV2 -> LV4 LV3 -> LV1 LV3 -> LV2 LV3 -> LV4 LV4 -> LV1 LV4 -> LV2 LV4 -> LV3					x

5 Technical Data

Mechanical Characteristics

Housing

Devices with header for DF4 connector:

Type	Lead connector	W x H x D in mm	Volume [cm^3]	Mass g
VR	DF4	60 x 61.5 x 10	30	75
VR DX	DF4	60 x 66.5 x 10	32	77
DR	DF4	60 x 66.5 x 10	32	77
HF	DF4	60 x 71.5 x 10	33	78
HF QP	DF4	60 x 75 x 10	35	82

Materials in contact with body tissue

- Housing: Titanium
- Header: Epoxy resin, polysulfone; DF4 seal: Silastic
- Silicone plugs and blind plugs (if applicable): Silopren or silastic

X-ray identification

Electrical Characteristics

Standards

The specifications are made according to ISO-14708-6:2010(E).

Measuring conditions

Unless otherwise indicated, all specifications refer to the following conditions:

- Ambient temperature: 37°C ± 2°C
- Pacing/sensing: 500 Ω ± 1%
- Shock: 50 Ω ± 1%

Factory settings

- Arrhythmia zones VT1, VT2, VF: OFF
- Antibradycardia pacing: OFF
- Home Monitoring: OFF

Telemetry data for Home Monitoring

- 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 "Radiocommunications Act 1992" and therefore it is labeled according to the "Radiocommunications (Compliance Labeling - Devices) Notice".

- Telemetry information for the USA:

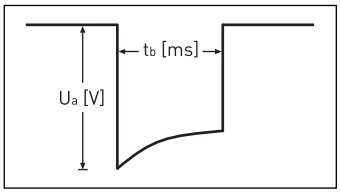
  This transmitter is authorized by rule under the Medical Device Radiocommunication Service (in part 95 of the FCC Rules) and must not cause harmful interference to stations operating in the 400.150 to 406.000 MHz band in the Meteorological Aids (i.e., transmitters and receivers used to communicate weather 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: QRI-ICD4200

- 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.
  R202-SMG025

Pulse waveform

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 upon the pacing impedance.

Resistance to interference

- Note on device type VR DX (only devices with a DF4/IS-1 connection): The requirements for electromagnetic compatibility are met as long as atrial sensitivity is set to 1.0 mV (factory settings) or values ⩾ 1.0 mV. Precautions must be taken to assure interference-free therapy if more sensitive values are set.
- Note on device type HF and HF QP: In the case of unipolar sensing, the requirement for interference voltages of ⩽ 0.3 mV (peak-to-peak) is met.

Common mode rejection ratio

Information for device type HF also applies to device type HF QP.

Rate	Common mode rejection ratio			
	Atrium: DX	Atrium: DR, HF	V right: VR, DR, HF	V left: HF
16.6 Hz	73 dB	66 dB	65 dB	58 dB
50 Hz	74 dB	69 dB	69 dB	59 dB
60 Hz	73 dB	70 dB	71 dB	62 dB

ATP amplitude

A burst was measured at 500 Ω, an amplitude of 7.5 V (tolerance ± 1.5 V), pulse width of 1.5 ms, R-S1 interval of 300 ms and an S1 count of 5:

ATP amplitude	Measured minimum	Measured maximum
RA	7.42 V	7.46 V
RV	7.41 V	7.44 V
LV	7.44 V	7.47 V

Automatic sensitivity control

Measurement of actual values and test signal wave shape: standard triangle. For the device type VR DX, the programmed atrial sensitivity is amplified by a factor of 4.

Sensitivity	Value	Tolerance	Measured value
A: positive	0.2 mV	0.2 ... 0.5	0.32 mV
A: negative			0.31 mV
DX: A: positive	0.2 mV	0.2 ... 0.52 (0.05 to 0.13)	0.11 mV
DX: A: negative			
RV: positive	0.5 mV	0.3 ... 0.7	0.58 mV
RV: negative			0.55 mV
LV: positive	0.5 mV	0.3 ... 0.7	0.54 mV 0.55 mV
LV: negative			

Shock energy/peak voltage

With shock path: RV to housing + SVC

Shock energy (Tolerance)	Tolerance Peak voltage	Measured value Shock energy	Measured value Peak voltage
1 J (0.7 ... 1.18)	90 ... 120 V	0.79 J	101 V
20 J (15.9 ... 21.6)	470 ... 510 V	18.20 J	486 V
40 J (33.8 ... 41.4)	670 ... 730 V	37.30 J	684 V

Battery Data

Battery characteristics

The following data is provided by the manufacturers:

Manufacturer	GREATBATCH, INC. Clarence, NY 14031	LITRONIK GmbH 01796 Pirna, Germany
Battery type	GB 3493	LiS 2592
System	Li/SVO/CFx	LiMnO2
Battery ID number shown on the programmer	8	9
Device type	VR, VR DX, DR, HF, HF QP	
Battery voltage at ERI	2.5 V	2.85 V
Charge time at BOS	8 s	8 s
Charge time at ERI	10 s	10 s
Usable capacity until ERI VR, VR DX, DR, HF, HF Q	1770 mAh	1600 mAh
Usable capacity until EOS	1900 mAh	1730 mAh

Storage period

The storage period affects the battery service time.

- Devices should be implanted within 25 months between the manufacturing date and the use by date (indicated on the package).
- If the ICD is implanted shortly before the use by date, the expected service time may be reduced by 16.4 months on average.

Calculation of service times

- The services times have been calculated as follows – in all chambers depending on the device type:
  - Pulse amplitude: 2.5 V
  - Pulse width: 0.4 ms
  - Pacing impedance: 500 Ω ± 5%
  - Basic rate VR, VR DX: 40 bpm
    Basic rate DR, HF, HF QP: 60 bpm
  - Home Monitoring: ON, 1 device message each day and 24 IEGM-Online HD transmissions per year
  - Diagnostic functions and recordings: permanently set
- Capacitor reforming is performed 2 times per year and therefore at least 2 maximum charges for shocks have to be assumed per year even if less than 2 are delivered.

Calculation of the number of shocks

Calculation of the maximum number of shocks =

Service time [in years] x number of shocks per year

Acticor 7 VR-T

Service times with GB 3493 or LiS 2592 battery:

Pacing	Service time [in years] at number of shocks per year					
	2	4	8	12	16	20
0%	15.4	13.3	10.5	8.7	7.4	6.4
15%	15.1	13.1	10.4	8.6	7.3	6.4
50%	14.3	12.5	10.0	8.3	7.1	6.2
100%	13.4	11.8	9.5	8.0	6.9	6.0

Acticor 7 VR-T DX Service times with GB 3493 or LiS 2592 battery:

Pacing	Service time [in years] at number of shocks per year					
	2	4	8	12	16	20
0%	14.1	12.5	10.0	8.3	7.1	6.2
15%	13.8	12.3	9.8	8.2	7.0	6.1
50%	13.3	11.8	9.5	8.0	6.9	6.0
100%	12.5	11.1	9.1	7.7	6.6	5.8

Acticor 7 DR-T Service times with GB 3493 or LiS 2592 battery:

Pacing	Service time [in years] at number of shocks per year					
	2	4	8	12	16	20
0%	14.1	12.5	10.0	8.3	7.1	6.2
15%	13.3	11.8	9.5	8.0	6.9	6.0
50%	11.7	10.5	8.7	7.4	6.4	5.7
100%	10.0	9.1	7.7	6.6	5.8	5.2

Acticor 7 HF-T Service times with GB 3493 or LiS 2592 battery:

Pacing	Service time [in years] at number of shocks per year					
	2	4	8	12	16	20
0%	13.0	11.6	9.5	7.9	6.8	6.0
15%	12.0	10.8	8.9	7.5	6.5	5.8
50%	10.2	9.3	7.8	6.7	5.9	5.3
100%	8.3	7.6	6.6	5.8	5.2	4.7

Acticor 7 HF-T QP Service times with GB 3493 or LiS 2592 battery, without MultiPole Pacing:

Pacing	Service time [in years] at number of shocks per year					
	2	4	8	12	16	20
0%	13.0	11.6	9.5	7.9	6.8	6.0
15%	12.0	10.8	8.9	7.5	6.5	5.8
50%	10.2	9.3	7.8	6.7	5.9	5.3
100%	8.3	7.6	6.6	5.8	5.2	4.7

Service times with GB 3493 or LiS 2592 battery, with MultiPole Pacing:

Pacing	Service time [in years] at number of shocks per year					
	2	4	8	12	16	20
0%	12.9	11.5	9.4	7.9	6.8	6.0
15%	11.7	10.5	8.7	7.4	6.4	5.7
50%	9.4	8.6	7.3	6.4	5.6	5.1
100%	7.3	6.8	6.0	5.3	4.8	4.4

Legend for the Label

Label on the package

The label icons symbolize the following:

	Manufacturing date		Use by
	Storage temperature	REF	Order number
SN	Serial number	PID	Product identification number
	Dangerous voltages	CE	CE mark

	Contents		Screwdriver

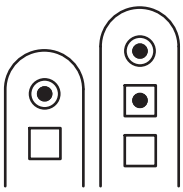
manuals.biotronik.com  Follow the electronically available instructions for use		Follow the instructions for use

STERILE EO Sterilized with ethylene oxide			
	Do not resterilize		Single use only. Do not reuse!
	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	Compatibility with telemetry protocol version 2 of BIOTRONIK Home Monitoring

 Example	Device: NBG code and compatible leads Factory settings for therapy: OFF

 Examples of the header configuration:
DF4/IS-1 • DF4/IS4/IS-1