Rivacor 3/5/7

ProMRI

ICD Family | VR-T, VR-T DX, DR-T, HF-T, HF-T QP

Technical Manual

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excellence for life

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Table of Contents

1 Product Description

Intended Medical Use

Intended Purpose

Rivacor are implantable cardioverter-defibrillators (ICDs: VR-T, VR-T DX and DR-T) and cardiac resynchronization therapy defibrillators (CRT-Ds: HF-T and HF-T QP).

An ICD/CRT-D is part of an implantable system comprising an implantable ICD/CRT-D and leads. The primary function of the ICD system is the ability, first, to sense and record the intrinsic heart rhythm/rate and, second, to provide antitachycardia pacing by electrical pulses of low energy or a shock by electrical pulses of high energy, as well as to provide pacing by electrical pulses of low energy to ensure a stable heart rate or to support the intrinsic heart rate. CRT systems share all mentioned functions and in addition provide permanent sensing and pacing of the left ventricle.

The implantation of an ICD/CRT-D is a symptomatic therapy with the following objectives:

- Sensing and recording the heart rhythm and automatically detecting cardiac arrest (ICDs and CRT-Ds).
- Termination of ventricular fibrillation (VF) or ventricular tachycardia (VT) through shock delivery (ICDs and CRT-Ds).
- Termination of ventricular tachycardia (VT) through antitachycardia pacing (ATP) (ICDs and CRT-Ds).
- Compensation of bradycardia through ventricular or AV sequential pacing (ICDs and CRT-Ds).
- Cardiac resynchronization through multisite ventricular pacing (CRT-Ds, e.g., biventricular 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 gives physicians the ability to manage therapy at any time.

Intended User

In addition to having basic medical and cardiological knowledge, the user must be thoroughly familiar with the functionality and the operating conditions of the 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.
- 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 Rivacor ICD is the detection of the unphysiological high heart rate and/or unphysiological rhythm (tachyarrhythmia) of a patient and, subsequently, the restoration of a physiological heart rate after fast ventricular arrhythmia or cardiac arrest. The performance outcome of this clinical benefits is the termination of fast ventricular arrhythmia or cardiac arrest either by ATP or by shock delivery.

Moreover, the devices provide the patient benefit to detect an unphysiological low heart rate and/or unphysiological rhythm (bradycardia arrhythmia) if present. Subsequently, the devices restore a physiological heart rate. The performance outcome of this clinical benefits is the compensation of bradycardia by antibradycardia pacing.

CRT Ds provide the additional clinical benefit to improve the ejection fraction and/or cardiac output in patients with ventricular dyssynchrony. The performance outcome of this clinical benefit is cardiac resynchronization through multisite ventricular pacing.

Indications

ICD indications

Single- and dual-chamber ICDs are indicated to treat life-threatening ventricular arrhythmias with antitachycardia pacing and defibrillation in patients who have experienced life-threatening ventricular tachyarrhythmias (secondary prevention) or patients who have an underlying cardiac condition that is associated with a significant excess mortality caused by life-threatening ventricular tachyarrhythmias (primary prevention).

Furthermore, the ICDs are capable of treating bradycardia arrhythmias. VR-T DX type devices are only indicated for patients who do not require atrial pacing.

CRT-D indications

CRT-Ds are indicated for patients with an ICD indication who additionally have chronic heart failure with reduced left ventricular ejection fraction (LVEF ⩽ 35%) and dyssynchrony (defined as QRS duration ⩾ 120 ms), or who additionally have reduced ejection fraction in combination with a high ventricular pacing demand, i.e., due to high degree AV block.

HF-T/HF-T QP type devices with DX functionality are only indicated for patients who do not require atrial pacing.

Patient Target Group

ICDs and CRT-Ds of the Rivacor device family are intended for:

- adults, including immuno-compromised or elderly patients.
- 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.
- children who are suited to bear an implanted device of the physical dimensions of an ICD/CRT-D device. Challenges may arise due to the growth of the patient and the size of the used leads.

Rivacor are not intended for neonates/infants.

As there are no randomized clinical trials of antitachycardia pacing and defibrillation in pediatric or pregnant patients, the level of evidence for guideline recommendations is consensus-based.

Contraindications

- Tachyarrhythmia caused by temporary or reversible conditions, e.g., poisoning, electrolyte imbalance, hypoxia, or acute myocardial infarction
- Such frequent VT or VF that the therapies would cause an unacceptably rapid depletion of the device batteries
- VT without clinically relevant symptoms
- VT or VF treatable by surgery
- Concomitant diseases that would preclude a patient benefit
- Accelerated intrinsic rhythm

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

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

System Overview

Device family

The complete Rivacor 3/5/7 device family consists of several device types with a DF4/IS-1 or DF4/IS-1/IS4 connector port.

The following device variants are available:

Device type	Variants with Home Monitoring	
Single-chamber	Rivacor 3 VR-T Rivacor 5 VR-T Rivacor 5 VR-T DX Rivacor 7 VR-T Rivacor 7 VR-T DX	Device type with DF4 connector port only
Dual-chamber	Rivacor 3 DR-T Rivacor 5 DR-T Rivacor 7 DR-T	
Triple-chamber	Rivacor 3 HF-T Rivacor 3 HF-T QP Rivacor 5 HF-T Rivacor 5 HF-T QP Rivacor 7 HF-T Rivacor 7 HF-T QP	

Note

Not all device types are included in every device family.
Not all device types are available in every country.
Not all device families and device types are approved in every country.
Not all functions and parameters mentioned in this technical manual are featured in every device type of each device family.

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.

3 series:

Device type	UDI-DI	B-UDI-DI
VR-T	04035479157005	4035479BUDI00053Q7
DR-T	04035479156992	4035479BUDI00053Q7
HF-T	04035479156985	4035479BUDI00065QE
HF-T QP	04035479156978	4035479BUDI00065QE

5 series:

Device type	UDI-DI	B-UDI-DI
VR-T	04035479156916	4035479BUDI00053Q7
VR-T DX	04035479156909	4035479BUDI00053Q7
DR-T	04035479156893	4035479BUDI00053Q7
HF-T	04035479156886	4035479BUDI00065QE
HF-T QP	04035479156879	4035479BUDI00065QE

7 series:

Device type	UDI-DI	B-UDI-DI
VR-T	04035479156817	4035479BUDI00053Q7
VR-T DX	04035479156800	4035479BUDI00053Q7
DR-T	04035479156794	4035479BUDI00053Q7
HF-T	04035479156787	4035479BUDI00065QE
HF-T QP	04035479156770	4035479BUDI00065QE

Device

The device's housing is made of biocompatible titanium, welded from the outside and is, 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 two suture holes are used for threading the fixation suture.

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

Lead connections

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

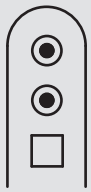
Note

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

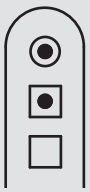
The labeling on each device provides information pertaining to the connector port assignment in the header:

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, VR DX, DR, HF
RA	IS-1	Bipolar	Atrium	VR DX, 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 assignment 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 leads 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 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 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. 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 device.

Modes: overview

Note

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

Note

CLS modes are only available in Series 7 devices.

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.

Series 3:

Device type	Pacing modes	Standard
VR	VVI; VVIR; V00; OFF	VVI
DR, HF (QP)	DDD; DDDR; DDI; DDIR; D00; VDD; VDDR; VDI; VDIR; VVI; VVIR; V00; AAI; AAIR; OFF	DDD

Series 5:

Device type	Pacing modes	Standard
VR	VVI; VVIR; V00; OFF	VVI
VR DX	VDD; VDDR; VDI; VDIR; VVI; VVIR; V00; OFF	VVI
DR, HF (QP)	DDD; DDDR; DDD-ADI; DDDR-ADIR; DDI; DDIR; D00; VDD; VDDR; VDI; VDIR; VVI; VVIR; V00; AAI; AAIR; OFF	DDD

Series 7:

Device type	Pacing modes	Standard
VR	VVI-CLS; VVI; VVIR; V00; OFF	VVI
VR DX	VDD; VDDR; VDI; VDIR; VVI-CLS; VVI; VVIR; V00; OFF	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 pacing 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	Pacing in the ventricle
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	Pacing in the ventricle
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 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 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 events in the patient's heart or in the device are transmitted immediately.
- A test message can be initiated at any time using the programmer to immediately check the Home Monitoring function.

Rivacor order numbers

Not all device types are available in every country:

Rivacor 3 series

Device type	Lead connection	Number of connector ports	NBD/NBG code	Order number
VR-T	DF4	1	VVE-VVIR	429574
DR-T	DF4/IS-1	2	VVE-DDDR	429573
HF-T	DF4/IS-1/IS-1	3	VVE-DDDRV	429572
HF-T QP	DF4/IS4/IS-1	3	VVE-DDDRV	429571

Rivacor 5 series

Device type	Lead connection	Number of connector ports	NBD/NBG code	Order number
VR-T	DF4	1	VVE-VVIR	429565
VR-T DX	DF4/IS-1	2	VVE-VDDR	429564
DR-T	DF4/IS-1	2	VVE-DDDR	429563
HF-T	DF4/IS-1/IS-1	3	VVE-DDDRV	429562
HF-T QP	DF4/IS4/IS-1	3	VVE-DDDRV	429561

Rivacor 7 series

Device type	Lead connection	Number of connector ports	NBD/NBG code	Order number
VR-T	DF4	1	VVE-VVIR	429536
VR-T DX	DF4/IS-1	2	VVE-VDDR	429535
DR-T	DF4/IS-1	2	VDE-DDDR	429534
HF-T	DF4/IS-1/IS-1	3	VDE-DDDRV	429533
HF-T QP	DF4/IS4/IS-1	3	VDE-DDDRV	429532

Package contents

The storage package includes the following:

- Sterile packaging with implantable device
- Serial number label
- Implant card
- Instructions for completing 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.

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

Therapeutic and Diagnostic Functions

Diagnostic Functions

- Data from implantation and the most recent interrogations and follow-ups, as well as arrhythmia episodes, are recorded; they are stored with other data to assess the patient's condition and the device status at any time.
- To check proper lead function, an automatic impedance measurement is performed in the device using sub-threshold pulses. 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 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 rhythms or with high-rate pacing (HF bursts) in case of unstable heart rhythms.
- Depending on the device type, the device software not only contains 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 abort the charge if necessary.
- The shock paths can be set between the different shock coils (SVC/RV) and/or the housing.

Antibradycardia pacing

- Rate hysteresis, 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 can be determined automatically in the device. Additionally, (not applicable to Series 3), capture control is used to set the pulse amplitudes so that pacing is performed with the optimum atrial and ventricular amplitude for patients with each change of the pacing threshold.
- Setting an upper rate for the atrium prevents unspecific atrial pacing, thus reducing the risk of pacemaker-mediated tachycardias.
- Positive AV hysteresis functions support the physiological contraction sequence by promoting intrinsic conduction. Negative AV hysteresis functions support the cardiac resynchronization therapy by maintaining pacing during stress situations.
- Additional, special form of rate adaptation with devices from series 7: An increased cardiac output requirement is detected using physiological impedance measurements. The measuring principle is based on contractile changes (ionotropy) of the myocardium (CLS function: closed loop stimulation). Rate adaptation is automatically initialized and optimized in CLS mode.
- Ventricular pacing suppression with devices from Series 5 and 7: 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

- 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 are available with the HF QP device type.
- For the HF QP device type of the 7 series: Two stimuli can be configured for the left ventricle with a view 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 the pacing configuration to 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 preconfigured programs (ProgramConsult).
- For individual programs, parameter settings can be stored for as many as 3 therapy programs.

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 for a maximum of 14 days using the MRI AutoDetect function during an in-office follow-up.

If the patient is in the vicinity of an MRI scanner during the programmed time duration, the device recognizes the static magnetic field and automatically activates the preset MRI program. Reprogramming to the permanent program also 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 immediately 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:
  - Appointments for Home Monitoring-supported follow-ups can be scheduled.
  - Applies to 7 series: Current device data can be requested by the Home Monitoring Service Center using the QuickCheck function. Provided that 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 data transfer takes place in a timely manner. This process is called "interrogation-on-demand" and normally 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 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 general safety warnings, which are fundamentally 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 related to implantation, which educate about actions and provide instructions for safe operation. 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.

Avoiding Hazardous Situations

All safety-related information is categorized as follows:

- 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.

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 implanted device
- 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

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 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 in-range pacing impedance measurement.

Temperature during shipping and storage

Both extremely low and high temperatures affect the service time of the device's battery.

- 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 packaged 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

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 specific complications. They must be considered to avoid impairment of the functionality of the device and, as a result, not to put patients 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 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.

Possible Undesired Side Effects and Adverse Events

Normal complications may include fluid accumulation within the device pocket, infections, or tissue reactions. Possible residual risks mentioned in the literature are:

- Infection in blood circulation, infection of device pocket, peripheral infection by skin lesion
- Ongoing ventricular tachycardia, prolonged anesthesia or sedation, cardiac arrest, 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 patient's 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 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

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 electromagnetic interference (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 with the device

Cardiac electrotherapy is subject to specific risks. They must be considered in order not to impair the functionality of the device and, as a result, not to put patients 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:

- 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. During lithotripsy, damaging pressure levels may arise. Therapeutic ultrasound may cause excessive warming of body tissue near the device system. The effects on the device are not always immediately apparent.

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

- Keep an external defibrillator ready.
- Electrically insulate the patient.
- Disable the ICD's detection function; the pacemaker function can 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 each procedure.
- After each procedure, (re)enable the detection function and verify normal device function.

During lithotripsy, the following additionally applies:

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

For HF ablation or HF surgery, the following additionally applies:

- Set the pacing mode to minimize the effects of oversensing (for example, incorrect tracking or inhibition). For patients dependent on their pacemaker, program an asynchronous mode. For patients not dependent on their pacemaker, 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.
- 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

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 the 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 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. 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.

3 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

- Device with torque wrench 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: one pentapolar DX lead with poles for the atrium and ventricle and with shock coil
- 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 one unipolar, bipolar, or quadripolar LV lead; for compatible BIOTRONIK leads, see the "ProMRI – MR conditional device systems" manual
- Blind plugs compatible with IS4/IS-1 connections for closing unused connector ports in the header
- DF4 lead connections, as well as IS4 and IS-1, are permitted. In order to prevent a contact problem and consequently deficient therapy, only use the adapters approved by BIOTRONIK for leads with different lead connections 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 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 interference and eliminate it, 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.
- Do not use parts from damaged package.
- 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 the patient's anatomy, the devices are implanted in the pectoral or abdominal region.

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 torque wrench. Use only BIOTRONIK torque wrenches!
- If lead repositioning is necessary, reorder sterile torque wrenches 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 suture holes 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 respective lead connectors are connected to the ports in the header of the device:

1. Remove stylets and stylet guides.
2. Connect the lead for defibrillation and sensing/pacing: DF4/IS-1 or DF4/IS4/IS-1
   Connect the DF4 connector to RV.
3. Connect the lead for sensing/pacing: DF4/IS-1 or DF4/IS4/IS-1
   Connect the bipolar IS-1 connector for the atrium to RA.
   Connect the 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 becomes 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 torque wrench 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 torque wrench without retracting the set screw.
   The silicone plug automatically seals the access to the screw head safely when the torque wrench is withdrawn.

Keeping distance between leads

⚠ WARNING

Inadequate therapy

Leads that are not sufficiently spaced far enough 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 bar.
- Remove the programming head.

Activating ICD therapy

- Load the software that is suitable for the device type in the programmer.
- Activating 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 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.

- For telemetry using programming head: lift the PGH by at least 30 cm.
- For 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.
- 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 recently implanted.
- 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 AutoAdapt.

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. A MorphMatch threshold can be programmed 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.

- Program 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.

- Observe the automatic sensitivity control.
- For manual programming: Determine whether there is far-field sensing and, where appropriate, adapt the blanking period to the sensing setting.

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), DDI(R), AAI(R), DDD-ADI(R) Series 7: DDD-CLS	DDI
VDD(R), VDI(R)	VDI
VVI(R) and OFF Series 7: VVI-CLS	VVI

- The following post-shock program parameters can be adjusted: post-shock duration, basic rate, 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.

- 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 via 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.

Series 7: The QuickCheck function, with which current device data can be requested at any time by the Home Monitoring Service Center (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 active, except during the diagnostic tests. If ICD therapy is not programmed 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 the head application to establish wandless telemetry contact.

Application of a permanent magnet

Applying a permanent magnet disables 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 interval restarts when the magnet is re-applied.

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

Home Monitoring 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 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 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.

Implant Card

An implant card is included in the package contents.

1. Fill in the implant card in accordance with the enclosed filling instructions.
2. Hand over the implant card to the patient after the implantation.

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 the 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/

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 opposite side of the device location within their body.
  - 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 prohibitive 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 physician, environmental hazard

Explanations and device replacement require special measures.

- Please follow all procedures carefully.

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 remain 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 sound 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 with the cleaned device.

4 Parameters

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 and 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	OFF	x	x	x	x
Interval VF	OFF; 150 ... 250 bpm	200 bpm	x	x	x	x

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	x	x	x	x
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	x	x	x	x
Redetection counter VT1	10 ... (2) ... 50	20	x	x	x	x
Redetection counter VT2	10 ... (2) ... 40	14	x	x	x	x
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, onset, 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%		x	x	x
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	x	x	x	x

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

The following parameters apply to series 7 devices:

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

The following parameters apply to series 7 devices:

Atrial therapy in the presence of instable atrial flutter

Parameter	Range of values	Standard	VR	DX	DR	HF
Therapy	OFF; HF burst (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 VT1 and VT2

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
Number S1	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 in 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
Number S1	1 ... (1) ... 15	8	x	x	x	x
R-S1 interval	70 ... (5) ... 85; 88; 90; 95%	88%	x	x	x	x
For ATP type ramp: S1 decrement	5 ... (5) ... 40 ms	10 ms	x	x	x	x
Series 5 and 7: 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	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	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
Series 3: Polarity	Normal; Reverse; Normal -> alternating	Normal	x	x	x	x
Series 5 and 7: Polarity	Normal; Reverse; Normal -> alternating; Reverse -> alternating	Normal	x	x	x	x
Series 3: Shock waveform	Biphasic; Biphasic 2;	Biphasic	x	x	x	x
Series 5 and 7: 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	STD; OFF	STD		x	x	x
Series 5 and 7: DX sensing	ON; OFF	OFF				x
Upper threshold	25; 50; 75%	50%			x	x
	Series 5 and 7: With DX sensing: 25, 50; 75%	75%		x		x

Right ventricular sensing parameters

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

Timing: basic rate day/night and rate hysteresis

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) ... 11:59 PM hh:mm	10:00 PM hh:mm	x	x	x	x
Night ends	00:00 ... (1 min) ... 11:59 PM hh:mm	6:00 AM hh:mm	x	x	x	x

Timing: 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
Series 5 and 7: Rate fading	OFF; ON	OFF	x	x	x	x

Timing: rate adaptation via CLS

The following parameters apply to series 7 devices:

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				x

Timing: 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

Note

In case of a technical malfunction in the device, the high rate protection function limits the pacing rate to a maximum value of 186 bpm.

Timing: 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 VDD(R) mode: VDI(R)	VDIR		x	x	x
	Series 3: After DDD(R) mode: DDI(R)	DDIR			x	x
	Series 5 after mode DDD(R), DDD-ADI(R): DDI(R)	DDIR			x	x
	Series 7 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	3 ... (1) ... 8 (out of 8)	5		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
Series 5 and 7: Rate stabilization with mode switching	ON; OFF	OFF		x	x	x

Pacing: ventricular pacing suppression

The following parameters apply to series 5 and series 7 devices:

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

Pacing: 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), 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

The following parameters apply to series 7 devices:

Parameter	Range of values	Standard	VR	DX	DR	HF
CRT AutoAdapt	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

Timing: 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
AV hysteresis (negative)	10 ... (10) ... 150 ms	50 ms		x	x	x
AV scan and repetitive (positive)	OFF; ON	ON		x	x	x

Pacing: post-shock

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

Pacing: 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 width A	0.4; 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	AUTO	x	x	x	x
Pulse width RV	0.4; 0.5 ... (0.25) ... 1.5 ms	0.4 ms	x	x	x	x
Pulse amplitude LV	0.5 ... (0.25) ... 4.0 ... (0.5) ... 6.0; 7.5 V	AUTO				x
Pulse width LV	0.4; 0.5 ... (0.25) ... 1.5 ms	0.4 ms				x

Pacing: ventricular MultiPole pacing

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

Pacing: atrial capture control

The following parameters apply to series 5 and series 7 devices:

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

The following parameters apply to series 3 devices:

Parameter	Range of values	Standard	VR	DX	DR	HF
Atrial capture control	OFF; ATM	ATM			x	x
Threshold test start	With ATM: 3.5 V	Permanent			x	x

Pacing: ventricular capture control

The following parameters apply to series 5 and series 7 devices:

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

The following parameters apply to series 3 devices:

Parameter	Range of values	Standard	VR	DX	DR	HF
Ventricular capture control RV + LV	OFF; ATM	ATM	x	x	x	x
Threshold test start	With ATM: 3.5 V	Permanent	x	x	x	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	50 ... (10) ... 100 ms	80 ms				x
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	
Pacing polarity LV (IS4)	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

Parameter	Range of values	Standard	HF	QP
7 series: 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
Sensing polarity LV (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	OFF; ON	ON	x	x	x	x
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 (HMSC):

Parameter	Range of values	Standard	VR	DX	DR	HF
Transmission on	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 Series 7: Extended ON	ON		x	x	x
For SVT	OFF; ON	ON	x	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	02:00 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
Series 5 and 7: Thoracic impedance (TI)	OFF, ON	OFF	x	x	x	x

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	V00; OFF	OFF	x	x		
	V00; D00; OFF	OFF			x	
	V00; V00-BiV; D00; D00-BiV; OFF	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 permanent program				x
Pulse width LV	As in permanent program; 0.4; 0.5 ... (0.25) ... 1.5 ms	As in permanent program				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	As in permanent program				x

5 Technical Data

Mechanical Characteristics

Housing

	Devices with header for DF4 connector			
Type	**Lead connector**	**W x H x D in mm**	**Volume [cm³]**	**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
  - Seal IS4/DF4 connector port: silicone (0.16 cm^2 per connector port)
  - Cap IS4/DF4 connector port: polysulfone/epoxy (0.05 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)

Type	Lead connector	Contact surface housing: titanium	Contact surface header: epoxy	Number of silicone plugs
VR	DF4	59.3 cm^2	15.1 cm^2	1
VR DX	DF4	59.3 cm^2	18.8 cm^2	2
DR	DF4	59.3 cm^2	18.8 cm^2	2
HF	DF4	59.3 cm^2	22.2 cm^2	3
HF QP	DF4	59.3 cm^2	25.9 cm^2	3

Note

Information according to Section 33 of REACH, Regulation (EC) No. 1907/2006 is available in digital form on the internet at: https://www.biotronik.com/material-compliance

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

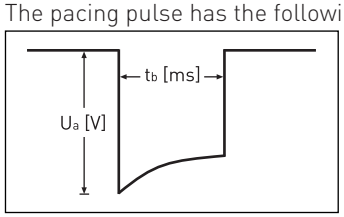
- Arrhythmia zones VT1, VT2, VF: OFF
- Antibradycardia pacing: OFF
- Home Monitoring: OFF

Telemetry data for Home Monitoring

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

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 on the pacing impedance.

Resistance to interference

- Note on device type VR DX (devices only with a DF4/IS-1 connector port): The EMC requirements are met as long as atrial sensitivity is set to values ≥ 1.0 mV. Measures must be taken to assure interference-free therapy if more sensitive values are set.
- Note on device type DR, HF, and HF QP: The EMC requirements are met as long as atrial sensitivity is set to values ≥ 0.3 mV. Measures must be taken to assure interference-free therapy if more sensitive values are set.
- Note on device type HF and HF QP: For unipolar sensing, the requirement for interference voltages of ≤ 0.3 mV (peak-to-peak) is met.

Common mode rejection ratio

The common mode rejection ratio for the frequencies 16.6 Hz, 50 Hz, and 60 Hz is at least 40 dB.

ATP amplitude

ATP type: burst; number S1: 5; R-S1 interval: 300 ms; pulse width: 1.5 ms; maximum amplitude: 7.5 V

Chamber	Maximum amplitude	Averaged value according to ISO 14708-6:2019 section 28.8.2 d) 3)
RA	7.5 V (± 1.5 V)	4.9 V (± 1.0 V)
RV	7.5 V (± 1.5 V)	4.9 V (± 1.0 V)
LV	7.5 V (± 1.5 V)	4.9 V (± 1.0 V)

Automatic sensitivity control

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
A: positive	0.2 mV	0.2 ... 0.5
A: negative	0.2 mV	0.2 ... 0.5
DX: A: positive	0.2 mV	0.2 ... 0.52 (0.05 to 0.13)
DX: A: negative	0.2 mV	0.2 ... 0.52 (0.05 to 0.13)
RV: positive	0.5 mV	0.3 ... 0.7
RV: negative	0.5 mV	0.3 ... 0.7
LV: positive	0.5 mV	0.3 ... 0.7
LV: negative	0.5 mV	0.3 ... 0.7

Shock energy/peak voltage

With shock path: RV to housing + SVC

Shock energy (tolerance)	Peak voltage	Measured value shock energy
1 J (0.7 ... 1.18)	90 ... 120 V	0.79 J
20 J (15.9 ... 21.6)	470 ... 510 V	18.2 J
40 J (33.8 ... 41.4)	670 ... 730 V	37.3 J

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 QP	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 service 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 [years] x number of shocks per year

Rivacor 3/5/7 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

Rivacor 5/7 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

Rivacor 3/5/7 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

Rivacor 3/5/7 HF-T, Rivacor 3/5 HF-T QP

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

Rivacor 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:

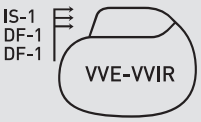
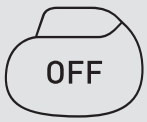
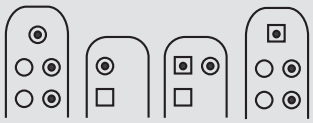
Pacing	Service time [in years] at number of shocks per year					
	2	4	8	12	16	20
0%	12.9	11.5	9.4	7.9	6.8	6.0
15%	11.7	10.5	8.7	7.4	6.4	5.7
50%	9.4	8.6	7.3	6.4	5.6	5.1
100%	7.3	6.8	6.0	5.3	4.8	4.4

Legend for the Label

Label on the package

The label icons symbolize the following:

Symbol	Meaning
	Manufacturing date
	Use by
	Temperature limit Observe the information on temperatures during shipping and storage in this technical manual.
	BIOTRONIK order number
	Serial number
	Unique device identifier
	Medical device
	Product identification number
	Dangerous voltages
	CE mark
	Manufacturer
	Contents
	Torque wrench
manuals.biotronik.com 	Follow the electronically available instructions for use!
	Observe the technical manual (white image on blue background)
	Sterilized with ethylene oxide

Symbol	Meaning
	Do not resterilize
	Single sterile barrier system with protective packaging inside
	Do not reuse
	Do not use if packaging is damaged and consult the technical manual
	Transmitter with non-ionizing radiation at designated frequency
	MR conditional
TP2	Compatibility with telemetry protocol version 2 of BIOTRONIK Home Monitoring
 Example	Device: NBG code and compatible leads
 Example	Factory settings for therapy: OFF
	Examples of the header configuration: DF-1/IS-1 • DF4/IS-1 • DF4/IS-1/IS4 • DF-1/IS-1/IS4
	Scannable QR code