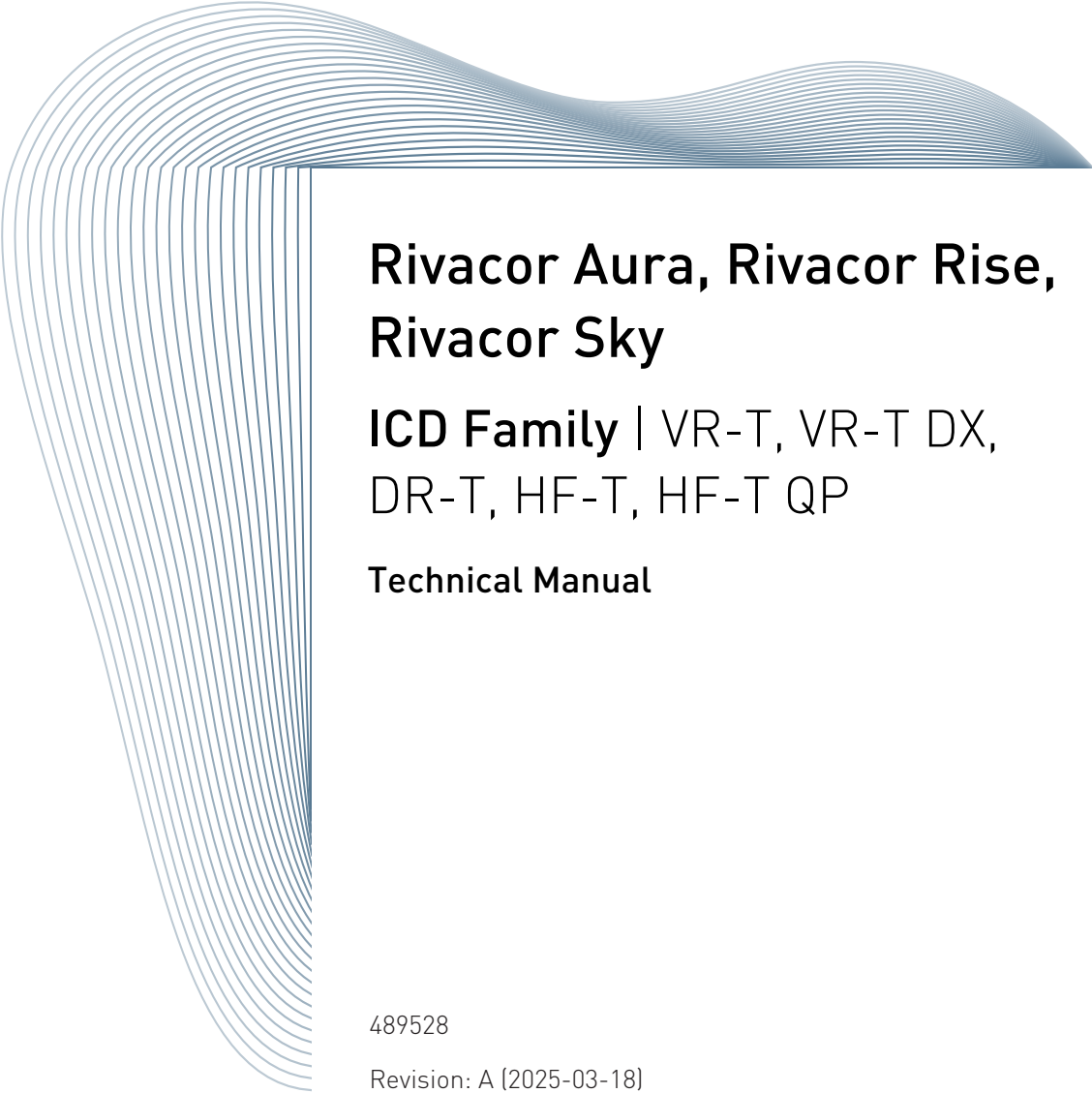




Rivacor Aura, Rivacor Rise, ProMRI Rivacor Sky

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

Technical Manual

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1 **About This Technical Manual**

Objective

This technical manual contains information for physicians and medical professionals regarding the device, the implantation, programming, and follow-up of an implantable cardioverter-defibrillator (ICD) as well as information on safe handling of the device.

Technical manuals

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

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

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

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

Conventions

Identification of Safety Warnings

The following symbol draws attention to potential safety risks:



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

Safety warnings are also indicated by a signal word.

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

Typographical Conventions

The following typographical conventions are used in this technical manual:

Instructions

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

Prerequisite

- This is a prerequisite.
1. Step
 2. Step
 - ▶ Intermediate result
 3. Step

Result

This is the result.

Cross references

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

Highlights

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

Gender

If personal designations are used only in the male or female form for reasons of better readability, this expressly includes all other gender identities.

2 Product Description

Intended Medical Purpose

Intended Purpose

Rivacor Aura, Rivacor Rise and Rivacor Sky 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 along with pacing and defibrillation leads. The implantation of an ICD/CRT-D device is performed for the following objectives:

- Monitoring the intrinsic heart rhythm and rate and detecting ventricular arrhythmias (ICDs and CRT-Ds)
- Termination of ventricular tachycardia (VT) through antitachycardia pacing (ATP) (ICDs and CRT-Ds)
- Termination of atrial tachycardia (AT/AF) through antitachycardia pacing (ATP) (ICDs and CRT-Ds)
- Termination of ventricular fibrillation (VF) or ventricular tachycardia (VT) through shock delivery (ICDs and CRT-Ds)
- Correction of bradycardia through atrial, ventricular or AV sequential pacing (ICDs and CRT-Ds)
- Cardiac resynchronization through biventricular or left ventricular pacing (CRT-Ds)
- Physiological pacing of the left ventricle by stimulating the conduction system/LBBAP (CRT-Ds)

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 having 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@biotronic.com

Intended Clinical Benefit

The clinical benefits for the patients inherent to the use of the Rivacor Aura, Rivacor Rise and Rivacor Sky ICDs/CRT-Ds are:

- Detection of tachyarrhythmias and subsequent restoration of a physiological heart rate and rhythm
The related performance outcome for this clinical benefit is defined as successful termination of arrhythmias or cardiac arrest either by ATP or by shock delivery.
- Detection of bradycardia if present, and subsequent establishment of a physiologically appropriate heart rate
The related performance outcome for this clinical benefit is defined as successful compensation of bradycardia by antibradycardia pacing.

CRT-Ds provide the additional clinical benefit of improving the ejection fraction and / or cardiac output in patients with heart failure and intraventricular dyssynchrony. The related performance outcome for this clinical benefit is defined as successful cardiac resynchronization through biventricular or physiological pacing.

Patient Target Group

Rivacor Aura, Rivacor Rise and Rivacor Sky ICDs and CRT-Ds 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 another imaging method should be considered
- Children, if it is determined that their physical proportions can accommodate the physical dimensions of an ICD/CRT-D. Challenges may arise due to the growth of the patient and the length of the used leads.

ICDs and CRT-Ds 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 of guideline recommendations is consensus-based.

Indications**ICD indications**

Single- and dual-chamber ICDs are indicated to treat life-threatening ventricular arrhythmias as primary or secondary prevention by means of ventricular antitachycardia pacing and/or ventricular defibrillation. Furthermore, ICDs are capable of treating bradycardia. 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 who are candidates for an ICD and additionally have:

- Heart failure in sinus rhythm with reduced left ventricular ejection fraction (LVEF $\leq$ 35%) and ventricular dyssynchrony (defined as QRS duration $\geq$ 120 ms)
- Reduced ejection fraction and high-degree AV block, this includes patients with AF

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

Contraindications

- Tachyarrhythmia caused by temporary or reversible conditions, e.g., poisoning, electrolyte imbalance, hypoxia, sepsis, or acute myocardial infarction

For further information on indications and contraindications of ICDs and CRT-Ds, please refer to the current applicable guidelines of the Heart Rhythm Society (HRS), the American College of Cardiology (ACC), the American Heart Association (AHA), and the European Society of Cardiology (ESC) as well as directives from other national cardiology associations.

System Overview

Device Family

The complete Rivacor 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
Single-chamber	Rivacor Aura VR-T Rivacor Aura VR-T DX Rivacor Rise VR-T Rivacor Rise VR-T DX Rivacor Sky VR-T Rivacor Sky VR-T DX
Dual-chamber	Rivacor Aura DR-T Rivacor Rise DR-T Rivacor Sky DR-T
Triple-chamber	Rivacor Aura HF-T Rivacor Aura HF-T QP Rivacor Rise HF-T Rivacor Rise HF-T QP Rivacor Sky HF-T Rivacor Sky 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.

Rivacor Aura		
Device type	UDI-DI	B-UDI-DI
VR-T	04035479183011	4035479BUDI00099QX
VR-T DX	04035479185695	4035479BUDI00099QX
DR-T	04035479183004	4035479BUDI00099QX
HF-T	04035479182991	4035479BUDI00100PP
HF-T QP	04035479182984	4035479BUDI00100PP

Rivacor Rise		
Device type	UDI-DI	B-UDI-DI
VR-T	04035479183066	4035479BUDI00099QX
VR-T DX	04035479183059	4035479BUDI00099QX
DR-T	04035479183042	4035479BUDI00099QX
HF-T	04035479183035	4035479BUDI00100PP
HF-T QP	04035479183028	4035479BUDI00100PP

Rivacor Sky		
Device type	UDI-DI	B-UDI-DI
VR-T	04035479182793	4035479BUDI00099QX
VR-T DX	04035479182779	4035479BUDI00099QX
DR-T	04035479182755	4035479BUDI00099QX
HF-T	04035479182861	4035479BUDI00100PP
HF-T QP	04035479182854	4035479BUDI00100PP

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/IS-1/IS4

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

DF4/IS-1

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

VR-T	VR-T DX	DR-T	HF-T
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-T, VR-T DX, DR-T, HF-T
RA	IS-1	Bipolar	Atrium	VR-T DX, DR-T, HF-T
LV	IS-1	Unipolar, bipolar	Left ventricle, left bundle branch area	HF-T

DF4/IS-1/IS4

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

HF-T 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-T QP
RA	IS-1	Bipolar	Atrium	HF-T QP
LV	IS4	Unipolar, bipolar, quadripolar	Left ventricle	HF-T 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. The 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 2502.A or higher, or NEO software version 2502.A or higher.

The programmer contains an integrated module for RF telemetry.

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

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

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

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 Rivacor Rise and Rivacor Sky 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 below.

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

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

Rivacor Sky		
Device type	Pacing modes	Standard
VR-T	VI-CLS; VI; VIR; V00; OFF	VI
VR-T DX	VDD; VDDR; VDI; VDIR; VI-CLS; VI; VIR; V00; OFF	VI
DR-T, HF-T (QP)	DDD-CLS; DDD; DDDR; DDD-ADI; DDDR-ADIR; DDI; DDIR; D00; VDD; VDDR; VDI; VDIR; VI-CLS; VI; VIR; 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

WVIR is the NBD 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.

Order Numbers

Not all device types are available in every country.

Rivacor Aura				
Device type	Lead connection	Number of connector ports	NBD/NBG code	Order number
VR-T	DF4	1	VE-WVIR	482015
VR-T DX	DF4/IS-1	2	VE-VDDR	487199
DR-T	DF4/IS-1	2	VE-DDDR	482014
HF-T	DF4/IS-1/IS-1	3	VE-DDDRV	482013
HF-T QP	DF4/IS4/IS-1	3	VE-DDDRV	482012

Rivacor Rise				
Device type	Lead connection	Number of connector ports	NBD/NBG code	Order number
VR-T	DF4	1	VE-WVIR	482020
VR-T DX	DF4/IS-1	2	VE-VDDR	482019
DR-T	DF4/IS-1	2	VE-DDDR	482018
HF-T	DF4/IS-1/IS-1	3	VE-DDDRV	482017
HF-T QP	DF4/IS4/IS-1	3	VE-DDDRV	482016

Rivacor Sky				
Device type	Lead connection	Number of connector ports	NBD/NBG code	Order number
VR-T	DF4	1	WE-WIR	481984
VR-T DX	DF4/IS-1	2	WE-VDDR	481983
DR-T	DF4/IS-1	2	VDE-DDDR	481982
HF-T	DF4/IS-1/IS-1	3	VDE-DDDRV	481991
HF-T QP	DF4/IS4/IS-1	3	VDE-DDDRV	481990

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

Diagnostic and Therapy 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 lead II or III (Einthoven).
- When 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). In the VT1 and VT2 zone, up to 2 ATP sequences can be programmed, each with up to 10 individually adjustable ATP attempts. Stable ventricular tachycardia in the VF zone can be treated with ATP One Shot before a shock is delivered.
- Rivacor Sky: With the atrial ATP function, dual- and triple-chamber devices can treat atrial tachycardias with ATP in case of stable heart rhythms. 2 sequences can be programmed, each with up to 10 individually adjustable ATP attempts. If needed, atrial ATP can be repeated to better support termination of diverse arrhythmias.
 Unstable atrial tachyarrhythmias can be treated with high-rate pacing (HF burst). One burst of ATP with up to 10 attempts is available and programmable.
 Before delivering the therapy, an automatic lead check verifies the correct positioning of the atrial lead.
 If the atrial tachycardia cannot be terminated, it is possible to deliver ATP therapy multiple times after a specific amount of time has expired, based on programming, or when the device determines there has been a defined change in the atrial tachycardia frequency or stability.
 Additionally, ventricular backup stimulation can be programmed.
- Depending on the device type, the device software contains not only the ICD functions but also all pacemaker functions for two or three chambers. The heart rhythm is continuously monitored; each arrhythmia is classified according to the heart rate and the adjustable detection criteria. Depending on the programmed parameters, 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 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 patients with each change of the pacing threshold.
- Setting an atrial upper rate 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.
- Rivacor Rise and Rivacor Sky: Additional, special form of rate adaptation: 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.
- Rivacor Rise and Rivacor Sky: 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

- 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-T QP device type.
- Rivacor Sky HF-T QP: Two stimuli can be configured for the left ventricle to improve the ventricular resynchronization. The stimuli can be delivered sequentially or simultaneously.
- Rivacor Rise and Rivacor Sky: The effectiveness of resynchronization can be improved if intrinsic AV delays exist: The CRT AutoAdapt function 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.
- The CRT AutoResync function shall allow to recognize LVURI lock-in behavior and re-establish CRT and thereby resolve such a lock-in scenario. LVURI lock-in behavior at the end of the automatic Amplitude Measurement, PMT-suspicious phase, CRT AutoAdapt conduction test and automatic threshold searches for A/RV/LV (ATM/ACC) can be prevented.

Physiological Pacing

Rivacor Rise and Rivacor Sky: With triple-chamber HF-T devices most physiological therapy can be achieved through stimulation of the conduction system, thereby supporting the hemodynamics of the heart.

- A lead can be implanted in the left bundle branch or in the left bundle branch area for left bundle branch area pacing.

Storing Programs

There are different therapy programs:

- For the most common pacemaker indications there are preset parameters (ProgramConsult).
- Up to 3 therapy programs can be stored for individual parameter settings.

Brady AutoInitialization

Brady AutoInitialization begins the automatic initialization of the device once the RV lead is detected. The process is usually terminated 10 minutes after connection of the RV lead.

Patient data, bradycardia programs and tachycardia programs can be pre-programmed before a lead is connected. After Brady AutoInitialization, the pre-programmed bradycardia parameters are activated. If no program has been transferred before or during Brady AutoInitialization, the device subsequently works with active automatic bradycardia functions in the factory settings.

The tachycardia parameters are not configured and set during Brady AutoInitialization. Those parameters need to be configured and activated manually after the initialization. Preset tachycardia programs also need to be activated manually.

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

Behavior during Brady AutoInitialization

- Transmission of a permanent program:
Brady AutoInitialization is terminated and the transferred program is active.
- Testing:
Tests cannot be performed during Brady AutoInitialization; stop it beforehand. Brady AutoInitialization will not be continued upon completion of the test.
- Shock delivery:
If a shock is delivered during the Brady AutoInitialization, the Brady AutoInitialization is terminated.

ProMRI Devices Recognize Magnetic Resonance Imaging Scanners**Rivacor Aura:**

With the MRI AutoDetect function, the implanted device has a sensor which recognizes the magnetic and gradient magnetic fields of an MRI scanner.

After the implantation or during a follow-up, the sensor can be activated for a maximum of 14 days and an MRI mode can be programmed.

If the patient is in the vicinity of an MRI scanner during the programmed time duration, the implanted device automatically switches to this predefined MRI mode. When the patient leaves the scanner, the implanted device automatically switches back to the programmed permanent mode.

For more information refer to the "ProMRI – MR conditional device systems" manual.

Rivacor Rise and Rivacor Sky:

With the MRI Guard 24/7 function, the implanted device has a sensor which recognizes the magnetic and gradient magnetic fields of an MRI scanner.

After the implantation or during a follow-up, the device system has to be approved for MRI exams and an MRI brady mode can be programmed for 1 year. The MRI brady mode can also be programmed to OFF, this setting is also valid for 1 year.

If the patient is in the vicinity of an MRI scanner, the implanted device automatically switches to this predefined MRI brady mode. When the patient leaves the scanner, the implanted device automatically switches back to the programmed permanent mode.

For more information refer to the "ProMRI – MR conditional device systems" manual.

Home Monitoring Functions

- The device automatically sends information to the transmitter once a day. It also sends messages related to events, which are forwarded to the Home Monitoring Service Center (HMSC). In addition, test messages can be initiated using the programmer.
- Important medical information in the device messages include the following:
 - Atrial and ventricular arrhythmias
 - Parameters relevant to leads in the atrium and ventricle: pacing thresholds, sensing amplitudes, impedances
 - Current statistics
 - IEGM-Online HD with up to 3 high-definition channels
- The following remote functions are possible via the Home Monitoring Service Center:
 - A schedule for Home Monitoring-supported follow-ups can be established.
 - Rivacor Sky: Current device data can be requested by the Home Monitoring Service Center using the QuickCheck function. If the patient is in the vicinity of the CardioMessenger transmitter, the usual data for a Home Monitoring-supported follow-up is compiled, an IEGM is added, and transmitted. This process usually runs within a maximum 15 minutes.
- Rivacor Rise and Rivacor Sky: The usual data for a Home Monitoring-supported follow-up, including a periodic IEGM recording, is transmitted to the Home Monitoring Service Center approximately 2 hours after the implantation using the EarlyCheck function. This message type can

therefore be used to carry out the first follow-up after implantation using remote monitoring. As is also common with daily message transmission, pacing thresholds are only measured automatically if capture control is activated.

3 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**

Use of electronic implanted devices in close proximity to the heart is subject to special conditions. With regard to transport and storage, sterility, technical complications, instructions regarding implantation or high-risk procedures or therapies for persons who have an implanted device, note that the device is very sensitive. In order not to harm patients, it must not be damaged.

- Observe and follow all instructions in this and related technical manuals.

Safety Instructions and Warnings in this Technical Manual

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

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

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 [Page 65].

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.
- Do not resterilize or reuse the device.

The torque wrench is also intended for single use only.

Possible Complications



WARNING

Risk to patient and interferences with the device

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

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

General Information on Medical Complications

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

It is impossible to guarantee the efficacy of antiarrhythmia therapy, even if the programs have proven successful during tests or subsequent electrophysiological studies. In 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

Possible residual risks as well as undesirable side effects and adverse events 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.

Magnetic Fields

If the magnetic sensor in the device recognizes a magnetic field, the device switches to the programmed MRI mode. If the device switches to the MRI mode unintendedly, this can lead to a loss of therapy.

- Inform the patient that the magnetic sensor in the device detects magnetic fields starting at a magnetic flux density of approximately 10 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.

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 procedures such as electrocautery, HF ablation, or HF surgery. During lithotripsy, damaging pressure levels may arise. Therapeutic ultrasound and diathermy may cause excessive warming of body tissue near the device system. Transcutaneous electrical nerve stimulation can cause damage to the implanted device. 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.

During diathermy, the following additionally applies:

- Do not apply diathermy in the immediate vicinity of the implanted 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.
- After external defibrillation always evaluate the device's status and functionality.

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. Apply the following measures during the administration of therapeutic ionizing radiation:

- Adhere to instructions for risky therapeutic and diagnostic procedures.
- Shield the device against radiation.
- Disable the device's detection function.
- 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.

Increased Ambient Pressure

Conditions with high ambient pressure can cause device damage, which can lead to therapy failure. The device has been tested in conditions of up to 4.5 bar abs.

- Apply caution when using hyperbaric oxygen therapy and verify normal device function afterwards.
- Instruct the patient to avoid environments with an ambient pressure that could cause device damage.

4 Implantation

Implantation Procedure


WARNING
Risk to patient, risk to physician and interferences of device

Work preparations and implantation procedures require special measures.

- Please follow all procedures carefully.

Having Parts Ready

The following parts are required:

- Device with torque wrench from BIOTRONIK
- Blind plugs compatible with IS4/IS-1 connections for closing unused connector ports in the header
- BIOTRONIK programmer and approved cables
- External multi-channel ECG device

Additionally, the following leads are required:

Single-chamber **VR-T** devices:

- 1 bipolar ICD lead with 1 or 2 shock coils for the ventricle

Single-chamber **VR-T DX** devices:

- 1 bipolar DX lead with electrodes for the atrium and ventricle and with shock coil

Dual-chamber **DR-T** devices:

- 1 bipolar lead for the atrium
- 1 bipolar ICD lead for the ventricle with 1 or 2 shock coils

Triple-chamber **HF-T** devices:

- 1 bipolar lead for the atrium
- 1 bipolar ICD lead for the ventricle with 1 or 2 shock coils
- 1 unipolar or bipolar LV lead for the left ventricle
or 1 bipolar pacemaker lead for the left bundle branch area

or

- 1 bipolar DX lead with electrodes for the atrium and ventricle and with shock coil
- 1 unipolar or bipolar LV lead for the left ventricle
or 1 bipolar pacemaker lead for the left bundle branch area

Triple-chamber **HF-T QP** devices:

- 1 bipolar lead for the atrium
- 1 bipolar ICD lead for the ventricle with 1 or 2 shock coils
- 1 unipolar, bipolar, or quadripolar LV lead for the left ventricle

or

- 1 bipolar DX lead with electrodes for the atrium and ventricle and with shock coil
- 1 unipolar or bipolar LV lead for the left ventricle

Only use compatible leads to ensure that therapy is delivered adequately. For compatible BIOTRONIK leads, see "ProMRI – MR conditional device systems" manual.

IS4 and IS-1 lead connections are permitted. Only use adapters approved by BIOTRONIK for leads with different lead connections or leads from other manufacturers.

Have spares of all sterile parts 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 unpackaged 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.
1. 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!
 2. Take hold of the inner blister by the gripping tab and take it out of the outer blister.
 3. 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.

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.

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.

Lead Implantation in the Left Bundle Branch Area

Implanting a lead in the left bundle branch area is associated with specific risks and therefore requires special attention.

The following must be considered when implanting a lead:

- Use suitable implant accessories to ensure the correct positioning and fixation of the lead in the septum.
- During implantation continuously check the morphology in the ECG to ensure lead contact with the septum and to avoid septum perforation.

Keeping Distance between Leads



WARNING

Inadequate therapy caused by wrong lead position

If the shock coil of an ICD lead is too close to another lead, the sensing may be interfered. This can cause oversensing and ineffective defibrillation.

If there is contact between 2 leads, delivered therapies may be misdirected. This can reduce the effect of the therapies.

- Position the leads with sufficient space between the leads.
- Check the lead positions during the implantation. Reposition the leads if necessary.

Avoiding Damage to the Header

Set screws and blind plugs (if applicable) must be tightened or loosened with care. If the screws are not tightened, the lead contacts may be insufficient which could result in a loss of therapy.

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

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 connectors 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. Prior to testing and configuration, wait for the successful completion of Brady AutoInitialization.
9. Configure and activate tachycardia parameters.

Note

If necessary, the device can also be programmed before or during Brady AutoInitialization.

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.

Connecting the Lead Connectors 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 for the **right ventricle** to RV.
3. Connect the first lead for sensing/pacing (DF4/IS-1 or DF4/IS4/IS-1):
Connect the bipolar IS-1 connector for the **atrium** to RA.
4. Connect the second lead for sensing/pacing (DF4/IS-1 or DF4/IS4/IS-1):
Connect the quadripolar IS4 connector or unipolar or bipolar IS-1 connector for the **left ventricle** to LV.
or
Connect the unipolar or bipolar IS-1 connector for the **left bundle branch area** to LV.
5. 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.
6. If you cannot easily plug the lead connector into the connection, use only sterile water as lubricant.
7. 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.
8. Carefully loosen the set screw without completely unscrewing it, so that it does not become tilted upon retightening.
9. Turn the set screw clockwise until torque control starts.
 - ▶ You will hear a clicking sound.
10. 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.

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.

Applying the Programming Head

The programming head (PGH) features a diagram of the device. This can be used to assist in positioning the head to ensure proper telemetry. If the programming head is removed during temporary programming, the program cannot be transferred.

- Make sure the PGH is positioned correctly during programming of the implanted device.

Establishing Wandless Telemetry

The programmer must be no more than 3 m from the device; ideally, there should be no obstructions between the patient and the programmer.

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



- ▶ The wandless telemetry symbol is displayed in the navigator and the signal strength is displayed in the status bar.
3. Remove the programming head.

Activating ICD therapy

ICD therapy needs to be activated after implantation detection.

1. Load the software that is suitable for the device type in the programmer.
2. Activate ICD therapy.
3. Take precautionary measures while programming.

Shipment mode is permanently deactivated and device data is saved once the following steps have been completed during implantation:

- The RV lead has been connected to the device.
 - Brady AutoInitialization has been completed successfully.
- or

A program has been transmitted, and initial measurement of the pacing impedance has been performed successfully.

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 Failures



WARNING

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

If leads are dislocated or their function is impaired, sensing and therapy delivery may be affected. 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.

- 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.
- Perform a threshold test to determine whether the threshold is clinically and technically justifiable. If necessary, adjust the pacing parameters.
- Continuously monitor the ECG and the patient's condition.
- Cancel testing if necessary.

Enabling ICD Detection and Therapies After Brady AutoInitialization

The Brady AutoInitialization function does not automatically enable ICD detection and therapies.

- Enable ICD detection and therapies manually after the Brady AutoInitialization.

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.

- Consider using 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.

Preventing Device-Induced Ventricular Tachycardia

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

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

Avoiding AV Crosstalk

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

- Check the settings for the presence of crosstalk.
- If necessary, temporarily set VVI and a rate for backup stimulation so that 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 $> 25 \Omega$.

Preventing Recurrence after Therapy Shock

After a shock delivery, the pacing threshold may be temporarily elevated. This can lead to a loss of pacing therapy.

- Chose appropriate post-shock program parameters.
- 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

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, DDDR, DDD-CLS, DDD-ADI, DDD-ADIR, DDI, DDIR, AAI, AAIR	DDI
VDD, VDDR, VDI, VDIR	VDI
WVI, WVR, WVI-CLS and OFF	WVI

Preventing Interferences from Backup Stimulation and Intrinsic Rhythm

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

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

No Shock Delivery During ATP Therapies

During the delivery of ATP therapies, the implanted device cannot deliver shocks. When long ATP therapies are delivered, a shock might not be delivered in time.

- When programming long ATP sequences, observe that a shock is only delivered after an unsuccessful ATP attempt.

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.

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.

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

MultiPole 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 the programming head application to establish wandless telemetry contact.

Application of a Permanent Magnet

- ICD detection and therapy remain active, when a permanent magnet is applied to the ICD while the ICD is communicating with the programmer.
- ICD detection and therapy are temporarily disabled, when a permanent magnet is applied to the ICD if the ICD is **not** communicating with the programmer.

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:

- Inform the patient about residual risks, adverse events and side effects.
- Request that patients contact their 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 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.

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, taking into account current medical guidelines and the use of BIOTRONIK Home Monitoring.

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.

Follow-Up with BIOTRONIK Home Monitoring

Home Monitoring does not serve to replace regular in-office follow-ups 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.

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

Checking the Battery Charge with the Programmer

The measurement of the battery voltage that can be initiated with the programmer is only reliable, if, in the last 24 hours, no shock has been delivered and no capacitor reforming has occurred.

- Use the battery status indicator on the programmer to check the remaining battery charge.

Elective Replacement Indication (ERI)

Elective Replacement Indication can be detected by Home Monitoring and is displayed on the programmer after interrogation of the implanted device.

When the device reaches ERI, the following applies:

- The device can monitor the heart rhythm for at least 3 more months.
- Chose an appropriate follow-up interval to check the remaining service time. Replace device soon.
- At least 6 maximum energy shocks can be delivered until EOS occurs.
- The set parameters in the device do not change.

EOS Replacement Indication



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!

End of Service can be detected by Home Monitoring and is displayed on the programmer after interrogation of the implanted device.

When the device reaches EOS, the following applies:

- 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

Explantations and device replacement require special measures.

- Please follow all procedures carefully.

Explantation

1. Interrogate the device status.
2. Deactivate VT and VF therapies prior to explantation.
3. Remove the leads from the header. Do not simply cut them loose.
4. 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.

5 Parameters

Note
The parameter values in the following tables correspond to the displayed values on the programmer.

ICD Therapy

Parameter	Range of values	Standard	VR-T	DX	DR-T	HF-T	QP
ICD therapy	OFF ; ON	ON	X	X	X	X	X

Tachycardia

Detection: Interval/Rate

Note

Values can be set both in bpm and in ms.

Parameter	Range of values	Standard	VR-T	DX	DR-T	HF-T	QP
AT/AF interval	240; 250; 261; 273; 286; 300; 316; 333; 353; 375; 400; 429; 462; 500; 545; 600 ms	300 ms		X	X	X	X
VT1 interval	OFF; 270 ... (10) ... 600 ms	OFF	X	X	X	X	X
VT2 interval	OFF; 270 ... (10) ... 500 ms	320 ms	X	X	X	X	X
VF interval	OFF; 240 ... (10) ... 400 ms	260 ms	X	X	X	X	X

Detection: Detection Counter

Parameter	Range of values	Standard	VR-T	DX	DR-T	HF-T	QP
Counter: Detection VT1	10 ... (2) ... 100	48	X	X	X	X	X
Counter: Detection VT2	10 ... (2) ... 80	30	X	X	X	X	X
Counter: Detection 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	30 out of 40	X	X	X	X	X

Detection: Redetection Counter

Parameter	Range of values	Standard	VR-T	DX	DR-T	HF-T	QP
Counter: Redetection VT1	10 ... (2) ... 50	20	X	X	X	X	X
Counter: Redetection VT2	10 ... (2) ... 40	14	X	X	X	X	X
Counter: Redetection 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	X

Detection: SMART Detection

Parameter	Range of values	Standard	VR-T	DX	DR-T	HF-T	QP
SMART detection: VT1	OFF; ON	ON		X	X	X	X
SMART detection: VT2	OFF; ON	ON		X	X	X	X

Detection: Onset

Parameter	Range of values	Standard	VR-T	DX	DR-T	HF-T	QP
SMART detection ON: Onset VT1/VT2	4 ... (4) ... 32 %	20 %		X	X	X	X
SMART detection OFF: Onset VT1/VT2	OFF; 4... (4) ... 32 %	20 %	X	X	X	X	X

Detection: Stability

Parameter	Range of values	Standard	VR-T	DX	DR-T	HF-T	QP
SMART detection ON: Stability VT1/VT2	8 ... (4) ... 48 ms	48 ms		X	X	X	X
SMART detection OFF: Stability VT1/VT2	OFF; 8 ... (4) ... 48 ms	48 ms	X	X	X	X	X

Detection: Morphology**Note**

The following parameters are only programmable if SMART detection is programmed to OFF and no biventricular pacing is programmed.

Parameter	Range of values	Standard	VR-T	DX	DR-T	HF-T	QP
VT1 MorphMatch	OFF; ON	ON	X	X	X	X	X
VT2 MorphMatch	OFF; ON	ON	X	X	X	X	X
MorphMatch threshold*	Low; Std.; High	Std.	X	X	X	X	X

*Maximum values for MorphMatch threshold: Low: 58; Std.: 76; High: 86

Detection: Sustained VT**Note**

The following parameters are only programmable if SMART detection is programmed to OFF and no onset or stability are programmed.

Parameter	Range of values	Standard	VR-T	DX	DR-T	HF-T	QP
Sustained VT	OFF; 1 ... (1) ... 3; 5; 10 ... (10) ... 30 min	OFF	X	X	X	X	X

Therapy: AT

The following parameters apply to Rivacor Sky:

Parameter	Range of values	Standard	VR-T	DX	DR-T	HF-T	QP
Coagulation time out	OFF; 48 h	48 h			X	X	X

Therapy: AT stable (ATP)

The following parameters apply to Rivacor Sky:

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

Therapy: AF unstable (HF burst)

The following parameters apply to Rivacor Sky:

Parameter	Range of values	Standard	VR-T	DX	DR-T	HF-T	QP
HF burst - Attempts	OFF; 1 ... (1) ... 4	OFF			X	X	X
HF burst - Therapy	HF burst	HF burst			X	X	X
HF burst - Rate	10 ... (5) ... 40 Hz	40 Hz			X	X	X
HF burst - Duration	2 ... (1) ... 10 s	3 s			X	X	X
Backup stimulation	OFF; 70; 90 bpm	OFF			X	X	X

Therapy: ATP (VT1)

Parameter	Range of values	Standard	VR-T	DX	DR-T	HF-T	QP
ATP - Attempts	OFF; 1 ... (1) ... 10	OFF	X	X	X	X	X
ATP type	Burst; Ramp	Burst	X	X	X	X	X
Ventricular pacing	RV; LV; BiV	RV				X	X
Number S1	1 ... (1) ... 15	8	X	X	X	X	X
Add S1	OFF; ON	OFF	X	X	X	X	X
R-S1 interval	70 ... (5) ... 85; 88; 90; 95 %	80 %	X	X	X	X	X

Parameter	Range of values	Standard	VR-T	DX	DR-T	HF-T	QP
S1-S2 interval	50 ... (5) ... 85; 88; 90; 95 %	75 %	X	X	X	X	X
S2-S3 interval	OFF; 50 ... (5) ... 85; 88; 90; 95 %	OFF	X	X	X	X	X
S3-S4 interval	OFF; 50 ... (5) ... 85; 88; 90; 95 %	OFF	X	X	X	X	X
For ATP type Ramp: S1 decrement	5 ... (5) ... 40 ms	10 ms	X	X	X	X	X
Scan decrement	OFF; 5 ... (5) ... 40 ms	10 ms	X	X	X	X	X
ATP optimization	OFF; ON	OFF	X	X	X	X	X
Blocking accelerating ATPs	OFF; ON	OFF	X	X	X	X	X

Therapy: ATP (VT2)

Parameter	Range of values	Standard	VR-T	DX	DR-T	HF-T	QP
ATP - Attempts	OFF; 1 ... (1) ... 10	3	X	X	X	X	X
ATP type	Burst; Ramp	Burst	X	X	X	X	X
Ventricular pacing	RV; LV; BiV	RV				X	X
Number S1	1 ... (1) ... 15	8	X	X	X	X	X
Add S1	OFF; ON	OFF	X	X	X	X	X
R-S1 interval	70 ... (5) ... 85; 88; 90; 95 %	88 %	X	X	X	X	X
S1-S2 interval	50 ... (5) ... 85; 88; 90; 95 %	80 %	X	X	X	X	X
S2-S3 interval	OFF; 50 ... (5) ... 85; 88; 90; 95 %	OFF	X	X	X	X	X
S3-S4 interval	OFF; 50 ... (5) ... 85; 88; 90; 95 %	OFF	X	X	X	X	X
For ATP type Ramp: S1 decrement	5 ... (5) ... 40 ms	10 ms	X	X	X	X	X
Scan decrement	OFF; 5 ... (5) ... 40 ms	10 ms	X	X	X	X	X
ATP optimization	OFF; ON	OFF	X	X	X	X	X
Blocking accelerating ATPs	OFF; ON	OFF	X	X	X	X	X

Therapy: ATP One Shot (ATP in VF)

Parameter	Range of values	Standard	VR-T	DX	DR-T	HF-T	QP
ATP type	OFF; Burst; Ramp	Burst	X	X	X	X	X
Ventricular pacing	RV; LV; BiV	RV				X	X
Number S1	1 ... (1) ... 15	8	X	X	X	X	X
R-S1 interval	70 ... (5) ... 85; 88; 90; 95 %	88 %	X	X	X	X	X
For ATP type Ramp: S1 decrement	5 ... (5) ... 40 ms	10 ms	X	X	X	X	X
Early ATP delivery	OFF ; ON*	OFF	X	X	X	X	X
ATP One Shot timing	Regular; Early; Adaptive	Regular	X	X	X	X	X

* Only programmable, if the parameter Counter: Detection VF is programmed to 16 out of 20 or higher.

Therapy: Shock

Parameter	Range of values	Standard	VR-T	DX	DR-T	HF-T	QP
VT1, VT2: 1st shock	OFF; 2 J; 4 J; 6 J; 8 J; 10 J; 12 J; 14 J; 16 J; 18 J; 20 J; 25 J; 30 J; 35 J; 40 J	OFF	X	X	X	X	X
VT1, VT2: 2nd shock	OFF; 4 J; 6 J; 8 J; 10 J; 12 J; 14 J; 16 J; 18 J; 20 J; 25 J; 30 J; 35 J; 40 J	40 J	X	X	X	X	X
VT1, VT2: 3.- nth	OFF; 4*40 J; 6*40 J	6*40 J	X	X	X	X	X
VF: 1st shock	2 J; 4 J; 6 J; 8 J; 10 J; 12 J; 14 J; 16 J; 18 J; 20 J; 25 J; 30 J; 35 J; 40 J	40 J	X	X	X	X	X
VF: 2nd shock	4 J; 6 J; 8 J; 10 J; 12 J; 14 J; 16 J; 18 J; 20 J; 25 J; 30 J; 35 J; 40 J	40 J	X	X	X	X	X
VF: 3.- nth	4*40 J; 6*40 J	6*40 J	X	X	X	X	X

Therapy: Shock Details

Parameter	Range of values	Standard	VR-T	DX	DR-T	HF-T	QP
Confirmation	OFF; ON	ON	X	X	X	X	X
Rivacor Aura: Polarity	Normal; Reversed; Normal → alter- nating	Normal	X	X	X	X	X
Rivacor Rise, Rivacor Sky: Polarity	Normal; Reversed; Normal → alter- nating; Reversed → alternating	Normal	X	X	X	X	X

Parameter	Range of values	Standard	VR-T	DX	DR-T	HF-T	QP
Rivacor Aura: Waveform	Biphasic; Biphasic 2	Biphasic	X	X	X	X	X
Rivacor Rise, Rivacor Sky: Waveform	Biphasic; Biphasic 2; Biphasic → alternating; Biphasic 2 → alternating	Biphasic	X	X	X	X	X
Shock path	RV → Can+SVC; RV → Can; RV → SVC	RV → Can+SVC	X		X	X	X
		RV → Can		X			

Bradycardia/CRT

Lead Position, LBBA Pacing and Mode

The following parameters apply to Rivacor Rise and Rivacor Sky:

Parameter	Range of values	Standard	VR-T	DX	DR-T	HF-T	QP
Lead position	LV	LV				X	
LBBA pacing	NO , YES	NO				X	
Mode LBBAP ON	DDD , DDDR, DDI, VDIR, D00, VDD, VDDR, VDI, VDIR, VVI, VVIR, V00, AAI, AAIR, OFF	DDD				X	
LV pacing polarity	LV1 → LV2 , LV1 → RV, LV1 → Can, LV2 → LV1, LV2 → RV, LV2 → Can					X	
LV sensing polarity	LV1 → LV2 , LV1 → Can					X	

Basic Rate

Parameter	Range of values	Standard	VR-T	DX	DR-T	HF-T	QP
Basic rate	30 ... (5) ... 100 ... (10) ... 160 bpm	60 bpm			X		
		40 bpm	X	X			
		50 bpm				X	X
Rate hysteresis*	OFF; -5 ... (-5) ... -25 ... (-20) ... -65 bpm	OFF	X	X	X	X	X
Scan/Repetitive	OFF; ON	ON	X	X	X	X	X
Night rate*	OFF; 30 ... (5) ... 100 bpm	OFF	X	X	X	X	X
Night begins	00:00 ... (00:01) ... 23:59 hh:mm	22:00 hh:mm	X	X	X	X	X
Night ends	00:00 ... (00:01) ... 23:59 hh:mm	06:00 hh:mm	X	X	X	X	X

*Not programmable in combination with CLS modes.

CLS (Closed Loop Stimulation)

Note

The following parameters are only programmable, if no LBBAP is programmed.

The following parameters apply to Rivacor Rise and Rivacor Sky:

Parameter	Range of values	Standard	VR-T	DX	DR-T	HF-T	QP
CLS	OFF ; 80 ... (10) ... 180 bpm	120 bpm	X	X	X	X	X
CLS response	Very high; High; Medium; Low; Very low	Medium	X	X	X	X	X
Max. CLS rate at rest	Max. CLS rate; Basic rate + 50; Basic rate + 40; Basic rate + 30; Basic rate + 20; Basic rate + 10 bpm	Basic rate + 20	X	X	X	X	X
Vp required	Yes ; No	No	X	X	X		
Vp required	Yes ; No*	Yes				X	X

*Only programmable, if ventricular pacing is programmed to RV only.

Max. Sensor Rate (Rate Adaption, Acceleration Sensor)

Parameter	Range of values	Standard	VR-T	DX	DR-T	HF-T	QP
Max. sensor rate	80 ... (10) ... 180 bpm	120 bpm	X	X	X	X	X
Sensor gain	AUTO; Very low; Low; Medium; High; Very high	Medium	X	X	X	X	X
Sensor threshold	Very low; Low; Medium; High; Very high	Medium	X	X	X	X	X
Rate increase	1; 2; 4; 8 bpm/cycle	2 bpm/cycle	X	X	X	X	X
Rate decrease	0.1; 0.2; 0.5; 1.0 bpm/cycle	0.5 bpm/cycle	X	X	X	X	X
Rivacor Rise, Rivacor Sky: Rate fading	OFF; ON	OFF	X	X	X	X	X

Upper Rate

Parameter	Range of values	Standard	VR-T	DX	DR-T	HF-T	QP
Upper rate	90 ... (10) ... 180 bpm	130 bpm		X	X	X	X
Atrial upper rate	OFF; 175; 200; 240 bpm	200 bpm			X	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 197 bpm.

Mode Switching and Post Mode Switching Response

Parameter	Range of values	Standard	VR-T	DX	DR-T	HF-T	QP
Intervention rate	OFF; 100 ... (10) ... 250 bpm	160 bpm		X	X	X	X
Rivacor Aura: Mode after permanent mode DDD and DDDR	DDI ; DDIR	DDIR			X	X	X
Rivacor Rise: Mode after permanent mode DDD, DDDR, DDD-AID and DDDR-ADIR	DDI : DDIR	DDIR			X	X	X
Rivacor Sky: Mode after permanent mode DDD, DDDR, DDD-CLS, DDD- ADI and DDDR- ADIR	DDI ; DDIR; VDI ; VDIR	DDIR			X	X	X
Mode after permanent mode VDD and VDDR	VDI ; VDIR	VDIR		X	X	X	X
Change of basic rate	OFF; +5 ... (5) ... +30 bpm	+10 bpm		X	X	X	X
Post ModeSw rate	OFF; +5 ... (5) ... +50 bpm	+10 bpm		X	X	X	X
Post ModeSw duration	1 ... (1) ... 30 min	1 min		X	X	X	X
Onset criterion	3 ... (1) ... 8 out of 8	5 out of 8		X	X	X	X
Resolution criterion	3 ... (1) ... 8 out of 8	5 out of 8		X	X	X	X
Rivacor Rise, Rivacor Sky: Rate stabilization during mode switching	OFF; ON	OFF		X	X	X	X
2:1 Lock-in protection*	OFF; ON	ON			X	X	X

*Only programmable, if ventricular pacing is programmed to RV only.

Ventricular Pacing Suppression

The following parameters apply to Rivacor Rise and Rivacor Sky:

Parameter	Range of values	Standard	VR-T	DX	DR-T	HF-T	QP
Vp suppression	OFF , ON	OFF (ON*)			X	X	X
Pacing suppression	1 ... (1) ... 8 consecutive Vs	6 consecutive Vs			X	X	X
Pacing support	1 ... (1) ... 4 out of 8 cycles	3 out of 8 cycles			X	X	X

*Applicable if ADI or ADIR mode is activated.

Ventricular Pacing

Parameter	Range of values	Standard	HF-T	QP
Ventricular pacing: DDD-CLS, DDD, DDDR, DDI, DDIR, VDD, VDDR, VDI, VDIR, VVI-CLS, VVI, VWIR, V00, D00	RV ; BiV	BiV	X	X
Ventricular pacing: DDD, DDDR, VDD, VDDR	LV	BiV	X	X
Ventricular pacing: DDD-ADI, DDDR-ADIR	RV	BiV	X	X
Ventricular pacing: DDD, DDDR, DDI, DDIR, VDD, VDDR, VDI, VDIR, VVI, VWIR, DDD-CLS, DDI-CLS, VVI-CLS	BiV-MPP	BiV		X
Triggering*	OFF ; RVs; RVs+PVC	RVs (OFF**)	X	
LV T-wave protection	OFF; ON	ON	X	X
Maximum trigger rate: DDD-CLS, DDD, DDDR, VDD, VDDR	UTR + 20 ; 90 ... (10) ... 180 bpm	UTR + 20	X	X
Maximum trigger rate: DDI, DDIR, VDI, VDIR VVI-CLS, VVI, VWIR, D00, V00	90 ... (10) ... 180 bpm	150 bpm	X	X
Shortened minimum trigger interval	OFF; 275 ... (25) ... 400 ms	325 ms	X	X
Max. number of sMTI attempts	1 ... (1) ... 3; 5; 10	3	X	X
sMTI delay	0 ... (1) ... 3; 5; 10 cycles	3 cycles	X	X
Initially paced chamber	RV; LV	LV	X	X
VV delay after Vp	0 ... (5) ... 100 ms	0 ms	X	X
LV-2nd LV delay	0 ... (5) ... 50 ms	0 ms		X

*Not programmable in combination with D00 or V00 modes.

**Applicable if LBBA pacing is used.

CRT AutoAdapt

The following parameters apply to Rivacor Rise and Rivacor Sky:

Parameter	Range of values	Standard	HF-T	QP
CRT AutoAdapt	OFF ; AVadapt; ON*	OFF	X	X
Adaptive AV reduction	0.5 ... (0.05) ... 0.9	0.7	X	X
Adaptive AV lower limit	50 ... (10) ... 150 ms	50 ms	X	X

*Only programmable if LBBA pacing is not used.

AV Delay

Parameter	Range of values	Standard	VR-T	DX	DR-T	HF-T	QP
AV dynamics	Low; Medium; High; Fixed	Low		X	X	X	X
AV delay after pace at lower rate	40 ... (5) ... 350 ms	180 ms 150 ms			X		
Only for fixed: AV delay after pace at lower rate	15 ... (5) ... 300 ms			X			
Lower rate for AV delay	50 ... (10) ... 120 bpm	60 bpm		X	X	X	X
AV delay after pace at upper rate	40 ... (5) ... 350 ms	140 ms 120 ms			X		
Only for fixed: AV delay after pace at upper rate	15 ... (5) ... 300 ms			X			
Upper rate for AV delay	70 ... (10) ... 140 bpm	130 bpm		X	X	X	X
AV hysteresis mode	OFF; Positive; Negative; IRSplus	OFF		X	X		
	OFF; Positive; Negative	OFF				X	X
AV hysteresis (positive)	70; 110; 150; 200; 250 ms	70 ms		X	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	X
AV scan/repetitive (positive)	OFF; ON	ON		X	X	X	X

Post-Shock Pacing

Parameter	Range of values	Standard	VR-T	DX	DR-T	HF-T	QP
Post-shock duration	OFF; 10 s; 30 s; 1 min; 2 min; 5 min; 10 min	10 s	X	X	X	X	X
Post-shock basic rate	30 ... (5) ... 100 ... (10) ... 160 bpm	60 bpm	X	X	X	X	X
Only for fixed: Post-shock AV delay	50 ... (10) ... 350 ms	140 ms		X	X	X	X
Post-shock ven. pacing	RV; BiV	RV				X	X
PS: LV T-wave protection	OFF; ON	OFF				X	X
PS: Triggering	OFF; RVs; RVs+PVC	OFF				X	X

Pulse Amplitude and Pulse Width
Note

If the value AUTO is programmed, Capture Control calculates the pulse amplitude automatically.
 The possible range is 0.8 ... (0.1) ... 6.2 V.

Parameter	Range of values	Standard	VR-T	DX	DR-T	HF-T	QP
Pulse amplitude A	0.5 ... (0.25) ... 4.0 ... (0.5) ... 6.0; 7.5 V	AUTO			X	X	X
Pulse width A	0.1 ... (0.1) ... 0.5 ... (0.25) ... 1.5 ms	0.4 ms			X	X	X
Pulse amplitude RV	0.5 ... (0.25) ... 4.0 ... (0.5) ... 6.0; 7.5 V	AUTO	X	X	X	X	X
Pulse width RV	0.1 ... (0.1) ... 0.5 ... (0.25) ... 1.5 ms	0.4 ms	X	X	X	X	X
Pulse amplitude LV	0.5 ... (0.25) ... 4.0 ... (0.5) ... 6.0; 7.5 V	AUTO				X	X
Pulse width LV	0.1 ... (0.1) ... 0.5 ... (0.25) ... 1.5 ms	0.4 ms				X	X
2nd LV pulse amplitude	0.5 ... (0.25) ... 4.0 ... (0.5) ... 6.0; 7.5 V	AUTO					X
Pulse width 2nd LV	0.1 ... (0.1) ... 0.5 ... (0.25) ... 1.5 ms	0.4 ms					X

Capture Control RA

The following parameters apply to Rivacor Aura:

Parameter	Range of values	Standard	VR-T	DX	DR-T	HF-T	QP
Right atrial capture control	OFF; ATM; ON	ON			X	X	X
Threshold test start	2.5 ... (0.5) ... 5.0 V	3.5 V			X	X	X

Parameters

Bradycardia/CRT

The following parameters apply to Rivacor Rise and Rivacor Sky:

Parameter	Range of values	Standard	VR-T	DX	DR-T	HF-T	QP
Right atrial capture control	OFF; ATM; ON	ON			X	X	X
Threshold test start	2.5 ... (0.5) ... 5.0 V	3.5 V			X	X	X
Atr. safety margin	0.5; 1.0; 1.2 V	1.0 V			X	X	X

Capture Control RV / LV

The following parameters apply to Rivacor Aura:

Parameter	Range of values	Standard	VR-T	DX	DR-T	HF-T	QP
Right ventricular capture control	OFF; ATM; ON	ON	X	X	X	X	X
Threshold test start	2.5 ... (0.5) ... 5.0 V	3.5 V	X	X	X	X	X

The following parameters apply to Rivacor Rise and Rivacor Sky:

Parameter	Range of values	Standard	VR-T	DX	DR-T	HF-T	QP
Right ventricular capture control	OFF; ATM; ON	ON	X	X	X	X	X
Threshold test start	2.5 ... (0.5) ... 5.0 V	3.5 V	X	X	X	X	X
Minimum Amplitude	1.0 V	1.0 V			x	x	
RV safety margin	1.0; 1.2 V	1.0 V	X	X	X	X	X
LV safety margin	0.5; 1.0; 1.2 V	1.0 V				X	X

Atrial Sensing Parameters

Parameter	Range of values	Standard	VR-T	DX	DR-T	HF-T	QP
Sensing A	Std.; OFF	Std.		X	X	X	X
DX sensing	OFF; ON	OFF				X	X

Right Ventricular Sensing Parameters

Parameter	Range of values	Standard	VR-T	DX	DR-T	HF-T	QP
Sensing RV	Std.; TWS; VFS	Std.	X	X	X	X	X
Upper threshold RV	50; 75 %	50 %	X	X	X	X	X
Upper threshold duration RV	110; 150 ... (50) ... 500 ms	350 ms	X	X	X	X	X
Upper threshold duration after RVp	110; 150 ... (50) ... 500 ms	400 ms	X	X	X	X	X
Lower threshold	25; 50 %	25 %	X	X	X	X	X

Parameter	Range of values	Standard	VR-T	DX	DR-T	HF-T	QP
Post pace T-wave suppression	OFF; ON	OFF	X	X	X	X	X
Blanking after atrial pacing RV	40 ... (10) ... 100 ms	50 ms			X	X	X
Blanking after LV pacing RV	50 ... (10) ... 100 ms	80 ms				X	X

Left Ventricular Sensing Parameters

Parameter	Range of values	Standard	HF-T	QP
Sensing LV	Std.; OFF	Std.	X	X
Upper threshold LV	50; 75 %	50 %	X	X
Upper threshold duration LV	110; 150 ... (50) ... 500 ms	350 ms	X	X
Upper threshold duration after LVp	110; 150 ... (50) ... 500 ms	400 ms	X	X
Blanking after atrial sense	OFF; 20 ... (10) ... 50 ms	OFF	X	X
Blanking after RV pacing LV	50 ... (10) ... 100 ms	80 ms	X	X
If LBBAP is programmed to ON: Blanking after LV-only pacing LV	100 ... (10) ... 350 ms	140 ms	X	X

Minimum Threshold

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

Refractory Periods / Blankings

Parameter	Range of values	Standard	VR-T	DX	DR-T	HF-T	QP
PVARP	AUTO; 175 ... (25) ... 600 ms	AUTO		X	X	X	X
PVARP extension	OFF; ON	ON		X	X	X	X
Far-field protection after Vs	AUTO; OFF; 25 ... (25) ... 225 ms	AUTO		X	X	X	X
Far-field protection after Vp	50 ... (25) ... 225 ms	75 ms		X	X	X	X
PMT detection/termination	OFF; ON	ON		X	X	X	X
VA criterion	250 ... (10) ... 500 ms	350 ms		X	X	X	X

*If the value AUTO is programmed, the far-field protection is set to 75 ms for rates below the VT1 zone limit and to 25 ms for rates above the VT1 zone limit.

Pacing and Sensing Polarity, MultiPole pacing

Parameter	Range of values	Standard	HF-T	QP
LV pacing polarity	LV1 → LV2; LV2 → LV1; LV3 → LV1; LV4 → LV1; LV1 → LV3; LV2 → LV3; LV3 → LV2; LV4 → LV2; LV1 → LV4; LV2 → LV4; LV3 → LV4; LV4 → LV3; LV1 → RV; LV2 → RV; LV3 → RV; LV4 → RV; LV1 → Can; LV2 → Can; LV3 → Can; LV4 → Can	LV1 → LV2		X
	LV1 → LV2; LV2 → LV1; LV1 → RV; LV2 → RV; LV1 → Can; LV2 → Can	LV1 → RV	X	
Rivacor Sky: 2nd LV pacing polarity	OFF; LV1 → LV2; LV2 → LV1; LV3 → LV1; LV4 → LV1; LV1 → LV3; LV2 → LV3; LV3 → LV2; LV4 → LV2; LV1 → LV4; LV2 → LV4; LV3 → LV4; LV4 → LV3; LV1 → RV; LV2 → RV; LV3 → RV; LV4 → RV; LV1 → Can; LV2 → Can; LV3 → Can; LV4 → Can	OFF		X
LV sensing polarity	LV1 → LV2; LV2 → LV3; LV3 → LV4; LV1 → Can; LV2 → Can; LV3 → Can; LV4 → Can	LV1 → LV2		X
	LV1 → LV2; LV1 → Can	LV1 → Can	X	

Home Monitoring

Setting Options on the Programmer

Parameter	Range of values	Standard	VR-T	DX	DR-T	HF-T	QP
Home Monitoring	OFF; ON	ON	X	X	X	X	X
Time of transmission	Std.; 00:00 ... (01:00) ... 23:00 hh:mm	Std.	X	X	X	X	X
IEGM for therapy episodes	OFF; ON	ON	X	X	X	X	X
IEGM for monitoring episodes	OFF; ON	ON	X	X	X	X	X
Ongoing atrial episode	OFF; 6 h; 12 h; 18 h	12 h		X	X	X	X
Rivacor Sky: QuickCheck	OFF; ON	ON	X	X	X	X	X

Setting Options in the Home Monitoring Service Center (HMSC)

Parameter	Range of values	Standard	VR-T	DX	DR-T	HF-T	QP
First Remote FU date	Date input	Today + 91 days	X	X	X	X	X
Cycle duration	20 ... [1] ... 366 days	91	X	X	X	X	X
RemoteScheduling	No alignment; any non-weekend day; Monday; Tuesday; Wednesday; Thursday; Friday; Saturday; Sunday	No alignment	X	X	X	X	X

Diagnostics

Diagnostics - Recording Episodes

Parameter	Range of values	Standard	VR-T	DX	DR-T	HF-T	QP
Rivacor Aura, Rivacor Rise: For AT/AF	OFF; ON	ON		X	X	X	X
Rivacor Sky: For AT/AF	OFF; ON; Advanced ON	ON		X	X	X	X
For SVT	OFF; ON	ON	X	X	X	X	X
For nsT	OFF; ON (<220ms); ON	ON	X	X	X	X	X
For CRT pacing interrupt	OFF; ON	ON				X	X
For Home Moni- toring programmed to OFF: Periodic recording	OFF; 30 ... (30) ... 120; 180 days	90 days	X	X	X	X	X
IEGM configura- tion	RA, RV, LV; RA, RV, FF; FF, RV, LV	RA, RV, LV				X	X

Diagnostics - Statistics

Parameter	Range of values	Standard	VR-T	DX	DR-T	HF-T	QP
Start resting period	00:00 ... (01:00) ... 23:00 hh:mm	02:00 hh:mm	X	X	X	X	X
Resting period duration	0.5 ... (0.5) ... 12.0 h	4.0 h	X	X	X	X	X
AV delay adj. sensing test	OFF; 300 ms	300 ms		X	X	X	X
Rivacor Rise, Rivacor Sky: Thoracic imped- ance (TI)	OFF; ON	ON	X	X	X	X	X

MRI

The following parameters apply to Rivacor Aura:

Parameter	Range of values	Standard	VR-T	DX	DR-T	HF-T	QP
MRI program	ON; OFF; AUTO	OFF	X	X	X	X	X
When MRI program is programmed to AUTO: Expiration date	XX.XX.XXXX	XX.XX.XXXX	X	X	X	X	X
MRI mode	V00; OFF (000)	OFF (000)	X	X			
	A00; V00; D00; OFF (000)	OFF (000)			X		
	A00; V00; V00/BiV; D00; D00/BiV; OFF (000)	OFF (000)				X	X
Basic rate	70 ... (5) ... 100 ... (10) ... 160 bpm	90 bpm	X	X	X	X	X
Pulse amplitude LV	0.5 ... (0.25) ... 4.0 ... (0.5) ... 6.0; 7.5 V	2.5 V				X	X
Pulse width LV	0.1 ... (0.1) ... 0.5 ... (0.25) ... 1.5 ms	0.4 ms				X	X
Pacing polarity LV	LV1 → LV2; LV2 → LV1; LV3 → LV1; LV4 → LV1; LV1 → LV3; LV2 → LV3; LV3 → LV2; LV4 → LV2; LV1 → LV4; LV2 → LV4; LV3 → LV4; LV4 → LV3; LV1 → RV; LV2 → RV; LV3 → RV; LV4 → RV; LV1 → Can; LV2 → Can; LV3 → Can; LV4 → Can	LV1 → LV2					X
	LV1 → LV2; LV2 → LV1; LV1 → RV; LV2 → RV; LV1 → Can; LV2 → Can	LV1 → LV2				X	

The following parameters apply to Rivacor Rise and Rivacor Sky:

Parameter	Range of values	Standard	VR-T	DX	DR-T	HF-T	QP
MRI brady mode	D00; V00; A00; AUTO; OFF (000)	AUTO			X		
	V00; AUTO; OFF (000)	AUTO	X	X			
	D00/BiV; D00; V00/BiV; V00; A00; AUTO; OFF (000)	AUTO				X	X

Parameter	Range of values	Standard	VR-T	DX	DR-T	HF-T	QP
Basic rate	Mean rate + 15 bpm; 70 ... (5) ... 100 ... (10) ... 160 bpm	Mean rate + 15 bpm	X	X	X	X	X
LV pacing polarity	LV1 → LV2; LV2 → LV1; LV3 → LV1; LV4 → LV1; LV1 → LV3; LV2 → LV3; LV3 → LV2; LV4 → LV2; LV1 → LV4; LV2 → LV4; LV3 → LV4; LV4 → LV3; LV1 → RV; LV2 → RV; LV3 → RV; LV4 → RV; LV1 → Can; LV2 → Can; LV3 → Can; LV4 → Can	LV1 → LV2					X
	LV1 → LV2; LV2 → LV1; LV1 → RV; LV2 → RV; LV1 → Can; LV2 → Can	LV1 → LV2				X	

Preset Programs

Standard and Safe Program

Mode after Brady AutoInitialization:

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

Lead configuration, automatically determined and set immediately after connection:

Parameter	Factory setting	Standard	Safe program	VR-T	DX	DR-T	HF-T
Pacing polarity A/RV	Unipolar	Unipolar	Unipolar		x	x	x
Pacing polarity LV	TCUP	TCUP	—				x
Sensing polarity A/RV	Unipolar	Unipolar	Unipolar		x	x	x
Sensing polarity LV	Unipolar	Unipolar	—				x
Automatic lead impedance measurement	ON	ON	—		x	x	x

Parameters after Brady AutoInitialization:

Parameter	Factory setting	Standard	Safe program	VR-T	DX	DR-T	HF-T
Basic rate	60 bpm	60 bpm	70 bpm		x	x	
	50 bpm	50 bpm	70 bpm				x
Night rate	OFF	OFF	OFF		x	x	x
Rate hysteresis	OFF	OFF	OFF		x	x	x
Upper rate	130 bpm	130 bpm	—			x	x
AV dynamics	Low	Low	—			x	x
AV hysteresis mode	OFF	OFF	—			x	x
Sense compensation	-45 ms	-45 ms	—			x	x
AV safety delay	100 ms	100 ms	—			x	x
VV delay	0	0	—				x
LV T-wave protection	ON	ON	—				x
Far-field protection after Vs	100 ms	100 ms	—			x	x

Parameter	Factory setting	Standard	Safe program	VR-T	DX	DR-T	HF-T
Far-field protection after Vp	150 ms	150 ms	—			x	x
Ventricular blanking period after Ap	30 ms	30 ms	—			x	x
PMT protection	ON	ON	—			x	x
VA criterion	350 ms	350 ms	—			x	x
Magnet response	AUTO	AUTO	AUTO		x	x	x
Pulse amplitude A	3.0 V	3.0 V	—			x	x
Pulse amplitude RV	3.0 V	3.0 V	4.8 V		x	x	x
Pulse amplitude LV	3.0 V	3.0 V	—				x
Pulse width A	0.4 ms	0.4 ms	—			x	x
Pulse width RV	0.4 ms	0.4 ms	1.0 ms		x	x	x
Pulse width LV	0.4 ms	0.4 ms	—				x
Sensitivity A	AUTO	AUTO	—			x	x
Sensitivity RV	AUTO	AUTO	2.5 mV		x	x	x
Sensitivity LV	AUTO	AUTO	—				x
Refractory period A	AUTO	AUTO	—			x	x
Refractory period RV	250 ms	250 ms	300 ms		x	x	x
Refractory period LV	200 ms	200 ms	—				x
Mode switching	ON	ON	—			x	x
Onset criterion	5 out of 8	5 out of 8	—			x	x
Resolution criterion	5 out of 8	5 out of 8	—			x	x
Intervention rate	160 bpm	160 bpm	—			x	x
Switch to	DDIR	DDIR	—			x	x
Basic rate with mode switching	+10 bpm	+10 bpm	—			x	x
Rate stabilization with mode switching	OFF	OFF	—			x	x
PVARP	AUTO (start 250 ms)	225 ms	—			x	x
PVARP after PVC	400 ms	Automatically set	—			x	x
Capture control A	ON	ON	OFF		x	x	x
Capture control RV	ON	ON	OFF			x	x
Capture control LV	ON	ON	OFF				x

Parameter	Factory setting	Standard	Safe program	VR-T	DX	DR-T	HF-T
Atrial overdrive pacing	OFF	OFF	—			x	x
Vp suppression	OFF	OFF	—				x
IEGM recording (HAR)	ON	AT	OFF		x	x	x
IEGM recording (HVR)	ON	ON	OFF		x	x	x
Home Monitoring	OFF	OFF	OFF		x	x	x

Tolerances of Parameter Values

Parameter	Range of Values	Tolerance
Basic rate	70 ... (5) ... 100 ... (10) ... 160 bpm	
Rate hysteresis	-5 ... [-5] ... -25 ... [-20] ... -65 bpm	
Interference rate		
Basic interval		
Magnet rate (magnet interval)		
Pulse amplitude	0.5 ... 7.5 V	
Pulse width	0.1 ... (0.1) ... 0.5 ... (0.25) ... 1.5 ms	
Sensitivity A ISO 14708-2 Figure D.3		
Sensitivity RV/LV ISO 14708-2 Figure D.3		
AV delay	40 ... 350 ms	
Atr. refractory period after Ap and As	225 ms	
RV Refractory period after RVs	200 ms	
RV Refractory period after RVp		
LV Refractory period after LVs	200 ms	
LV Refractory period after LVp		
PVARP	175 ... 600 ms	
High Rate Protection	197 bpm	
Maximum activity rate		
Maximum tracking rate	90 ... (10) ... 180 bpm	

6 Technical Data

Mechanical Characteristics

Housing

Type	W x H x D [mm]	Volume [cm ³]	Mass [g]
VR-T	60 x 61.5 x 10	30	75
VR-T DX	60 x 66.5 x 10	32	77
DR-T	60 x 66.5 x 10	32	77
HF-T	60 x 71.5 x 10	33	78
HF-T QP	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 cm² per connector port)
 - Cap IS4/DF4 connector port: polysulfone (0.05 cm² per connector port)
 - Front of the connector housing: polysulfone (0.45 cm² per IS-1 connector port)
- Silicone plug: silicone (0.1 cm² per piece)

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

Note

Information according to Article 33 of Regulation (EC) No. 1907/2006 (REACH) see <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: $37^{\circ}\text{C} \pm 2^{\circ}\text{C}$
- Pacing/sensing: $500 \Omega \pm 1\%$
- Shock: $50 \Omega \pm 1\%$

Factory Settings

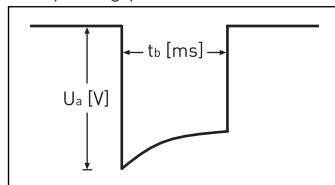
- Arrhythmia zones VT1, VT2, VF: OFF
- Antibradycardia pacing: OFF
- Home Monitoring: OFF
- AT/AF recordings: OFF

Telemetry Data

- RF telemetry
 - MICS frequency: 402 - 405 MHz
 - Maximum power of transmission: $< 25 \mu\text{W}$ (-16 dBm)
- PGH telemetry
 - Operating frequency: 9 - 90 kHz
 - Maximum magnetic field strength: $< 30 \text{ dB}\mu\text{A/m}$ (at 10 m)

Pulse Waveform

The pacing pulse has the following form:



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

Resistance to Interference

- Note on device type VR-T DX (only devices with a DF4/IS-1 connector port): The EMC requirements are met as long as atrial sensitivity is set to 1.0 mV (factory settings) or to values $\geq 1.0 \text{ mV}$. Measures must be taken to assure interference-free therapy if more sensitive values are set.
- Note on device type DR-T, HF-T, and HF-T QP: The EMC requirements are met as long as atrial sensitivity is set to values $\geq 0.3 \text{ mV}$. Measures must be taken to assure interference-free therapy if more sensitive values are set.
- Note on device type HF-T and HF-T QP: For unipolar sensing, the requirement for interference voltages of $\leq 0.3 \text{ mV}$ (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; peak amplitude: 7.5 V

Chamber	Peak amplitude
RA	7.5 V (± 1.5 V)
RV	7.5 V (± 1.5 V)
LV	7.5 V (± 1.5 V)

Automatic Sensitivity Control

Test signal wave shape: standard triangle. For the device type VR-T 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		
20 J		
40 J		

Battery Data

Battery Characteristics

The following data is provided by the manufacturers:

Manufacturer	GREATBATCH, INC. 10,000 Wehrle Drive Clarence, NY 14031 USA	LITRONIK Batterietechnologie GmbH Birkwitzer Str. 79 01796 Pirna Germany
Battery type	GB 3493	LiS 2592
System	Li/SVO/CFx	LiMnO ₂
Battery ID shown on the programmer	8	9
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	1770 mAh	1600 mAh
Usable capacity until EOS	1900 mAh	1730 mAh

Storage Period

The storage period affects the battery service time.

- The devices should be implanted before the use-by date indicated on the package.
- 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. The values apply for all chambers, depending on the device type.

- Pulse amplitude: 2.5 V
- Pulse width: 0.4 ms
- Pacing impedance: 500 Ω $\pm$ 5%
- Basic rate
 - VR-T, VR-T DX: 40 bpm
 - DR-T, HF-T, HF-T 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

Service Times VR-T Devices

Service Times VR-T DX Devices

Service Times DR-T Devices

Service Times HF-T Devices

Service Times HF-T QP Devices

International radio certification

Telemetry information for Canada:

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

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

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

This device will be registered with Innovation, Science and Economic Development Canada under the following number:

IC: 4708A-ICD4200P2

Telemetry information for the USA:

This device complies with part 15 of the FCC Rules.

Operation is subject to the following two conditions:

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

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

This device complies with part 95 of the FCC Rules.

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

This device will be registered with the Federal Communications Commission under the following number:

FCC-ID: QRI-ICD4200P2

Telemetry information for Japan:

This device is granted pursuant to the Japanese Radio Law.

Rivacor Sky VR-T

Rivacor Rise VR-T

Rivacor Aura VR-T

Rivacor Sky DR-T

Rivacor Rise DR-T

Rivacor Aura DR-T



R 202-JMV023

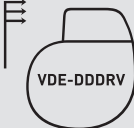
Rivacor Sky HF-T (QP)

Rivacor Rise HF-T (QP)

Rivacor Aura HF-T (QP)

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

Legend for the Label

Symbol	Meaning
	Manufacturing date
	Use by
	Temperature limit Observe the information on temperatures during shipping and storage in this technical manual.
IS-1 IS4-LLLL DF4-LLHH  Example	Device: NBG code and compatible leads
	BIOTRONIK order number
	Serial number
	Unique device identification
	Medical device
	Product identification number
	Dangerous voltages
	CE mark
	Manufacturer
 Example	NBG code
RA: IS-1 BI RV: DF4-LLHH 	Example of the header configuration: IS-1/DF4
	Contents
	Factory settings for therapy: OFF

Symbol	Meaning
	Torque wrench
	Sterilized with ethylene oxide
	Do not resterilize
manuals.biotronik.com 	Consult the technical manual
	Comply with the technical manual (white image on blue background)
	Single sterile barrier system with protective packaging inside
	Single use only. 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