Inlexa 1

VR-T, DR-T, HF-T

ICD-Familie | Tachyarrhythmietherapie |
Kardiale Resynchronisationstherapie

Gebrauchsanweisung

420651

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1 Product Description

Intended Medical Use

Intended use

Inlexa 1 is part of a family of implantable cardioverter-defibrillators (ICDs). The primary objective of the therapy is to prevent sudden cardiac death. Furthermore, the device is capable of treating bradycardia arrhythmias and cardiac resynchronization therapy with multisite ventricular pacing.

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

- Termination of spontaneous ventricular fibrillation (VF) through shock delivery
- Termination of spontaneous ventricular tachycardia (VT) through antitachycardia pacing (ATP); in case of ineffective ATP or hemodynamically not tolerated VT, with shock delivery
- Cardiac resynchronization through multisite ventricular pacing (triple-chamber devices)
- Compensation of bradycardia through ventricular (single-chamber devices) or AV sequential pacing (dual- and triple-chamber devices)

Diagnosis and therapy forms

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

Required expertise

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

- Only qualified medical specialists having this required special knowledge are permitted to use implantable devices.
- If users do not possess this knowledge, they must be trained accordingly.

Indications

Inlexa 1 can treat life-threatening ventricular arrhythmias with antitachycardia pacing and defibrillation.

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

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

Single-chamber and dual-chamber

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

- Sudden cardiac death caused by ventricular arrhythmias

Triple-chamber

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

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

Contraindications

Known contraindications:

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

System Overview

Device family

The complete Inlexa 1device family consists of several device types with a DF-1/IS-1 connection.

- Single-chamber: VR-T
- Dual-chamber: DR-T
- Triple-chamber: HF-T

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

Device

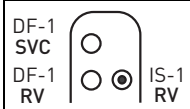
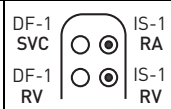
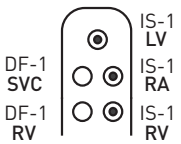
The device's housing is made of biocompatible titanium, welded from outside and thus hermetically sealed. The ellipsoid shape facilitates implantation in the pectoral muscle area.

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

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

DF-1/IS-1

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

VR	DR	HF
		

Connector port	Lead connector	Configuration	Implantation site	Device type
RA	IS-1	Bipolar	Atrium	DR, HF
(R)V	IS-1	Bipolar	(Right) ventricle	VR, DR, HF
RV	DF-1	Shock coil	Right ventricle	VR, DR, HF
SVC	DF-1	Shock coil	Superior vena cava	VR, DR, HF
LV	IS-1	Unipolar, bipolar	Left ventricle	HF

Leads

BIOTRONIK leads are sheathed with biocompatible silicone. They can be flexibly maneuvered, are stable long-term, and are equipped for active or passive fixation. They are implanted using a lead introducer set. Some leads are coated with polyurethane which is known to increase the sliding properties for the lead. Leads with steroids reduce inflammatory processes. The fractal design of the electrodes provides for low pacing thresholds. BIOTRONIK provides adapters to connect already implanted leads to new devices.

Telemetry

Telemetric communication between the device and the programmer can be carried out following initialization either by applying the programming head (PGH) to the device or by using wireless radio frequency (RF) telemetry in the programmer. BIOTRONIK calls this function SafeSync®.

Programmer

Implantation and follow-up are performed with BIOTRONIK's portable programmer: Programmer software PSW version N.N. and higher

There is a programmer with integrated RF telemetry and one with a separate SafeSync Module.

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

Using the programmer, the pacing thresholds can be determined and all tests can be performed during in-office follow-up. If necessary, the current software is transferred to the device during implantation.

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

Modes

The mode setting depends on the individual diagnosis:

Device type	Modes
VR	VVI; VVIR; VOO; OFF
DR, HF	DDD; DDDR; DDDR-ADIR; DDD-ADI; DDI; DDIR; VDD; VDDR; VDI; VDIR VVI; VVIR; AAI; AAIR; VOO; DOO; OFF

NBD and NBG codes

VVE is the NBD code for the antitachycardia mode of the single-chamber, dual-chamber, and triple-chamber devices:

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

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

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

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

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

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

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

BIOTRONIK Home Monitoring®

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

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

Inlexa 1order numbers

Not all device types are available in every country:

VR-T	DR-T	HF-T
405797	405796	40579

Package contents

The storage package includes the following:

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

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

The sterile container includes the following:

- Device, blind plugs (if applicable)
- Screwdriver

Therapeutic and Diagnostic Functions

Diagnostic functions

- Data from implantation and the most recent interrogations and follow-ups are recorded as well as arrhythmia episodes; they are stored together with other data to assess both the patients' and the device's state at any time.
- To check the lead for proper functioning, an automatic impedance measurement using subthreshold pacing pulses is performed in the device.
- Leadless ECG function: For all device types, far-field derivation can be measured without external leads between the right ventricular shock coil and housing, which, depending on the implantation site, corresponds to ECG derivation II or III (Einthoven).
- Once a telemetry connection has been established during a test procedure in an in-office follow-up, the leadless ECG and the IEGM are displayed with markers.

Antitachycardia pacing

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

Cardioversion, defibrillation

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

Antibradycardia pacing and CRT

- Innovative rate hystereses, automatic sensor functions, and a night program promote the patient's intrinsic rhythm, avoid overdrive pacing, and facilitate adaptation of the device to the individual needs of the patient.
- Thresholds: atrial as well as ventricular pacing thresholds are automatically determined in the device, automatic threshold monitoring (ATM) for trend analysis.
- Setting an upper tracking rate for the atrium prevents unspecific atrial pacing, thus reducing the risk of pacemaker-mediated tachycardia.
- Positive AV hysteresis functions support intrinsic conduction and thus the natural contraction sequence. Negative AV hysteresis functions support the cardiac resynchronization therapy by maintaining pacing in stress situations.
- For resynchronization of the ventricles, triple-chamber implants have functions for multisite 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.

Storing programs

There are different therapy programs:

- Parameter settings effective for the most common indications in pre-configured programs (Program Consult).
- For special indications, individual parameter settings can be stored in up to three therapy programs.

Home Monitoring functions

- The device automatically sends information to the transmitter once a day. It also sends messages related to events, which are immediately forwarded to the Service Center. In addition to this, test messages can be initiated using the programmer.
- Appointments for Home Monitoring-supported follow-ups can be scheduled via the HMSC.
- 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

2 General Safety Instructions

Operating Conditions

Technical manuals

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

— Technical manual for the device

— Technical manual for the HMSC

— Technical manual for the electrodes

— Technical manuals for the programmer and its accessories

— Technical manuals for the user interface

— Technical manuals for cables, adapters and accessories

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

Care during shipping and storage

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

Delivery in shipment mode

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

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

Temperature

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

- Temperatures of +5°C to +45°C are permitted for transport, storage, and use.

Sterile delivery

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

Sterile packaging

The device and screwdriver are 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 only

The device and screwdriver are intended for single use only.

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

Possible Complications

General information on medical complications

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

- Normal complications may include fluid accumulation within the device pocket, infections, or tissue reactions. Primary sources of complication information include current scientific and technological knowledge.
- It is impossible to guarantee the efficacy of antitachycardia therapy, even if the programs have proven successful during tests or subsequent electrophysiological examinations. In rare cases the set parameters may become ineffective. It is possible for therapies to induce or accelerate tachycardia and cause sustained ventricular flutter or fibrillation.

Skeletal myopotentials

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

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

Possible technical failures

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

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

Electromagnetic interference (EMI)

Any device can be sensitive to interference if external signals are sensed as intrinsic rhythm or if measurements prevent rate adaptation.

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

Device behavior in case of EMI

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

Static magnetic fields

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

Possible Risks

Procedures to avoid

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

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

Risky therapeutic and diagnostic procedures

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

Arrhythmia or ventricular fibrillation can be induced during diathermic procedures such as electrocautery, HF ablation or HF surgery. For example, damaging pressure levels may arise during lithotripsy. For example, excessive warming of body tissue near the device system may occur during therapeutic ultrasound. Influences on the device are not always immediately clear.

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

- Electrically insulate the patient.
- Switch off the ICD's detection function. The pacemaker function can remain active. The device may need to be switched to asynchronous modes for this.
- Do not introduce energy near the device system.
- Additionally check the peripheral pulse of the patient.
- Monitor the patient during and after every intervention.

External defibrillation

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

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

Radiation therapy

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

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

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

Magnetic resonance imaging

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

3 Implantation

Implantation Procedure

Having parts ready

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

- BIOTRONIK device with blind plug and screwdriver
- BIOTRONIK leads and lead introducer set
  - Single-chamber device: one bipolar ICD lead with 1 or 2 shock coils for the ventricle
  - Dual-chamber device: one bipolar lead for the atrium and one bipolar ICD lead for the ventricle with 1 or 2 shock coils
  - Triple-chamber device: an additional unipolar or bipolar LV lead
- The lead connections DF-1 and IS-1 are permitted. Use only adapters approved by BIOTRONIK for leads with different lead connections or leads from other manufacturers.
- BIOTRONIK programmer (with integrated SafeSync RF telemetry or with separate SafeSync Module) and approved cables
- External multi-channel ECG device
- Keep spare parts for all sterile components.

Keeping an external defibrillator ready

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

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

Unpacking the device

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

- Peel the sealing paper off of the outer blister at the marked position in the direction indicated by the arrow. The inner blister must not come into contact with persons who have not sterilized their hands or gloves, nor with non-sterile instruments!
- Take hold of the inner blister by the gripping tab and take it out of the outer blister.
- Peel the sealing paper off of the sterile inner blister at the marked position in the direction indicated by the arrow.

Checking parts

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

- Check for damage before and after unpacking all parts.
- Replace damaged parts.
- Upon delivery, the tachyarrhythmia therapy function in the ICD is deactivated. The ICD must only be implanted in this state.
- Leads must not be shortened.

Implantation site

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

Preventing leakage currents

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

- Electrically insulate the patient.

Preventing unintentional shock delivery

WARNING
Shock delivery with activated ICD
There is a risk of unintended shock delivery when handling an activated ICD. • Deactivate ICD therapy before touching the device during implantation, device replacement and explantation.

Avoiding damage to the header

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

- Loosen set screws with the supplied screwdriver. Use only BIOTRONIK screwdrivers with torque control!
- Do not forcibly pull out the blind plug!
- If lead revision is necessary, re-order sterile screwdrivers from BIOTRONIK.

Preventing short circuits in the header

WARNING
Short circuit due to open lead connector ports
Connector ports in the header which are open and thus not electrolyte-proof may cause undesired current flows to the body and penetration of body fluid into the device. • Close unused connector ports with blind plugs.

Ensure that connector ports are clean

In case of contamination during implantation:

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

Overview: Implanting

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

Connecting the device

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

1	Disconnect stylets and stylet guides.
2	DF-1/IS-1 connection: • Connect the DF-1 connector for the right-ventricular shock coil to RV. • Connect the DF-1 connector for the supraventricular shock coil to SVC. Or connect a subcutaneous array to SVC.

3	DF-1/IS-1 connection: • Connect the bipolar IS-1 connector for the atrium to RA. • Connect the bipolar IS-1 connector for the right ventricle to RV. • Connect the unipolar or the bipolar IS-1 connector for the left ventricle to LV.
4	Push the lead connector into the header without twisting or bending the connector or conductor until the connector tip (on the DF-1 connector) becomes visible behind the set screw block. This indicator can vary depending on the manufacturer of the lead used.
5	If you cannot easily plug the lead connector into the connection: • Use only sterile water as lubricant.
6	If the lead connector cannot be inserted completely, the set screw may be protruding into the drill hole of the set screw block. • Use the screwdriver to perpendicularly pierce through the slitted point in the center of the silicone plug until it reaches the set screw. • Carefully loosen the set screw without completely unscrewing it, so that it does not become tilted upon retightening.
7	Turn the set screw clockwise until torque control starts (you will hear a clicking sound).
8	Carefully withdraw the screwdriver without retracting the set screw. • In case of IS-1 connections with 2 set screws, tighten both screws! • When you withdraw the screwdriver, the silicone plug automatically seals the access to the screw head safely.

Keeping distance between leads

WARNING

Inadequate therapy

When leads are not spaced sufficiently apart or are positioned inappropriately, this can lead to far-field sensing or insufficient defibrillation.

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

Applying the programming head

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

- Make sure the PGH is positioned correctly.

Establishing telemetry contact

The programmer (or the SafeSync Module) can be no more than 3 m from the device; ideally there should be no hindrances between the patient and the programmer.

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

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

- Remove the programming head.

Activating ICD therapy

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

Precautionary Measures while Programming

Performing standard tests and monitoring the patient

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

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

Cancelling telemetry

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

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

Avoiding critical parameter settings

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

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

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).

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 sensing and therefore without ICD therapy.

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

Setting sensing

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

- Note automatic sensitivity control.

Preventing device-induced complications

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

- Measure the retrograde conduction time.
- Set PMT protection.
- Set the VA criterion.

Preventing conduction of atrial tachycardia

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

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

Note the reduced pulse amplitude due to a battery voltage drop

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

- Continuously check the pacing efficiency using ECG monitoring.

Observe when inducing short-term cardiac arrest

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

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

Avoiding AV crosstalk

When pacing using atrial ATP parameters, atrial pacing pulses can either be conducted into the ventricle or be sensed such 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 if the shock impedance is too low.

- The shock impedance must be > 25 Ω.

Preventing recurrence after therapy shock

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

Permanent program	Post-shock program
DDD DDI, AAI	DDI
VDD, VDI	VDI
VVI and OFF	VVI

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

Phrenic nerve stimulation that cannot be terminated

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

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

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, induction of atrial arrhythmias.

- Consider sensing and pacing parameters with reference to loss of therapy.
- Exclusive LV pacing is not recommended for patients who depend on the device.
- Please note that capture control is not available.
- In the case of follow-ups and threshold tests, take loss of synchronized ventricular pacing into consideration.
- Mode switching and post shock do not permit exclusive LV pacing. Please note the effects when programming mode switching and the post shock parameters.

Recognizing lead failure

Automatic impedance measurement is always switched on.

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

Considering power consumption and service time

RF telemetry requires somewhat more power: Consumption during implantation corresponds to approximately 10 days of service time and consumption during a 20-minute follow-up corresponds to approximately 3 days.

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

Magnet Response

Application of the programming head when ICD therapy is set

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

Programming head application

When the programming head is applied, time remains for device interrogation and for manual activation or deactivation of the therapy before the device switches back to the previously set permanent therapy mode. The same applies to programming head application to establish RF telemetry contact.

Application of a permanent magnet

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

- If detection interruptions of longer than 8 hours are required, the magnet has to be briefly removed from the device. The 8 hour countdown restarts when the magnet is applied again.
- Use BIOTRONIK magnets: type M-50 permanent magnets.

Follow-up

Follow-up intervals

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

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

Follow-up with BIOTRONIK Home Monitoring®

Monitoring using the Home Monitoring function does not serve to replace regular in-office appointments with the physician required for other medical reasons. Follow-up supported by Home Monitoring can be used to functionally replace in-office follow-up under the following conditions:

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

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

Follow-up with the programmer

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

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

Patient Information

Patient ID card

A patient ID card is included in delivery.

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

Prohibitory signs

Premises with prohibitive signs must be avoided.

- Draw the patient's attention to prohibitory signs.

Possible sources of interference

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

- 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 patients to do the following:
  - Use cell phones on the side of their body that is opposite of the device.
  - Keep the cell phone at least 15 cm away from the device both during use and when stowing.

Replacement Indications

Possible battery levels

- BOS: Beginning of Service: > 90% charge
- MOS 1: Middle of Service: 90% to 40% residual charge
- MOS 2: Middle of Service: < 40% residual charge
- ERI: Elective Replacement Indication (i.e. RRT: Recommended Replacement Time)
- EOS: End of Service

Elective Replacement Indication (ERI)

Elective Replacement Indication can be detected by Home Monitoring.

CAUTION

Temporally limited therapy

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

- Replace device soon.

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

EOS replacement indication

End of Service can be detected by Home Monitoring.

WARNING

Patient at risk of death

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

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

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

Explantation and Device Replacement

Explantation

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

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

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

Device replacement

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

- Deactivate VT and VF therapies prior to device replacement.
- Insulate connector ports that are not used.

Basic principles:

- The device must not be resterilized and reused.

Cremation

Devices must not be cremated.

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

Disposal

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

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

4 Parameters

Bradycardia / CRT

General ICD therapy

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

Timing: Basic rate day/night and rate hystereses

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

Timing: AV delay

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

Timing: Post-shock pacing

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

Timing: Upper rate

Parameter	Range of values	Standard	VR	DR	HF
Upper rate	90 ... (10) ... 160 bpm	130 bpm		x	x
Atrial upper rate	OFF; 175; 200; 240 bpm	200 bpm		x	x

Timing: Mode switching

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

Timing: Ventricular pacing

Parameter	Range of values	Standard	VR	DR	HF
Permanent	RV; BiV; LV	BiV			x
Triggering	OFF; RVs; RVs+PVC	RVs			x
LV T-wave protection	OFF; ON	ON			x
Maximum trigger rate:					
– DDD(R) and VDD(R)	UTR + 20; 90 ... (10) ... 160 bpm	UTR + 20			x
– DDI(R), VDI(R) and VVI(R)	90 ... (10) ... 160 bpm	130 bpm			
Initially paced chamber	RV; LV	LV			x
VV delay after Vp	0 ... (5) ... 100 ms	0 ms			x

Timing: Refractory periods and blanking periods

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

Timing: PMT protection

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

Timing: Rate adaptation via accelerometer

Parameter	Range of values	Standard	VR	DR	HF
Maximum sensor rate	80 ... (10) ... 160 bpm	120 bpm	x	x	x
Sensor gain	AUTO; Very low; Low; Medium; High; Very high	Medium	x	x	x
Sensor threshold	Very low; Low; Medium; High; Very high	Medium	x	x	x
Rate increase	1; 2; 4; 8 bpm/cycle	2 bpm/ cycle	x	x	x
Rate decrease	0.1; 0.2; 0.5; 1.0 bpm/ cycle	0.5 bpm/ cycle	x	x	x

Pacing: Pulse amplitude and pulse width

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

Pacing: Atrial capture control

Parameter	Range of values	Standard	VR	DR	HF
Atrial capture control	OFF; ATM	ON		x	x
Threshold test start	2.5 ... (0.5) ... 5.0 V	3.5 V		x	x

Pacing: Ventricular capture control

Parameter	Range of values	Standard	VR	DR	HF
Ventricular capture control	OFF; ATM	ON	x	x	x
Threshold test start	2.5 ... (0.5) ... 5.0 V	3.5 V	x	x	x

Lead configuration LV on IS-1 connection

Parameter	Range of values	Standard	VR	DR	HF
Pacing polarity LV (IS-1)	LV tip -> LV ring LV tip -> RV shock coil LV ring -> LV tip LV ring -> RV shock coil UNIP	LV tip -> RV shock coil			x
Sensing polarity LV (IS-1)	UNIP; BIPL	UNIP			x

Tachycardia

Detection

Parameter	Range of values	Standard	VR	DR	HF
Interval AT/AF	240 ... 600 ms	300 ms		x	x
Interval VT1	OFF; 270 ... (10) ... 600 ms	OFF	x	x	x
Interval VT2	OFF; 270 ... (10) ... 500 ms				
Interval VF	OFF; 240 ... (10) ... 400 ms	300 ms			
Detection counter VT1	10 ... (2) ... 100	28	x	x	x
Detection counter VT2	10 ... (2) ... 80	20			
Detection counter VF	6 out-of 8; 8 out-of 12; 10 out-of 14; 12 out-of 16; 16 out-of 20; 18 out-of 24; 20 out-of 26; 22 out-of 30; 24 out-of 30; 30 out-of 40	18 out of 24			
Redetection counter VT1	10 ... (2) ... 50	20	x	x	x
Redetection counter VT2	10 ... (2) ... 40	14			
Redetection counter VF	6 out-of 8; 8 out-of 12; 10 out-of 14; 12 out-of 16; 16 out-of 20; 18 out-of 24; 20 out-of 26; 22 out-of 30; 24 out-of 30	8 out of 12	x	x	x
SMART detection VT1/VT2	OFF; ON	ON		x	x
SMART detection ON:					
– Onset VT1/VT2	4 ... (4) ... 32%	20%		x	x
– Stability VT1/VT2	8 ... (4) ... 48%	12%			
SMART detection OFF:					
– Onset VT1/VT2	4 ... (4) ... 32%	20%	x	x	x
– Stability VT1/VT2	OFF; 8 ... (4) ... 48 ms	24 ms			
MorphMatch	OFF; Monitoring; ON	OFF	x	x	x
Sustained VT	OFF; 1; 2; 3; 5; 10; 20; 30 min	OFF	x	x	x
Forced termination	OFF; 1 ... (1) ... 10 min	1 min		x	x

Therapy: ATP

Parameter	Range of values	Standard	VR	DR	HF
Attempts	OFF; 1 ... (1) ... 10	OFF	x	x	x
ATP type for VT1/VT2	Burst; Ramp	Burst	x	x	x
ATP type for VF	OFF; Burst; Ramp	Burst	x	x	x
ATP optimization	OFF; ON	OFF	x	x	x
Number S1 for VT1/VT2	1 ... (1) ... 10	5	x	x	x
Number S1 for VF		8			
S1 decrement for VT1/VT2 and for VF	5 ... (5) ... 40 ms	10 ms	x	x	x
Scan decrement	OFF; 5 ... (5) ... 40 ms	OFF	x	x	x
Add S1 for VT1/VT2	OFF; ON	ON	x	x	x
Ventricular pacing for VT1/VT2	RV; LV; BiV	RV			x
Ventricular pacing for VF		RV			
R-S1 interval for VT1/VT2	70 ... (5) ... 95%	80%	x	x	x
R-S1 interval for VF		85 %			

Therapy: Shock

Parameter	Range of values	Standard	VR	DR	HF
Number of shocks VT1/VT2	0; 1; 2; 6; 8	8	x	x	x
Number of shocks VF	6; 8	8	x	x	x
1st Shock for VT1/VT2	OFF; 2 ... (2) ... 20 ... (5) ... 40 J	40 J	x	x	x
2nd Shock for VT1/VT2	OFF; 4 ... (2) ... 20 ... (5) ... 40 J	40 J	x	x	x
3rd - nth shock for VT1/VT2	OFF; 4*40 J; 6*40 J	6*40 J	x	x	x
1st Shock for VF	2 ... (2) ... 20 ... (5) ... 40 J	40 J	x	x	x
2nd Shock for VF	4 ... (2) ... 20 ... (5) ... 40 J	40 J	x	x	x
3rd - nth shock for VF	4*40 J; 6*	6*40 J	x	x	x
For shock in VT1/VT2 and VF:					
– Confirmation	OFF; ON	ON	x	x	x
– Polarity	Normal; Reverse; Alternating	Normal			
– Shock form	Biphasic; Biphasic 2	Biphasic			
– Shock path	RV -> ICD+SVC RV -> ICD RV -> SVC	RV-> ICD+SVC	x	x	x
		RV -> ICD			

Sensing

Sensitivity and thresholds

Parameter	Range of values	Standard	VR	DR	HF
Sensing A	STD; OFF	STD		x	x
Sensing RV	STD; TWS; VFS; IND	STD	x	x	x
Sensing LV	STD; OFF; IND	STD			x
Upper threshold RV	50; 75%	50%	x	x	x
Upper threshold LV	50; 75%	50%			x
Upper threshold duration after detection	110; 150 ... (50) ... 500 ms VFS: 110 ms	350 ms	x	x	x
Upper threshold duration after pacing		400 ms			
Lower threshold RV	25; 50%	25%	x	x	x
T-wave suppression after pacing	OFF; ON	OFF	x	x	x
Minimum threshold A	0.2 ... (0.1) ... 2.0 mV	0.4 mV		x	x
Minimum threshold RV	0.5 ... (0.1) ... 2.5 mV	0.8 mV	x	x	x
Minimum threshold LV	0.5 ... (0.1) ... 2.5 ... (0.5) ... 5.0 mV	1.6 mV			x

Diagnostics

The following can be set:

Parameter	Range of values	Standard	VR	DR	HF
For AT/AF	OFF; ON	ON		x	x
For SVT	OFF; ON	ON		x	x
Periodic recording	When Home Monitoring OFF: OFF; 30 ... (30) ... 180 days	90 days	x	x	x
IEGM configuration	RA, RV, LV RA, RV, FF FF; RV; LV	RA, RV, LV			x
Start resting period	00:00 ... (1:00 AM) ... 23:00 hh:mm	2:00 AM hh:mm	x	x	x
Duration of resting period	0.5 ... (0.5) ... 12 h	4 h	x	x	x
AV delay adjusted in sensing test	OFF; 300 ms	300 ms		x	x
Thoracic impedance (TI)	OFF, ON	OFF	x	x	x

Home Monitoring

Parameter	Range of values	Standard	VR	DR	HF
Home Monitoring	OFF; ON	OFF	x	x	x
Time of transmission	STD; 00:00 ... (1:00 AM) ... 23:00 hh:mm	STD	x	x	x
IEGM for therapy episodes	OFF; ON	ON	x	x	x
IEGM for monitoring episodes					
Ongoing atrial episode	OFF; 6; 12; 18 h	12 h		x	x
Transmission date	XX.XX.XXXX	Follow-up + 91 days	x	x	x
Cycle duration	20 ... (1) ... 366 days	91 days	x	x	x

5 Technical Data

Mechanical Characteristics

Housing

Devices with header for DF-1 connector:

Type	Lead connector	W x H x D in mm	Volume cm^3	Mass g
VR	DF-1	69 x 55 x 12,5	38	71
DR	DF-1	69 x 55 x 12,5	39	71
HF	DF-1	69 x 58.5 x 12,5	40	73

Materials in contact with body tissue

- Housing: Titanium
- Header: Epoxy resin
- Silicone plugs and blind plugs (if applicable): Silopren or silastic

X-ray identification

HK

Electrical Characteristics

Standards

The specifications are made according to EN 45502-2-2:2008.

Measuring conditions

If not indicated otherwise, all specifications refer to the following conditions:

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

Factory settings

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

Telemetry data

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

International radio certification

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

Telemetry information for Canada:

This device must neither interfere with meteorological and earth resources technology satellites nor with meteorological stations working in the 400,150 to 406,000 MHZ band, and it must accept any interference received, including interference that may cause undesired operation.

- This device will be registered with Industry Canada under the following number:
  IC: 4708A-TACHBORAX
  The code IC in front of the certification/ registration number only indicates that the technical requirements for Industry Canada are met.

Telemetry information for the USA:

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

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

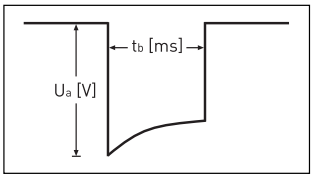
FCC ID: QRITACHBORAX

Telemetry data for Japan:

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

- R: 202-SMD021

Pulse form



The pacing pulse has the following form:

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

Common mode rejection ratio

Rate	Common mode rejection ratio		
	Atrium: DR, HF	V right: VR, DR, HF	V left: HF
16.6 Hz	72 dB	59 dB	57 dB
50 Hz	73 dB	66 dB	57 dB
60 Hz	71 dB	66 dB	62 dB

ATP amplitude

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

ATP amplitude	Measured minimum	Measured maximum	Mean value
RA	7.57 V	7.49 V	5.1 V
RV	7.54 V	7.49 V	5.1 V
LV	7.55 V	7.51 V	5.1 V

Automatic sensitivity control

Measurement of actual values and test signal wave shape: standard triangle.

Sensitivity	Value	Tolerance	Measured value
A: positive	0.2 mV	0.2 ... 0.5	0.23 mV
A: negative			0.24 mV
RV: positive	0.5 mV	0.3 ... 0.7	0.55 mV
RV: negative			0.58 mV
LV: positive	0.5 mV	0.3 ... 0.7	0.52 mV
LV: negative			

Shock energy / peak voltage

With shock path: RV to housing + SVC

Shock energy (Tolerance)	Tolerance Peak voltage	Measured value Shock energy	Measured value Peak voltage
1 J (0.7 ... 1.18)	100 ... 140 V	0.89 J	125,0 V
20 J (15.9 ... 21.6)	500 ... 550 V	16,62 J	530,4 V
40 J (32.0 ... 43.2)	710 ... 790 V	33,84 J	750,9 V

Battery Data

Battery characteristics

The following data is provided by the manufacturers:

Manufacturer	**LITRONIK Batterietechnologie GmbH & Co 01796 Pirna, Germany**
Battery type	LiS 3410 RR
System	LiMnO2
Battery ID number shown on the programmer	6
Device type	VR-T, DR-T, HF-T
Battery voltage at ERI	2.85 V
Charge time at BOS	8 s
Charge time at ERI	10 s
Usable capacity until ERI: VR, DR, HF	1390 mAh
Usable capacity until EOS	1520 mAh

Storage period

The storage period affects the battery service time.

- Devices should be implanted within 19 months between the manufacturing date and the use by date (indicated on the package).
- If the ICD is implanted shortly before the use by date, the expected service time may be reduced by up to 17 months.

Calculation of service times

- The services times have been calculated as follows – in all chambers depending on the device type:
  - Pulse amplitude: 2.5 V
  - Pulse width: 0.4 ms
  - Pacing impedance: 500 Ω
  - Basic rate: 60 bpm
  - Home Monitoring: ON, 1 device message each day and 12 IEGM online HD transmissions per year
  - Diagnostic functions and recordings: permanently set
- Capacitor reforming is performed 4 times per year and therefore at least 4 maximum charges for shocks have to be assumed per year even if less than 4 are delivered.

Calculation of the number of shocks

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

Inlexa 1 VR-T

Service times with LiS 3410 RR battery:

Pacing	**Service time [in years] at number of shocks per year**				
	4	**8**	**12**	**16**	**20**
0%	10.3	8.3	7.0	6.0	5.3
15%	10.1	8.1	6.8	5.9	5.2
50%	9.5	7.8	6.6	5.7	5.0
100%	8.8	7.3	6.2	5.4	4.8

Inlexa 1 DR-T Service times with LiS 3410 RR battery:

Pacing	Service time [in years] at number of shocks per year				
	4	8	12	16	20
0%	9.4	7.7	6.5	5.7	5.0
15%	9.0	7.4	6.3	5.5	4.9
50%	8.1	6.8	5.9	5.2	4.6
100%	7.1	6.1	5.3	4.7	4.3

Inlexa 1 HF-T Service times with LiS 3410 RR battery:

Pacing	Service time [in years] at number of shocks per year				
	4	8	12	16	20
0%	8.9	7.4	6.3	5.5	4.9
15%	8.3	7.0	6.0	5.2	4.7
50%	7.2	6.1	5.4	4.8	4.3
100%	6.0	5.3	4.7	4.2	3.9

Legend for the Label

Label on the package

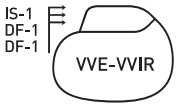
The label icons symbolize the following:

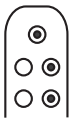
	Manufacturing date		Use by
	Storage temperature		Order number
	Serial number		Product identification number
	Dangerous voltages!		CE mark
	Contents		Follow the instructions for use

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

	Transmitter with non-ionizing radiation at designated frequency

TP2	Compatibility with telemetry protocol version 2 of BIOTRONIK Home Monitoring

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

 Example of lead connection: DF-1/IS-1