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BIOTRONIK
excellence for life

Cardiac Rhythm Management

Bradycardia therapy

Technical Manual

Evia

Pacemaker with automatic Functions and BIOTRONIK Home Monitoring®

BIOTRONIK
excellence for life

Evia DR-T, DR, SR-T, SR

Pacemaker
Bradycardia therapy

Technical manual for the implant

Doc. Id.: 365353-A

BIOTRONIK

Table of Contents

1 Product Description

Intended Medical Use

Intended use

Evia is a family of implantable pacemakers that may be implanted for all bradycardia arrhythmia indications. The primary objective of the therapy consists of improving patients' symptoms that can be clinically manifested.

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

- Compensation of bradycardia by atrial, ventricular, or AV sequential pacing

Diagnosis and therapy forms

The cardiac rhythm is automatically monitored and bradycardia arrhythmias are treated. All major therapeutic approaches from the field of cardiology and electrophysiology are unified in the Evia family.

BIOTRONIK Home Monitoring® enables physicians to perform therapy management any time.

Required expertise

In addition to having basic medical knowledge, the user must be thoroughly familiar with the operation of an implant system. Only qualified medical specialists having the special knowledge required for the proper use of implants are permitted to use them. If users do not possess this knowledge, they must be trained accordingly.

System Overview

Parts

The implant system consists of the following parts:

- Implant with connections for unipolar or bipolar sensing and pacing
- Suitable leads and approved accessories
- Programmer
- Current implant programs

Implant

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

The housing serves as an antipole in the case of unipolar lead configuration. BIOTRONIK provides silicone-coated implants to avoid muscle twitching near the implanted pacemaker in the case of unipolar pacing.

The labeling provides information about the implant type and arrangement of the connections.

Leads

The leads are sheathed with biocompatible silicone. They can be flexibly maneuvered, are long-term stable, and are equipped for active or passive fixation. They are implanted using a lead introducer set. Some leads are coated with polyurethane to increase the sliding properties of the lead.

The coating of steroid-eluting leads reduces inflammatory processes. The fractal design of the leads provides for low pacing thresholds, high pacing impedance, and a low risk of oversensing.

Programmer

The transportable programmer is used to transfer the appropriate implant program to the implant. In addition to this, the programmer is used for interrogation and storage of data from the implant. And it acts as an ECG and IEGM monitor with Miniclinic.

The programmer communicates with the implant via the programming head. The operation module of the programmer has a TFT touch screen with color display, on which the ECG, IEGM, marker and functions are shown simultaneously.

The programmer has, among others, the following functions:

- Perform all tests during follow-up
- Display and print real-time and saved IEGMs with annotated markers
- Determine the pacing threshold

BIOTRONIK Home Monitoring®

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

- With Home Monitoring, diagnostic and therapeutic information and technical data are sent via an antenna in the implant header to a mobile or stationary transmitter. The encrypted data are 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 fax, SMS or E-mail.
- A clear overview of the analysis results is displayed for the attending physicians on the protected Internet platform HMSC (Home Monitoring Service Center).
- Data transmission from the implant is performed on a daily basis with the trend message. Depending on the transmitter used, these data are passed on immediately or, if the data is normal, it is collected for up to 2 weeks. If certain events occur in the patient's heart or in the implant itself, an event message is sent. Additionally, patients can send a patient message by applying the magnet.

Technical manuals

The following technical manuals provide information about usage of the implant system:

- Technical manual for the implant
- Technical manual for the programmer
- User manual for the implant program:
  - — As a help function in the user interface
  - — As a file on CD
- Technical manual for the leads

Implant Variants and NBG Codes

Evia family

The following implant variants are available:

Implant type	Variant with Home Monitoring	Variant without Home Monitoring
Dual-chamber	Evia DR-T	Evia DR
Single-chamber	Evia SR-T	Evia SR

Note: The setting of the pacing mode depends on the individual diagnosis; the modes are listed in the section pertaining to adjustable parameters.

NBG-Code for Evia DR(-T)

The NBG code for dual-chamber implants is DDDR:

D	Pacing in both chambers
D	Sensing in both chambers
D	Pulse inhibition and pulse triggering
R	Rate adaptation

NBG-Code for Evia SR(-T)

The NBG code for single-chamber implants is AAIR or VVIR:

A/V	Pacing in one chamber
A/V	Sensing in one chamber
I	Pulse inhibition in A/V
R	Rate adaptation

Diagnostic and Therapy Functions

General overview

All the systems have extensive features that allow quick diagnosis and delivery of safe therapy for bradycardia conditions.

- Automatic functions make it easy and fast to implant, configure, and check the pacemaker.
- Auto-initialization after implantation: the implant automatically detects the implanted leads, sets the polarity and activates the automatic functions after 10 min.

Diagnostic functions

- Data from the last 10 interrogations and follow-ups are recorded as well as arrhythmia episodes; they are stored together with other data to assess patients and the state of the implant at any time.
- Automatic below-threshold impedance measurement is performed in the implant independent of the pacing pulse in order to check the lead for proper functioning.
- When performing follow-ups using the programmer, the IEGM is indicated with markers after applying the programming head during the test procedure.

Antibradycardia pacing

- Sensing: the amplitudes of the P and R waves are measured in the implant fully automatically to record varying amplitudes. The sensitivity for the atrium and ventricle is adapted automatically on an ongoing basis. The measurement data are averaged and the trend can be displayed.
- Thresholds: atrial as well as ventricular pacing thresholds are automatically determined in the implant. Active capture control is used to set the pacing amplitudes so that pacing is performed with the optimum atrial and ventricular amplitude for the patients with each change of the pacing threshold.
- Timing: pacing is particularly checked in the atrium by automatic adaptation of the atrial refractory period to avoid pacemaker-induced tachycardia. (Auto PVARP function: automatic postal-atrial refractory period)
- Additional, special form of rate adaptation: an increased cardiac output requirement is detected using physiological impedance measurement. The measuring principle is based on contractile changes (ionotropy) of the myocardium (CLS function: Closed Loop Stimulation). The suitable rate adaptation is automatically initialized and optimized in CLS mode.
- Ventricular pacing suppression: unnecessary ventricular pacing is avoided by promoting intrinsic conduction (V_p suppression function). The implant can adapt itself to conduction changes. In the case of intrinsic conduction, the implant switches to a mode similar to AAI.

Home Monitoring

The implant automatically sends information to the transmitter once a day. Additionally, the test messages can be initiated using the programmer. Important medical information include, among others, the following:

- Ongoing atrial and ventricular arrhythmia
- Parameters relevant to leads in the atrium and ventricle: thresholds, sensing amplitudes, impedances
- Current statistics on bradycardia therapy
- Individually adjustable remote interrogation messages which enhance the standard message with additional information relevant for follow-up
- IEGM online HD® with up to 3 channels in high definition with markers for RA and RV, which each include the intrinsic rhythm and sequences with encouraged sensing and encouraged pacing
- Sending of these IEGM recordings with remote interrogation messages
- Test message triggered by the programmer to immediately check the Home Monitoring function including notification of the physician

Scope of Delivery

Standard

The storage package includes the following:

- Implant in sterile packaging
- Patient's manual
- Serial number label
- Patient ID card
- Warranty card
- Technical manual

The sterile container contains the following:

- Implant
- Screwdriver

Order numbers Evia

The implants can be obtained as follows:

Implant	Order number: uncoated	Order number: coated
DR-T	359529	359530
DR	359524	359528
SR-T	359533	359534
SR	359531	359532

Accessories

All BIOTRONIK products correspond to the requirements of the EC Directive 90/385/EEC:

- BIOTRONIK leads
- BIOTRONIK programming and monitoring devices
- Permanent magnet
- For Home Monitoring: BIOTRONIK transmitters

2 General Safety Instructions

Possible Medical Complications

General information on medical complications

Complications for patients and implant systems generally recognized among practitioners also apply to BIOTRONIK implants.

- Normal complications may include fluid accumulation within the implant 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. In particular it cannot be excluded that tachyarrhythmias be induced.

Skeletal myopotentials

Bipolar sensing and control of sensitivity are adapted by the implant to the rate spectrum of intrinsic events so that skeletal myopotentials are usually not sensed. Skeletal myopotentials can nonetheless be sensed as intrinsic events especially with a unipolar configuration and, depending on the interference pattern, may cause inhibition or antiarrhythmia therapy.

Nerve and muscle stimulation

An implant system consisting of a unipolar lead and an uncoated implant may result in undesirable pacing of the diaphragm in the case of an initial or permanent high setting of the pacing amplitude.

- BIOTRONIK also provides coated implants.

Possible Technical Complications

Technical malfunctions

Technical implant malfunctions cannot entirely be excluded. Possible causes can include the following:

- Lead dislocation
- Lead fracture
- Insulation defects
- Implant component failures
- Battery depletion

Possible Electromagnetic Complications

Electromagnetic interference (EMI)

Any implant can be sensitive to interference, for example, when external signals are sensed as intrinsic rhythm or if measurements prevent rate adaptation.

- BIOTRONIK implants 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 in patients - if any.
- 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 fixed-rate pacing.
- Under unfavorable conditions, for example during diagnostic or therapeutic procedures, the interference sources may induce such a high level of energy into the pacing system that the implant or cardiac tissue around the lead tip is damaged.

Implant behavior in case of EMI

Upon exceeding the interference rate, the implant switches to another pacing mode. Depending on whether the interference occurs in one chamber or both chambers, the implant switches to the A00(R), V00(R) or D00(R) mode for the duration of the interference.

Static magnetic fields

The Reed contact in the pacemaker closes beginning at a field strength of 1.5 tesla.

Possible Risks

Risky diagnostic and therapeutic procedures

If electrical current from an external source is conducted through the body for diagnostic or therapeutic purposes, then the implant can be subjected to interference and the patient placed at risk. Therefore the following always applies:

- Monitor the patient.

External defibrillation

The implant 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 implant to the heart at least 10 cm away from the device and from implanted leads.

Contraindicated procedures

The following procedures are contraindicated:

- Therapeutic ultrasound and diathermy: damage to the patient via excess warming of body tissue near the implant system
- Transcutaneous electrical nerve stimulation (TENS)
- Lithotripsy
- Electrocautery and high-frequency surgery: damage to the patient via the induction of arrhythmia or ventricular fibrillation
- Hyperbaric oxygen therapy
- Applied pressures higher than normal pressure

Magnetic resonance imaging

Magnetic resonance imaging is contraindicated due to the associated magnetic flux density: damage or destruction of the implant system by strong magnetic interaction and damage to the patient by excessive warming of the body tissue in the area surrounding the implant system.

- Under certain conditions one can perform special measures with magnetic resonance imaging to protect the patient and implant.

Therapeutic ionizing radiation

Radiation can cause latent damage. This damage cannot be recognized immediately. Therefore, the following applies to X-ray diagnosis and radiation therapy:

- Sufficiently shield implant against radiation.
- After applying radiation, double-check the implant system to make sure it is functioning properly.

3 Prior to Implantation

Indications and Contraindications

Guidelines of cardiologic societies

Generally approved differential diagnostics methods, indications, and recommendations for pacemaker therapy apply to BIOTRONIK implants.

The guidelines provided by cardiology associations offer decisive information.

Indications

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). Likewise those published by the Heart Rhythm Society (HRS), the American College of Cardiology (ACC), the American Heart Association (AHA) as well as other national cardiology associations.

Contraindications

No contraindications are known for the implantation of multiprogrammable and multifunctional single-chamber or dual-chamber implants, provided differential diagnostics precedes implantation according to the appropriate guidelines and no modes or parameter combinations are configured which pose a risk to the patient.

Note: The compatibility and effectiveness of parameter combinations must be checked after programming.

Ambient Conditions

Temperature

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

- The following temperatures are permitted for transport, storage, and use:
  – 10°C to 45°C (50°F to 113°F)

Storage location

- Implants are not to be stored close to magnets or sources of electromagnetic interference.

Storage period

The duration of storage affects the service time of the battery of the implant (see battery data).

Sterility

Delivery The implant and the accessories have been gas sterilized. Sterility is guaranteed only if the plastic container and quality control seal have not been damaged.

Sterile container The implant and accessories are packaged respectively in two separately sealed plastic containers. The inner plastic container is also sterile on the outside so that it can be transferred in a sterile state during implantation.

Single use only The implant and the screwdriver are only intended for one-time use.

- Do not use if package is damaged.
- Do not resterilize.
- Do not reuse.

Preparing the Implantation

Have parts ready

- Ensure that sterile spare parts are available for all parts that are to be implanted.
- Only use products that correspond to the requirements of the EC Directive 90/385/EEC:
  - BIOTRONIK implant and blind plugs
  - BIOTRONIK leads and lead introducer
  - BIOTRONIK programmer with approved cable and adapter accessories
  - External multi channel ECG recorder
  - External defibrillator and paddles or adhesive electrodes

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

Unpacking the implant

Proceed as follows:

1	Peel off the sealing paper of the outer plastic container at the marked position in the direction indicated by the arrow. The inner plastic container may not come into contact with persons who have not sterilized their hands or gloves, nor with non-sterile instruments.
2	Use the gripping tab on the inner plastic container to remove it from the outer plastic container.
3	Peel off the sealing paper of the sterile inner plastic container at the marked position in the direction indicated by the arrow.

Note: The implant is disabled on delivery and can be implanted immediately after unpacking without manual activation.

4 Implantation

Implanting

Implantation site

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

Sequence

Proceed as follows:

1	Shape the implant pocket and prepare the vein.
2	Implant the leads and perform measurements.
3	Connect implant and leads. The implant starts auto-initialization on its own.
4	Insert the implant.
5	Guide the fixation suture through the opening in the header and fixate the implant in the prepared pocket.
6	Close the implant pocket.
7	Prior to testing and configuration, wait for the successful completion of automatic implant initialization.

Note: If necessary, the implant can also be programmed before or during auto-initialization.

Connecting PM Leads

Connection options

BIOTRONIK pacemakers are designed for leads with unipolar or bipolar IS-1 connection. A unipolar or bipolar lead can be connected to Evia for sensing and pacing:

	DR-T and DR	SR-T and SR
Atrium	IS-1 unipolar or bipolar	
Ventricle		

Note: Use only adapters approved by BIOTRONIK for leads with different connections.

- If you have any questions concerning the compatibility of other manufacturers' leads, please contact BIOTRONIK.

Connection schemes

Connection scheme for dual-chamber and single-chamber implants:

DR-T and DR	SR-T and SR
DDDR  **A** **V** **IS-1**	**VVIR/AAIR**  **IS-1**

Connecting the lead connector to the implant

Proceed as follows:

1	Disconnect stylets and insertion aids from the lead connector.
2	• Connect the unipolar or bipolar IS-1 lead connector atrium to A. • Connect the unipolar or bipolar IS-1-lead connector ventricle to V.
3	Push the lead connector into the header without bending the conductor until the connector tip becomes visible behind the set screw block.
4	If the lead connector cannot be inserted completely, the set screw may be protruding into the cavity of the set screw block. Carefully loosen the set screw without completely unscrewing it, so that it does not become tilted upon retightening.
5	Use the screwdriver to perpendicularly pierce through the slitting in the center of the silicone plug until it reaches the set screw.
6	Turn the set screw clockwise until the torque control starts (you will hear a clicking sound).
7	Carefully withdraw the screwdriver without retracting the set screw. • When you withdraw the screwdriver, the silicone plug automatically seals the lead connection safely.

WARNING

Short circuit due to open lead connections

Open, and thus not electrolyte-tight, IS-1 connections may cause undesired current flow to the body and penetration of bodily fluid into the implant.

- Close IS-1 connections that are not in use with IS-1 blind plugs.

Auto-initialization

Auto-initialization begins automatically once the first connected lead is detected.

Auto-initialization is terminated 10 minutes after connection of the first lead. If no other program has been transferred in the meantime, the implant subsequently works with active automatic functions in the standard program.

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

Note: After auto-initialization, all parameters are activated as in the standard program with the following exceptions:

- DDD-CLS
- VVI
- The automatically determined lead configuration (unipolar or bipolar) is set.

Behavior during auto-initialization

- During reprogramming: auto-initialization is canceled and the transferred program is immediately active.
- During testing: auto-initialization is subsequently continued.
- During transmission of a permanent program: auto-initialization is terminated and the transferred program is active.

Precautionary Measures while Programming

Checking the implant system

- After auto-initialization perform follow-up to see if the implant system is functioning properly.
- Perform a pacing threshold test to determine the pacing threshold.

Monitoring the patient

The patient could be subjected to critical states if, for example, inadequate parameters are set or due to telemetry interference during a temporary program.

- Continuously monitor the ECG and the patient's condition.
- Remove the programming head to a distance of at least 30 cm and the permanent program will be reactivated immediately.

Manually setting lead polarity

Due to the risk of an entrance/exit block, bipolar lead polarity (sensing/pacing) should only be set if bipolar leads are implanted.

Setting the triggered pacing mode

Triggered pacing modes perform pacing regardless of intrinsic cardiac events. To prevent undersensing due to electromagnetic interference in special cases, a triggered pacing mode can be displayed.

Avoiding asynchronous pacing

High pacing rates with long refractory periods (a/v) can lead to intermittent, asynchronous pacing. Such programming can be contraindicated in some cases.

Setting sensing

- In order to avoid errors in manually set parameters, set automatic sensitivity control.
- Unsuitable far-field protection can hinder pacemaker sensing (undersensing).

Setting the sensitivity

A value set to < 2.5 mV/unipolar for implant sensitivity may result in noise caused by electromagnetic fields.

- Therefore, it is recommended that a value of ≥ 2.5 mV/unipolar be set according to paragraph 28.22.1 of the EN 45502-2-1 standard. Setting sensitivity values < 2.5 mV/unipolar requires explicit clinical need. Values like this can only be set and retained with physician supervision.

Preventing implant-induced complications

- Measure the retrograde conduction time.
- If the function is not yet automatically set: activate PMT protection.
- Set the VA criterion.

Information on magnet response

Applying a magnet or the programming head can result in an unphysiological rhythm change and asynchronous pacing. The magnet response is set as follows in the standard program of BIOTRONIK pacemakers:

- Asynchronous: for the duration of the magnet application – mode D00 (possibly V00 / A00) without rate adaptation; magnet rate: 90 ppm
- Automatic: for 10 cycles – mode D00, subsequently mode DDD without rate adaptation; magnet rate: 10 cycles with 90 ppm, subsequently set basic rate
- Synchronous: mode DDD without rate adaptation; magnet rate: set basic rate

Note: See information pertaining to replacement indications for magnet behavior at ERI.

Preventing conduction of atrial tachycardia to the ventricle

- If the function is not yet automatically set: activate 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.

If an ICD is implanted at the same time, do not permit unipolar pacing

If an ICD is implanted in addition to a pacemaker and a lead failure occurs, it is possible to switch to unipolar pacing after a pacemaker reset or using the automatic lead check. The ICD could therefore falsely inhibit or trigger tachyarrhythmia therapy activity.

- Unipolar leads are not permitted in this configuration.

Consider power consumption and service time

The pacemaker permits programming of high pulse amplitudes with long pulse widths at high rates to be able to adequately treat even rare diagnoses. In combination with low lead impedance, this results in a very high level of power consumption.

- When programming large parameter values, take into account that the battery depletion indicator ERI will be activated very early because the service time of the battery may be reduced to less than 1 year.

5 After Implantation

Follow-up

Follow-up intervals

Follow-ups must be performed at regular agreed intervals.

- Follow-ups with the programmer should take place in intervals between 6 to 12 months considering the expected service life of the implant.

Follow-up with the programmer

Proceed as follows:

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

Notes for the Physician

Notes for patients

A patient brochure and a patient ID card are supplied with the device.

- Provide the patient with the patient brochure and patient ID card.
- Draw the patient's attention to prohibitory signs: places with prohibitory signs must be avoided.

Possible sources of interference

Interference can be caused by, among others, the following:

- Household appliances
- Safety locks or anti-theft installations
- Strong electromagnetic fields
- Cellular phones and transmitters

Using cellular phones

Electromagnetic interference has a temporary effect only. Generally, BIOTRONIK implant functions return to normal when the respective cellular phone is removed from the proximity of the implant.

- Patients are advised to hold cellular phones to the ear opposite the side on which the device is implanted. Cellular phones should also be kept at least 15 cm away from the implant. If the power of transmission is greater than 3 watts, they must be kept at least 30 cm away.
- Some cellular phones emit signals when in stand-by mode, i.e., even when not in use. Therefore, patients should not carry a cellular phone in a chest pocket or attached to a belt or within a radius of 15 cm from the implant.

Magnet application by patients

If patients are to be entrusted with magnet application, the synchronous magnet mode has to have been programmed. Patients should also know the following:

- When may the magnet be used?

  In cases of severe dizziness and indisposition
- How long is the magnet placed on the pacemaker?

  1 to 2 seconds
- What happens when the magnet is applied?

  The IEGM of the last 10 seconds is stored.
- What has to happen after magnet application?

  The patient has to contact the physician for a check-up

Replacement Indications

Pacemaker operational status indications

The time span from the beginning of service (BOS) to elective replacement indication (ERI) is determined by, among others, the following:

- Battery capacity
- Lead impedance
- Pacing program
- Pacing to inhibition ratio
- Pacemaker circuit properties

The following are the defined pacemaker operational statuses:

BOS	Beginning of Service	Battery is in good condition; normal follow-up.
ERI	Elective Replacement Indication	The replacement time has been reached. The pacemaker must be replaced.
EOS	End of Service	End of service time with regular pacemaker activity.

ERI activation

ERI detection is automatically activated after the following events:

- Successful auto-initialization
- Storage for longer than 24 months

ERI display

ERI is displayed as follows:

- By a defined decrease in the basic rate as well as the magnet rate
- After interrogation of the pacemaker

Change of the pacing mode with ERI

From dual-chamber modes, the pacemaker switches to single-chamber pacing. This replacement mode depends on the programmed mode and is displayed on the programmer.

Deactivated functions with ERI

The following functions are deactivated:

- Atrial pacing
- Night program
- Rate adaptation
- Atrial and ventricular active capture control
- Rate fading
- Atrial overdrive pacing
- IEGM recordings
- Statistics
- Home Monitoring
- Rate hysteresis
- Ventricular pacing suppression

Rate decrease

The decrease of basic rate and magnet rate is defined as follows:

- In the following pacing modes the pacing rate decreases by 11%: DDD(R); DDT(R); DOO(R) VDD(R); VDI(R); VVI(R), VVT(R) AAI(R); AAT(R); AOO(R).
- In the pacing modes DDI(R) and DVI(R), only the VA interval is extended by 11%. This reduces the pacing rate by 4.5 to 11%, depending on the configured AV delay.

Magnet response at ERI

After reaching ERI pacing is performed as follows after applying the magnet or programming head:

Magnet mode		
	Cycles 1 to 10:	**After 10th cycle:**
Automatically	Asynchronous with rate at 80 ppm	Synchronous with basic rate reduced by 4.5 to 11%
Asynchronous	Asynchronous with rate at 80 ppm	Asynchronous with rate at 80 ppm
Synchronous	Synchronous with basic rate reduced by 4.5 to 11%	Synchronous with basic rate reduced by 4.5 to 11%

Expected service time after ERI

- The information is based on a lead impedance of 500 Ohm at 100% pacing and the data of the battery manufacturer.
- For a lead impedance of 300 Ohm instead of 500 Ohm, these times decrease by max. 30%.
- Parameter with high pulse energy: 110 ppm; 4.6 V; 1.5 ms; 500 Ohm
- Parameter with low pulse energy: 30 ppm; 0.2 V; 0.1 ms; 500 Ohm
- Dual-chamber implant in DDDR mode; single-chamber implant in AAIR/VVR mode:

[in months]

ERI to EOS interval	**Standard program**	**With high pulse energy**	**With low pulse energy**
Mean value	8	8	8
Minimum value	6	6	6

Explantation and Implant Replacement

Explantation

- Disconnect the leads from the header.
- Remove the implant and, if necessary, leads using state-of-the-art technology.
- Explants are biologically contaminated and must be disposed safely due to risk of infection.

Implant replacement

- Implanted leads of a predecessor implant must be checked before they are connected to a new implant.

WARNING

Interference with functioning of the implant system

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

- Insulate connections that are not used.

Cremation

Implants should not be cremated.

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

Disposal

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

- Clean the explant with an at least 1% sodium-hyperchlorine solution.
- Rinse off with water.
- Fill out explantation form and send to BIOTRONIK together with the cleaned implant.

6 Parameters

Pacing Modes

Evia family The following pacing modes are available:

Implant type	Pacing mode	Standard
DR(-T)	• DDD-CLS, VVI-CLS • DDDR, DDIR, DVIR, DOOR VDDR, VDIR, VVIR, VVTR, VOOR AAIR, AATR, AOOR • DDD, DDT, DDI, DVI, DOO VDD, VDI, VVI, VVT, VOO AAI, AAT, AOO OFF	DDDR
SR(-T)	• VVI-CLS • VVIR, VOOR AAIR*, AATR*, AOOR* • VVI, VVT, VOO AAI*, AAT*, AOO* OFF *depends on the programmer software	VVIR

Note: Home Monitoring is possible in all pacing modes.

Timing DR(-T)

Basic rate day/night

Parameter	Range of values	Standard
Basic rate	30 ... (1) ... 90 ... (2) ... 122 ... (3) ... 140 ... (5) ... 200 ppm	60 ppm
Night rate	OFF; 30 ... (1) ... 90 ... (2) ... 122 ... (3) ... 140 ... (5) ... 200 ppm	OFF
Night begins	00:00 ... (10 min) ... 23:59 hh:mm	22:00 hh:mm
Night ends	00:00 ... (10 min) ... 23:59 hh:mm	06:00 hh:mm

Rate hysteresis

Parameter	Range of values	Standard
Rate hysteresis	OFF; -5 ... (-5) ... -90 ppm	OFF
Repetitive hysteresis	OFF; 1 ... (1) ... 15	OFF
Scan hysteresis	OFF; 1 ... (1) ... 15	OFF

AV delay

Parameter	Range of values	Standard
AV delay	Low; medium; high; fixed; individual	Low
AV delay	15 ... (5) ... 350 ms (in 6 rate ranges)	180 ms
Sense compensation	OFF; -10 ... (5) ... -120 ms	-45 ms
AV safety delay	100 ms	100 ms

AV hystereses

Parameter	Range of values	Standard
AV hysteresis mode	OFF; Negative, low; medium; high; IRSplus	OFF
Positive repetitive AV hysteresis	OFF; 1 ... (1) ... 10	OFF
Negative repetitive AV hysteresis	OFF; 1 ... (1) ... 15 ... (5) ... 100 ... (10) ... 180	OFF
AV scan hysteresis	OFF; 1 ... (1) ... 10	OFF

Ventricular pacing suppression

Parameter	Range of values	Standard
V_p suppression	OFF; ON	OFF
Pacing suppression after consecutive V_s	1 ... (1) ... 8	6
Pacing supports after X-out-of-8 cycles	1; 2; 3; 4	3

Upper rate

Parameter	Range of values	Standard
Upper rate	90 ... (10) ... 200 ppm	130 ppm
Atrial upper rate	OFF; 240 ppm	240 ppm

Mode switching

Parameter	Range of values	Standard
Mode switching	OFF; ON	ON
Intervention rate	100 ... (10) ... 250 ppm	160 ppm
Switch to (mode)	DDI; DDI(R) when permanent DDD(R) VDI; VDI(R) when permanent VDD(R)	DDIR VDIR
Onset criterion	3 ... (1) ... 8	5
Resolution criterion	3 ... (1) ... 8	5
Change of the basic rate with mode switching	OFF; +5 ... (5) ... +30 ppm	+10 ppm
Rate stabilization with mode switching	OFF; ON	OFF

Refractory periods

Parameter	Range of values	Standard
Atrial refractory period	AUTO	AUTO
Atrial refractory period in the modes AAI(R); AAT(R); DDT	300 ... (25) ... 775 ms	350 ms
PVARP	AUTO; 175 ... (5) ... 600 ms	AUTO
PVARP after PVC	PVARP + 150 ms (max: 600 ms) is automatically programmed	400 ms
Ventricular refractory period	200 ... (25) ... 500 ms	250 ms

Blanking periods

Parameter	Range of values	Standard
Far-field protection after V_s	100 ... (10) ... 220 ms	100 ms
Far-field protection after V_p	100 ... (10) ... 220 ms	150 ms
Ventricular blanking after A_p	30 ... (5) ... 100 ms	30 ms

PMT protection

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

Timing SR(-T)

Basic rate day/night

Parameter	Range of values	Standard
Basic rate	30 ... (1) ... 90 ... (2) ... 122 ... (3) ... 140 ... (5) ... 200 ppm	60 ppm
Night rate	OFF 30 ... (1) ... 90 ... (2) ... 122 ... (3) ... 140 ... (5) ... 200 ppm	OFF
Night begins	00:00 ... (10 min) ... 23:59 hh:mm	22:00 hh:mm
Night ends	00:00 ... (10 min) ... 23:59 hh:mm	06:00 hh:mm

Rate hysteresis

Parameter	Range of values	Standard
Rate hysteresis	OFF -5 ... (-5) ... -90 ppm	OFF
Repetitive hysteresis	OFF; 1 ... (1) ... 15	OFF
Scan hysteresis	OFF; 1 ... (1) ... 15	OFF

Upper rate

Parameter	Range of values	Standard
Upper rate	90 ... (10) ... 200 ppm	130 ppm

Refractory period

Parameter	Range of values	Standard
Refractory period	200 ... (25) ... 500 ms	250 ms

Pacing and Sensing DR(-T)

Pulse amplitude and pulse width

Parameter	Range of values	Standard
Pulse amplitude A	0.2 ... (0.1) ... 6.2; 7.5 V	3.0
Pulse width A	0.4; 0.5; 0.7; 1.0; 1.2; 1.5 ms	0.4 ms
Pulse amplitude V	0.2 ... (0.1) ... 6.2; 7.5 V	3.0 V
Pulse width V	0.4; 0.5; 0.7; 1.0; 1.2; 1.5 ms	0.4 ms

Sensitivity

Parameter	Range of values	Standard
Sensitivity A	AUTO 0.1 ... (0.1) ... 1.5 ... (0.5) ... 7.5 mV	AUTO
Sensitivity V	AUTO 0.5 ... (0.5) ... 7.5 mV	AUTO

Atrial capture control

Parameter	Range of values	Standard
Atrial capture control	ATM (monitoring only); OFF	OFF
Min. amplitude	0.5 ... (1) ... 4.8 V	1.0 V
Threshold test start	2.4; 3.0; 3.6; 4.2; 4.8 V	3.0 V
Safety margin	0.5 ... (1) ... 1.2 V	1.0 V
Search time	Interval; time of day	Interval
Interval	0.1; 0.3; 1; 3; 6; 12; 24 h	24 h
Time of day	00:00 ... (15 min) ... 23:45	02:00

Ventricular capture control

Parameter	Range of values	Standard
Ventricular capture control	ON; ATM (monitoring only); OFF	ON
Min. amplitude	0.7 V	0.7 V
Threshold test start	2.4; 3.0; 3.6; 4.2; 4.8 V	3.0 V
Safety margin	0.3 ... (1) ... 1.2 V	0.5 V
Search time	Interval; time of day	Interval
Interval	0.1; 0.3; 1; 3; 6; 12; 24 h	24 h
Time of day	00:00 ... (15 min) ... 23:45 hh:mm	02:00 hh:mm

Lead configuration

Parameter	Range of values	Standard
Pacing polarity A	Unipolar; bipolar	Unipolar
Pacing polarity V	Unipolar; bipolar	Unipolar
Sensing polarity A	Unipolar; bipolar	Unipolar
Sensing polarity V	Unipolar; bipolar	Unipolar

IEGM recordings

Parameter	Range of values
IEGM recordings	20 (quantity); each max. 10 s
Types of IEGM recordings	High atrial rate (HAR)
	Mode switching (MSW)
	High ventricular rate (HVR)
	Patient triggered (Pt.)
IEGM recording prior to event	0; 25; 50; 75; 100%
IEGM signal	Filtered; unfiltered

Rates for statistics

Parameter	Range of values	Standard
High atrial rate (HAR)	100 ... (5) ... 250 bpm 600; 572 ... 245; 240 ms	200 bpm 300 ms
High ventricular rate (HVR)	150 ... (5) ... 200 bpm 400; 378 ... 308; 300 ms	180 bpm 333 ms
HVR counter	4; 8; 12; 16	8

Pacing and Sensing SR(-T)

Pulse amplitude and pulse width

Parameter	Range of values	Standard
Pulse amplitude	0.2 ... (0.1) ... 6.2; 7.5 V	3.0 V
Pulse width	0.1; 0.2; 0.3; 0.4; 0.5; 0.75; 1.0; 1.25; 1.5 ms	0.4 ms

Sensitivity

Parameter	Range of values	Standard
Sensitivity	AUTO 0.5 ... (0.5) ... 7.5 mV	AUTO

Ventricular capture control

Parameter	Range of values	Standard
Ventricular capture control	ON; ATM (monitoring only) OFF	ON
Min. amplitude	0.7 V	0.7 V
Threshold test start	2.4; 3.0; 3.6; 4.2; 4.8 V	3.0 V
Safety margin	0.3 ... (1) ... 1.2 V	0.5 V
Search time	Interval; time of day	Interval
Interval	0.1; 0.3; 1; 3; 6; 12; 24 h	24 h
Time of day	00:00 ... (15 min) ... 23:45 hh:mm	02:00 hh:mm

Lead configuration

Parameter	Range of values	Standard
Pacing polarity	Unipolar; bipolar	Unipolar
Sensing polarity	Unipolar; bipolar	Unipolar

IEGM recordings

Parameter	Range of values
IEGM recordings	20 (quantity); each max. 10 s
Types of IEGM recordings	High rate (HR)
	Patient triggered (Pt.)
IEGM recording prior to event	0; 25; 50; 75; 100%
IEGM signal	Filtered; unfiltered

Rates for statistics

Parameter	Range of values	Standard
High rate (HR)	150 ... (5) ... 200 bpm 400; 387 ... 308; 300 ms	180 bpm 333 ms
HF counter	4; 8; 12; 16	8

Rate Adaptation

Closed Loop Stimulation rate adaptation

CLS modes:

Parameter	Value range	Standard
Max. CLS rate	80 ... (5) ... 160 ppm	120 ppm
CLS response	Very low; low; medium; high; very high	Medium
Resting rate control	OFF; +10 ... (10) ... +50 ppm	+20 ppm
CLS required	Yes; no	No

Rate adaptation via accelerometer

R modes:

Parameter	Range of values	Standard
Sensor gain	1 ... 23	4
Max. activity rate	80 ... (5) ... 160 ppm	120 ppm
Automatic gain	OFF; ON	ON
Sensor threshold	Very low; low; medium; high; very high	Medium
Rate increase	1; 2; 4; 8 ppm/cycle	4 ppm/cycle
Rate decrease	0.1; 0.2; 0.5; 1.0 ppm/cycle	0.5 ppm/ cycle
Rate fading	OFF; ON	OFF

Preset Programs DR(-T)

Standard and safe program

Only the auto-initialization function is activated as a factory setting. All the other functions of the standard program are deactivated.

Parameter	Standard program	Safe program
Mode (after auto initialization: DDD-CLS)	DDDR	VVI
Basic rate	60 ppm	70 ppm
Night program	OFF	OFF
Rate hysteresis	OFF	OFF
Upper rate	130 ppm	—
Dynamic AV delay	Low	—
AV hysteresis	OFF	—
Sense compensation	–45 ms	—
AV safety delay	100 ms	—
Far-field protection after V_s	100 ms	—
Far-field protection after V_p	150 ms	—
Ventricular blanking period after A_p	32 ms	—
PMT protection	ON	—
VA criterion	380 ms	—
Magnet response	AUTO	AUTO
Pulse amplitude A	3.0 V	—
Pulse amplitude V	3.0 V	4.8 V
Pulse width A	0.4 ms	—
Pulse width V	0.4 ms	1.0 ms
Sensitivity A	AUTO	—
Sensitivity V	AUTO	2.5 mV
Refractory period A	AUTO	—
Refractory period V	250 ms	300 ms
Mode switching	ON	—
Onset criterion	5-out-of 8	—
Resolution criterion	5-out-of 8	—
Intervention rate	160 ppm	—
Switches to	DDIR	—
Basic rate with mode switching	+10 ppm	—
Rate stabilization with mode switching	OFF	—
PVARP	AUTO	AUTO
PVARP after PVC	400 ms	—

Parameter	Standard program	Safe program
Lead configuration, automatically determined and set:		
Pacing polarity	Unipolar	Unipolar
Sensing polarity	Unipolar	Unipolar
Automatic lead check A/V	ON	ON
Active capture control	ATM	OFF
IEGM recording (HAR)	ON	OFF
Home Monitoring	OFF	OFF

Preset Programs SR(-T)

Standard and safe program

Only the auto-initialization function is activated as a factory setting. All the other functions of the standard program are deactivated.

Parameter	Standard program	Safe program
Mode (after auto initialization: VVI)	VVI	VVI
	In the AAI mode, the safe program is also AAI.	
Basic rate	60 ppm	70 ppm
Night program	OFF	OFF
Rate hysteresis	OFF	OFF
Magnet response	AUTO	AUTO
Pulse amplitude	3.0 V	4.8 V
Pulse width	0.4 ms	1.0 ms
Sensitivity	AUTO	2.5 ms
Refractory period	250 ms	300 ms
Lead configuration, automatically determined and set		
Pacing polarity	Unipolar	Unipolar
Sensing polarity	Unipolar	Unipolar
Automatic lead check	ON	ON
Active capture control	ATM	OFF
IEGM recording	ON	OFF
Home Monitoring	OFF	OFF

Tolerances of Parameter Values

DR(-T)

Parameter	Range of values	Tolerance
Basic rate	30 ... 100 ppm	+/-1.5 ppm
	102 ... 195 ppm	+/-2.0 ppm
	200 ppm	+0.0/-3.0 ppm
Basic interval	1000 ms	+/-20 ms
Magnet rate	90 ppm	+/-1.5 ppm
Magnet interval	664 ms	+/-20 ms
AV delay	15 ... 350 ms	+20/-5 ms
A/V pulse amplitude	0.2 V	+/-0.10 V
	0.3 ... 7.5 V	+20/-25%
A/V pulse duration	0.1 ... 0.4 ms	+/-0.04 ms
	0.5 ... 1.0 ms	+/-0.10 ms
	1.25 ... 1.5 ms	+/-0.15 ms
Sensitivity A 45502-2-1 Delta pulse	0.1 ... 0.5 mV	+/-0.10 mV
	0,6 ... 7.5 mV	+/-20%
Sensitivity V 45502-2-1 Delta pulse	0.5 ... 7,5 mV	+/-20%
Refractory period A	300 ... 775 ms	+10/-30 ms
Refractory period V	200 ... 500 ms	+10/-30 ms
PVARP	175 ... 600 ms	+10/-30 ms
PVARP after PVC	325 ... 600 ms	+10/-30 ms
Max. activity rate	80 ... 100 ppm	+/-1.5 ppm
	105 ... 160 ppm	+/-2.0 ppm
Upper rate	90 ... 190 ppm	+/-2.0 ppm
	200 ppm	+0/-2.0 ppm
High rate protection	200 ppm	+20/-0 ppm
Lead impedance	100 ... 200 Ohm	+/-50 Ohm
	201 ... 2500 Ohm	+/-25%

SR(-T)

Parameter	Range of values	Tolerance
Basic rate	30 ... 100 ppm	+/-1.5 ppm
	102 ... 195 ppm	+/-2.0 ppm
	200 ppm	+0.0/-3.0 ppm
Basic interval	1000 ms	+/-20 ms
Magnet rate	90 ppm	+/-1.5 ppm
Magnet interval	664 ms	+/-20 ms
Pulse amplitude	0.2 V	+/-0.10 V
	0.3 ... 7.5 V	+20/-25%
Pulse width	0.1 ... 0.4 ms	+/-0.04 ms
	0.5 ... 1.0 ms	+/-0.10 ms
	1.25 ... 1.5 ms	+/-0.15 ms
Sensitivity 45502-2-1 Delta pulse	0.5 ... 7.5 mV	+/-20%
Refractory period	200 ... 500 ms	+10/-30 ms
Max. activity rate	80 ... 100 ppm	+/-1.5 ppm
	105 ... 160 ppm	+/-2.0 ppm
High rate protection	200 ppm	+20/-0 ppm
Lead impedance	100 ... 200 Ohm	+/-50 Ohm
	201 ... 2500 Ohm	+/-25%

7 Technical Data

Mechanical Characteristics

Measurements for the housing

The measurements refer to the housing without header.

Implant	W x H x D [mm]	Volume [cm^3]	Mass [g]
DR-T	53 x 44.5 x 6.5	12	25
DR	53 x 43 x 6.5	11	26
SR-T	53 x 39 x 6.5	11	24
SR	53 x 39 x 6.5	10	25

Radiopaque marker

BIO SF

Materials in contact with body tissue

- Housing: titanium
- Header: epoxy resin
- Sealing plug: silicone
- Coating, if applicable: silicone

FCC Statement

(FCC ID: QRIPRIMUS) 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.

Electrical Characteristics

Components and input values

Electrical characteristics determined at 37°C, 500 Ohm

Circuit	Hybrid electronics with VLSI-CMOS chip
Input impedance	> 10 kOhm
Pulse form	Biphasic, asymmetric
Polarity	Cathodic

Housing shape

The implant housing has the following shape:

Implant type	**DR(-T), SR(-T)**
Uncoated	Flattened ellipsoid
Coated	Ellipse

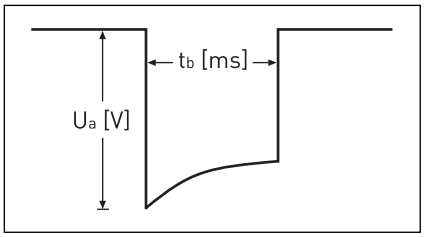
Electrically conductive surface

The implant housing has the following surface:

Implant type	**DR(-T), SR(-T)**
Uncoated [cm^2]	33
Coated [cm^2]	7

Pulse form

The pacing pulse has the following form:



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

Resistance to interference

All variants of BIOTRONIK implants comply with the requirements of prEN 45502-2-2: 2006, Section 27.5.1 at the highest sensitivity.

Telemetry

Telemetry data for Home Monitoring:

Nominal carrier frequency	**Maximum power of transmission**
403.62 MHz	< 25 W -16 dBm

Battery Data

Battery type characteristics

The following data is entered by the manufacturer:

Manufacturer	**GREATBATCH, INC. Clarence, NY 14031, USA**		**LITRONIK GmbH 01796 Pirna, Germany**	
Battery type	GB 8431	GB 2596	LiS 3150	LiS 3150M
System	LiJ	Ag/SVO/CFx QMR®	LiJ	$LiMn0_2$
Implant	DR SR	DR-T SR-T	DR SR	DR-T SR-T
Battery voltage at BOS	2.8 V	3.0 V	2.8 V	3.1 V
Open-circuit voltage	2.8 V	3.0 V	2.8 V	3.1 V
Nominal capacity	1.3 Ah	1.3 Ah	1.3 Ah	1.2 Ah
Usable capacity until EOS	1.2 Ah	1.1 Ah	1.2 Ah	1.0 Ah

Power consumption

The implant has the following power consumption:

Power consumption	**DR(-T)**	**SR(-T)**
BOS, inhibited	6 µA	6 µA
BOS, 100% pacing	13 µA	9 µA

Average service time

Average service times are precalculated using the battery manufacturer's technical specifications, a basic rate of 60 ppm and the setting of different pulse amplitudes and lead impedances.

Service times DR(-T)

For dual-chamber implants, the following times (in years) result:

Amplitude	**Impedance [Ohms]**	**Pacing**					
		10%		**50%**		**100%**	
		DR-T	**DR**	**DR-T**	**DR**	**DR-T**	**DR**
1.5 V	500	19.3	17.8	17.2	15.8	15.0	13.9
	1000	19.7	18.0	18.3	16.9	17.0	15.7
2.5 V	500	17.8	16.6	13.6	12.8	9.4	10.0
	1000	18.8	17.4	15.3	14.9	12.5	12.7
3.0 V	500	17.3	15.8	11.8	10.9	8.5	7.8
	1000	18.5	16.9	14.6	13.4	11.6	10.7
3.5 V	500	16.5	15.1	10.4	9.7	7.2	6.6
	1000	18.0	16.5	13.4	12.4	10.2	9.4
5.0 V	500	12.4	12.1	5.4	6.2	3.2	3.8
	1000	15.2	14.6	8.3	9.2	5.3	6.3

Service times SR(-T)

For single-chamber implants, the following times (in years) result:

Amplitude	Impedance [Ohms]	Pacing					
		10%		50%		100%	
		SR-T	SR	SR-T	SR	SR-T	SR
1.5 V	500	23.3	21.3	21.7	19.8	19.9	18.3
	1000	23.6	21.5	22.7	20.7	21.6	19.8
2.5 V	500	22.1	20.3	17.8	17.3	14.3	14.6
	1000	22.8	21.0	20.2	19.2	17.5	17.2
3.0 V	500	21.7	19.8	16.8	15.5	13.2	12.2
	1000	22.7	20.7	19.5	17.8	16.6	15.3
3.5 V	500	20.9	19.1	15.3	14.2	11.5	10.7
	1000	22.3	20.3	18.4	16.9	15.1	13.9
5.0 V	500	17.2	16.3	9.1	10.1	5.7	6.8
	1000	19.8	18.7	12.8	13.7	8.9	10.2

Shortening of the service time after long storage period

Depending on the storage period, the service time from the beginning of service BOS to the replacement time ERI decreases as follows:

- After 1 year:
  - DR(-T) by 6 months
  - SR(-T) by 8 months
- After 1.5 years:
  - DR(-T) by 9 months
  - SR(-T) by 12 months

Country-Related Information

International certification

Other notes specific to each country will follow in the course of international product certification.

Industry Canada

Telemetry data

- This device may not interfere with stations operating in the rate range of 400.150 - 406.000 MHz 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 implant will be registered with Industry Canada under the following number:

  IC: 4708A-PRIMUS
- The code IC in front of the certification/ registration number only indicates that the technical requirements for Industry Canada are met.

China

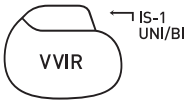
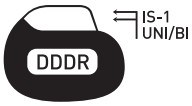
The following provides information according to the ordinance no. 39 issued by the 'Ministry for Industry and Information Technology' of the People's Republic of China pertaining to the materials which are contained in BIOTRONIK's pacemakers, ICDs and external devices:

Dangerous material		**In PCBs**	**In cables**
Lead	Pb	Yes (soldering agent)	Yes
Mercury	Hg	No	No
Cadmium	Cd	No	No
Chrome compounds	Cr6+	No	No
Polybrominated biphenyls	PBB	No	No
Polybrominated diphenyl ether	PBDE	No	No

Legend for the Label

The label icons symbolize the following:

	Manufacturing date
	Expiration date: Use by
	Storage temperature
	BIOTRONIK order number
	Serial number
	Product identification number
	Sterilization with ethylene oxide
	Resterilization prohibited
	Not for reuse
	Non-sterile
	Usage information
	Contents
	Do not use if packaging is damaged.
	European approval mark
	Non-ionizing radiation

 5/6 mm	Transfer sheath for leads with PIN-lock PE lead connector (5 mm) to connect to pacemakers with PEC sockets (6 mm)
	Implant with NBG encoding and name of compatible leads (example)
	Silicone-coated implant with NBG encoding and designation of the compatible leads (example)
	Screwdriver
	Position of connector ports in the header (example)
	Unipolar IS-1 connector
	Bipolar IS-1 connector
A	Atrium
V	Ventricle
UNI/BI	Unipolar/bipolar configuration
V_p V_s	Ventricular pace Ventricular sense
A_p A_s	Atrial pace Atrial sense