Enticos 4

ProMRI

Pacemaker |
Bradyarrhythmia Therapy

Technical Manual

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BIOTRONIK
excellence for life

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1 Product Description

Intended Medical Purpose

Intended purpose

An implantable pacemaker is part of an implantable system comprising of a pacemaker and leads to pace the heart on demand. The function of the system is the ability, first, to sense the intrinsic heart rhythm/rate and, second, to provide pacing by electrical pulses of low energy when necessary to ensure a stable heart rate or to support the intrinsic heart rate when needed.

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

- Monitoring the heart rhythm and automatically detecting bradycardia
- Compensation of bradycardia through atrial or ventricular (single-chamber devices), or AV sequential pacing (dual-chamber and triple-chamber devices)
- Cardiac resynchronization through multisite ventricular pacing (triple-chamber devices)

Diagnosis and therapy forms

The device monitors the heart rhythm and automatically detects and treats bradycardia.
BIOTRONIK Home Monitoring® enables physicians to supervise therapy management at any time.

Intended user group

In addition to having basic medical knowledge, the user must be thoroughly familiar with the operation and the operating conditions of a device system. Only qualified medical specialists who have this required special knowledge are permitted to use implantable devices.

If users do not possess this knowledge, they are not entitled to use the device system until they are trained accordingly.

BIOTRONIK offers user trainings for specific target groups.
Current information on training and education opportunities can be requested from:
education.training@biotronik.com

Intended clinical benefit

The clinical benefits for the patients inherent to the use of the implantable pacemakers are the detection of an unphysiological low heart rate (bradycardia) of a patient and, subsequently, the restoration of a physiological heart rate. The related performance outcome for this clinical benefit is defined as successful compensation of bradycardia by antibradycardia pacing.

Triple-chamber pacemakers provide the additional clinical benefit to improve the ejection fraction and/or cardiac output in patients with heart failure and interventricular dyssynchrony. The related performance outcome for this clinical benefit is defined as successful cardiac resynchronization through multisite ventricular pacing.

Indications

Single- and dual-chamber pacemakers are indicated to treat symptomatic bradycardia with antibradycardia pacing.

Triple-chamber pacemakers are indicated for patients

- who suffer from chronic heart failure with reduced left ventricular ejection fraction (LVEF ⩽ 35%) and dyssynchrony (defined as QRS duration ⩾ 130 ms).
- with heart failure and reduced LVEF (< 40%) who have a high-degree atrioventricular (AV) block with high ventricular pacing demand.
- with chronic heart failure and symptomatic atrial fibrillation with uncontrolled heart rate who are candidates for AV junctional ablation (irrespective of the QRS duration).

The most common indications for permanent pacemaker implantation are symptomatic sinus node dysfunction (SND) and symptomatic high-grade AV block.

Beside the most common indications mentioned above the following conditions are included but are not limited to:

- Chronic bifascicular block
- Neurocardiogenic syncope and hypersensitive carotid sinus syndrome
- Hypertrophic cardiomyopathy
- Pacing to detect and terminate tachycardia
- Patients with congenital heart disease

Patients who demonstrate hemodynamic benefit through maintenance of AV synchrony should be considered for dual chamber pacing modes. Dual chamber modes are specifically indicated for treatment of conduction disorders that require both restoration of heart rate and AV synchrony such as AV nodal disease, diminished cardiac output or congestive heart failure associated with conduction disturbances, and tachyarrhythmias that are suppressed by chronic pacing.
Rate-adaptive pacing with pacemakers is indicated for patients exhibiting chronotropic incompetence and who would benefit from increased pacing rates concurrent with physical activity.

Generally approved differential diagnostic methods, indications, and recommendations for pacemaker therapy apply to BIOTRONIK devices. See the current guidelines of cardiology associations for guidance. We recommend observing the indications published by the European Society of Cardiology (ESC). This also applies to the guidelines published by the Heart Rhythm Society (HRS), the American College of Cardiology (ACC), the American Heart Association (AHA), the German Cardiac Society (Deutsche Gesellschaft fur Kardiologie, Herz- und Kreislaufforschung, (DGK)), and other national cardiology associations.

Depending on the patient's anatomy, the pacemakers are implanted in the pectoral or abdominal region.

Intended patient groups

The pacemakers are intended for adults (including immuno-compromised or elderly patients).
The pacemakers are intended for pregnant patients but the need to limit fluoroscopy in pregnant women may complicate device implantation or the patient should be resorted to another imaging method.
The pacemakers are intended for children who are suited to bear an implant of the physical dimensions of a pacemaker device. Significant technical challenges may arise due to the growth of the patient and the size of the used leads.
The pacemakers are not intended for neonates or infants.
As there are no randomized clinical trials of bradycardia pacing in pediatric or pregnant patients, the level of evidence for guideline recommendations is consensus based.

Contraindications

- Sepsis
- Transient or reversible AV block/sinus bradycardia

No further contraindications apply to the implantation of multifunctional single-chamber, dual-chamber, or triple-chamber pacemakers, provided differential diagnostics precedes implantation according to the current guidelines of cardiology published by the ESC and ACC/AHA/HRS and no modes or parameter combinations are configured that pose a risk to the patient (i.e., unipolar pacing in combination with an implantable cardioverter-defibrillator).

System Overview

Device family

This device family consists of single-chamber and dual-chamber devices. Not all device types are available in every country.

The following device variants are available:

Device type	Variant without Home Monitoring
Single-chamber	Enticos 4 S
	Enticos 4 SR
Dual-chamber	Enticos 4 D
	Enticos 4 DR

Product identification

Each product is identified by a so-called unique device identification (UDI). It enables products to be uniquely identified.

The first part of the UDI is the product-specific identifier UDI-DI (Unique Device Identification Device Identifier), which can be found next to the UDI symbol on the label.

Enticos 4

Device type	UDI-DI
S	04035479147877
SR	04035479147860
D	04035479147754
DR	04035479147747

In addition, a basic identifier called B-UDI-DI (Basic Unique Device Identification Device Identifier) is assigned to several products.

The B-UDI-DI is: 4035479BUDI00005PU

Using this B-UDI-DI, it will be possible to search the European Database on Medical Devices (EUDAMED) for additional information on the product.

Device

The device's housing is made of biocompatible titanium, welded from the outside and is, therefore, 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.

Lead connections

BIOTRONIK provides pacemakers with headers for different standardized lead connections:

- IS-1

Note

Suitable leads must comply with the norms:

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

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.

IS-1

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

S	SR	D	DR
VVI/AAI **IS-1**	**VVIR/AAIR** **IS-1**	**DDD**  **IS-1**	**DDDR**  **IS-1**

Connector port	Lead connector	Configuration	Implantation site	Device type
A/RA	IS-1	Unipolar, bipolar	Atrium	D, DR
V/RV	IS-1	Unipolar, bipolar	Right ventricle	S, SR, D, DR

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 gliding properties for the lead. Steroid-eluting leads reduce inflammatory processes. The fractal design of the leads allows for low pacing thresholds, high pacing impedance, and a low risk of oversensing.

BIOTRONIK provides a series of adapters to connect a variety of already implanted leads to new devices.

Telemetry

Telemetric communication between the device and the programmer is possible following initialization either by applying the programming head (PGH) to the device or by using wireless wandless telemetry in the programmer.

Programmer

The programmer contains an integrated module for wandless telemetry.
ECG, IEGM, markers, and functions are displayed simultaneously on the color display.
The programmer allows for the determination of thresholds and the performance of all tests during an in-office follow-up. In addition, the permanent program can be changed and sent to the implanted device.
Furthermore, the programmer is used to set mode and parameter combinations, as well as for the interrogation and saving of data from the device.

Pacing modes

The pacing mode setting depends on the individual diagnosis:

Device type	Pacing modes	Standard
S	• VVI, VVT, V00, AAI, AAT, A00 • OFF	VVI
SR	• VVIR, V00R, AAIR, A00R • VVI, VVT, V00, AAI, AAT, A00 • OFF	VVIR
D	• DDD, DDT, DDI, DVI, D00, VDD, VDI • VVI, VVT, V00, AAI, AAT, A00, VVIR, V00R • OFF	DDD
DR	• DDDR, DDIR, DVIR, D00R, VDDR, VDIR • VVIR, V00R, AAIR, A00R • DDD, DDT, DDI, DVI, D00, VDD, VDI • VVI, VVT, V00, AAI, AAT, A00 • OFF	DDDR

NBG codes

AAI or VVI is the NBG code for the antibradycardia pacing mode of the single-chamber device without rate adaptation (device type S and D); AAIR or VVIR is the NBG code for the antibradycardia pacing of the single-chamber device with rate adaptation (device type SR and DR):

A/V	Pacing in the atrium or ventricle
A/V	Sensing in the atrium or ventricle
I	Pulse inhibition in the atrium and ventricle
R	Rate adaptation

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

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

Order numbers for Enticos

Enticos 4

The devices are available as follows:

	IS-1
S	407168
SR	407167
D	407156
DR	407155

Package contents

The storage package includes the following:

- Sterile packaging with device
- Serial number label
- Patient implant card

Note

The technical manual pertaining to the device is either included in hard copy form in the storage package or is available in digital form on the internet: https://manuals.biotronik.com

Note

The warranty booklet for this device is either included in hard copy form in the storage package or is available in digital form on the internet: https://www.biotronik.com/warranty-booklet

The sterile packaging includes the following:

- Device
- Torque wrench

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 device recognizes the implanted leads autonomously and sets the polarity. The automatic functions of the software are activated after 10 min.

Diagnostic functions

- Continuous automatic below-threshold impedance measurements are performed in the device independent of the pacing pulse in order to check the lead for proper functioning.
- Once a telemetry connection has been established during a test procedure in an in-office follow-up, the IEGM is displayed with markers.

Antibradycardia pacing

- Sensing: The amplitudes of the P and R waves are permanently measured in the device fully automatically to record varying amplitudes. The sensitivity for the atrium and ventricle is also adapted fully automatically on an ongoing basis. The measurement data is averaged and the trend can be displayed.
- Pacing thresholds: Pacing thresholds are automatically identified in the device: in single-chamber devices the right ventricular and in dual-chamber devices the atrial and right ventricular pacing thresholds. Capture control adjusts the pulse amplitudes in such a way that every change of the pacing threshold results in the patient being paced at an optimal amplitude.
- Timing: Pacing in the atrium is checked particularly carefully in dual-chamber devices by an automatic adaptation of the atrial refractory period in order to avoid pacemaker-mediated tachycardia (Auto PVARP function: automatic post-ventricular atrial refractory period).

Programs

There are different therapy programs:

- Default parameters are offered for the most common pacemaker indications (ProgramConsult function).
- Individual settings can be saved in 3 individual therapy programs.

2 General Safety Instructions

General Information on Safe Handling of the Device

Observe notes and follow instructions

⚠ **WARNING**

Risk to patient, risk to physician and interferences of device

Cardiac electrotherapy is subject to specific conditions. From the transport to the storage, in terms of sterility, concerning technical complications, what requires special care during implantation or what needs to be observed regarding risky therapies with persons wearing a pacemaker:
The device system is sensitive and must not be damaged, in order not to harm patients.

- It is always necessary to observe and follow all information in this manual, as well as related technical manuals.

Safety instructions and warnings in this technical manual

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

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

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

Avoiding hazardous situations

All safety-related information is categorized as follows:

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

Technical manuals

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

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

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

- Technical manual for the implanted device
- Technical manuals for the leads
- Technical manuals for the programmer and its accessories
- Technical manuals for the programmer's software
- Technical manuals for cables, adapters, accessories
- "ProMRI – MR conditional device systems" manual

Summary report on safety and clinical performance

The technical documentation of a device includes a brief report on safety and clinical performance (SSCP, Summary of safety and clinical performance). A current summary will be made available digitally on the internet by the European Commission: https://ec.europa.eu/tools/eudamed

Reporting of serious incidents

Serious incidents relating to the product must be reported to the manufacturer and the competent authority.

The competent authorities can be found at: https://ec.europa.eu

Operating Conditions

⚠ WARNING

Risk to patient and interferences of device

Cardiac electrotherapy is subject to special operating conditions. If these are not fulfilled, the functionality of the device may be impaired; if the functionality of the device is impaired, the patient may be at risk.

- Please observe the following operating conditions.

Care during shipping and storage

No electromagnetic interference should occur in the vicinity of devices.

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

Temperature during shipping and storage

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

- Permissible temperature range: +5°C to +30°C
- Short-term permissible temperature range: -10°C to +45°C

Sterile delivery

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

- Check the package for damage.
- Do not use parts from damaged package.

Sterile packaging

The device and torque wrench are each packaged in 2 separately sealed blisters. The inner blister is sterile on the outside so that it can be transferred and remain sterile during implantation.

Single use

The device and torque wrench are intended for single use only.

The device must not be used more than once or resterilized because of the following risks:

- Mechanical and electrical damage to the device, especially damage to the lead connections in the header
- Improper battery status
- Device-side infection risks

To ensure that the device is in perfect condition and can function properly:

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

The torque wrench is also intended for single use only.

Possible Complications

⚠ WARNING

Risk to patient and interferences with the device

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

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

General information on medical complications

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

- It is impossible to guarantee the efficacy of antiarrhythmia therapy, even if the programs have proven successful during tests or subsequent electrophysiological studies. In rare cases the set parameters may become ineffective. In particular, it cannot be excluded that tachyarrhythmias are induced or accelerated by a therapy attempt, i.e., that long-lasting ventricular flutter or fibrillation occurs.

  Primary sources of complication information include current scientific and technological knowledge.

Possible undesired side effects and adverse events

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

- Infection in blood circulation, infection of device pocket, peripheral infection by skin lesion
- Prolonged anesthesia or sedation, cardiac arrest, acute and serious heart failure, pulmonary embolism, venous embolism, acute and chronic toxic or allergic reaction
- Nausea/sickness/slight dizziness, impairment of performance ability
- Muscle twitching, thermal tissue load, mechanical tissue irritation
- Prolonged undesired medical condition, environmental impairment, repeated invasive intervention

Skeletal myopotentials

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

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

Nerve and muscle stimulation

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

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, for example, when external signals are sensed as intrinsic rhythm:

- 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 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 asynchronous pacing.
- Under unfavorable conditions, especially in the context of diagnostic or therapeutic procedures, sources of interference may induce such a high level of energy into the pacing system that the cardiac tissue surrounding the device or lead tip is damaged.
- Always evaluate the setting of sensing and triggered pacing mode.

Device behavior in case of EMI

In the case of electromagnetic interference or undesired myopotentials, the device paces asynchronously for the duration of the time that the interference rate is exceeded.

Static magnetic fields

The pacemaker switches to magnet response from a field strength > 1.0 mT.

Possible Risks

⚠ WARNING

Risk to patient and interferences with the device

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

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

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:

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

Risky therapeutic and diagnostic procedures

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

Arrhythmia or ventricular fibrillation can be induced during diathermic procedures such as electrocautery, HF ablation, or HF surgery. For example, damaging pressure levels may arise during lithotripsy. The effect on the device is not always immediately apparent.

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

- Have an external defibrillator ready.
- Electrically insulate the patient.
- Switch the pacemaker function to asynchronous modes if needed.
- 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. However, it is still possible for external defibrillation to damage the implanted device. Specifically, the current induced in the implanted leads may result in necrotic tissue formation close to the electrode/tissue interface. As a result, sensing properties and pacing thresholds may change.

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

Radiation therapy

The use of radiation therapy must be avoided due to possible damage to the device and the resulting impaired functional safety. If this type of therapy is nevertheless to be used, prior risk/benefit analysis is absolutely necessary. The complexity of influencing factors such as different sources of radiation, a variety of devices, and therapy conditions makes it impossible to issue directives that guarantee radiation therapy without an impact on the device. The ISO 14708 standard pertaining to active implantable medical devices requires the following measures during the administration of therapeutic ionizing radiation:

- Adhere to instructions for risky therapeutic and diagnostic procedures.
- Shield device against radiation.
- After applying radiation, repeatedly verify proper function of the device system.

Note

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

Magnetic resonance imaging

Magnetic resonance imaging (MRI) should only be performed under certain conditions. Damage or destruction of the device system by strong magnetic interaction or harm to the patient by excessive warming of the body tissue in the area surrounding the device system must be avoided.

BIOTRONIK devices with the "MR conditional" function display the identification ProMRI. Magnetic resonance imaging (MRI) should only be performed while following mandatory precautions to protect the device system and the patient.

- The "ProMRI – MR conditional device systems" manual contains detailed information on safely conducting an MR scan.
  Download the digital manual from the website: https://manuals.biotronik.com
- Order the printed manual from BIOTRONIK.
- Does approval as "MR conditional" apply in your country or region? Request current information from BIOTRONIK.

3 Implantation

Implantation Procedure

WARNING

Risk to patient, risk to physician and interferences of device

Work preparations and implantation procedures require special measures.

- Please follow all procedures carefully.

Having parts ready

The following parts are required:

- Device with torque wrench from BIOTRONIK
- BIOTRONIK leads and lead introducer set
  - Single-chamber device: unipolar or bipolar lead for the right ventricle or the right atrium
  - Dual-chamber device: one unipolar or bipolar lead each for the atrium and for the right ventricle
- Approved connections are IS-1: Use only adapters approved by BIOTRONIK for leads with different connections or leads from other manufacturers.
- BIOTRONIK blind plugs
- BIOTRONIK programmer (with integrated RF telemetry) and approved cables
- External multi-channel ECG device
- Have additional quantities of sterile parts readily available

Check the operating environment for EMI

WARNING

Harmful effects of electromagnetic interference (EMI) on the functionality of the device

Even though the device is protected against EMI by the use of filters, the sensing functions may have such strong interference in medical environments that the device may no longer function correctly.

- Check the operating environment for the presence of electromagnetic interferences and eliminate them if necessary.
- Maintain adequate distance from electromagnetic sources.

Keeping an external defibrillator ready

In order to respond to unforeseeable emergencies or possible technical failures of the device:

- Have a properly working external defibrillator and paddles or adhesive electrodes available.

Unpacking the device

WARNING

Inadequate therapy due to defective device

If an unpacked device is dropped on a hard surface during handling, electronic parts could be damaged and as a result, the device might no longer function correctly.

- Use a replacement device.
- Return the damaged device to BIOTRONIK.

1. Peel off the sealing paper of the outer blister at the marked position in the direction of 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.
2. Use the gripping tab on the inner blister to remove it from the outer blister.
3. Peel off the sealing paper of the sterile inner blister at the marked position in the direction of the arrow.

Note

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

Checking parts

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

- Check for damage before and after unpacking all parts.
- Do not use parts from damaged package.
- Replace damaged parts.
- Leads must not be shortened.

Implantation site

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

Overview: Implanting

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

Note

If necessary, the device can also be programmed before or during auto-initialization.

Avoiding damage to the header

Set screws must be tightened or loosened with care.

- Loosen set screws with the supplied torque wrench. Use only BIOTRONIK torque wrenches!
- If lead revision is necessary, re-order sterile torque wrenches from BIOTRONIK.

Preventing short circuits in the header

⚠ **WARNING**

Short circuit due to open lead connector ports

Connector ports in the header which are open and thus not electrolyte-proof may cause undesired current flows to the body and penetration of bodily fluids into the device.

- Close unused connector ports with blind plugs.

Keeping distance between leads

⚠ **WARNING**

Inadequate therapy

Insufficient lead spacing or inappropriate lead positioning may lead to far-field sensing.

- Leads must not contact each other. Position the tip and ring of newly implanted leads with a sufficient distance from old implanted leads.

Connecting the lead connector to the device

1. Remove stylets and stylet guides.
2. Connect the unipolar or bipolar IS-1 lead connector for the right ventricle to RV.
   Connect the unipolar or bipolar IS-1 lead connector atrium to A.
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 drill hole 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 torque wrench 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 torque wrench without retracting the set screw.
   ▶ When the torque wrench is withdrawn, the silicone plug automatically seals the lead connection safely.

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.

Auto-initialization

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

Auto-initialization is usually terminated 10 minutes after connection of the first lead. If no other program has been transferred in the meantime, the device subsequently works with active automatic functions in the factory settings or with the preset program of the user.

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.

Behavior during auto-initialization

- During transmission of a permanent program:

  Auto-initialization is terminated and the transferred program is active.

- During testing:

  Tests cannot be performed during auto-initialization; stop it beforehand. Auto-initialization will not be continued upon completion of the test.

Precautionary Measures while Programming

⚠ Caution

Safety information

The programming of devices requires special precautionary measures.

- Please take all the following precautionary measures carefully into account.

Checking the device system

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

Performing standard tests and monitoring the patient

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

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

Cancelling telemetry

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

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

Avoiding critical parameter settings

Modes and parameter combinations that pose a risk to the patient should not be programmed.

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

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 sensing

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

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

Setting the sensitivity

A value set to < 2.5 mV/unipolar for device 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 must only be set and retained with physician supervision.

Note

Sensitivity in the atrium meets the requirements for electromagnetic compatibility as long as it is ≥ 0.3 mV/bipolar. Measures must be taken to assure interference-free therapy if more sensitive values < 0.3 mV/bipolar are set.

Preventing device-induced complications

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

- Measure the retrograde conduction time.
- In dual-chamber devices: Activate PMT protection and program it using the VA criterion, so that high pacing rates do not occur with retrograde conduction.
- Program VA criterion: The aim is to set a VA criterion that is longer than the longest measured retrograde conduction time.

Preventing conduction of atrial tachycardia

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

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

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 resetting the pacemaker or using the automatic lead check. As a result, the ICD could falsely inhibit or trigger tachyarrhythmia therapy activity.

- Unipolar leads are not permitted in this configuration.

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.

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 replacement indication ERI will be reached very early because the service time of the battery may be reduced to less than 1 year.

Wandless telemetry: 15 minutes of usage reduces the service time by approximately 7 days.

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

Magnet Response

Programming head application

When the programming head is applied, time remains for device interrogation before the device switches back to the previously set permanent therapy mode. The same applies to the programming head application to establish wandless telemetry contact.

Magnet response in standard program

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 (where applicable V00/A00) without rate adaptation;

  magnet rate: 90 bpm
- Automatic:

  for 10 cycles – mode D00, subsequently mode DDDR;

  magnet rate: 10 cycles with 90 bpm, subsequently the set basic rate
- Synchronous:

  mode DDDR (where applicable VVIR);

  magnet rate: the set basic rate

Note

See also the replacement indication information for magnet response at ERI.

Magnet application by patients

If patients are performing their own magnet application, the synchronous magnet response must 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 s.
- 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 follow-up.

Follow-up

WARNING

Risk to patient

The follow-up of device systems requires special measures.

- Please follow all procedures carefully.

Follow-up intervals

During follow-ups, proper functioning of the device system is also checked. This includes testing of the sensing amplitudes, pacing thresholds, as well as the remaining service time.
Follow-ups must be performed at regular, agreed upon intervals; longer intervals may lead to the loss of therapy.

- Following the lead ingrowth phase, approximately 3 months after implantation, the first follow-up should be carried out by the physician using the programmer (in-office follow-up).
- Subsequent in-office follow-up intervals may be extended, taking into account current medical guidelines.

Follow-up with the programmer

Proceed as follows during an 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. Manually perform standard tests if necessary.
6. If applicable, evaluate statistics and IEGM recordings.
7. Customize program functions and parameters if necessary.
8. Transmit the permanent program to the device.
9. Print (print report) and document follow-up data.
10. Finish the follow-up for this patient.

Patient Information

WARNING

Risk to patient

The education of patients requires special information.

- Please share any of the following information carefully.

Patient implant card

A patient implant card is included in the package contents.

1. Fill in the patient implant card according to the enclosed instructions for completing.
2. Hand over the patient implant card to the patient after the implantation.

Patient information

Patient information also includes the following information:

- Information for patients is written in a language understandable to laypersons. Anatomy, technology and living with an implanted device are the topics discussed here. This information is available in digital form on the internet: https://patients.biotronik.com
- Request that patients contact the physician in case of uncertainties.
- Serious incidents relating to the product must be reported to the manufacturer and the competent authority. The competent authority can be found at: https://ec.europa.eu/

Possible sources of interference – prohibitive signs

Electromagnetic interference should be avoided during daily activities. Sources of interference should not be brought into close proximity of the device, in order to not impair the sensing functionality of device. There must be no electromagnetic interferences in the vicinity of the device, because tachycardia may not be detected and as a result the therapy might not be effective

- Educate the patient on sources of electromagnetic interference which include special household appliances, safety locks/anti-theft alarm systems, cell phones, and transmitters.
- Request patients to heed the following:
  - Use cell phones on the side of the body that is opposite of the device.
  - Keep the cell phone at least 15 cm away from the device both during use and during storage.
- Premises with prohibitive signs must be avoided. Educate the patient regarding prohibitive signs.

Replacement Indications

Possible charging status

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

ERI activation

ERI detection is automatically activated after the following events:

- Successful auto-initialization

ERI display

ERI is displayed as follows:

- On the programmer after interrogation of the pacemaker
- By a defined decrease in the basic rate as well as the magnet rate

Rate decrease

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

- In the following modes, the pacing rate decreases by 11%:

  DDD(R); DDT; D00(R); VDD(R); VDI(R); VVI(R); VVT; AAI(R); AAT; A00(R)
- In the modes DDI(R) and DVI(R), only the VA interval is extended by 11%. This reduces the pacing rate by up to 11%, depending on the configured AV delay.

Change of the mode with ERI

This change depends on the programmed pacing mode and is displayed on the programmer.

- Single-chamber modes: VVI
- Dual-chamber modes: VDD

Deactivated functions with ERI

The following functions are deactivated:

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

Magnet response at ERI

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

Magnet response	Cycles 1 to 10	After 10th cycle
Automatic	Asynchronous with 80 bpm	Synchronous with basic rate reduced by 11%
Asynchronous	Asynchronous with 80 bpm	Asynchronous with 80 bpm
Synchronous	Synchronous with basic rate reduced by 11%	Synchronous with basic rate reduced by 11%

Expected service times after ERI

The information is based on the following:

- Lead impedance of 500 Ω or 600 Ω
- 100% pacing
- Interval from ERI to EOS for single-chamber devices in AAI(R)/VVI(R) mode, for dual-chamber device in DDD(R) mode
- Standard program with both high and low pacing energy
- Data of the battery manufacturer (see Battery Data)

110 bpm 4.6 V 1.5 ms 500 Ω	30 bpm 0.2 V 0.1 ms 500 Ω	70 bpm 2.5 V 0.4 ms 500 Ω	70 bpm 5.0 V 0.4 ms 500 Ω	60 bpm 2.5 V 0.4 ms 600 Ω	60 bpm 5.0 V 0.4 ms 600 Ω
Mean value: 8 months Minimum value: 6 months		— Minimum value: 6 months		— Minimum value: 6 months	

Explantation and Device Replacement

WARNING

Risk to patient, risk to physician, environmental hazard

Explanations and device replacement require special measures.

- Please follow all procedures carefully.

Explantation

- Disconnect the leads from the header.
- Use state-of-the-art techniques to remove the device and, if necessary, the leads.
- Explants are biologically contaminated and must be disposed of safely due to risk of infection.

Device replacement

The following applies to leads from a previous device that are intended for further use:

- Check the leads prior to connecting to the new device.

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.

- Isolate unused lead connectors and close unused connector ports.

Basic principles:

- The device must not be resterilized or reused.

Cremation

Devices should 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 explanted device with an at least 1% sodium hypochlorite solution.
- Rinse off with water.
- Fill out the explantation form and send it to BIOTRONIK together with the cleaned device.

4 Parameter

Timing

Basic rate day/night

Parameter	Range of values	Standard	SR	DR
Basic rate	30 ... (5) ... 100 ... (10) ... 200 bpm	60 bpm	x	x
		50 bpm		
Night rate	OFF; 30 ... (5) ... 100 ... (10) ... 200 bpm	OFF	x	x
Night begins	00:00 ... (10 min) ... 11:50 PM hh:mm	—	x	x
Night ends				

Rate hystereses

Parameter	Range of values	Standard	SR	DR
Hysteresis	OFF; -5 ... (-5) ... -25 ... (-20) ... -65 bpm	OFF	x	x
Repetitive/scan cycles	OFF; ON	OFF	x	x

AV delay

Parameter	Range of values	Standard	SR	DR
AV delay	Low; Medium; High; Fixed; Individual	Low		x
	20 ... (5) ... 350 ms (in 6 rate ranges)	180-170-160 -150-140 ms		x
Sense compensation	OFF; -10 ... (-5) ... -120 ms	-45 ms		x

AV hystereses

Parameter	Range of values	Standard	SR	DR
AV hysteresis mode	OFF; Positive; Negative; IRSplus	OFF		x
Positive modes: AV hysteresis	70; 110; 150; 200 ms	70 ms		x
Negative modes: AV hysteresis	10 ... (10) ... 150 ms	50 ms		x
AV repetitive/scan cycles	OFF; ON	ON		x

Upper rate

Parameter	Range of values	Standard	SR	DR
Upper rate SR in VVT mode	90 ... (10) ... 200 bpm	130 bpm	x	x
Wenckebach response/ 2:1 rate	Automatically set	—		x
Atrial upper rate	OFF; 175; 200; 240 bpm	240 bpm		x

Note

In case of a technical malfunction in the device, the high rate protection function limits the pacing rate to a maximum value of 200 to 220 bpm.

Mode switching

Parameter	Range of values	Standard	SR	DR
Mode switching	OFF; ON	ON		x
Intervention rate	100 ... (10) ... 250 bpm	160 bpm		x
Switch to mode	DDI; DDI(R) when permanent DDD(R) VDI; VDI(R) when permanent VDD(R)	DDI(R)		x
Onset criterion	3 ... (1) ... 8 (out of 8)	5		x
Resolution criterion	3 ... (1) ... 8 (out of 8)	5		x
Change of the basic rate with mode switching	OFF; +5 ... (5) ... +30 bpm	+10 bpm		x
Rate stabilization with mode switching	OFF; ON	OFF		x
2:1 lock-in protection	OFF; ON	ON		x
	When setting RV: OFF; ON	ON		

Refractory periods

Parameter	Range of values	Standard	SR	DR
Refractory period	200 ... (25) ... 500 ms	250 ms	x	
Atrial refractory period	AUTO	AUTO		x
Atrial refractory period in the modes AAI(R); AAT; DDT	300 ... (25) ... 775 ms	350 ms		x
RV refractory period	200 ... (25) ... 500 ms	250 ms		x
Auto PVARP	OFF; ON	ON		x
PVARP	175 ... (25) ... 600 ms	225 ms		x
PVARP after PVC	PVARP + 150 ms (max: 600 ms)	Automati- cally set		x

Blanking periods

Parameter	Range of values	Standard	SR	DR
Far-field protection after Vs	100 ... (10) ... 220 ms	100 ms		x
Far-field protection after Vp	100 ... (10) ... 220 ms	150 ms		x
Ventricular blanking after Ap	30 ... (5) ... 70 ms	30 ms		x

PMT protection

Parameter	Range of values	Standard	SR	DR
PMT protection	OFF; ON	ON		x
VA criterion	250 ... (25) ... 500 ms	350 ms		x

Pacing and Sensing

Pulse amplitude and pulse width

Parameter	Range of values	Standard	SR	DR
Pulse amplitude A/RV	0.2 ... (0.2) ... 6.0 ... (0.5) ... 7.5 V	3.0 V	x	x
Pulse width A/RV	0.1 ...(0.1) ... 0.5 ... (0.25) ... 1.5 ms	0.4 ms	x	x

Sensitivity

Parameter	Range of values	Standard	SR	DR
Sensitivity	AUTO; 0.5 ... (0.5) ... 7.5 mV	AUTO	x	
Sensitivity A	OFF; AUTO; 0.1 ... (0.1) ... 1.5 ... (0.5) ... 7.5 mV	AUTO		x
Sensitivity RV	AUTO; 0.5 ... (0.5) ... 7.5 mV	AUTO	x	x

Atrial capture control

Parameter	Range of values	Standard	SR	DR
Atrial capture control	ATM (monitoring only); ON; OFF	ON		x
Minimum amplitude	0.5 ... (0.1) ... 4.8 V	1.0 V		x
Threshold test start	2.4 ... (0.6) ... 4.8 V	3.0 V		x
Safety margin	0.5 ... (0.1) ... 1.2 V	1.0 V		x
Search type	Interval; time of day	Time of day		x
Interval	0.1; 0.3; 1; 3; 6; 12; 24 h	24 h		x
Time of day	00:00 ... (00:10) ... 11:50 PM hh:mm	12:30 AM hh:mm		x

Ventricular capture control

Parameter	Range of values	Standard	SR	DR
Capture control RV	ATM (monitoring only); ON; OFF	ON	x	x
Minimum amplitude RV	0.7 V	0.7 V	x	x
Threshold test start	2.4 ... (0.6) ... 4.8 V	3.0 V	x	x
Safety margin RV	0.3 ... (0.1) ... 1.2 V	0.5 V	x	x
Search type	Interval; time of day	Time of day	x	x
Interval	0.1; 0.3; 1; 3; 6; 12; 24 h	24 h	x	x
Time of day	00:00 ... (00:10) ... 11:50 PM hh:mm	12:30 AM hh:mm	x	x

Lead configuration

Parameter	Range of values	Standard	SR	DR
Sensing polarity A	Unipolar; Bipolar	Unipolar	x	x
Sensing polarity RV	Unipolar; Bipolar	Unipolar	x	x
Pacing polarity A	Unipolar; Bipolar	Unipolar	x	x
Pacing polarity RV	Unipolar; Bipolar	Unipolar	x	x

IEGM recordings

Parameter	Range of values	Standard	SR	DR
Number of recordings (each max. 10 s)	4	—	x	x
High atrial rate (HAR)	OFF; AT; mode switching	AT	x	x
High ventricular rate (HVR)	OFF; ON	ON	x	x
Pre-trigger recording	0; 25; 50; 75; 100%	75%	x	x
IEGM signal	Filtered; Unfiltered	Filtered	x	x

Rates for statistics

Parameter	Range of values	Standard	SR	DR
HAR limit	100 ... (10) ... 250 bpm	200 bpm		x
HVR limit	150 ... (5) ... 200 bpm	180 bpm	x	x
HVR counter	4; 8; 12; 16 events	8 events	x	x
Resting period start	00:00 ... (1:00 AM) ... 11:00 PM hh:mm	2:00 AM hh:mm	x	x
Resting period duration	0.5 ... (0.5) ... 12 h	4 h	x	x
Enable lead check	OFF; ON	ON	x	x

Rate Adaptation

R modes: accelerometer

Parameters valid for devices with R modes:

Parameter	Range of values	Standard	SR	DR
Sensor gain	AUTO; Very low; Low; Medium; High; Very high	AUTO	x	x
Maximum activity rate	80 ... (10) ... 180 bpm	120 bpm	x	x
Sensor threshold	Very low; Low; Medium; High; Very high	Medium	x	x
Rate increase	1; 2; 4; 8 bpm/cycle	2 bpm/cycle	x	x
Rate decrease	0.1; 0.2; 0.5; 1.0 bpm/cycle	0.5 bpm/cycle	x	x

MRI Program

MRI modes

Mode	Range of values	Standard	SR	DR
MRI program	ON; OFF	OFF	x	x
MRI mode	OFF; A00; V00	Dependent on permanent program	x	
	OFF; D00; A00; V00			x

MRI parameters

Preset parameters in MRI program:

Parameter	Range of values	Standard	SR	DR
Basic rate	70 ... (10) ... 160 bpm	90 bpm	x	x
AV delay	110 ms	110 ms		x
Pulse amplitude A/RV	4.8 V	—	x	x
Pulse width A/RV	1.0 ms			

Preset Programs

Standard and safe program

Mode after auto-initialization:

Parameter	Factory setting	Standard	Safe program	SR	DR
Mode	VVI	VVIR	VVI In the AAI mode, the safe program is also AAI.	x	
Mode	DDD	DDDR	VVI		x

Lead configuration, automatically determined and set immediately after connection:

Parameter	Factory setting	Standard	Safe program	SR	DR
Pacing polarity A/RV	Unipolar	Unipolar	Unipolar	x	x
Sensing polarity A/RV	Unipolar	Unipolar	Unipolar	x	x
Automatic lead impedance measurement	ON	ON	—	x	x

Parameters after auto-initialization:

Parameter	Factory setting	Standard	Safe program	SR	DR
Basic rate	60 bpm	60 bpm	70 bpm	x	x
	50 bpm	50 bpm	70 bpm		
Night rate	OFF	OFF	OFF	x	x
Rate hysteresis	OFF	OFF	OFF	x	x
Upper rate	130 bpm	130 bpm	—		x
AV dynamics	Low	Low	—		x
AV hysteresis mode	OFF	OFF	—		x
Sense compensation	-45 ms	-45 ms	—		x
AV safety delay	100 ms	100 ms	—		x
Far-field protection after Vs	100 ms	100 ms	—		x
Far-field protection after Vp	150 ms	150 ms	—		x
Ventricular blanking period after Ap	30 ms	30 ms	—		x
PMT protection	ON	ON	—		x
VA criterion	350 ms	350 ms	—		x
Magnet response	AUTO	AUTO	AUTO	x	x
Pulse amplitude A	3.0 V	3.0 V	—		x
Pulse amplitude RV	3.0 V	3.0 V	4.8 V	x	x
Pulse width A	0.4 ms	0.4 ms	—		x
Pulse width RV	0.4 ms	0.4 ms	1.0 ms	x	x

Parameter	Factory setting	Standard	Safe program	SR	DR
Sensitivity A	AUTO	AUTO	—		x
Sensitivity RV	AUTO	AUTO	2.5 mV	x	x
Refractory period A	AUTO	AUTO	—		x
Refractory period RV	250 ms	250 ms	300 ms	x	x
Mode switching	ON	ON	—		x
Onset criterion	5 out of 8	5 out of 8	—		x
Resolution criterion	5 out of 8	5 out of 8	—		x
Intervention rate	160 bpm	160 bpm	—		x
Switch to	DDIR	DDIR	—		x
Basic rate with mode switching	+10 bpm	+10 bpm	—		x
Rate stabilization with mode switching	OFF	OFF	—		x
PVARP	AUTO (start 250 ms)	225 ms	—		x
PVARP after PVC	400 ms	Automati-cally set	—		x
Capture control A	ON	ON	OFF	x	x
Capture control RV	ON	ON	OFF		x
Atrial overdrive pacing	OFF	OFF	—		x
Vp suppression	OFF	OFF	—		
IEGM recording (HAR)	ON	AT	OFF	x	x
IEGM recording (HVR)	ON	ON	OFF	x	x

Tolerances of Parameter Values

Parameter	Range of values	Tolerance
Basic rate	30 ... (5) ... 100 ... (10) ... 200 bpm	± 20 ms
Basic interval	1000 ms	± 20 ms
Magnet rate (magnet interval)	90 bpm (664 ms)	± 20 ms
Pulse amplitude	0.2 ... 7.5 V	The greater value of ± 50 mV or 20/25%
Pulse width	0.1 ... 1.5 ms	The greater value of ± 20 µs or ± 10%
Sensitivity A EN 45502-2-1 triangle pulse	0.1 ... 0.2 mV	The greater value of ± 0.1 mV or ± 20%
	0.3 ... 7.5 mV	
Sensitivity RV EN 45502-2-1 triangle pulse	0.5 ... 7.5 mV	± 20%
Refractory period	200 ... 500 ms	± 20 ms
Maximum activity rate	80 ... 180 bpm	± 20 ms
Lead impedance	100 ... 200 Ω	± 50 Ω
	201 ... 2500 Ω	± 10%

5 Technical Data

Mechanical Characteristics

Housing

Device	W x H x D [mm]	Volume [cm^3]	Mass [g]
Single-chamber S, SR	48 x 40 x 6.5	10	20.8
Dual-chamber D, DR	48 x 44 x 6.5	11	23.2

Note

D = housing without header

Materials in contact with body tissue

- Housing: titanium
- Header: epoxy
- Cap:
  - IS-1 connector port (single- and dual-chamber devices): polysulfone (0.85 cm^2 per connector port)
- Silicone plug: silicone (0.1 cm^2 per piece)

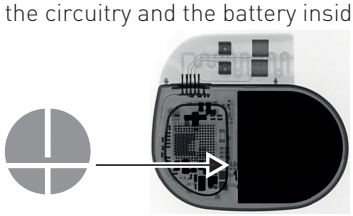
Device type	Contact surface titanium	Contact surface epoxy	Number of silicone plugs
Single-chamber S, SR	29.9 cm^2	9.8 cm^2	1
Dual-chamber D, DR	29.9 cm^2	11.6 cm^2	2

Note

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

X-ray identification

All device types receive the BIOTRONIK logo for X-ray identification. It can be found centrally between the circuitry and the battery inside of the housing and is visible in an X-ray image.



Electrical Characteristics

Components and input values

Electrical characteristics determined at 37°C, 500 Ω

Circuit technology	Dycostrate
Input impedance	> 10 kΩ
Pulse waveform	Biphasic, asymmetric
Polarity	Cathodic

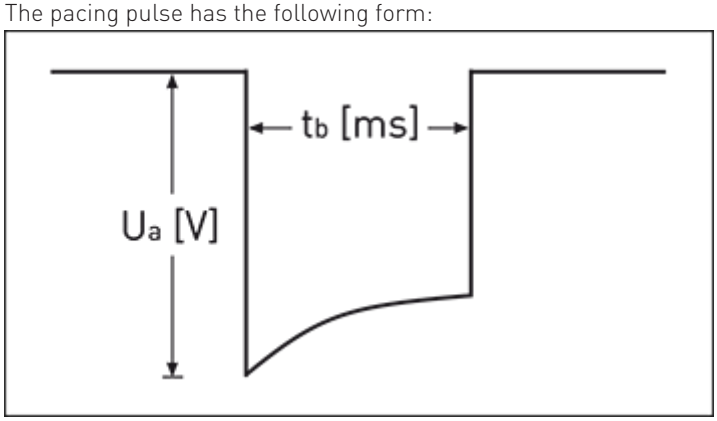
Electrically conductive surface

The device housing has the form of a flattened ellipsoid. The electrically conductive area is for:

- Single- and dual-chamber devices: 30 cm^2

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 devices comply with the requirements of EN 45502-2-1: 2003, Section 27.5.1 at the highest sensitivity.

Battery Data

Battery characteristics

The following data is provided by the manufacturers:

Manufacturer	Greatbatch Ltd. 10000 Wehrle Drive Clarence, NY, 14031, USA	LITRONIK Batterietechnologie GmbH Birkwitzer Strasse 79 01796 Pirna, Germany
Battery type	GB 3395	LiS 2650
System	Li-Iodine	Li-Iodine
Device type	S; SR; D; DR	S; SR; D; DR
Battery voltage at BOS	2.8 V	2.8 V
Open-circuit voltage	2.8 V	2.8 V
Nominal capacity	960 mAh	960 mAh
Usable capacity until EOS	905 mAh	905 mAh
Remaining capacity at ERI	55 mAh	55 mAh

Shortening of the service time after long storage period

In case of implantation after an average storage period – about 1 year before the end of the use by date – the average service time decreases by about 1%.

Devices should be implanted within 19 months between the manufacturing date and the use by date (indicated on the package).

Power consumption

- BOS, inhibited: SR, DR 6 µA
- BOS, 100% pacing: SR 8 µA; DR 11 µA

Calculation of service times

Mean service times pre-estimated from the following and other data:

- Storage period of 6 months
- Technical data of the battery manufacturer
- Basic rate of 60 bpm in AAIR/VVIR mode (single-chamber devices) or DDDR mode (dual-chamber devices)
- No wandless telemetry
- Configuration of different pulse amplitudes and lead impedances

Mean service times S, SR

For single-chamber devices, the following times result when set to AAI(R) or VVI(R) with a basic rate of 60 bpm and a pulse width of 0.4 ms at an impedance of 500 Ω:

Amplitude	Pacing	Average service time
2.5 V	100%	14 years
	50%	16 years, 10 months
3.0 V	100%	12 years
	50%	14 years, 10 months
5.0 V	100%	8 years, 1 months

Mean service times D, DR

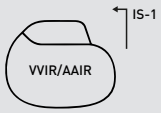
For dual-chamber devices, the following times result when set to DDD(R) with a basic rate of 60 bpm and a pulse width of 0.4 ms at an impedance of 500 Ω:

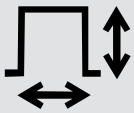
Amplitude	Pacing	Average service time
A: 2.5 V RV: 2.5 V	100%	9 years, 10 months
	50%	12 years, 4 months
A: 3.0 V RV: 3.0 V	100%	7 years, 11 months
	50%	10 years, 8 months
A: 5.0 V RV: 5.0 V	100%	4 years, 7 months

Legend for the Label

The label icons symbolize the following:

	Manufacturing date		Manufacturer
	Use by		Temperature limit Observe the information on temperatures during shipping and storage in this technical manual.
	Medical device		Order number
	Serial number		Product identification number
	Unique device identification		CE mark
	Consult the technical manual		Contents
	Comply with the technical manual (white image on blue background)		
	Sterilized with ethylene oxide		Single sterile barrier system with protective packaging inside
	Do not resterilize		Single use only. Do not reuse!
	Do not use if packaging is damaged and consult the technical manual		
	MR conditional		
	Implanted device		
	Torque wrench		

 Example	Uncoated device: NBG code and compatible leads
	Examples of the header configuration: IS-1

	Shipping setting: Pulse amplitude and pulse width		Shipping setting: Sensitivity
	Shipping setting: AV delay		Shipping setting: VV delay

	Scannable QR code