Effecta S(R), D(R)

Pacemaker • Bradyarrhythmia therapy

Technical manual

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1 Product Description

Intended Medical Use

Intended use

Effecta 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 Effecta family.

Required expertise

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

System Overview

Device family

Effecta S(-R) are single-chamber devices, Effecta D(-R) are double-chamber devices and belong to the Effecta family. Not all device types are available in every country.

Parts

The device system consists of the following parts:

- Device with connections for unipolar or bipolar sensing and pacing
- Suitable leads, adapters and approved accessories
- Programmer
- Current software

Device

The device'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 devices to avoid muscle twitching near the implanted pacemaker in the case of unipolar pacing. The labeling provides information about the device type and arrangement of the connections.

Leads

The leads are coated with biocompatible silicone. They can be flexibly maneuvered, are stable long-term, and are equipped for active or passive fixation. They are implanted using a lead introducer set. Some leads are coated with polyurethane which is known to increase the sliding properties for the lead. The coating of steroid-eluting leads reduces inflammatory processes. The fractal design of the leads allows for low pacing thresholds, high pacing impedance, and a low risk of oversensing.

Programmer

The portable programmer is used to transfer the current software to the device. In addition to this, the programmer is used for interrogation and storage of data from the device. The programmer acts as an ECG and IEGM monitor.

Note: It is not permitted to use the device's ECG display for diagnostic purposes because it does not meet all requirements of the norm (IEC 60601-2-25) concerning diagnostic ECG devices.

The programmer communicates with the device via the programming head. It has a TFT touch screen with a color display, on which the ECG, IEGM, markers and functions are shown simultaneously.

The programmer has, among others, the following functions:

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

Technical manuals

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

- Technical manual for the device
- Technical manual for the HMSC
- Technical manuals for the programmer
- Technical manual for software as online help on the user interface and as a PDF file in the Manual Library at www.BIOTRONIK.com
- Technical manuals for the leads
- Technical manuals for cables, adapters and accessories

Device Variants and NBG Codes

Effecta family

The following device variants are available:

Device type	Variant with rate adaption	Variant without rate adaption
Dual-chamber	Effecta DR	Effecta D
Single-chamber	Effecta SR	Effecta S

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

NBG code for Effecta D(R)

DDD(R) is the NBG code for the antibradycardia 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

NBG code for Effecta S(R)

AAI(R) or VVI(R) is the NBG code for the antibradycardia mode of the single-chamber device:

A/V	Pacing in the atrium or ventricle
A/V	Sensing in the atrium or ventricle
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 device, configure, and check the pacemaker.
- Auto-initialization after implantation: the device 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 device at any time.
- Automatic below-threshold impedance measurement is performed in the device 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 implanted device 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 device. Capture control is used to set the pulse amplitudes so that pacing is performed with the optimum atrial and ventricular amplitude for the patients with each change of the pacing threshold.

Package Contents

Standard

The storage package includes the following:

- Sterile packaging with device
- Serial number label
- Patient ID card
- Warranty booklet
- Technical manual for the device

The sterile container includes the following:

- Device
- Screwdriver

Order numbers Effecta

The devices can be obtained as follows:

Device	Order number: uncoated	Order number: coated
DR	371199	371201
D	375429	375428
SR	371202	371203
S	375431	375430

2 General Safety Instructions

Possible Medical Complications

General information on medical complications

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

- Normal complications may include fluid accumulation within the device pocket, infections, or tissue reactions. Primary sources of complication information include current scientific and technological knowledge.
- It is impossible to guarantee the efficacy of antitachycardia therapy, even if the programs have proven successful during tests or subsequent electrophysiological examinations. In rare cases the set parameters may become ineffective. In particular it cannot be excluded that tachyarrhythmias may be induced.

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.

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.

- BIOTRONIK also provides coated devices.

Possible Technical Complications

Technical malfunctions

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

Possible Electromagnetic Complications

Electromagnetic interference (EMI)

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

- BIOTRONIK devices have been designed so that their susceptibility to EMI is minimal.
- Due to the intensity and variety of EMI, there is no guarantee for safety. It is generally assumed that EMI produces only minor symptoms 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, for example during diagnostic or therapeutic procedures, interference sources may induce such a high level of energy into the pacing system that the cardiac tissue surrounding the lead tip is damaged.

Device behavior in case of EMI

In the case of electromagnetic interference or undesired myopotentials, the device switches to asynchronous pacing for the duration of the time that the interference rate is exceeded.

Static magnetic fields

The reed switch in the pacemaker starts to close at a field strength of 1.5 mT.

Possible Risks

Contraindicated procedures

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

- Therapeutic ultrasound: Harm to the patient via excess warming of body tissue near the device system
- Transcutaneous electrical nerve stimulation
- Hyperbaric oxygen therapy
- Applied pressures higher than normal pressure

Risky therapeutic and diagnostic procedures

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

Arrhythmia or ventricular fibrillation can be induced during diathermic procedures such as electrocautery, HF ablation or HF surgery. For example, damaging heat can result during lithotripsy. Influences on the device are not always immediately clear.

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

- Electrically insulate the patient.
- Switch 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. Nevertheless, any implanted device may be damaged by external defibrillation. Specifically, the current induced in the implanted leads may result in necrotic tissue formation close to the electrode/tissue interface. As a result, sensing properties and pacing thresholds may change.

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

Radiation therapy

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

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

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

Magnetic resonance imaging

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

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

3 Prior to Implantation

Indications

Guidelines of cardiological societies

Generally approved differential diagnostic methods, indications, and recommendations for pacemaker therapy apply to BIOTRONIK devices.

The guidelines provided by cardiology associations offer decisive information:

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

Device types

For the following symptoms/expectations, the following device types are indicated:

Symptom/expectation	SR	DR	HF
Disorientation due to bradycardia	x	x	x
Presyncope	x	x	x
Benefit from resynchronization of the right and left ventricles			x
Syncope	x	x	x

Pacing modes

For the following symptomatic, the following pacing modes are indicated:

Symptom/expectation	Pacing mode
Sick sinus syndrome	Dual-chamber pacing
Chronic, symptomatic second and third-degree AV block	Dual-chamber pacing
Adams-Stokes syndrome	Dual-chamber pacing
Symptomatic bilateral bundle branch block when tachyarrhythmia and other causes have been ruled out	Dual-chamber pacing
• Chronotropic incompetence • Benefit from increased pacing rate with physical activity	R mode or CLS
Sinus node dysfunction in the presence of normal AV and intraventricular conduction	Atrial pacing
Bradycardia in conjunction with the following: • Normal sinus rhythms with only rare episodes of AV block or sinus arrest • Chronic atrial fibrillation • Severe physical disability	Ventricular pacing

MR conditional

ProMRI® labeled MRI conditional pacemakers are safe for use in the MRI environment when used in conjunction with a complete MRI conditional pacing system and according to the instructions given in the ProMRI® manual.

Contraindications

Guidelines

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

Pacing modes and parameters

The compatibility and effectiveness of parameter combinations must be checked and, as the case may be, adapted after programming.

Set of facts	Contraindicated pacing mode
Additionally implanted ICD	Unipolar pacing

Set of facts	Inappropriate pacing mode
Chronic atrial tachycardia, chronic atrial fibrillation or flutter	Atrial-controlled modes (DDD, VDD, AAI)
Poor tolerance of pacing rates above the basic rate, e.g., angina pectoris	
AV conduction disorder	Atrial single-chamber pacing
Failing AV conduction	

Set of facts	Adapt parameters
Slow retrograde conduction after ventricular pacing: risk of pacemaker-mediated tachycardia	• Extend atrial refractory period (ARP) and/or: • Shorten AV delay • Rarely: Program to DDI, DVI or VVI
Poor tolerance of pacing rates above the basic rate, e.g., angina pectoris	• Lower atrial upper rate • Lower maximum sensor rate • Deploy atrial overdrive pacing

Ambient Conditions

Temperature

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

- The following temperatures are permitted for transport, storage, and use:
  –10°C to 45°C

Storage location

- Devices 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 device (see battery data).

- Please note the use by date.

Sterility

Delivery

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

Sterile packaging

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

Single use only

The device and the screwdriver are only intended for single use.

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

Preparing the Implantation

Keeping an external defibrillator ready

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

- Keep an external defibrillator ready.

Having parts ready

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

- Device with screwdriver from BIOTRONIK
- BIOTRONIK leads and lead introducer set
  - One unipolar or bipolar lead each for the atrium and for the right ventricle
- Use only adapters approved by BIOTRONIK for leads with different connections or leads from other manufacturers.
- BIOTRONIK programmer and approved cables
- External multi channel ECG device
- Keep spare parts for all sterile components.

Unpacking the device

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

- Peel the sealing paper off of the outer blister at the marked position in the direction indicated by the arrow. The inner blister must not come into contact with persons who have not sterilized their hands or gloves, nor with non-sterile instruments!
- Use the gripping tab on the inner plastic container to remove it from the outer plastic container.
- Peel the sealing paper off of the sterile inner blister at the marked position in the direction indicated by 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 damages before and after unpacking all parts.
- Replace damaged parts.
- Leads must not be shortened.

4 Implantation

Implanting

Implantation site

- Depending on lead configuration and the patient's anatomy, pacemakers are generally implanted subcutaneously or subpectorally on the right side.

Sequence

1	Shape the device pocket and prepare the vein.
2	Implant the leads, perform the measurements, and fixate the leads.
3	Connect device and leads. The device starts auto-initialization on its own.
4	Insert the device.
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.

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.

Connecting Pacemaker Leads

Connection options

BIOTRONIK pacemakers have been designed for use with leads with a unipolar or bipolar IS-1 connection. For sensing and pacing, a unipolar or a bipolar lead can be used:

- Atrium: IS-1 unipolar or bipolar
- Right ventricle: IS-1 unipolar or bipolar

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

Dual-chamber	Single-chamber
DDDR  **IS-1**	**VVIR/AAIR** **IS-1**

Preventing short circuits in the header

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

Connecting the lead connector to the device

1	Disconnect stylets and stylet guides from the lead connector.
2	• Connect the unipolar or bipolar IS-1 lead connector 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 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 (audible 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.

Keeping distance between leads

WARNING
Inadequate therapy When leads are not spaced sufficiently apart or are positioned inappropriately, this can lead to far-field sensing or insufficient defibrillation. • Tip and ring electrodes must not have contact with each other.

Auto-initialization

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

Auto-initialization is 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 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
- 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 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, it is helpful to cancel telemetry, in which case the device automatically switches to the permanent program.

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

Avoiding critical parameter settings

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

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

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.

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.

Setting triggered mode

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

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

- Use automatic sensitivity control.

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 can only be set and retained with physician supervision.

Preventing device-induced complications

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

- 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 bpm
- Automatic:

  For 10 cycles – mode D00, subsequently mode DDD without rate adaptation;
  Magnet rate: 10 cycles with 90 bpm, subsequently set basic rate
- Synchronous:

  Mode DDD without rate adaptation;
  Magnet rate: set basic rate

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

Preventing conduction of atrial tachycardia

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

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

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.

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

5 After Implantation

Follow-ups

Follow-up intervals

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

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

Follow-up with the programmer

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

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

Notes for the Physician

Patient ID card

A patient ID card is included in delivery.

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

Prohibitive signs

Draw the patient's attention to prohibitory signs.

- Places with prohibitive signs must be avoided.

Possible sources of interference

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

- Draw the patient's attention to special household appliances, security checkpoints, anti-theft alarm systems, strong electromagnetic fields, cell phones, and transmitters among other things.
- Request patients to do the following:
  - Use cell phones on the side of their body that is opposite of the device.
  - Keep the cell phone at least 15 cm away from the device both during use and when stowing.

Magnet application by patients

If patients are performing their own magnet application, the synchronous magnet response 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 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.

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:

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

Change of the 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 capture control
- Rate fading
- IEGM recordings
- Statistics
- Rate hysteresis

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(R); DOO(R); VDD(R); VDI(R); VVI(R); VVT(R); AAI(R); AAT(R); AOO(R)
- In the 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 with 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:**
Automatic	Asynchronous with 80 bpm	Synchronous with basic rate reduced by 4.5 to 11%
Asynchronous	Asynchronous with 80 bpm	Asynchronous with 80 bpm
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 pacing energy:
  110 bpm; 4.6 V; 1.5 ms; 500 ohm
- Parameters with low pacing energy:
  30 bpm; 0.2 V; 0.1 ms; 500 ohm
- Dual-chamber device in DDD(R) mode;
  Single-chamber device in AAI(R)/VVI(R) mode

Explantation and Device Replacement

Explantation

- Disconnect the leads from the header.
- Remove the device and, if necessary, leads using state-of-the-art technology.
- Explants are biologically contaminated and must be disposed 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.

- Insulate connections that are not used.

Basic principles

- The device must not be resterilized and reused.

Cremation

Devices must not be cremated.

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

Disposal

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

- Clean the explant with 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.

6 Parameter

Modes

Effecta family

The mode setting depends on the individual diagnosis:

Device type	Mode	Standard
DR	• 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
D	• DDD; DDT; DDI; DVI; DOO VDD; VDI; VVI, VVT; VOO; V00R; VVIR AAI; AAT; AOO • OFF	DDD
SR	• VVIR; VVTR; VOOR AAIR; AATR; AOOR • VVI; VVT; VOO AAI; AAT; AOO • OFF	VVIR
S	• VVI; VVT; VOO AAI; AAT; AOO • OFF	VVI

Timing: Dual-chamber

Basic rate day/night

Parameter	Range of values	Standard
Basic rate	30 ... (1) ... 88 ... (2) ... 122 ... (3) ... 140 ... (5) ... 200 bpm	60 bpm
Night rate	OFF 30 ... (1) ... 88 ... (2) ... 122 ... (3) ... 140 ... (5) ... 200 bpm	OFF
Night begins	00:00 ... (10 min) ... 11:50 PM hh:mm	10:00 PM hh:mm
Night ends	00:00 ... (10 min) ... 11:50 PM hh:mm	6:00 AM hh:mm

Rate hysteresis

Parameter	Range of values	Standard
Rate hysteresis	OFF -5 ... (-5) ... -90 bpm	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
	15 ... (5) ... 350 ms (in 6 rate ranges)	180 ms
Sense compensation	OFF -10 ... (5) ... -120 ms	-45 ms
AV safety interval	100 ms	100 ms

AV hystereses

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

Upper rate

Parameter	Range of values	Standard
Upper rate	90 ... (10) ... 200 bpm	130 bpm
Upper rate, atrium	OFF 240 bpm	240 bpm

Mode switching

Parameter	Range of values	Standard
Mode switching	OFF; ON	ON
Intervention rate	100 ... (10) ... 250 bpm	160 bpm
Switch to (mode)	DDI; DDI(R) when permanent DDD(R) VDI; VDI(R) when permanent VDD(R)	DDI(R) VDI(R)
Onset criterion	3 ... (1) ... 8	5
Resolution criterion	3 ... (1) ... 8	5
Change of the basic rate with mode switching	OFF +5 ... (5) ... +30 bpm	+10 bpm
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	175 ... (5) ... 600 ms	250 ms
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 Vs	100 ... (10) ... 220 ms	100 ms
Far-field protection after Vp	100 ... (10) ... 220 ms	150 ms
Ventricular blanking period after Ap	30 ... (5) ... 70 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: Single-chamber

Basic rate day/night

Parameter	Range of values	Standard
Basic rate	30 ... (1) ... 88 ... (2) ... 122 ... (3) ... 140 ... (5) ... 200 bpm	60 bpm
Night rate	OFF 30 ... (1) ... 88 ... (2) ... 122 ... (3) ... 140 ... (5) ... 200 bpm	OFF
Night begins	00:00 ... (10 min) ... 11:50 PM hh:mm	10:00 PM hh:mm
Night ends	00:00 ... (10 min) ... 11:50 PM hh:mm	6:00 AM hh:mm

Rate hysteresis

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

Upper rate

Parameter	Range of values	Standard
Upper rate in VVT(R) mode	90 ... (10) ... 200 bpm	130 bpm

Refractory period

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

Pacing and Sensing: Dual-chamber

Pulse amplitude and pulse width

Parameter	Range of values	Standard
Pulse amplitude A	0.2 ... (0.1) ... 6.0 ... (0.5) ... 7.5 V	3.0 V
Pulse width A	0,1 ...(0,1) ... 0.5; 0.75; 1.0; 1.25; 1.5 ms	0.4 ms
Pulse amplitude V	0.2 ... (0.1) ... 6.0 ... (0.5) ... 7.5 V	3.0 V
Pulse width V	0.1 ... (0.1) 0.5; 0.75; 1.0; 1.25; 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) ON; OFF	ON
Min. amplitude	0.5 ... (0.1) ... 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 ... (0.1) ... 1.2 V	1.0 V
Search type	Interval; time of day	Time of day
Interval	0.1; 0.3; 1; 3; 6; 12; 24 h	24 h
Time of day	00:00 ... (10 min) ... 23:50	02:00 hh:mm

Ventricular capture control

Parameter	Range of values	Standard
Ventricular capture control	ATM (monitoring only) ON; 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 ... (0.1) ... 1.2 V	0.5 V
Search type	Interval; time of day	Time of day
Interval	0.1; 0.3; 1; 3; 6; 12; 24 h	24 h
Time of day	00:00 ... (10 min) ... 23:50	2:00 AM hh:mm

Lead configuration

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

IEGM recordings

Parameter	Range of values	Standard
IEGM recordings	4 (quantity); each max. 10 s	
Types of IEGM recordings	High atrial rate (HAR)	HAR
	Mode switching	
	High ventricular rate (HVR)	ON
IEGM recording prior to event	0; 25; 50; 75; 100%	75 %
IEGM signal	Filtered; unfiltered	Filtered

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; 387 308; 300 ms	180 bpm 333 ms
High frequency counter	4; 8; 12; 16	8

Pacing and Sensing: Single-chamber

Pulse amplitude and pulse width

Parameter	Range of values	Standard
Pulse amplitude	0.2 ... (0.1) ... 6.0 ... (0.5) ... 7.5 V	3.0 V
Pulse width	0.1 ... (0.1) ... 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	ATM (monitoring only) ON; 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 ... (0.1) ... 1.2 V	0.5 V
Search type	Interval; time of day	Time of day
Interval	0.1; 0.3; 1; 3; 6; 12; 24 h	24 h
Time of day	00:00 ... (10 min) ... 23:50	2:00 AM hh:mm

Lead configuration

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

IEGM recordings

Parameter	Range of values
IEGM recordings	4 (quantity); each max. 10 s
Types of IEGM recordings	High atrial rate (HAR)
	Mode switching
	High ventricular rate (HVR)
IEGM recording prior to event	0; 25; 50; 75; 100%
IEGM signal	Filtered; unfiltered

Rates for statistics

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

Rate adaptation

Rate adaptation via accelerometer

R modes:

Parameter	Range of values	Standard
Sensor gain	1 ... 23	4
Max. activity rate	80 ... (5) ... 180 bpm	120 bpm
Automatic gain	OFF; ON	ON
Sensor threshold	Very low; low; medium; high; very high	Medium
Rate increase	1 ... (1) ... 10 bpm/cycle	4 bpm/cycle
Rate decrease	0.1; 0.2; 0.5; 1.0 bpm/cycle	0.5 bpm/cycle

Preset programs: Dual-chamber

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)	DDD(R)	VVI
Basic rate	60 bpm	70 bpm
Night program	OFF	OFF
Rate hysteresis	OFF	OFF
Upper rate	130 bpm	—
Dynamic AV delay	Low	—
AV hysteresis	OFF	—
Sense compensation	-45 ms	—
AV Safety delay	100 ms	—
Far-field protection after Vs	100 ms	—
Far-field protection after Vp	150 ms	—
Ventricular blanking period after Ap	30 ms	—
PMT protection	ON	—
VA criterion	350 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 bpm	—
Switches to	DDIR	—
Basic rate with mode switching	+10 bpm	—
Rate stabilization with mode switching	OFF	—
2:1 lock-in protection	ON	—
PVARP	250 ms	250 ms

Parameter	Standard program	Safe program
PVARP after PVC	400 ms	—
Lead configuration, automatically determined and set:		
Pacing polarity A/V	Unipolar	Unipolar
Sensing polarity A/V	Unipolar	Unipolar
Automatic lead check A/V	ON	—
A/V capture control	ON	OFF
IEGM recording (HAR, HVR)	ON	OFF

Preset programs: Single-chamber

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)	VVIR	VVI
	In the AAI mode, the safe program is also AAI.	
Basic rate	60 bpm	70 bpm
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 mV
Refractory period	250 ms	300 ms
Lead configuration, automatically determined and set		
Pacing polarity	Unipolar	Unipolar
Sensing polarity	Unipolar	Unipolar
Automatic lead check	ON	—
Capture control	ON	OFF
IEGM recording	ON	OFF

Tolerances of Parameter Values

Dual-chamber

Parameter	Range of values	Tolerance
Basic rate	30 ... 100 bpm	+/-1.5 bpm
	102 ... 195 bpm	+/-2.0 bpm
	200 bpm	+0.0/-3.0 bpm
Basic interval	1000 ms	+/-20 ms
Magnet rate	90 bpm	+/-1.5 bpm
Magnet interval	664 ms	+/-20 ms
AV delay	15 ... 350 ms	+20/-5 ms
Pulse amplitude A/V	0.2 V	+/-0.10 V
	0.3 ... 7.5 V	+20/-25%

Parameter	Range of values	Tolerance
Pulse width A/V	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 triangle pulse	0.1 mV	+0.2/-0.1 mV
	0.2 ... 0.5 mV	+/-0.1 mV
	0.6 ... 7.5 mV	+/-20%
Sensitivity V 45502-2-1 triangle pulse	0.5 mV	+/-50%
	1.0 ... 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 bpm	+/-1.5 bpm
	105 ... 180 bpm	+/-2.0 bpm
Upper rate	90 ... 190 bpm	+/-2.0 bpm
	200 bpm	+0/-2.0 bpm
High rate protection	200 bpm	+20/-0 bpm
Lead impedance	100 ... 200 Ω:	+/-50 Ω:
	201 ... 2500 Ω:	+/-25%

Single-chamber

Parameter	Range of values	Tolerance
Basic rate	30 ... 100 bpm	+/-1.5 bpm
	102 ... 195 bpm	+/-2.0 bpm
	200 bpm	+0.0/-3.0 bpm
Basic interval	1000 ms	+/-20 ms
Magnet rate	90 bpm	+/-1.5 bpm
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 triangle pulse	0.5 mV	+/-50 %
	1.0 ... 7.5 mV	+/-20%
Refractory period	200 ... 500 ms	+10/-30 ms
Max. activity rate	80 ... 100 bpm	+/-1.5 bpm
	105 ... 180 bpm	+/-2.0 bpm
High rate protection	200 bpm	+20/-0 bpm
Lead impedance	100 ... 200 Ω:	+/-50 Ω:
	201 ... 2500 Ω:	+/-25%

7 Technical Data

Mechanical Characteristics

Measurements for the housing

Device	W x H x D [mm]	Volume [cm^3]	Mass [g]
D(R)	53 x 43 x 6.5	11	26
S(R)	53 x 39 x 6.5	10	25

Note: D = housing without header

X-ray identification

BIO SF

Materials in contact with body tissue

- Housing: Titanium
- Header: Epoxy resin
- Coating, if applicable: Silicone

Electrical Characteristics

Components and input values

Electrical characteristics determined at 37°C, 500 Ω:

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

Housing shape

The device housing has the following shape:

Device type	Dual-chamber, single-chamber
Uncoated	Flattened ellipsoid
Coated	

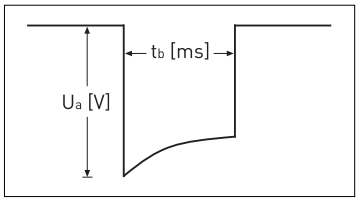
Electrically conductive surface

The device housing has the following surface:

Device type	Dual-chamber, single-chamber
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 devices comply with the requirements of prEN 45502-2-1: 2006, § 27.5.1 at the highest sensitivity.

Battery Data

Battery characteristics

The following data is provided by the manufacturers:

Manufacturer	GREATBATCH, INC. Clarence, NY 14031	LITRONIK GmbH 01796 Pirna, Germany
Battery type	GB 8431	LiS 3150
System	LiJ	LiJ
Device type	D(R) S(R)	D(R) S(R)
Battery voltage at BOS	2.8 V	2.8 V
Open-circuit voltage	2.8 V	2.8 V
Nominal capacity	1.3 Ah	1.3 Ah
Remaining capacity at ERI	0.1 Ah	0.1 Ah
Usable capacity until EOS	1.2 Ah	1.2 Ah

Power consumption

The device has the following power consumption:

Power consumption	Dual-chamber	Single-chamber
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 bpm and the setting of different pulse amplitudes and lead impedances.

Service times dual-chamber

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

Amplitude	Impedance [ohm]	Pacing		
		10%	50%	100%
		D(R)		
1.5 V	500	>15	14.8	13.0
	1000	>15	>15	14.7
2.5 V	500	13.6	12.1	9.4
	1000	>15	14.1	12.0
3.0 V	500	12.1	10.2	7.3
	1000	14.2	12.7	10.1
3.5 V	500	11.1	9.0	6.2
	1000	13.4	11.7	8.9
5.0 V	500	7.8	5.8	3.6
	1000	10.7	8.7	5.9

Service times single-chamber

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

Amplitude	Impedance [ohm]	Pacing		
		10%	50%	100%
		S(R)		
1.5 V	500	>15	>15	>15
	1000	>15	>15	>15
2.5 V	500	>15	>15	13.3
	1000	>15	>15	>15
3.0 V	500	>15	14.2	11.2
	1000	>15	>15	14.1
3.5 V	500	14.9	12.9	9.7
	1000	>15	>15	12.9
5.0 V	500	11.3	9.1	6.2
	1000	14.5	12.5	9.4

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:
  - Dual-chamber by 6 months
  - Single-chamber by 8 months
- After 1.5 years:
  - Dual-chamber by 9 months
  - Single-chamber by 12 months

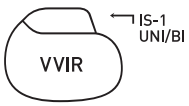
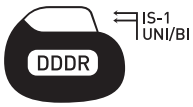
Legend for the Label

The label icons symbolize the following:

	Manufacturing date		Use by
	Temperature limit		Order number
	Serial number		Product identification number
	CE mark		
	Contents		Follow the instructions for use

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

	Transmitter with non-ionizing radiation at designated frequency

 Example	Uncoated device: NBG code and compatible leads
 Example	Coated device: NBG code and compatible leads
	Screwdriver
 Example	Header
	Bipolar IS-1 connector
	Unipolar IS-1 connector