Reocor D

External Pacemaker

Cardiac Rhythm Management

External Devices

Technical Manual en

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Contents

General Description

Product Description

Reocor D is a battery-powered, external dual-chamber pacemaker, which can be used in conjunction with temporary pacemaker leads (including endocardial leads and transvenous implantable catheters) for temporary atrial, ventricular and AV sequential pacing in clinical settings.
The connection is made directly or via a separate patient cable and adapter, if necessary.

There are six pacing modes available: DDD, D00, VDD, VVI, V00 and VVT, as well as an atrial burst function.

The pacing mode, rate, sensitivity and pulse amplitude, AV delay and burst rate are adjustable.

LEDs display the sense (Sense), pace (Pace) and battery status (Low battery).
An acoustic signal sounds when a very high frequency or very low sensitivity value is set and when the lead impedance is not optimal.

A defect of the device (failed self-test after the device was switched on) is indicated by continuously lit LEDs and an intermittent acoustic signal. If the self-test does not find any errors, the acoustic and visual signals will turn off after a few seconds.

The safety features of Reocor D include:

- Visual display of sensed and paced events
- Microprocessor-controlled pacing parameters
- Lead impedance monitoring
- Visual warning when the battery is almost depleted
- A movable, transparent cover of the controls to prevent accidental changes of the programmed parameters

Temporary catheters, heart wires and leads with 2-mm plugs can be connected directly to Reocor D.

Additional patient cables and adapters are available, too. This system offers a secure connection of transvenous catheters and myocardial leads, which are applied either as unipolar or bipolar.

Indications

Temporary pacing with Reocor D is suitable for the following applications for patients of any age:

- Treatment of arrhythmias and heart block
- Symptomatic sinus bradycardia
- Sick sinus syndrome
- Pre-, intra- and postoperative pacing of patients with heart surgery
- Termination of supraventricular tachyarrhythmias
- Prophylactic pacing for prevention of arrhythmias
- Emergency pacing
- Checking the pacing thresholds

Contraindications

- Reocor D cannot be sterilized and is therefore not suitable for use within the sterile field.
- The atrially triggered pacing modes (DDD and VDD) are contraindicated for atrial fibrillation, atrial flutter and other fast atrial rhythms.
- When high ventricular rates are not well tolerated by the patient (e.g., in the presence of angina pectoris), atrium-controlled modes can be contraindicated.
- If retrograde conduction is encountered after ventricular pacing, extending the atrial refractory period and/or shortening the AV delay may be necessary programming options to prevent pacemaker-mediated tachycardia. It may be necessary in such cases to program a VVI mode.

- Atrial single-chamber pacing is contraindicated for patients with existing AV conduction disturbances.
- The use of an external pacemaker is contraindicated in the presence of an active, implanted pacemaker.

Potential Side Effects

Potential complications associated with the application of temporary external pacing include asystole after abrupt cessation of pacing (e.g., if the patient cable is inadvertently disconnected, the leads are loosened or the settings are incorrect) or pacemaker dependency.

Complications when inserting transvenous leads include: Wound infection, arterial puncture, pericardial friction, cardiac perforation and dysrhythmia after lead insertion.

Handling Instructions

Depending on the pacing settings and the patient's underlying illness, pacing can induce arrhythmias. To ensure the patient's safety, certain procedures should be observed and the precautionary measures listed below taken. Please read about additional procedures and precautionary measures in appropriate medical publications.

Users

- Reocor D may only be used by persons with knowledge of cardiology who were trained in the handling of the device. Potential users are technical and medical hospital staff and physicians.

Mode of action

- Reocor D interacts with the human heart. There is also an interaction with the patient's skin and blood vessels.

Intended use

- Reocor D and the cables and accessories approved along with the device may only be used in accordance with this technical manual.
- Reocor D must not be connected to other electromedical devices.
- Reocor D must not be used in areas in which there is a danger of explosion.

Changes not permitted

- Only the manufacturer or a party expressly authorized by BIOTRONIK may perform corrective maintenance, enhancements or modifications to the device.

Replacement parts and accessories

- To ensure safety compliance, use only original replacement parts and accessories authorized by BIOTRONIK. Using any other parts voids the manufacturer's liability for any consequences, guarantee and warranty.

Devices on hand

- In case of pacemaker dependency of the patient, an emergency pacemaker should be kept on hand.
- Keep an external defibrillator, oxygen, intubation equipment and emergency drugs on hand.

Behavior before use

- Before use, Reocor D should be visually inspected for damages and dirt.
- Never use a device that is damaged or shows abnormal behavior. Replace any cable that shows even slight damage.
- Before using Reocor D, the patient cable or leads, the user should touch the patient to equalize electrical potentials.
- It is strongly recommended that users examine all set parameters before the leads are connected to Reocor D.
- Even though Reocor D is protected from dripping water, the device and all plugs should be kept clean and dry.
- Reocor D cannot be sterilized.

Lead connection

- The connections of Reocor D and the temporary pacing leads must be secured and checked regularly.
- The patient cable must first be connected to Reocor D and then to the leads.
- The temporary leads, to which the Reocor D is connected, represent a low-impedance conductor to the myocardium for electric current. Therefore line-powered devices that are operated in the patient's vicinity must be grounded in accordance with established guidelines.
- When handling already implanted leads, their connector pins and metal contact surfaces must not touch or come into contact with electrically conductive or wet surfaces.
- If the cable has become disconnected from the Reocor D, it must be reconnected immediately and the security of the connection inspected.
- When using unipolar leads, two unipolar leads must be used for each chamber for effective pacing.

Behavior during use

- During use of Reocor D, the protective cover must be completely closed to prevent inadvertent resetting of the programmed parameters.
- Secure Reocor D either horizontally on a non-slip surface or on the patient with an armband, or operate it from a hanging position on the infusion stand using the hanger on the back of the device.
- Reocor D must not be worn directly on the skin.
- During use of Reocor D, the heart rate of the patient is to be monitored with an ECG monitor with alarm function.
- For disturbances caused by electromagnetic interference (EMI), Reocor D will trigger asynchronous pacing when certain limits are exceeded. Depending on whether the interference was sensed in the atrium or in the ventricle, the

following operating modes will result for the duration of the interference:

Undisturbed operating mode	Interference by EMI
SSI, SST	S00
VDD	VAT, VVI, V00
DDD	DAD, DVI, D00

Pacing with high rates

- Pacing the heart with rates higher than 180 ppm over a long period of time can cause severe hemodynamic complications. Pacing with high rates should only be performed when continuous monitoring is ensured.

Behavior after use

- After a defibrillation or cauterization, the device should be subjected to a function test.
- If the device will be stored for a long period of time, the battery should be removed to prevent damage due to leakage.
- A damp cloth and mild soap can be used for cleaning. Strong cleaning agents or organic solvents should be avoided, as these can corrode the plastic housing.
- Inspection and maintenance work should be performed according to page 32.

Battery operation

- Do not use rechargeable batteries. The service time of these batteries is difficult to estimate, making it possible to inadvertently exceed the ERI[1] time, resulting in sudden cessation of pacing.

  Only 9-volt batteries with the international code IEC 6LR61 may be used. When using the battery type MN 1604 Duracell® Procell®, external pacing is possible for at least 500 hours before the battery must be replaced.

  It is possible to exchange a battery while Reocor D is in use. The device remains ready for use for at least 30 s at the ambient temperature (20 ± 2°C) when the battery is removed.

  For safety reasons, the patient should be paced by another source during the battery replacement.

1 Reocor D reminds you to replace the battery with the ERI signal (Low battery LED flashes).

Electrocautery

- Electrocautery should definitely not be performed at a distance less than 15 cm from the leads, as it is possible that ventricular fibrillation will be induced or the pacemaker could be damaged.

  The pacemaker should be set to asynchronous pacing to avoid pacemaker inhibition due to interference signals. During treatment, the peripheral pulse of the patient should be continuously monitored. After treatment, the pacemaker function must be inspected.

Defibrillation

- The circuitry of Reocor D is protected from the shock energy that can be induced by a defibrillation. Nonetheless, the following precautionary measures should be taken, if possible:
  — The set energy should not be higher than necessary for defibrillation.
  — The distance between the leads of the cardiac defibrillator and the leads of Reocor D should be at least 10 cm.
  — After a defibrillation, Reocor D must be switched off and then on again so that the device can perform a complete self-test.

  Additionally, after defibrillation the pacemaker function and pacing threshold must be checked and monitored for a sufficient period of time.

Interference resistance

- Reocor D is protected against interference due to electromagnetic radiation, electrostatic discharge and against transferred interference. The radiation emitted by Reocor D has also been minimized. Thus, the device meets the requirements of IEC 60601-1-2. However, it still is possible that strong electromagnetic fields which can occur (e.g., in the direct vicinity of electric motors, transformers, power lines, and other electric devices) may impair the function of Reocor D.

  Electromagnetic interference can lead to the following errors:
  — Unexpected reset (self-test is executed).
  — Cardiac events are sensed but do not appear on the ECG monitor.
  — Reocor D exhibits unexpected behavior.

Measures to restore proper function of Reocor D:
— Check the connection between device and temporary pacing leads and adjust, if necessary.
— Correctly adjust the sensitivity of the Reocor D: Often, the sensitivity safety margin is half the average intrinsic signal amplitude.
— Turn off all electric devices in the vicinity of Reocor D if they can cause electromagnetic interference and their operation is not absolutely necessary.
— Move the interference source to a location where the interference cannot have an affect on the Reocor D.
— If safe to do: Switch Reocor D off and then on again to reset the pacemaker to interference-free operation.
— If the technical failure persists, please contact BIOTRONIK.

- If the atrial sensitivity is set to a value less than 1 mV, interference from electromagnetic fields could result. Thus, if possible sensitivity values higher than 1 mV should be programmed. Programming sensitivity values to less than 1 mV requires explicit medical necessity. Values like this can only be set and retained with physician supervision.

Visual and Acoustic Signals

- During the self-test after switching on Reocor D, all LEDs light up and brief acoustic signals can be heard. The self-test is completed after a few seconds.
- If the self-test does not find any errors, the LEDs and warning signals turn off.
- When the self-test finds a defect, all LEDs flash continuously and warning signals sound.
- A required battery replacement is indicated by the flashing red Low battery LED.
- The Sense (green) LEDs signal sensing of a P wave or R wave.
- The Pace (yellow) LEDs signal pulse delivery.
- The LEDs and acoustic signals also provide the following warnings during operation:

Warning	Meaning	Error correction
Acoustic signal for 2 s	A pulse amplitude of < 1 V or a rate of > 180 ppm is programmed.	Check whether the set values are suitable for the patient.
Fast sequence of sounds	Impedance outside of the permissible range	Check whether all connectors are securely plugged in. Check whether the leads have the desired position.
Acoustic signal and flashing of the Pace and Sense LEDs	High rate protection has been triggered; self-test failed.	Turn the device off and return it to BIOTRONIK.
Low battery LED flashes.	ERI has been reached.	Replace the battery; about 36 hours[a)] of service time remain.

a) When using the battery type MN 1604 Duracell®, Procell®

Operating Notes

General Remarks

Caution! The connections of Reocor D and the temporary pacing leads must be secured and checked regularly.

Self-test After the device is switched on, Reocor D executes a self-test for a few seconds. This includes:

- Check of the program code and the microprocessor
- Memory test
- Function test of the LEDs and the acoustic signals
- Test of the pacing and sensing capability
- Test of the efficacy of high rate protection

When the self-test finds a defect, all LEDs flash continuously and acoustic warning signals sound. In this case, the pacemaker must be turned off and sent to BIOTRONIK.

If the self-test did not find any errors, Reocor D begins delivering pacing pulses in accordance with the programmed parameters. The negative electrode (cathode) should therefore only be connected when it has been ensured that the pacing mode, pacing rate, pulse amplitude and sensitivity have been programmed correctly.
Setting the rotary switch for the operating mode to OFF prevents pacing pulses from being delivered to the patient immediately after connecting the leads.

Warning messages

The following warnings can appear during use:

- A required battery replacement is indicated by the flashing Low battery LED.
- If the lead impedance is not within a permissible range (e.g. due to a fractured lead or a loose contact), a rapid sequence of sounds can be heard no earlier than 5 seconds after activation.
- If the pulse amplitude is set to values <1 V or the rate to values >180 ppm, an acoustic signal sounds for about 2 seconds.
- If the rate is too high (see page 38 "High rate protection") or if the self-test has not passed, an acoustic signal sounds and the Pace and Sense LEDs flash.

Operating Devices and LEDs

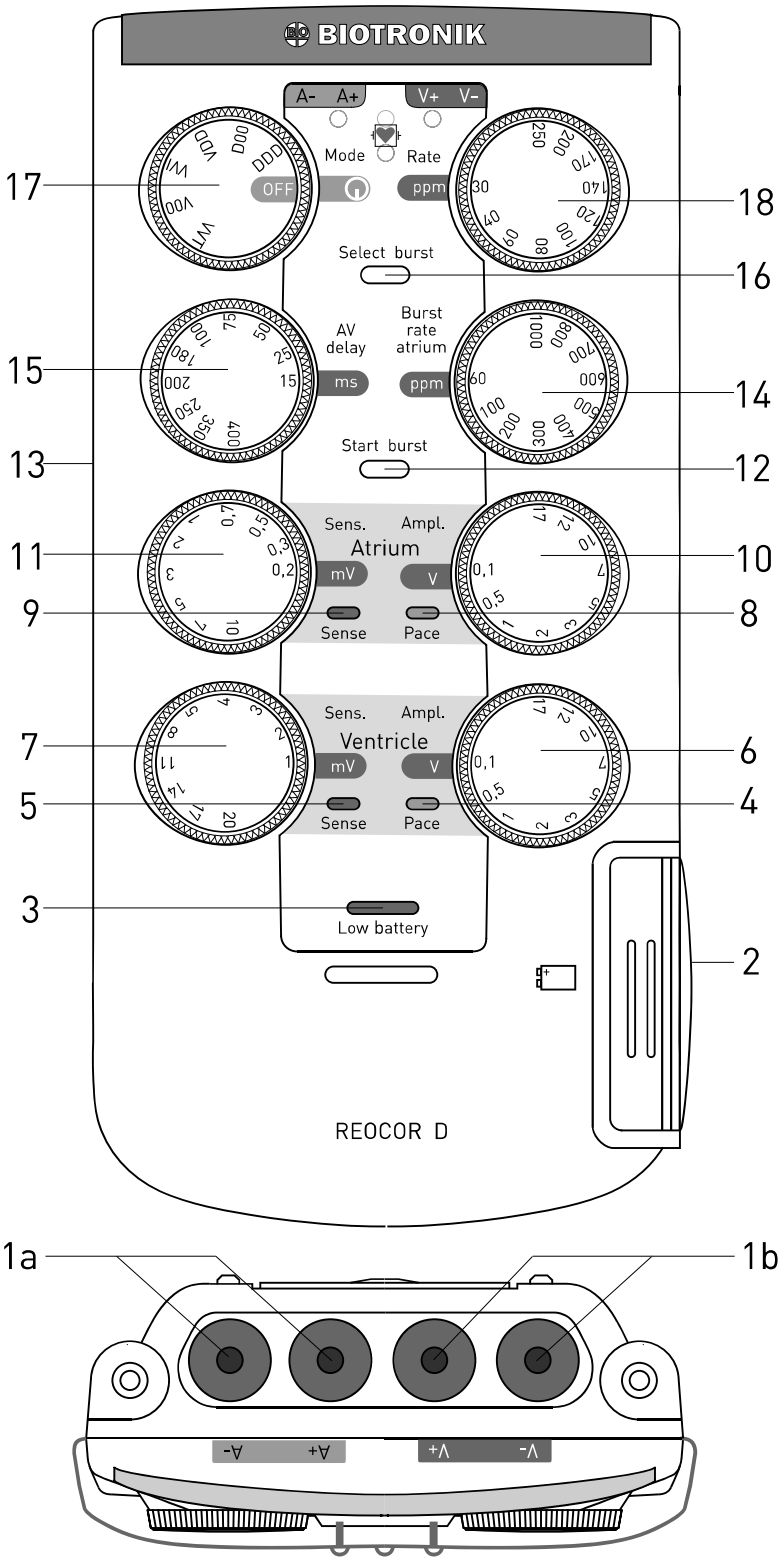


Figure 1: Reocor D operating panel

	Designation	Function
1a	Atrial channel connection	For cables and leads with 2-mm plugs or for Redel adapters (red = plus; blue = minus)
1b	Ventricular channel connection	
2	Battery compartment	For 9-V block battery
3	Low battery LED	Provides a warning when the battery voltage is too low
4	Ventricle Pace LED	Yellow display for ventricular stimulated event
5	Ventricle Sense LED	Green display for sensed R wave
6	Ventricle Ampl. control dial	Setting the ventricular pulse amplitude
7	Ventricle Sens. control dial	Setting the ventricular sensitivity (cannot be used in D00 and V00 operating modes)
8	Atrium Pace LED	Yellow display for atrial stimulated event
9	Atrium Sense LED	Green display for sensed P wave
10	Atrium Ampl. control dial	Setting the atrial pulse amplitude (cannot be used in VDD operating mode)
11	Atrium Sens. control dial	Setting the atrial sensitivity (cannot be used in D00 operating mode)
12	Start burst	Starts the atrial burst function
13	Velcro harness and hanger (on back)	Securing Reocor D to patient, bed or infusion stand
14	Burst rate atrium control dial	Setting the atrial burst rate
15	AV delay control dial	Setting the AV delay
16	Select burst	Selection of the atrial burst function
17	Mode dial	Selection of the pacing operating mode and off switch
18	Rate control dial	Setting the pacing rate

Table 1: Description of elements in Figure 1

Bold labels of the operating devices indicate safe values for the intended use of the device.

Protective Cover

The protective cover is locked when the cover has been pushed to the stop, passing two snap-in points and when the lever is resting on the rail (see Figure 2).

Correct: False:

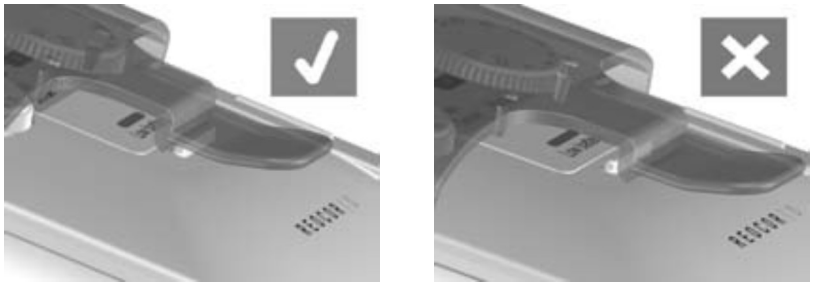


Figure 2: Correct positioning of the protective cover

To release the protective cover (see Figure 3):

Push the release lever up with one hand.

At the same time, use your other hand to slide down the protective cover.

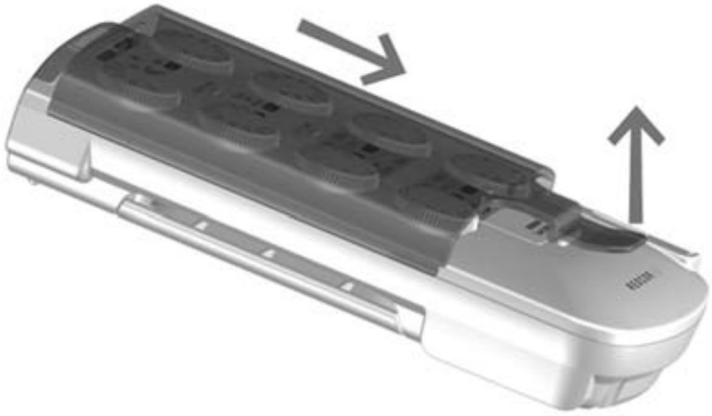


Figure 3: Unlocking the protective cover

To lock the protective cover:

Slide the protective cover upwards along the rail until it locks into place (see Figure 2).

The protective cover can be removed completely for cleaning. Push the cover all the way down to the stop and then remove it.

Caution! During use of Reocor D, the protective cover must be locked to prevent inadvertent resetting of the rotary switch and control dial, and thus of the programmed parameters.

Lead Connection

Reocor D has four connector ports for direct connection of leads with touch-proof 2-mm plugs.

To connect cables with Redel plugs, the Redel adapter must be fitted on the correct side and screwed in (Figure 4). The Redel adapter is attached to the correct side if it can be screwed on to the Reocor D.

Note: The function of the Redel adapter is only guaranteed if it is attached to the correct side!

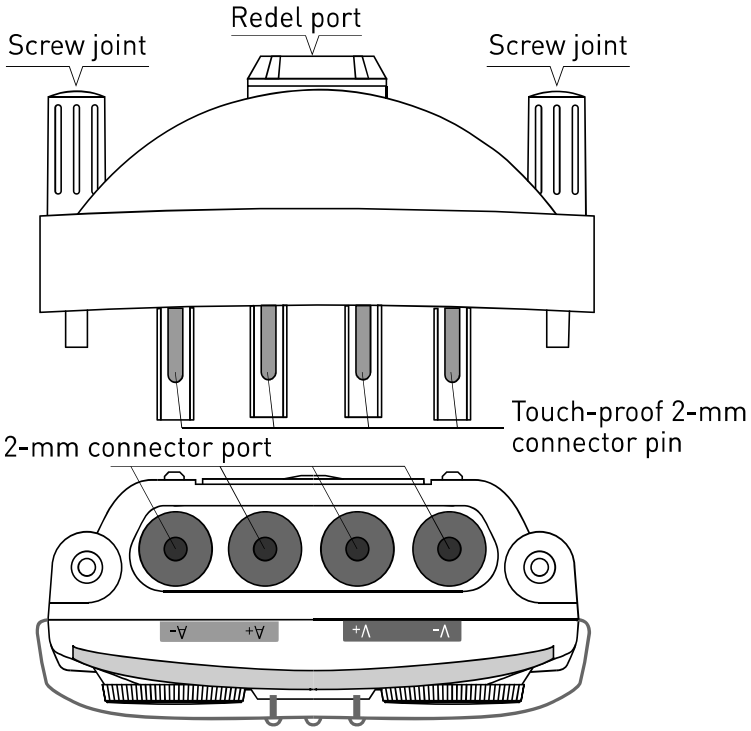


Figure 4: Redel adapter for Reocor D

Reocor D can be used with the following patient cables and adapters:

- **Patient cable PK-175** with four screw terminals for temporary leads on the patient side and Redel plug on the Reocor D side (use the Redel adapter)

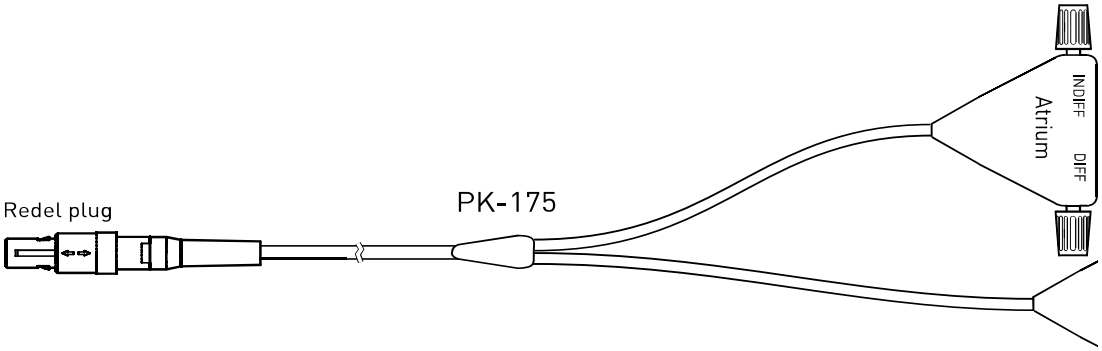


Figure 5: Patient cable PK-175

- **Patient cable PK-82** with two insulated alligator clips for temporary leads on the patient side and two touch-proof 2-mm plugs on the Reocor D side.

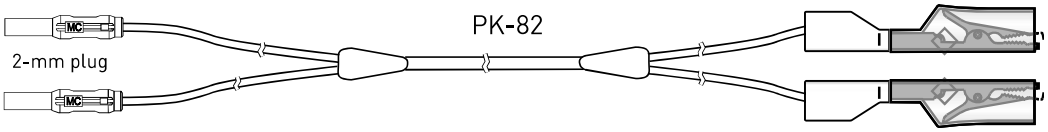


Figure 6: Patient cable PK-82

- **Patient cable PK-83-B** for single-chamber pacing with two screw terminals for temporary leads on the patient side and a Redel plug on the Reocor D side (use the Redel adapter). Temporary leads that are connected with the PK-83-B are connected to the ventricular channel of Reocor D.

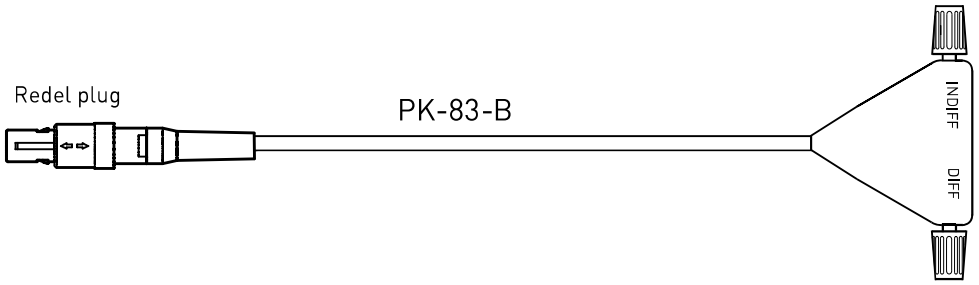


Figure 7: Patient cable PK-83-B

- **Patient cable PK-83** for single-chamber pacing with two insulated screw terminals for temporary leads on the patient side and two touch-proof 2-mm plugs on the Reocor D side.

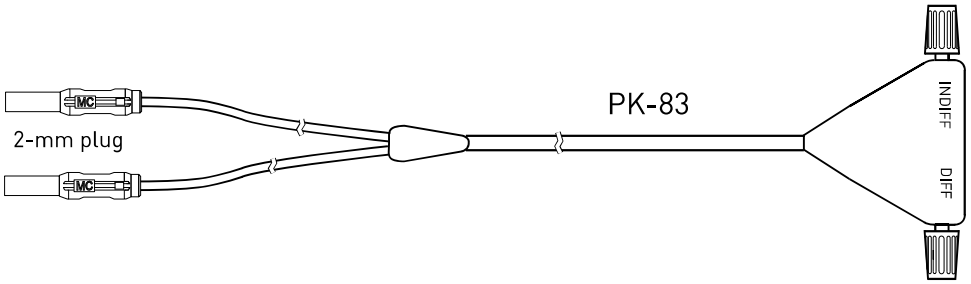


Figure 8: Patient cable PK-83

- **Patient cable PK-67-L, PK-67-S** differ only in length.

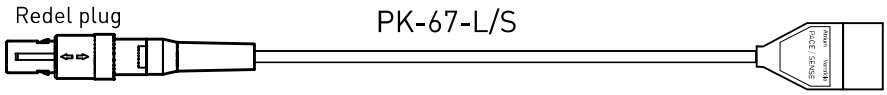


Figure 9: Patient cable PK-67-L (2.6 m) and PK-67-S (0.8 m)

- **Adapters**

The adapters from Figure 10 fit the patient cables PK-67 L/S (Figure 9):

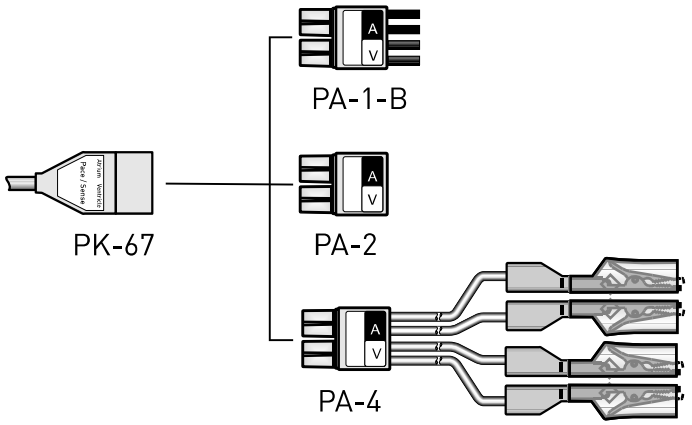


Figure 10: Adapters for the patient cables PK-67-L and PK-67-S

PA-1-B for the connection of touch-proof 2-mm plugs or MHW adapters (adapters for heart wires)

PA-2 IS-1

PA-4 with alligator clips

- **Patient cable PK-141** with four alligator clips on the patient side and Redel plug on the Reocor D side (use the Redel adapter).

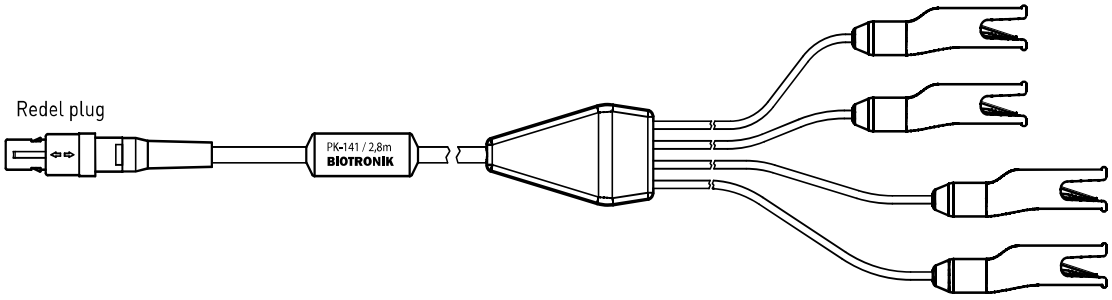


Figure 11: Patient cable PK-141

- **Adapter cable ADAP-2R** is a reusable cable to connect the single-use cables according to Figure 13 (for USA only) to Reocor D (use the Redel adapter).

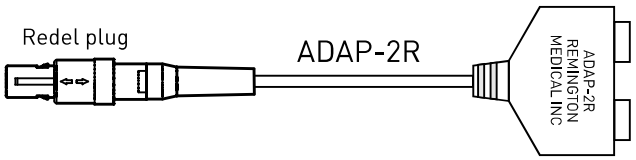


Figure 12: Adapter cable ADAP-2R

- **Cable for single use (USA only)**

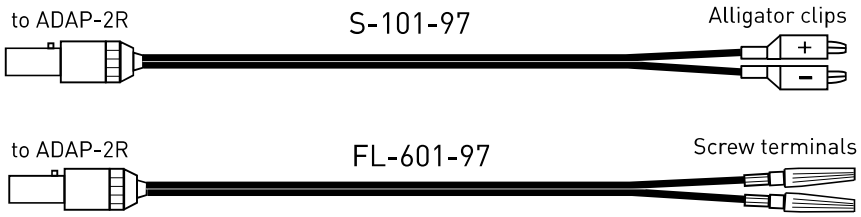


Figure 13: Single-use cable by Remington Medical Inc. (USA only)

- **Cable for single use**

The single-use cables PK-155 and Remington 301-CG (USA only) with alligator clips (Figure 14) are connected to the patient through the cable PK-67-S.

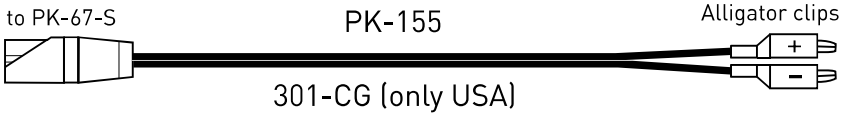


Figure 14: Cable PK-155

Connection

WARNING! Danger to patient by damaged cables.
Damaged cables are limited in functionality and pose a danger to patients. Do not use damaged cables.

WARNING! Danger from loss of function.
Damp cables have limited functionality and pose a danger to patients. Do not use damp cables.

WARNING! Danger from electrical currents.
Unused cable contacts can conduct electrical currents to patients. Adhere unused cable contacts close to the patient.

Caution! Allergic reactions and inflammations.
Prevent the cable from coming into contact with the patient's wounds or skin.

Note: Ensure correct fitting of the insulators prior to using the cables.

Note: Do not connect the patient cable to the temporary pacing lead of the patient before the connection has been established to the Reocor D.

Direct connection

If Reocor D is used without the Redel adapter, temporary catheters and heart wires can be connected to the patient cables PK-82 and PK-83 directly at the connector ports A+, A- and V+, V-.

Patient cable

The patient cable is connected via a Redel adapter to the Reocor D.

Fit the Redel adapter to Reocor D.

Screw the adapter in tight.

Insert the Redel plug of the patient cable into the Redel port of the adapter.

Note: No dual-chamber pacing is possible with the patient cable PK-83-B. Leads that are connected with the PK-83-B are connected to the ventricular channel of Reocor D.

Connection Variants

Temporary catheters with 2-mm plugs or heart wire with 2-mm adapter

You have the option to connect Reocor D directly to a temporary catheter with touch-proof 2-mm plug or to a heart wire with 2-mm adapter, without any other cables or adapters. All other options are listed in the following table.

Connection: patient-side	BIOTRONIK cable	Connection device-side	Reocor D connection
Recommended connections			
Direct connection (without BIOTRONIK cables)			2-mm connector port
2 mm	PK-67-S/L with PA-1-B	Redel plug	Redel adapter
Screw terminals	PK-175 with TC Adapt	Redel plug	Redel adapter
Screw terminals	PK-83 with TC Adapt (2x)	2-mm plug	2-mm connector port
Possible connections			
Alligator clips	PK-141	Redel plug	Redel adapter
Alligator clips	PK-67-S/L with PA-4	Redel plug	Redel adapter
Alligator clips	PK-67-S/L with PK-155 (2x)	Redel plug	Redel adapter
Alligator clips	PK-82 (2x)	2-mm plug	2-mm connector port

Heart wire with break-off needle or with flexible end (max. 2.3 mm in diameter)

Connection: patient-side	BIOTRONIK cable	Connection device-side	Reocor D connection
Recommended connections			
Screw terminals	PK-175	Redel plug	Redel adapter
Screw terminals	PK-83 (2x)	2-mm plug	2-mm connector port
Possible connections			
Alligator clips	PK-141	Redel plug	Redel adapter
Alligator clips	PK-67-S/L with PA-4	Redel plug	Redel adapter
Alligator clips	PK-67-S/L with PK-155 (2x)	Redel plug	Redel adapter
Alligator clips	PK-82 (2x)	2-mm plug	2-mm connector port

Implanted lead with IS-1 connector

Connection: patient-side	BIOTRONIK cable	Connection device-side	Reocor D connection
Recommended connections			
IS-1 connector port	PK-67-S/L with PA-2	Redel plug	Redel adapter
Possible connections			
Alligator clips	PK-141	Redel plug	Redel adapter
Alligator clips	PK-67-S/L with PA-4	Redel plug	Redel adapter
Alligator clips	PK-67-S/L with PK-155 (2x)	Redel plug	Redel adapter
Alligator clips	PK-82 (2x)	2-mm plug	2-mm connector port

Polarity

Reocor D principally paces in bipolar mode, but it can be used with bipolar or unipolar temporary pacing leads.

If unipolar leads are used, two leads must be connected for each chamber.

Separating connections

Disconnect patient cables from the temporary pacing leads of the patient or disengage the direct connection.

Separating Redel plug

- Retract the retaining ring at the Redel plug and pull the Redel plug off the Redel port.

Start Up

The operation of Reocor D is identical for all operating modes. The operating steps should be carried out in the following order (the numbers in parentheses refer to Figure 1 on page 14).

- Insert battery.
- Push protective cover down.
- Prepare patient: Place the leads but do not connect them to the pacemaker yet.

- Prepare Reocor D:

  Set the pacing rate with the Rate control dial (18).

  Set the AV delay with the AV delay control dial (15)[1].

  Set the pacing amplitudes for atrium[1] and ventricle with the Atrium Ampl. (10)[1] and Ventricle Ampl. (6) control dials.

- Select the pacing mode with the dial Mode (17). The device will be activated at the same time.
- After the internal self-test has been completed successfully, all 5 LEDs on the operating panel will simultaneously flash twice.
- If the Low battery LED (3) flashes, the battery needs to be exchanged (for battery exchange, see page 25).
- Connect leads, the yellow Atrium Pace (8)[1] and Ventricle Pace (4) LEDs will flash in synchrony with the atrial and ventricular pacing pulses.
- Set the sensitivity for atrium and ventricle with the Atrium Sens. (11)[1] and Ventricle Sens. control dials (7) such that the green Atrium Sense (9)[1] and Ventricle Sense (5) LEDs flash in synchrony with each sensed atrial or ventricular event.

  A sufficient safety margin should be considered to ensure reliable sensing.

- Monitor the ECG of the patient and adjust amplitude and/or sensitivity, if necessary.

Caution! During use of Reocor D, the heart rate of the patient must be monitored with an ECG monitor with an alarm function.

1 Only for 2-chamber pacing

Attachment

Reocor D must be operated either horizontally on a non-slip surface or affixed to the patient with an armband, or from a hanging position on the infusion stand using the hanger on the back of the device.

To attach Reocor D to an infusion stand, unscrew the hanger from the back of the device. This ensures safe operation and unburdens the patient cables.

Battery Exchange

When the Low battery LED (3) starts flashing, it indicates that the battery is almost depleted. When using the battery type MN 1604 Duracell® Procell® approximately 36 hours of service time remain. However, the battery should be replaced as soon as possible.

Reocor D must be operated with a 9-V battery, international code IEC 6LR61. Only alkaline manganese batteries should be used. When using the battery type MN 1604 Duracell® Procell®, external pacing is possible for at least 500 hours at 20 ± 2°C before the battery must be replaced.
It is possible to exchange a battery while Reocor D is in use. The device remains ready for use for at least 30 s at the ambient temperature (20 ± 2°C) when the battery is removed.

For safety reasons, the patient should be paced by another source during the battery replacement.

Do not use rechargeable batteries. The service time of these batteries is difficult to estimate, making it possible to inadvertently exceed the ERI, resulting in a sudden loss of pacing.

The battery compartment (2) is located on the right side of the device, and can be opened by pushing the blue slider upwards and pulling out the drawer towards the right. Remove the battery carefully.

To protect the battery poles, a rubber plug can be put on the new battery. Remove it before you insert the new battery.

Caution! The preferred pole orientation is marked in the battery compartment. When inserting the new battery you only need to ensure that the battery poles point to the middle of the housing. The position of the plus and minus pole can be selected freely.

Insert the new battery with the bottom (Figure 15) down first into the battery compartment.

Figure 15: Inserting the battery

Close the drawer and press the blue slider down until it snaps in place with an audible click.

Note: If the pacemaker is stored or will not be used for a long period of time, it is recommended to remove the battery to prevent damage due to leakage.

Pacing Modes and Parameters

Pacing Modes

Reocor D operates in one of the following six pacing modes:

DDD	Synchronous A-V pacing with sensing and pacing in the atrium as well as in the ventricle.
VDD	Synchronous, ventricular pacing with atrial tracking.
D00	Asynchronous A-V pacing, no sensing in both chambers.
VVI	Sensing and pacing in the ventricle
V00	Asynchronous pacing in the ventricle
VVT	Like VVI, but immediate pulse delivery upon sensing of a ventricular event outside the refractory period

In case of disturbances caused by electromagnetic interference (EMI), Reocor D will select asynchronous pacing when certain limits are exceeded. Depending on whether the interference is sensed in the atrium or in the ventricle, the following operating modes will result for the duration of the interference:

Undisturbed operating mode	Interference by EMI
SSI, SST	S00
VDD	VAT, VVI, V00
DDD	DAD, DVI, D00

Refractory Periods

The rate up to which the ventricles are paced synchronous to atrially sensed events (upper rate) is determined by the atrial refractory period (ARP). The temporal sequence is started by atrially sensed and paced events, as well as by premature ventricular contractions, which reset the timing cycle. If the upper rate is exceeded, every second atrial pulse will fall into the ARP, will not be sensed, and will not trigger a ventricular pulse. The ventricular pacing rate will continue at a ratio of 2:1. (Figure16).

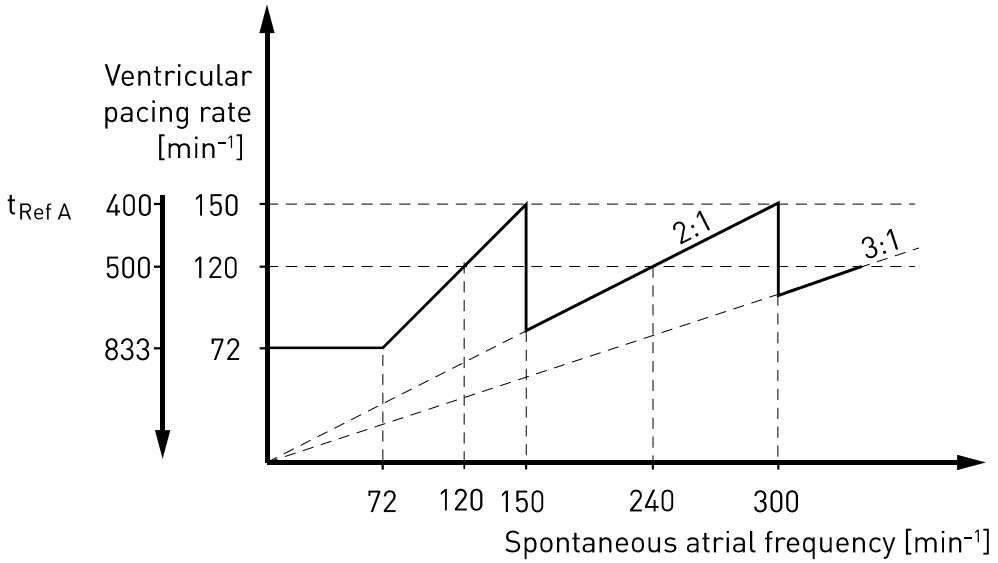


Figure 16: Reaction of the upper tracking rate during atrial tachycardia (basic rate 72 ppm).

The total atrial refractory period (TARP) of Reocor D is calculated by the sum of 175 ms and the programmed AV delay; however, its minimum value is 400 ms below a pacing rate of 120 ppm. Above this rate, the minimum TARP is reduced to 240 ms.
The ventricular refractory period VRP of Reocor D depends on the pacing rate:

Pacing rate	Refractory period VRP
Under 150 ppm	225 ms
150 ppm to 200 ppm	200 ms
Over 200 ppm	175 ms

Rate

The rate can be continuously adjusted from 30 ppm to 250 ppm with the Rate control dial (18). If a value greater than 180 ppm is set, the device will sound a warning signal for two seconds.

WARNING! Pacing the heart with rates higher than 180 ppm over a long time period can cause severe hemodynamic complications. Pacing with high rates should only be performed when continuous monitoring is ensured.

AV Delay

The AV delay can be continuously adjusted from 15 ms to 400 ms with the AV delay control dial (15). Short AV delays may be selected for special indications, e.g., in case of recurring tachycardia.

Reocor D limits the AV delay upwards to half the basic rate interval.

Pulse Amplitude – Atrium/Ventricle

The pulse amplitudes for the atrium and ventricle can be adjusted with the Ampl. control dials (10), (6) within a range from 0.1 V to 17 V. If a value less than 1 V is set, the device will sound a warning signal for two seconds.

The pulse width is 1 ms.

Pacing should be checked regularly to ensure that pacing takes place and that a sufficient safety margin has been set.

Sensitivity – Atrium

The sensitivity can be adjusted with the Atrium Sens. control dial (11) between 0.2 mV and 10 mV. It should be checked regularly to ensure that correct sensing takes place and that a sufficient safety margin has been set.

Sensitivity – Ventricle

The sensitivity can be adjusted with the Ventricle Sens. control dial (7) between 1 mV and 20 mV. The sensitivity should be checked regularly to ensure that correct sensing takes place and that a sufficient safety margin has been set.

Cross Channel Blanking

After a stimulus has been delivered, sensing is suppressed for 110 ms in the opposite channel to prevent far-field sensing.

Interference interval

The interference interval is started by both atrial and ventricular paced and sensed events.

The interval is reset by noise sensed in any channel during the interval length of 80 ms, leading to asynchronous pacing at the programmed rate while the interference lasts.

For instance, in the operation mode DDD, an atrial interference that does not affect the ventricular channel leads to DVI pacing. Sensing of noise in the ventricular channel leads to DAD pacing.

Interference in both channels results in D00 pacing.

Burst

The rate of the Burst rate atrium function can be selected with the control dial (14) between 60 ppm and 1000 ppm.

This function is activated with two key buttons: First the Select burst key button (16) must be pressed and then, within two seconds, the Start burst key button (12). The pulse delivery then lasts as long as the Start burst key button is pressed. During this activation, the ventricular channel will continue to pace at the programmed rate, (which can be adjusted during this process). If an inhibiting operating mode has been programmed, pacing will be inhibited in the ventricle.

WARNING! After a burst stimulation in the atrium, the ventricular blanking interval can prevent sensing of intrinsic signals and lead to asynchronous pacing in the ventricle.

Pacing the heart with rates higher than 180 ppm over a long time period can cause severe hemodynamic complications. Pacing at high rates should only be performed when continuous monitoring is ensured.

The mode for high-frequency pacing is used to terminate certain supraventricular tachycardias (SVT) and should only be considered for atrial applications. The application of asynchronous high-frequency stimuli can interrupt an SVT by depolarizing portions of a reentry path. When an ectopic atrial focus is responsible for an SVT, the application of high-frequency stimuli in the atrium can also lead to increased suppression of the ectopic center.

Various risks have to be considered in association with high-frequency atrial pacing. The risks include possible ventricular pacing and ventricular tachycardia or fibrillation. This can be caused by poor placement of the leads or the presence of anomalous stimulus conduction paths that circumvent the normal atrioventricular stimulus conduction (e.g. Wolff-Parkinson-White Syndrome). Patient discomfort and asystole after high-frequency pacing are other possible problems.

Handling, Care and Maintenance

Reocor D

Reocor D is a highly developed precision device that must be treated with care. Mechanical impact, e.g. by dropping the device, can impair its function.

Please return the device to BIOTRONIK in case of damage or impaired function.

Prior to use, the pacemaker should be stored at least two hours under the ambient conditions specified for operation (see page 39).

Housing, operating devices, connections, and patient cables must be visually inspected for mechanical damage, deformation, loose parts, cracks, and dirt before each use.

WARNING! Never use a damaged device or a device that exhibits abnormal behavior; especially if it has been dropped or could have been damaged by high-frequency or defibrillation voltage.

Secure Reocor D either horizontally on a non-slip surface or on the patient with an armband, or operate it from a hanging position on the infusion stand using the hanger on the back of the device.

Caution! If an armband is used, Reocor D must not be worn directly on the skin.

Cleaning A moist cloth and, if necessary, mild soap can be used to clean Reocor D. Strong cleaning agents or organic solvents (such as ether or gasoline) should be avoided, as these can corrode the plastic housing.

Disinfection For disinfection, wipe the device with a cloth soaked with a disinfectant solution (e.g. Aerodesin 2000 or Lysoform D). When mixing the solution, follow the dilution measure stated by the manufacturer.

Note: After cleaning or disinfection, Reocor D must not be used for one hour.

Sterilization Reocor D cannot be sterilized. If the device needs to be used in a sterile environment, it can be packed into a sterile cover.

Annual checks of the device by manufacturer-authorized technicians are recommended.

Caution! Even though Reocor D is protected from dripping water, the device should be kept clean and dry.

Reusable Patient Cables

Prior to opening, the package of a sterile cable must be inspected for damage to determine whether sterility has been compromised.

Cleaning The reusable patient cables can be cleaned and disinfected with hospital cleaning agents following many different methods. However, aggressive chemicals (such as acetone) may never be used.

The use of a wiping cloth with regular, alcohol-free hand soap or the cleaning agent Stabimed by Braun is the recommended cleaning method for the cables. Subsequently, the cables must be cleaned from cleaning agent residue with electrolyte-free water and then wiped with a clean, dry cloth.

Disinfection For disinfection in a disinfectant bath, an aldehyde-based (e.g. Lysoformin 3000) or alcohol-based (e. g. Aerodesin 2000) disinfectant agent must be used in accordance with the manufacturer information and in accordance to the respective hospital guidelines.

After disinfection, the cable must be cleaned from residues of the disinfectant by rinsing it in electrolyte-free water.

Sterilization A steam sterilization can be carried out at 121°C and 1.1 bar for 20 min.

Maintenance, Service, Inspections

The only required maintenance action is the replacement of the battery (see page 25).

No other maintenance work is required.

Test before use

A short test should be performed prior to each use of the device. It consists of a visual inspection and a simple function test.

Visual inspection:

- Inspect the housing for mechanical damage, deformation, loose parts, cracks, etc.
- Inspect the cable connection area for mechanical damage.
- Inspect the labeling for legibility.

Function test:

The result of the self-test that runs automatically after activation must be heeded.

Inspection

Inspections should be performed:

- after an application together with high-frequency surgical instruments or defibrillators,
- when malfunctions are suspected,
- once a year.

The inspection should follow the manufacturer specifications. These are made available upon request. The specification lists all required test steps and the necessary equipment.

Disposal

Reocor D is marked with the symbol of a crossed-out garbage can on its type plate. The symbol indicates that the European guideline 2002/96/EC on waste electrical and electronic equipment (WEEE directive) applies to the disposal method of the device.

Old devices and accessories that are no longer needed, such as patient cables and adapters, should be returned to BIOTRONIK. This ensures that proper disposal will be carried out in accordance with the national implementations of the WEEE directive.

Note: Cables to be disposed of due to contact with blood must be disposed of as medical waste, in accordance with environmental regulations. Non-contaminated cables must be disposed of in accordance with the European Directive 2002/96/EC regarding waste electrical and electronic equipment (WEEE).

Depleted batteries must be treated as hazardous waste and disposed of by the user.

If you have any questions, please contact BIOTRONIK.

Technical Safety

The external pacemaker Reocor D meets the international standards for the safety of electro-medical devices according to IEC 60601-1 and IEC 60601-1-2, as well as the international standard IEC 60601-2-31 for temporary, external pacemakers.

The following special features offer safety for the patient:

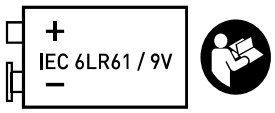
- No metal parts that can be touched, according to the definition of the IEC.
- The design meets the standard for the device class CF (cardiac floating) and is approved for direct treatment of the heart. The pacemaker complies with the requirements for defibrillation protection stipulated in the international standards.
- The closed protective cover protects the pacemaker against dripping water.

WARNING! The temporary leads that are connected to Reocor D represent a low-impedance conductor to the myocardium for electric current. Therefore line-powered devices that are operated in the patient's vicinity must be grounded in accordance with established guidelines.

The pacemaker must not be used in areas at risk for explosion.

All additional maintenance work and repairs should only be performed by BIOTRONIK.

Technical Data

Symbols	
	Follow the instructions for use in the technical manual.
	Indication of the placement of the battery in the compartment
	Disposal according to the WEEE directive
	Classification: CF (cardiac floating) applied part, defibrillation protected
IP31	Water-repellent, protection degree IP31
OFF	Off (on the Mode dial)

Adjustable parameters		
Pacing modes	DDD, D00, VDD, VVI, V00, VVT	
Basic rate	(30 ... 250 ppm) ± 1 ppm	At a rate of > 180 ppm a warning tone is emitted
Pulse amplitude (A, V)	0.1 ... 17 V ± max. (50 mV, 10%)	At a pulse amplitude of < 1 V a warning tone is emitted
Sensitivity (A)	0.2 ... 10 mV ± 15%	With respect to 15 ms $\sin^2$ pulse
Sensitivity (V)	1 ... 20 mV ± 15%	With respect to 40 ms $\sin^2$ pulse
AV delay	(15 ... 400 ms) ± 4 ms	
Burst rate (A)	(60 ... 1000 ppm) ± 20 ppm	

Fixed parameters		
Pulse width	1 ms ± 5%	
Auto short after pace	< 20 ms ± 10%	
Interference interval	80 ms ± 5 ms	
In channel blanking	110 ms ± 3 ms	
Cross channel blanking	19 ms ± 3 ms	

Fixed parameters		
Total atrial refractory period (TARP)	AVD + 175 ms ± 5 ms	
TARP minimum **for (30 ... 120) ppm** **for (121 ... 250) ppm**	 400 ms ± 5 ms 240 ms ± 5 ms	
Refractory period (V) **(30 ... 150) ppm** **(151 ... 200) ppm** **(201 ... 250) ppm**	 225 ms ± 5 ms 200 ms ± 5 ms 175 ms ± 5 ms	
Upper rate	260 ppm ± 10%	
High rate protection **1 ... 180 ppm** **181 ... 250 ppm**	 286 ms ± 10% 214 ms ± 10%	 286 ms = 210 ppm, does not apply for Burst 214 ms = 280 ppm, does not apply for Burst
Pulse waveform	Asymmetric, biphasic	

Lead impedance monitoring	
Acoustic warning	Above 2000 Ω ± 15%, at 5 V amplitude
Lead connection	Touch-proof 2-mm connector ports; Redel port, 6-pin via Redel adapter

Electrical data/battery	
Battery	• Alkaline-manganese type: IEC 6LR61 / ANSI 1604A • 9 V leak-proof • E.g. MN1604 Duracell® Procell®[a]
Polarity	Cathodic
Inverse-polarity protection	None: Polarity is irrelevant
Power consumption	Typically 1 mA (70 ppm, 5.0 V, 500 Ω)
Service time with new battery[b]	• 500 h (-10%) at 20°C (±2°C) • At: 70 ppm, 5 V, mode DDD, 500 ohm • Until: ERI signal (EOS warning)
End of service (EOS)	Flashing "Low battery" LED
Remaining service time after ERI signal[b]	• 36 hours • At: 70 ppm, 5 V, mode DDD, 500 ohm
Behavior during battery exchange	• Device remains ready for use for at least 30 s when the battery is removed. • The set Mode is retained.

a) Registered trademark of Duracell Inc., Bethel, CT 06801
b) When using the battery type MN 1604 Duracell® , Procell®

Ambient conditions	
Temperature range for operation	+10°C ... +40°C
Temperature range for storage	0°C ... +50°C
Relative humidity	30% ... 75%, non-condensing
Atmospheric pressure	700 hPa ... 1060 hPa
Noise level	50 dB

Dimensions, weight, material	
Reocor D dimensions	160 mm x 75 mm x 35 mm (without Redel adapter)
Reocor D weight	With battery, with Redel adapter: 325 g ± 10%
	Without battery, with Redel adapter: 280 g ± 10%
	Without battery, without Redel adapter: 240 g ± 10%
Dimensions of the Redel adapter for Reocor D	76 mm x 35.5 mm x 29.4 mm
Weight of Redel adapter for Reocor D	40 g ± 10%
Housing material	Babyblend FR 3000 (PC-ABS)

Classification	
Applied part classification	CF (cardiac floating), defibrillation protected
Safety class	II b
Protection degree	IP31 (water-repellent)
Defibrillation-proof level	5 kV
Operating mode	Continuous operation

Estimated service life[a)] (according to EN 60601-1:2007, 4.4)	12 years

a) The service life describes the expected maximum operating life time of the device after distribution. The expected maximum operating life time is not supported by any test data.

Conformity According to IEC 60601-1-2

Manufacturer guidelines and declaration – electromagnetic radiation (IEC 60601-1-2: Table 1)

The device is intended for use in an electromagnetic environment as described below. The user should make sure that the device is used in such an environment.

Emissions test	Compliance level	Guidelines for the electromagnetic environment
HF emission according to CISPR 11	Group 1	The device uses HF energy exclusively for its own function. Therefore, the high-frequency interference is very low and not likely to cause any interference in nearby electronic equipment.
HF emission according to CISPR 11	Class B	The device is suitable for use in all areas, excluding residential areas and buildings that are connected directly to the public power supply.
Emission of harmonic oscillations according to IEC 61000-3-2	Not applicable	
Voltage fluctuations according to IEC 61000-3-3	Not applicable	

Manufacturer guidelines and declaration – resistance to electromagnetic interference (IEC 60601-1-2: Table 2)

The device is intended for use in an electromagnetic environment as described below. The user of the device should make sure that it is used in such an environment.

Checking the resistance to interference	Test level according to IEC 60601	Compliance level	Guidelines for the electromagnetic environment
Electrostatic discharge (ESD) according to IEC 61000-4-2	±6 kV contact discharge ±8 kV air discharge	±6 kV contact discharge ±15 kV air discharge	Floors should be made of wood, cement or ceramic tiles. When the floor consists of a synthetic material, the relative humidity must be at least 30%.
Fast transient electric interference/ bursts according to IEC 61000-4-4	Not applicable		
Surges voltages (surges) according to IEC 61000-4-5	Not applicable		
Voltage drops, brief interruptions and fluctuations in the supply voltage according to IEC 61000-4-11	Not applicable		
Magnetic field at the supply frequencies (50/60 Hz) according to IEC 61000-4-8	3 A/m	30 A/m	The magnetic field strength should correspond to the typical value in business and hospital environments.

Manufacturer guidelines and declaration – resistance to electromagnetic interference for all external pacemaker models (IEC 60601-1-2: Table 3)

The device is intended for use in an electromagnetic environment as described below. The user of the device should make sure that it is used in such an environment.

Checking the resistance to interference	Test level according to IEC 60601	Compliance level	Guidelines for the electromagnetic environment
			Portable and mobile radio devices are not used closer to any part of the device, including cables, than the recommended safe distance.
			Recommended safe distance:
Conducted HF interferences according to IEC 61000-4-6	10 V_{rms} 10 kHz to 80 MHz outside of the ISM bands[a]	10 V_{rms}	$d = 0.35 \sqrt{P}$
	10 V_{rms} 10 kHz to 80 MHz inside of the ISM bands[a)]	10 V_{rms}	$d = 1.2 \sqrt{P}$
Radiated HF interference according to IEC 61000-4-3	10 V/m 800 MHz to 2.5 GHz	10 V/m	$d = 1.2 \sqrt{P}$ for 80 MHz to 800 MHz
			$d = 2.3 \sqrt{P}$ for 800 MHz to 2.5 GHz

Checking the resistance to interference	Test level according to IEC 60601	Compliance level	Guidelines for the electromagnetic environment
			P is the maximum rated power of the transmitter in watts [W] according to the information from the transmitter manufacturer and d is the recommended safe distance in meters [m][b]. The field strength of stationary transmitting devices must be measured on site[c] and must be lower than the compliance level at all frequencies[d]. Interference can occur in devices that have the following warning sign. 
COMMENT: These guidelines do not necessarily apply in all situations. The spread of electromagnetic waves is influenced by absorption and reflection from buildings, objects, and humans.			

a) The ISM bands (for industrial, scientific and medical applications) between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz and 40.66 MHz to 40.70 MHz.

b) The compliance level in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz is designed to reduce the likelihood that mobile communication devices cause interference if they are unintentionally brought into the patient area. For this reason a greater safety distance is recommended in these frequency ranges (factor 1.2 instead of 0.35).

c) The field strengths of stationary transmitters, such as base stations for cellular phones and land mobile radios, amateur radio stations and radio and TV broadcasts cannot be predicted with accuracy. To assess the electromagnetic environment by fixed HF transmitters, a study of the location should be considered. If the measured field strength exceeds the HF compliance level at the location where the device is used, the device must be observed to ensure correct functioning. Additional measures may be necessary, such as re-orienting or relocating the external pacemaker.

d) In the frequency range of 150 kHz to 80 MHz the field strengths should be less than 10 V/m.

Recommended safe distances to portable and mobile RF communications equipment (IEC 60601-1-2: Table 5)

The device is intended for use in an electromagnetic environment, in which the RF interference is controllable. The user of the device can help to prevent electromagnetic interference by maintaining the safe distance to mobile RF communication equipment (transmitters) – depending on the power output of the communication equipment.

Rated power of the transmitter P [W]	**Safe distance d [m] corresponding to transmission frequency**			
	150 kHz to 80 MHz outside the ISM bands	150 kHz to 80 MHz inside the ISM bands	80 MHz to 800 MHz	800 MHz to 2.5 GHz
	$d = 0.35 \sqrt{P}$	$d = 1.2 \sqrt{P}$	$d = 1.2 \sqrt{P}$	$d = 2.3 \sqrt{P}$
0.01	0.04	0.12	0.12	0.23
0.10	0.11	0.38	0.38	0.73
1.00	0.35	1.20	1.20	2.30
10.00	1.11	3.79	3.79	7.27
100.00	3.50	12.00	12.00	23.00

For transmitters whose rated power is not specified in the table above, the safe distance can be calculated using the specified formula for the corresponding frequency. Here P is the rated power of the transmitter in watts [W] and d is the safe distance in meters [m].

COMMENT 1: The ISM bands (for industrial, scientific and medical applications) between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz and 40.66 MHz to 40.70 MHz.

COMMENT 2: The compliance level in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz is designed to reduce the likelihood that mobile communication devices cause interference if they are unintentionally brought into the patient area. For this reason a greater safety distance is recommended in these frequency ranges (factor 1.2 instead of 0.35).

COMMENT 3: These guidelines do not necessarily apply in all situations. The spread of electromagnetic waves is influenced by absorption and reflection from buildings, objects, and humans.

Scope of Delivery and Accessories

Note: Reocor D may only be used with the accessories developed and tested for this pacemaker.

Scope of delivery

Item description	Number of	Comments	Order no.
Reocor D	1		365529
Battery	1	Duracell Plus, 6LR61	–
Armband			
– For Japan	1	Short	391843
– For all other countries	1	Standard	103704
Redel adapter	1		371262
Protective cover	1		378007
Technical manual	1		394271
Technical manual ZH			368702
Quick Reference Guide DE			370123
Quick Reference Guide EN	1		371300
Quick Reference Guide ES			371301
Quick Reference Guide FR			371302
Quick Reference Guide IT			371303
Quick Reference Guide PT			372230
Quick Reference Guide ZH			371304
Case	1		379384

Accessories

Item	Order no.	Description	Connection
PK-82	128564	Patient cable with two insulated alligator clips, can be resterilized	Direct connection
PK-83 (2.5 m)	128563	Patient cable with two insulated screw terminals, can be resterilized	Direct connection
PK-83 (1.5 m)	128562	Patient cable with two insulated screw terminals, can be resterilized	Direct connection
PK-83-B (2.5 m)	347485	Patient cable with two insulated 2.3 mm screw terminals	Redel adapter
PK-83-B (1.5 m)	347606	Patient cable with two insulated 2.3 mm screw terminals	Redel adapter
PK-175	333959	Patient cable, with four screw terminals for connection of temporary leads, can be resterilized	Redel adapter

Item	Order no.	Description	Connection
PK-67-L	123672	Patient cable, can be resterilized, for combination with adapter PA-1-B, PA-2, PA-4	Redel adapter
PK-67-S	128085	Patient cable, can be resterilized, for combination with PK-155 and Remington model 301-CG	Redel adapter
PK-141 (2.8 m)	353181	Patient cable, can be resterilized, with four touch-proof alligator clips	Redel adapter
Reocor armband, standard	103704	Standard armband	–
Reocor armband, short	391843	Smaller-sized armband. Suitable for small arms.	–

Only for the USA

Item	Manufac-turer	Description	Connection
ADAP-2R (0.24 m)	Remington Medical Inc.	Reusable adapter for cable model S-101-97 and model FL-601-97	Redel adapter

Adapters for PK-67-S and PK-67-L

Item	Order no.	Description
PA-1-B	123751	For connection to 2-mm adapter or MHW adapter (adapter for heart wires), can be resterilized
PA-1-C	349723	For connection to 2-mm adapter or MHW adapter (adapter for heart wires), can be resterilized
PA-2	123157	For connection to IS-1 connector, can be resterilized
PA-4	123090	With alligator clips, can be resterilized
PK-155 (set with two cables)	337358	Sterile patient cable, 2-wire with alligator clips for single use

Adapters for PK-67-S and PK-67-L (USA only)

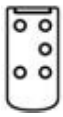
Item	Manufacturer	Description
Model 301-CG	Remington Medical Inc.	Sterile patient cable, 2-wire with alligator clips for single use

Adapters for ADAP-2R (USA only)

Item	Manufacturer	Description
Model 301-CG	Remington Medical Inc.	Sterile patient cable, 2-wire with alligator clips for single use
Model S-101-97 (2.5 m)	Remington Medical Inc.	Patient cable, 2-wire with alligator clips for single use
Model FL-601-97 (2.0 m)	Remington Medical Inc.	Patient cable, 2-wire with screw terminals for single use

Legend for the Label

The label icons symbolize the following:

Symbol	Meaning
	Reocor D
	Redel adapter
	BIOTRONIK order number
	Serial number of the device
	Date of manufacture of the device
	Acceptable temperature range for storage
	Acceptable atmospheric pressure range for storage
	Acceptable relative humidity range for storage
	Patient with implanted lead
	Contents
	Disposal sign
	Follow the instructions for use!
	Caution: Federal (U.S.A.) law restricts this product to sale by, or on the order of, a physician.
	CE mark