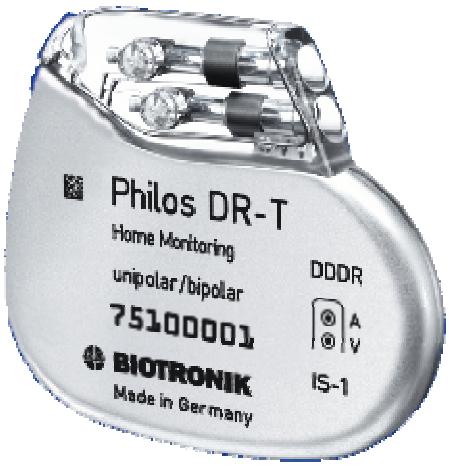
Philos DR-T

DDDR Dual Chamber Pulse Generator with Home Monitoring

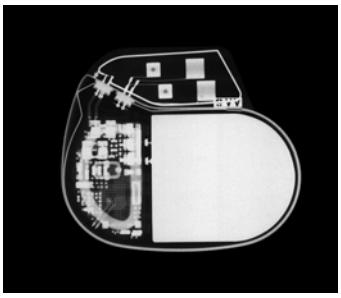


Technical Manual

BIOTRONIK

Philos DR-T

Implantable Pulse Generator



Philos DR-T
X-Ray identification

Radiopaque Identification

A radiopaque identification code is visible on standard x-ray, and identifies the pulse generator:

Philos DR-T VV

CAUTION

Because of the numerous available 3.2-mm configurations (e.g., the IS-1 and VS-1 standards), lead/pulse generator compatibility should be confirmed with the pulse generator and/or lead manufacturer prior to the implantation of a pacing system.

IS-1, wherever stated in this manual, refers to the international standard, whereby leads and generators from different manufacturers are assured a basic fit. [Reference ISO 5841-3:1992(E)].

CAUTION

Federal (U.S.A.) law restricts this device to sale by or on the order of, a physician (or properly licensed practitioner).

Contents

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1. Home Monitoring-Overview

Philos DR-T offers the complete functionality of a DDDR pacemaker while being equipped with the additional features associated with Home Monitoring. Consult the Philos technical manual for a description and overview of the standard pacemaker functionality of the Philos DR-T.

1.1 Home Monitoring

Home Monitoring is a novel system, which enables the exchange of information about a patient's cardiac status between implant, patient, and physician. Home Monitoring can be used to provide the physician with advance reports from the implant and process them into graphical and tabular formats. This information helps the physician optimize the therapy process, as it may result in the patient being scheduled for additional clinical appointments between regular follow-up visits if necessary.

The implant's Home Monitoring function can be used for the entire operational life of the implant (prior to ERI) or for shorter periods, such as several weeks or months.

1.2 Transmission of Information

The implant transmits information with a small transmitter, which has a range of about 2 meters. The patient's implant data are sent daily to the corresponding patient device (i.e., CardioMessenger) at a configurable time. The transmissions may also be activated by the patient with the application of a magnet over the implant and by certain cardiac events, as programmed. The types of transmissions are discussed in **Section 4**.

The minimal distance between the implant and the patient device must be 15 cm.

1.3 Patient Device with Components

The patient device (Figure 1) is designed for use in the home and is comprised of the mobile device and the associated charging station. The patient can carry the mobile device with them during his or her occupational and leisure activities. The patient device comes with a rechargeable battery that has an approximate operational time of 24 hours after a charge time of 5 hours. It receives information from the implant and forwards it via the mobile network to a BIOTRONIK Service Center.

For additional information about the patient device, please refer to its manual.

Figure 1: Patient Device with Charging Stand (CardioMessenger)

1.4 Receiving Patient Data

The implant's information is digitally formatted by the BIOTRONIK Service Center and processed into a concise report called a Cardio Report. The Cardio Report, which is adjusted to the individual needs of the patient, contains current and previous implant data. The Cardio Report is sent to the attending physician via fax or is available on the Internet, which is selected during registration of the patient. For more information on registering for Home Monitoring, contact your BIOTRONIK sales representative.

The password protected BIOTRONIK Home Monitoring website can be accessed by registered users at the following URL:

www.biotronik-homemonitoring.com

An online help menu is available in order to assist with the use of the Home Monitoring website.

Use of the Internet for reviewing Home Monitoring data must be in conjunction with the system requirements listed in **Table 1**. Additionally, **Table 1** provides system specifications that are recommended for optimizing usage of the Internet.

Table 1: System Requirements / Recommendations

	System Requirements	System Recommendations (for Optimal Usage)
Screen Resolution	800 x 600	≥ 1024 x 768
Internet Bandwidth	56 kB/sec	≥ 128 kB/sec (DSL, cable modem)
PC	600 MHz, 128 MB RAM	N/A
Internet Browser	MS Internet Explorer 5.0 - or - Netscape Navigator 4.72	≥ MS Internet Explorer 5.5 - or - ≥ Netscape 7/Mozilla
Acrobat Reader	Version 4	Version 5 or higher
Communication Channel	Fax (G3) or e-mail	Fax (G3), e-mail or mobile phone

Additionally, the attending physician may register to be informed of the occurrence of an Event Triggered Message through email or SMS (i.e., mobile phone) with a brief text message. If registered for Internet availability, the patient's detailed implant data can then be viewed by logging onto the Home Monitoring website.

2. Indications and Contraindications

For the general indications and contraindications, please refer to the Philos Family technical manual. The indications and contraindications of the Philos DR-T are identical to those of the rate adaptive dual chamber Philos DR pulse generator.

3. Warnings and Precautions

Certain therapeutic and diagnostic procedures may cause undetected damage to a pulse generator, resulting in malfunction or failure at a later time. Please note the following warnings and precautions:

Magnetic Resonance Imaging (MRI) – Avoid use of magnetic resonance imaging as it has been shown to cause movement of the pulse generator within the subcutaneous pocket and may cause pain and injury to the patient and damage to the pulse generator. If the procedure must be used, constant monitoring is recommended, including monitoring the peripheral pulse.

Rate-Adaptive Pacing – Use rate-adaptive pacing with care in patients unable to tolerate increased pacing rates.

High Output Settings – High output settings combined with extremely low lead impedance may reduce the life expectancy of the pulse generator to less than 1 year. Programming of pulse amplitudes, higher than 4.8 V, in combination with long pulse widths and/or high pacing rates may lead to premature activation of the replacement indicator.

3.1 Home Monitoring

Patient's Ability – Use of Home Monitoring requires the patient and/or caregiver to follow the system instructions and cooperate fully when transmitting data.

If the patient cannot understand or follow the instructions because of physical or mental challenges, another adult who can follow the instructions will be necessary for proper transmission.

Cellular Phone Availability – Home Monitoring is not practical for patients who live in areas where cellular telephone networks, utilizing the GSM standard, are not available or are not likely to become available in the near future.

Electromagnetic Interference (EMI) – Precautions for EMI interference with the Philos DR-T pulse generator are provided in the Philos technical manual in section 4.5. Sources of EMI including cellular telephones, electronic article surveillance systems, and others are discussed therein.

Use in Cellular Phone Restricted Areas – The mobile patient device (transmitter/receiver) should not be utilized in areas where cellular phones are restricted or prohibited (i.e., commercial aircraft).

Event Triggered Message – A timely receipt of the corresponding event report cannot be guaranteed. The receipt is also dependent on whether the patient was physically situated in the required coverage range of the patient device at the time the event information was sent.

Patient-Activated Message – The magnet effect must be programmed “synchronous” if the [Patient Message] function is activated. Otherwise, this function will not be available.

Not for Diagnosis – The data transmitted by Home Monitoring are not suitable for diagnosis, because not all information available in the implant is being transmitted.

Follow-Ups – When using Home Monitoring, the time period between follow-up visits may not be extended.

The use of Home Monitoring does not replace regular follow-up examinations. The data transmitted via Home Monitoring are not suitable for a conclusive diagnosis.

Magnet Effect – The magnet effect must be programmed “synchronous” if the attending physician enables the patient to transmit messages.

Lead Connection – Because of the numerous available 3.2-mm configurations (e.g., the IS-1 and VS-1 standards), lead/pulse generator compatibility should be confirmed with the pulse generator and/or lead manufacturer prior to the implantation of a pacing system.

IS-1, wherever stated in this manual, refers to the international standard, whereby leads and generators from different manufacturers are assured a basic fit. [Reference ISO 5841-3:1992(E)].

Consult the Philos manual for additional warnings and precautions associated with this device.

4. Types of Messages

When the Home Monitoring function is activated, the transmission of a message from the implant can be triggered as follows:

- Trend Message – the time period (daily) initiates the report
- Event Message – the pacemaker detects certain events, which initiate a message immediately
- Patient Message – the patient initiates transmission of a message

The attending physician decides whether or not the patient will be able to initiate the transmission of a message on their own through application of a magnet. Transmissions initiated through magnet application do not affect event or trend message transmissions.

4.1 Event Message

When certain cardiac and technical events are detected by the implant, a message transmission is automatically triggered. This is described as an “event message”.

The following cardiac and technical events initiate a report:

- Atrial Lead Check < 300 and > 3000 Ohm
- Ventricular Lead Check < 300 and > 3000 Ohm
- Ventricular Bursts (Runs)
- Ventricular Events (Episodes)
- Low P-Wave Amplitude[1] (< 50% safety margin)
- Low R-Wave Amplitude[1] (< 50% safety margin)
- ERI Activation
- 1st Mode Switch/24 hours

WARNING

A timely receipt of the corresponding event report cannot be guaranteed. The receipt is also dependent on whether the patient was physically situated in the required coverage range of the patient device at the time the event information was sent.

NOTE:

When ERI mode is reached, this status is transmitted. Further measurements and transmissions of Home Monitoring data are no longer possible.

NOTE:

The attending physician must notify the BIOTRONIK Service Center about which of these events he/she wishes to be informed.

[1] Examples: The programmed sensitivity is 1.0 mV.
A) Average of the measured P/R-Wave amplitudes is 2.6 mV. Therefore, measured value is greater than 100% of the safety margin. Event message is not triggered.
B) Average of the measured P/R-Wave amplitudes is 1.9 mV. Therefore, measured value is less than 100%, but greater than 50% of the safety margin. Event message is not triggered.
C) Average of the measured P/R-Wave amplitudes is 1.4 mV. Therefore, measured value is smaller than 50% of the safety margin. As a result, an event message is triggered.

4.2 Trend Message

An additional type of message is the programmable “Trend Message”. Trend messages occur at a programmable time of transmission (i.e., at the end of the Monitoring Interval). The time can be set anywhere between 0:00 and 23:50 hours. It is recommended that you select a time during the late night or early morning hours (between 0:00 and 4:00), or other time when the patient is usually in his or her home.

The length of the time interval (monitoring interval) is not programmable – it is preset to “daily”.

4.3 Patient Message

It is possible to trigger a transmission through magnet application over the pacemaker. The attending physician must inform the patient in detail about operating the device and about the physical symptoms which would warrant a magnet application by the patient.

WARNING

The magnet effect must be programmed “synchronous” if the [Patient Message] function is activated. Otherwise, this function will not be available.

5. Description of Transmitted Data

The following data are transmitted by Home Monitoring, when activated. In addition to the medical data, the serial number of the implant is also transmitted.

5.1 The Monitoring Interval

The monitoring interval is considered the time period since the last trend message was transmitted. For a trend message, the monitoring interval since the previous trend message is set at 24 hours. For an event or patient message, the monitoring interval would typically be less than 24 hours. This occurs when these messages are sent after the programmed transmission time of the trend message.

5.2 Heart Rate

- Average (mean) ventricular heart rate (bpm)

5.3 Atrial Rhythm

- Intrinsic rhythm (As / Ax) (%)
- Number of Mode Switching
- Duration of Mode Switching (%)

5.4 Ventricular Rhythm

- Intrinsic rhythm (Vs/ Vx) (%)
- Ventricular rate at Mode Switching (bpm)
- Number of ventricular runs (4...8 sequential VES)
- Number of ventricular events (more than 8 sequential VES), defined as a ventricular episode
- Duration of the longest ventricular event (sec)

5.5 AV Conduction

- AV Synchronicity (Ax Vx/Vx) (%)
  - with intrinsic rhythm (AsVs) (%)
  - with atrial stimulation (ApVs) (%)
  - with ventricular stimulation (AsVp) (%)
  - with dual-chamber stimulation (ApVp) (%)

5.6 System Status

- Atrial lead check
- Ventricular lead check
- Mean P-Wave amplitude / programmed sensitivity (%)
- Mean R-Wave amplitude / programmed sensitivity (%)
- Battery status

NOTE:

Atrial and Ventricular Lead Check must be programmed ON to enable Home Monitoring functionality of this data.

6. Technical Data

6.1 Modes

The following modes are available in the Philos DR-T when Home Monitoring is deactivated:

DDDR, DDTR/A, DDTR/V, DDTR, DDIR, DDIR/T, DVIR, DVTR, DOOR, VDDR, VDTR, VDIR, VVIR, VVTR, VOOR, AAIR, AATR, AOOR, DDD, DDT/A, DDT/V, DDT, DDI, DDI/T, DVI, DVT, DOO, VDD, VDT, VDI, VVI, VVT, VOO, AAI, AAT, AOO, OFF

The Home Monitoring function is available for the following pacing modes:

DDDR, DDTR/A, DDTR/V, DDTR, DDIR, DDIR/T, VDDR, VDTR, VDIR, DDD, DDT/A, DDT/V, DDT, DDI, DDI/T, VDD, VDT, VDI

NOTE:

Bold parameters indicate factory settings.

6.2 Home Monitoring Parameters

Home Monitoring

Off, On

Monitoring Interval

1 day

Time of Transmission

0:00...(10)...23:50 hours

Patient Message

Off, On

Event Message

Off, On

6.3 Pulse and Control Parameters

Basic rate

30...(1)...**60**...(1)...88...(2)...122...(3)...140...(5)...180 ppm

Night rate

Off, 30...(1)...60...(1)...88...(2)...122...(3)...140...(5)...180 ppm

Rate Hysteresis

Off; -5...(5)...-50 bpm

Repetitive Hysteresis

Off; 1…(1)…10

Scan Hysteresis

Off: 1…(1)…10

Upper Tracking Rate (UTR)

100; 110; 120; **130**; 140; 160; 185 ppm

UTR Response

2:1; WRL (automatic selection)

Rate Limitation[2,3,4]

190…220 ppm

Dynamic AV Delay (Dual chamber only)

low; medium; high; individual; fixed

AV Delay Values (Dual chamber only)

15; 50; 75; 100; 120...(10)...200; 225; 250; 300 ms

(Programmable in 5 ranges)

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[2] The corresponding intervals t correlate with the rates f by the formula t = 60.000 / f (t in ms, f in ppm).

[3] In the event of electronic defect.

[4] Rate Limitation changes as the Pacemaker approaches End of Service. The Rate Limitation is nominally 190 ppm at Beginning of Service (BOS) and can reach 220 ppm at End of Service (EOS) due to battery depletion.

AV Hysteresis

Off; low; medium; high

AV Repetitive Hysteresis

Off; 1...(1)...6

AV Scan Hysteresis

Off; 1...(1)...6

AV safety delay (Dual chamber only)

100 ms

Sense Compensation

Off; -15...(15)...-120 ms

Ventricular Blanking Time

16; 24; 32; 40; 48; 56; 72 ms

Magnet effect

Automatic; asynchronous; synchronous

Asynchronous Magnet Effect: paces at 90 ppm.

Automatic Magnet Effect; 10 cycles at 90 ppm asynchronous; thereafter synchronous with the programmed basic rate

Synchronous Magnet Effect; synchronous with programmed basic rate

Pulse amplitude

A 0.1...(0.1)...**3.6**...(0.1)...4.8...(1.2)...8.4 V

V 0.1...(0.1)...**3.6**...(0.1)...4.8...(1.2)...8.4 V

Ventricular Pulse Amplitude for Safe Program

4.8V

Pulse width

A 0.1; 0.2; 0.3; **0.4**; 0.5; 0.75; 1.0; 1.5 ms

V 0.1; 0.2; 0.3; **0.4**; 0.5; 0.75; 1.0; 1.5 ms

Sensitivity

A 0.1...(0.1)...**1.0**...(0.1)…1.5…(0.5)...7.5 mV

V 0.5...(0.5)...**2.5**...(0.5)...7.5 mV

Refractory period[5]

A 200...(25)…**425**...(25)...775 ms

V 170, 195, 220, **250**; 300; 350; 400 ms

PVARP (minimum)

Off, dependent on TARP and AV Delay settings

ARP Extension

0...(50)...350 ms

Lead Check

Off; On

Automatic Mode Conversion

Off; On (in modes DDD(R), DDT(R)/A, DDT(R)/V, and VDD(R))

Mode Switch (X out of Y)

Off; On (in modes DDD(R), DDT(R)/A, DDT(R)/V and VDD(R))

X = 3...(1)...8

Z = 3...(1)...8

Lead Polarity

Pace: A **unipolar**; bipolar

V **unipolar**; bipolar

Sense: A **unipolar**; bipolar

V **unipolar**; bipolar

Far-Field Blanking

50...(25)...200 ms

[5] In the DDIR, VVIR and VOOR modes, lower maximum sensor rates result than indicated here (partly depending on the selected AV interval). The correct values are indicated by the programmer.

PMT Management

Off; On

6.3.1 Rate Adaptation

Sensor gain

1.0, 1.1, 1.3, 1.4, 1.6, 1.8, 2.0, 2.2, 2.6, 3.0, 3.3, 3.7, 4.0, 4.5, 5.0, 6.0, 7.0, 8.0, 8.5, 10, 11, 12, 14, 16, 18, 20, 22, 24, 28, 32, 35, 40

Sensor threshold

very low; low; mean; high; very high

Rate increase

1, 2, 4, 8 ppm/s

Maximum sensor rate

80...(5)...180 ppm

Rate decrease

0.1, 0.2, 0.4, 0.8 ppm/s

Automatic Sensor Gain

Off; On

6.3.2 Parameters at Replacement Indication

Basic Rate

Programmed value minus 11%

(in modes DVI(R), DDI(R), DVT(R), DDI/T(R) minus 4.5–11%, depending on programmed AV Delay)

Magnet Rate

The magnet rate in all modes decreases as shown in the following table.

Magnet Mode	Cycles 1-10 after magnet application	After Cycle 10
Automatic	Asynchronous, basic rate at 80 ppm	Synchronized with basic rate reduced by 4.5 - 11%
Asynchronous	Asynchronous, basic rate at 80 ppm	Asynchronous with basic rate at 80
Synchronous	Synchronized with basic rate reduced by 4.5 - 11%	Synchronized with basic rate reduced by 4.5 - 11%

Pulse Widths

Programmed values

Sensitivities

Programmed values

6.3.3 Additional Functions

Home Monitoring

Additional functions conform with Philos DR:

- Temporary Program Activation
- High Precision Threshold test in the range of 0.1 up to 4.8 V with 0.1 V resolution
- PAC (pulse amplitude control) system produces consistent pulses
- Analog Telemetry with measuring of battery, pulse and lead data
- Two channel Real Time IEGM Transmission with markers
- Patient Data Memory
- Sensor Simulation
- Position Indicator for the programmer head
- 24 hour Trend
- Heart Rate Histogram
- Sensor Rate Histogram
- Sensor Test Trend with complete Rate Forecast
- Automatic Sensor Gain with Trend Monitor
- VES Analysis
- AES Analysis
- Retrograde Conduction Test
- Automatic Mode Conversion
- Mode Switching
- PMT Management
- Activity Report
- Event counter
- P-/R-wave Tests with Trend Data
- External Pulse Control up to 800 ppm
- Night Program

- Arrhythmia Detection Recordings (note that only 3 ADRs can be stored by the Philos DR-T; however, 10 can be stored by the Philos DR)
- Lead Impedance Trends
- Lead Check

6.4 Programmers

Home Monitoring functions and their parameters can be configured with the following programming devices:

EPR 1000^{PLUS}, TMS 1000^{PLUS}

6.5 Materials in Contact with Human Tissue

Housing: Titanium

Connector receptacle: Epoxy resin

Sealing Plugs: Silicone Rubber

Coating for unipolar devices: Silicone Rubber

6.6 Electrical Data/Battery

NOTE:

At 37ºC, with pacing impedance of 500 Ohms.

ELECTRICAL DATA

Circuit

Hybrid electronics with VLSI CMOS Chip

Input Impedance

A 240 kOhm

V 240 kOhm

Pulse Form

biphasic, asymmetric

Polarity

cathodic

Power Consumption

BOS, inhibited: 14 µA

BOS, 100 % pacing: 22 µA

Conducting Surface

uncoated: 32.8 cm^2

coated: 7.23 cm^2

Conducting Shape

uncoated: flattened ellipsoidal

coated: ellipsoidal

BATTERY

Power Source

Li/I

Open-Circuit Voltage

2.8 V

Voltage at ERI

2.5 V

Nominal Capacity[6]

1.3 Ah

6.7 Mechanical Data

Lead Connector

IS-1 (accepts unipolar and bipolar)

Weight

27 g

[6] Battery manufacturer's specification.

Volume

12 cm^3

Dimensions

6 x 44 x 51 mm

X-Ray Identification

VV

7. Order Information

Product Name	Order Number
Philos DR-T	331 440

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