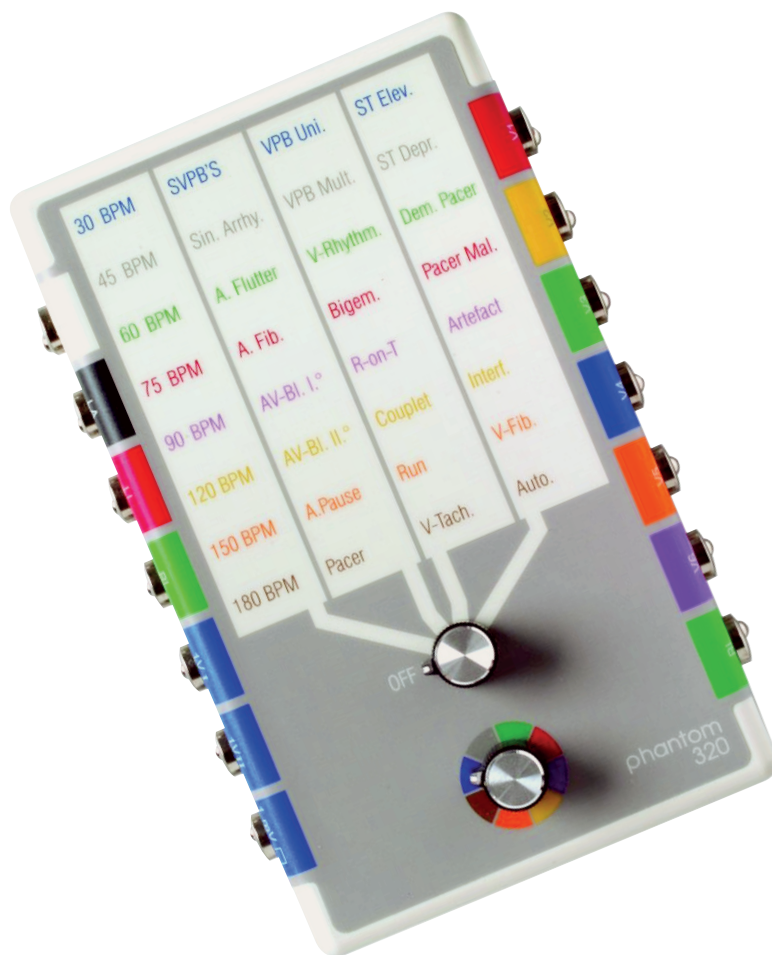


INSTRUCTION MANUAL

phantom 320 ECG Simulator



This instruction manual is an essential part of the system, in accordance with EN61010-1. Comply with it and keep it.

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1 | PRODUCT INFORMATION

The phantom 320 is a simulator, which can be used in many ways. With the device you can test the precise function of:

- **ECG and prolonged ECG devices**
- **monitors**
- **ECG recorders**
- **arrhythmia computers etc.**

The handy battery-powered device is especially used:

- **in the testing laboratories of TÜV, Dekra and other inspecting authorities**
- **in the quality assurance of medical engineering**
- **by service and test technicians**
- **for sales demonstrations.**

In all, the phantom 320 can simulate 32 programs, such as:

- **eight normal sinus rhythm**
- **seven supraventricular and**
- **nine ventricular arrhythmia as well as**
- **three pacemakers.**

phantom 320 is available in two releases:

ArtNo. 59.009 Code1 (Europe) with German labelling

ArtNo. 59.010 Code2 (America) with English labelling

The digital storage technology guarantees independent and genuine ECG waves for all 32 programs.

A special automatic program executes a typical selection of normal and pathological signals within approx. 17 minutes.

At the signal output jacks you can connect ECG cables with pushbuttons, plugs or clips.

2 | SAFETY PRECAUTIONS, CLEANING, CALIBRATION

Proper use

- Check if the device is free of damage.
- Check if the batteries or rechargeable batteries are free of damage, such as dents or leaks (liquids, electrolyte or acid).

Liability exclusion in case of improper use



NOTE

In case of improper use or maintenance, MedTec & Science GmbH will not be liable!

The manufacturer is only responsible for the security and reliability of the device if:

- all changes, enhancements, repairs and any other work on the device is performed by a person authorized by MedTec & Science GmbH, e.g. a distribution partner or service technician of MedTec & Science GmbH and
- the user complies with this instruction manual when using the device.

Safety precautions



WARNING

We direct your attention to the following safety precautions.

- Do not touch the signal output jacks when patient or signal cables are connected.
- Do not connect external voltages to the signal output jacks.

- Do not keep or use the device near strong electrical fields (e.g. near X-ray or diathermy machines).
- Do not spill liquids on the device.
- Avoid direct solar radiation.
- Do not expose the device to extreme heat or cold (e.g. sauna, refrigerator or freezer).
- Remove the batteries from the battery compartment if you will not be using the device for a long time.
- Use only rechargeable batteries and batteries of the same type. Do not mix them.



NOTE

The phantom 320 is not protected against any defibrillation impulse!

Cleaning



NOTE

Clean the device only with a soft, lint-free cloth and a common cleaner for plastics. The cloth should be moist, not dripping wet. Do not spray the cleaner directly onto the device.

Do not use spray cleaners, solvents, benzenes, spirits or similar agents.

Calibrating



NOTE

We recommend calibrating the device every five years.

3 | OPERATING ELEMENTS AND SIGNAL OUTPUT JACKS

Front-panel operating elements

The programs, which you can execute with the phantom 320, are ordered in a table at the front panel of the device:

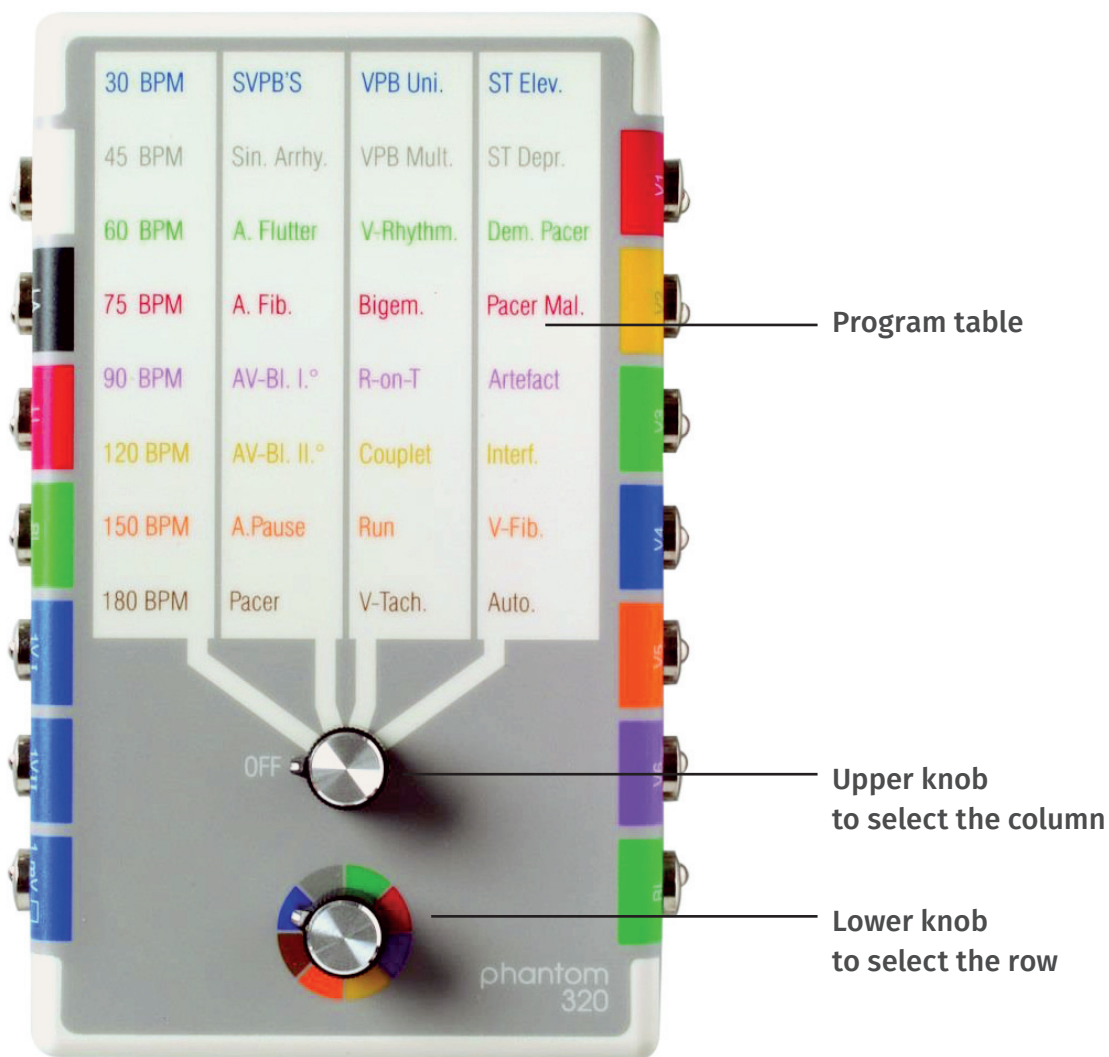


Figure 3-1: Front-panel operating elements of the phantom 320



NOTE

The colours in the program table are corresponding to the colours round the lower knob. These colours do not refer to the colours of the signal output jacks.

Reverse side

On the reverse side of the phantom 320 the programs are listed with a detailed description (see also **8 | 8 Overview of programs and descriptions**):



Figure 3-2: Reverse side of the phantom 320

Signal output jacks

The signal output jacks for the connection of the ECG cables are on the left and on the right side of the phantom 320. The signal output jacks are coloured in accordance with the standards for ECG cables. Each signal output jack is labelled with the output voltages in accordance with Code1 (Europe) or Code2 (America). The blue signal output jacks on the left side (1VI, 1VII and 1mV square signal) are especially used for testing monitors.

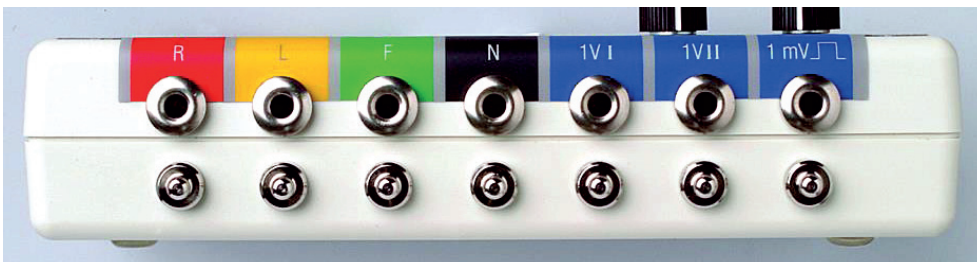


Figure 3-3: The phantom 320 – Code1: R, L, F, N (ArtNo. 59.009)

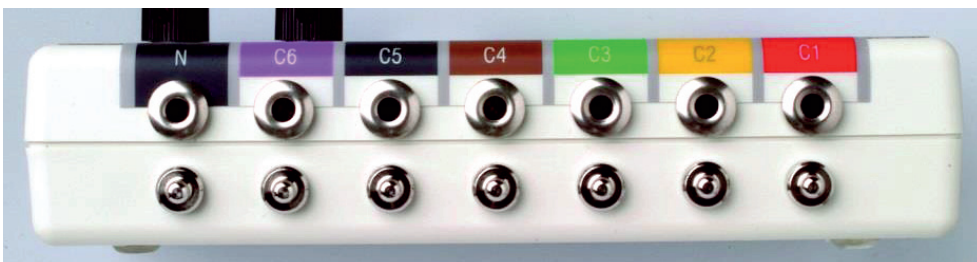


Figure 3-4: The phantom 320 – Code1: C1, C2, C3, C4, C5, C6, N (ArtNo. 59.009)

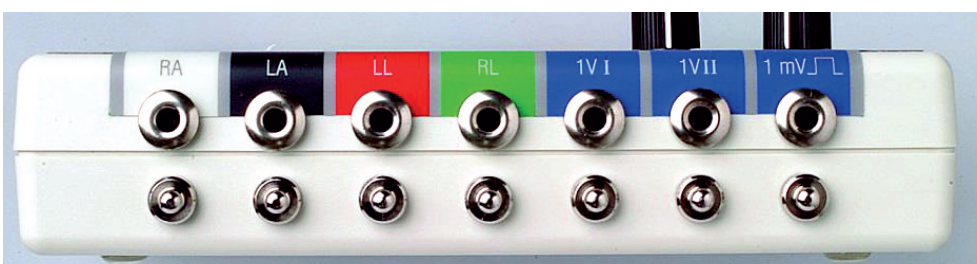


Figure 3-35: The phantom 320 – Code2: RA, LA, LL, RL (ArtNo. 59.010)

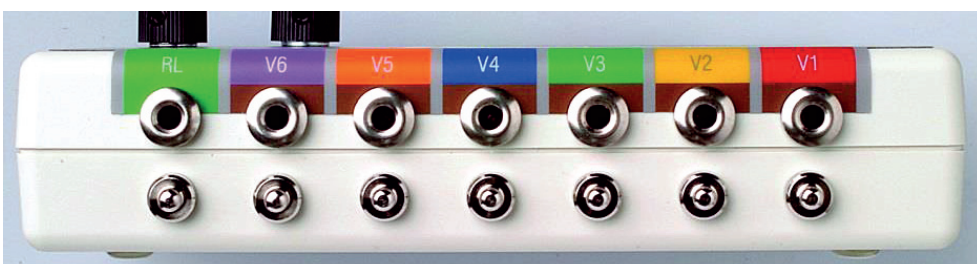


Figure 3-6: The phantom 320 – Code2: V1, V2, V3, V4, V5, V6, RL (ArtNo. 59.010)

4 | CONNECTING THE PHANTOM 320

You can connect the ECG cables to the phantom 320 with pushbuttons, plugs or clips.



Figure 4-1:
Connection
with pushbuttons

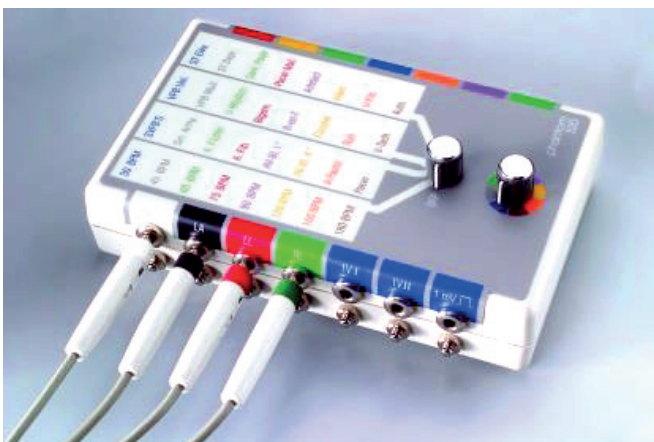


Figure 4-2:
Connection with plugs



Figure 4-3:
Connection with clips

5 | SELECTING A PROGRAM

The programs, which you can execute with the phantom 320, are ordered in a table at the front panel of the device. The rows of the program table are coloured differently.

In all 32 programs are available in four columns with each eight rows.

| Column 1 | ... | Column 4 | | |
|----------|-------------|-----------|------------|-------|
| 30 BPM | SVPB'S | VPB Uni. | ST Elev. | Row 1 |
| 45 BPM | Sin. Arrhy. | VPB Mult. | ST Depr. | |
| 60 BPM | A. Flutter | V-Rhythm. | Dem. Pacer | |
| 75 BPM | A. Fib. | Bigem. | Pacer Mal. | |
| 90 BPM | AV-BI. I.° | R-on-T | Artefact | ... |
| 120 BPM | AV-BI. II.° | Couplet | Interf. | |
| 150 BPM | A.Pause | Run | V-Fib. | |
| 180 BPM | Pacer | V-Tach. | Auto. | Row 8 |

Figure 5-1: Program table of the phantom 320

**NOTE**

The colours in the program table are corresponding to the colours round the lower knob. These colours do not refer to the colours of the signal output jacks.

Selecting a program

Select a program by turning the upper and lower knob as described in the following:

- **Turn the upper knob so that it points to the column from which you want to select a program.**
- **Turn the lower knob so that it points to the colour of the row from which you want to select a program.**

**NOTE**

You can turn the upper and lower knob in any order and direction.

Example

You want to select the program “Bigeminy”.

- **Turn the upper knob so that it points to the column three.**
- **Turn the lower knob so that it points to the colour red.**

For the description of testing devices in chapter 6 Testing devices the following short form is used for the procedure:

- **Select the program “Bigeminy” at the phantom 320:
Upper knob → column three
Lower knob → colour red.**

Selecting the automatic program

The automatic program is a special feature of the phantom 320. It executes a typical selection of normal and pathological signals within approx. 17 minutes.

- Turn the upper knob so that it points to the column four.
- Turn the lower knob so that it points to the colour brown.

Finishing tests



NOTE

If you do not need the phantom 320, always switch it off to save battery power.

- Turn the upper knob to “OFF”.

6 | TESTING DEVICES

6.1 Testing ECG recorders

- Connect the phantom 320 to the ECG recorder.
- Make the following settings at the ECG recorder:
recording speed 25 mm/s amplification 10 mm/mV Filter: switch off.
- Select the program “60 BPM” at the phantom 320:
upper knob → column one
lower knob → colour green.
- At the ECG recorder set the lead selector dial to the first leads.
Not necessary for 12 lead electrocardiographs.
- Start recording.
- Turn the lead selector dial after approx. 5 seconds to the next position until all 12 leads have been recorded.

Evaluation

The amplitude of the R wave (baseline to the peak of the wave) should not deviate more than $\pm 10\%$ (see 10 Specification). The R-R interval must be 25 mm.

Testing the filter function

- Select the program “Interf.” (Interference) at the phantom 320:
upper knob → column four
lower knob → colour yellow.
- At the ECG recorder set the lead selector dial to the first leads.
Not necessary for 12 lead electrocardiographs.
- Start recording.
- Turn the lead selector dial after approx. 5 seconds to the next position until all 12 leads have been recorded.

Evaluation

An ECG with 75 BPM is recorded. The ECG is overlaid with an interference of approx. 2 mm 50 or 60 Hz. When the filter is switched on the interference should disappear. The amplitude of the R waves can be up to 10% smaller.

6.2 Testing a monitor

Central ECG monitors used in ICU and CCU and monitors with a built-in ECG amplifier can be tested like an ECG recorder (see 6.1 Testing ECG recorders). For monitors without a built-in ECG amplifier a preamplified signal is needed. The phantom 320 offers two blue coloured signal output jacks (1V I and 1V II). Both ECG leads are preamplified with 1 Volt.

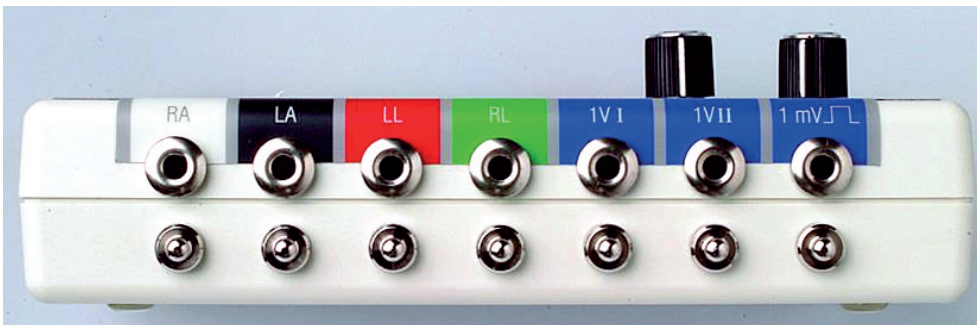


Figure 6-1: Preamplified ECG and 1mV square signal

- Connect the signal output of the monitor to one of the blue signal output jacks at the phantom 320.
- Connect the earth of the monitor to the green signal output jack at the phantom 320.
- Select the program “60 BPM” at the phantom 320:
upper knob → column one
lower knob → colour green.
- Switch on the monitor.

The monitor should display an ECG with amplitude of 1mV and a frequency of 60 BPM.

- Select the program “120 BPM” at the phantom 320:
upper knob → column one
lower knob → colour yellow.

The monitor should display an ECG with a frequency of 120 BPM.

Monitors with adjustable alarms for the heartbeat

- **Make the following settings at the monitor:**
lower alarm limits 50 BPM
upper alarm limits 145 BPM.
- **Select the program “45 BPM” at the phantom 320:**
upper knob → column one
lower knob → colour grey.
The monitor should trigger the alarm after a short time.
- **Switch of the alarm at the monitor.**
- **Select the program “150 BPM” at the phantom 320:**
upper knob → column one
lower knob → colour orange.
The monitor should trigger the alarm after a short time.

6.3 Testing an arrhythmia computer

Arrhythmia computers with a built-in ECG amplifier can be connected to the phantom 320 like an ECG recorder (see **6.1 Testing ECG recorders**).

Arrhythmia computers without an ECG amplifier are connected like monitors to the (see **6.2 Testing a monitor**).

- **Select the program “75 BPM” at the phantom 320**
upper knob → column one
lower knob → colour red.
- **Switch on the computer and order memorising this ECG.**
- **When the memorising is complete select different programs with pathological ECGs for 1 to 2 minutes, such as:**
“SVPB’S” – Supraventricular Premature Beats
“VPB Mult.” – Multifocal Ventricular Premature Beats
“R-on-T” – R-on-T Phenomena
“Run” – Ventricular Premature Beats-Runs of 3 VPB’s

The arrhythmia computer must recognise and display the pathological ECGs.

6.4 Testing prolonged ECG devices

- Connect the prolonged ECG devices to the phantom 320 like an ECG recorder (see 6.1 Testing ECG recorders).
- Select the program “Auto” at the phantom 320:
upper knob → column four
lower knob → colour brown.
- Start the recorder.
The monitoring will last 24 hours.
- Check the stored data in the recorder.

7 | REPLACING THE BATTERIES



NOTE

If you do not need the phantom 320, always switch it off to save battery power (“OFF” at the upper knob).

Before the batteries are completely out of charge, the phantom 320 alters with a beep.

Use batteries Mignon standard 1.5-V LR 6.

Replacing the batteries

- Open the battery cover on the reverse side of the device.
- Pull the transparent strap outside and remove the batteries.
- Press the strap to the bottom of the battery compartment.
- Put in the new batteries, as indicated in the battery compartment.



Figure 7-1: Battery compartment of the phantom 320

- Close the battery compartment



Please bring consumed batteries to a recycling center.

8 | OVERVIEW OF PROGRAMS AND DESCRIPTIONS

The following table provides an overview of the phantom 320 programs and their detailed description:

| Program | Description |
|---------------|---|
| ■ 30 BPM | Normal Sinus Rhythm, HR=30 BPM |
| ■ 45 BPM | Normal Sinus Rhythm, HR=45 BPM |
| ■ 60 BPM | Normal Sinus Rhythm, HR=60 BPM |
| ■ 75 BPM | Normal Sinus Rhythm, HR=75 BPM |
| ■ 90 BPM | Normal Sinus Rhythm, HR=90 BPM |
| ■ 120 BPM | Normal Sinus Rhythm, HR=120 BPM |
| ■ 150 BPM | Normal Sinus Rhythm, HR=150 BPM |
| ■ 180 BPM | Normal Sinus Rhythm, HR=180 BPM |
| ■ SVPB'S | Supraventricular Premature Beats |
| ■ Sin. Arrhy. | Sinus Arrhythmia |
| ■ A. Flutter | Atrial Flutter |
| ■ A. Fib. | Atrial Fibrillation |
| ■ AV-Bl. I.° | AV-Block, First Degree |
| ■ AV-Bl. II.° | AV-Block, Second Degree |
| ■ A. Pause | Atrial Pauses (> 2,5 sec.) |
| ■ Pacer | Artificial Pacemaker Rhythm |
| ■ VPB Uni. | Unifocal Ventricular Premature Beats |
| ■ VPB Mult. | Multifocal Ventricular Premature Beats |
| ■ V-Rhythm | Ventricular Rhythm |
| ■ Bigem. | Bigeminy |
| ■ R-on-T | R-on-T Phenomena |
| ■ Couplet | Ventricular Premature Beats-Couplets |
| ■ Run | Ventricular Premature Beats-Runs of 3 VPB's |
| ■ V-Tach. | Ventricular Tachycardia |
| ■ ST Elev. | ST-Segment Elevation |
| ■ ST Depr. | ST-Segment Depression |
| ■ Dem. Pacer | Ventricular Demand Pacemaker |
| ■ Pacer Mal. | Pacemaker Malfunction |
| ■ Artefact | Sinus Rhythm with Artefact |
| ■ Interf. | Sinus Rhythm with 50/60 Hz Interference |
| ■ V-Fib. | Ventricular Fibrillation |
| ■ Auto. | Automatic Arrhythmia Program (17 Min.) |

9 | OVERVIEW OF THE AUTOMATIC PROGRAM

The following table provides an overview of the sequence of the programs in the automatic program and their length.

The basis ECG has an attendance of 75 pulsations per minute.

| Time | Occurrence |
|----------|----------------------------------|
| Begin | HR 75 BPM |
| 12 sec. | HR 60 BPM |
| 24 sec. | HR 45 BPM |
| 36 sec. | HR 60 BPM |
| 48 sec. | HR 45 BPM |
| 60 sec. | HR 75 BPM |
| 72 sec. | HR 90 BPM |
| 84 sec. | HR 120 BPM |
| 96 sec. | HR 90 BPM |
| 108 sec. | Supraventricular Premature Beats |
| 123 sec. | Atrial Pauses 1.6 sec |
| 128 sec. | Supraventricular Premature Beats |
| 136 sec. | Ventricular Premature Beats |
| 144 sec. | Bigeminy |
| 172 sec. | Ventricular Premature Beats |
| 179 sec. | AV-Block , First Degree |
| 191 sec. | Atrial Pauses 3.2 sec. |
| 200 sec. | Ventricular Premature Beats |
| 204 sec. | Ventricular Premature Beats |
| 212 sec. | Couplets |
| 220 sec. | Salve |
| 223 sec. | ST-Segment Elevation |
| 231 sec. | ST-Segment Elevation descending |
| 239 sec. | ST-Segment Elevation |
| 247 sec. | ST-Segment Elevation ascending |
| 255 sec. | ST-Segment Elevation |
| 267 sec. | Supraventricular Premature Beats |
| 275 sec. | Atrial Pauses 2.4 sec. |
| 284 sec. | Ventricular Premature Beats |
| 296 sec. | Couplets |
| 304 sec. | Salve |
| 316 sec. | Ventricular Premature Beats |
| 323 sec. | R-on-T Phenomena |
| 335 sec. | Artefact |

to be continued: Overview of the automatic program >>

| Time | Occurrence |
|-------------|---|
| 339 sec. | Atrial Fibrillation |
| 347 sec. | Artefact |
| 375 sec. | ST Segment Depression |
| 407 sec. | ST-Segment Depression descending |
| 439 sec. | ST-Segment Depression |
| 471 sec. | ST-Segment Depression ascending |
| 535 sec. | ST-Segment Depression |
| 543 sec. | Bigeminy |
| 563 sec. | Salve |
| 571 sec. | Couplets |
| 575 sec. | Couplets |
| 583 sec. | Bigeminy |
| 599 sec. | HR 45 BPM |
| 607 sec. | HR 60 BPM |
| 651 sec. | Supraventricular Premature Beats |
| 658 sec. | AV-Block , Second Degree |
| 666 sec. | AV-Block , Second Degree |
| 679 sec. | Ventricular Premature Beats |
| 691 sec. | Ventricular Premature Beats |
| 703 sec. | Couplets |
| 718 sec. | Artefact |
| 722 sec. | Artefact |
| 726 sec. | Sinus Rhythm with 50/60 hz Interference |
| 750 sec. | Electrodes error |
| 771 sec. | Ventricular Premature Beats |
| 779 sec. | Ventricular Premature Beats |
| 799 sec. | Atrial Flutter |
| 824 sec. | Atrial Pauses 4.8 sec. |
| 846 sec. | Ventricular Premature Beats |
| 854 sec. | Supraventricular Premature Beats |
| 871 sec. | Ventricular Premature Beats |
| 882 sec. | HR 60 BPM |
| 890 sec. | HR 45 BPM |
| 898 sec. | Ventricular Premature Beats |
| 902 sec. | Ventricular Premature Beats |
| 906 sec. | Ventricular Premature Beats |
| 922 sec. | Atrial Flutter |
| 946 sec. | Supraventricular Premature Beats |
| 966 sec. | F 180 1/min |
| 994 sec. | Ventricular Premature Beats |
| 1004 sec. | Salve |
| 1024 sec. | Program starts again |

10 | SPECIFICATION

| | |
|----------------------------------|--|
| 12 leads | I,II,III,avR,avL,avF,V1,V2,V3,V4,V5,V6 |
| 14 connections | 4 mm banana plugs and pushbuttons identification and colour code: DIN EN 60601-2-25 |
| Digital storage | 1.6 Mbit |
| Amplitude resolution | 8 Bit |
| Scanning frequency | 256 Hz |
| Signal bandwidth | 0 – 120 Hz |
| Signal amplitudes (min – max) | Lead I + 1.35 – 1.49 mV Lead II + 2.35 – 2.49 mV Lead III + 0.95 – 1.06 mV Lead V1 - 2.12 – 2.30 mV Lead V2 - 0.55 – 0.61 mV Lead V3 + 1.03 – 1.14 mV Lead V4 + 2.11 – 2.21 mV Lead V5 + 1.75 – 1.85 mV Lead V6 + 1.40 – 1.51 mV |
| Time base | Quarz 32768 Hz |
| Output impedance | Electrode connections: 20 Ohm 1V outputs: 100 Ohm |
| Waveforms | 8 sinus rhythms (normal QRS) 30,45,60,75,90,120,150,180 BPM 7 supraventricular arrhythmia 9 ventricular arrhythmia 3 pacemaker 2 ST segments (elevation, depression) each with horizontal, ascending and descending ST wave bradycardia tachycardia ECG with artefacts ECG with interference 50/60 Hz |
| Signal width | PQ, QRS, QT depending on RR interval (after Lepeschkin) |
| Battery | Standard 2 x 1.5-V LR 6 |
| Battery life | approx. 100 hours continuous operation |
| Dimensions (LxWxH) | 150 x 100 x 40 mm |
| Weight | 400 gram |

11 | TROUBLESHOOTING AND ERROR CORRECTION

If the device to be tested indicates no signal, check the following items:

- **Is the device switched on?**
- **Are the cables connected correctly?**
- **Is the phantom 320 switched on?**
- **Do the batteries in the phantom 320 have enough voltage?**

12 | DECLARATION OF CONFORMITY



EU-Konformitätserklärung *EU-Declaration of Conformity*

Hersteller / manufacturer: MedTec & Science GmbH | Maria-Merian-Str. 6 | 85521 Ottobrunn, Germany

Wir erklären hiermit in alleiniger Verantwortung, dass das Produkt/ die Produkte
 We hereby declare under our sole responsibility that the product/ the products

| Typ / type | Bezeichnung / description | Artikelnummer / part number |
|---|---------------------------|-----------------------------|
| EKG-Simulator ECG-Simulator | Phantom 320 Code1 | 59.009 |
| EKG-Simulator ECG-Simulator | Phantom 320 Code2 | 59.010 |
| EKG-Simulator ECG-Simulator | MS 410 | 59.022 |
| Defibrillations-Simulator Defibrillation-Simulator | Zeus V1 | 59.101 |
| Defibrillations-Simulator Defibrillation-Simulator | Zeus V2 | 59.102 |

den Bestimmungen der nachstehenden EG/EU-Richtlinie(n)/Verordnung(en) entspricht/entsprechen:
 is/are in conformity with the following EG/EU-Directive(s)/Regulation(s):

| | |
|-------------------------------------|---|
| 2014/35/EU | EU-Niederspannungs-Richtlinie Electrical Equipment designed for use within certain voltage limits |
| 2014/30/EU | Elektromagnetische Verträglichkeit Electromagnetic Compatibility |
| 2011/65/EU (inkl. (EU) 2015/863) | Beschränkung der Verwendung bestimmter gefährlicher Stoffe in Elektro- und Elektronikgeräten (ROHS II und Änderungsrichtlinie 2015) Restriction of the use of certain hazardous substances in electrical and electronic equipment with amendment 2015 |

Angewandte (harmonisierte) Normen / Applied (harmonised) standards:

| | |
|----------------|--|
| EN IEC 61010-1 | Sicherheitsbestimmungen für elektrische Mess-, Steuer-, Regel-, und Laborgeräte Safety requirements for electrical equipment for measurement, control, and laboratory use |
| EN IEC 61326-1 | Elektrische Mess-, Steuer-, Regel-, und Laborgeräte – EMV Anforderungen Electrical equipment for measurement, control and laboratory use – EMC requirements |
| EN IEC 63000 | Technische Dokumentation zur Beurteilung von Elektro- und Elektronikgeräten hinsichtlich der Beschränkung gefährlicher Stoffe Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances |

Ottobrunn, 2021-04-28

Michael Ecker
Geschäftsführer / Director

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