



MyDiagnostick 1001R

Device Manual



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1 Introduction

1.1 Intended use

The MyDiagnostick 1001R assists qualified medical personnel in diagnosing Atrial Fibrillation (AF).

1.2 Software

Use the appropriate MyDiagnostick software to configure and interrogate the device. Software is available from the MyDiagnostick website (www.mydiagnostick.com).

1.3 Regulatory information

Manufacturer

Applied Biomedical Systems
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Tel: +31 (88) 243 2500

Sales and Support







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1.4 Warnings

The doctor may make a wrong diagnosis for a patient if the device was used by multiple persons between interrogations.







2 Packaging

2.1 Packaging symbols

| Symbol | Explanation |
|---|--|
|  | The device is compliant with European Union regulations regarding medical devices (NB 0344). |
|  | Read the manual before operating the device. |
|  | The packaging can and should be recycled. |
|  | Identifies the location of the manufacturer information. |
|  | The product has to be recycled as an electrical appliance. |
|  | Identifies the location of the device serial number. |





3 Device Description

3.1 Device label symbols

| Symbol | Explanation |
|--|--|
|  | The device is compliant with European Union regulations regarding medical devices (NB 0344). |
|  | Read the manual before using the device to obtain best results. |
|  | The device can be connected to a computer via USB. |
|  | Identifies the location of the manufacturer information. |
|  Type BF | The device meets the safety requirements for Type BF Applied Parts (EN 60601). |
|  | The product has to be recycled as an electrical appliance. |
| IPX4 | Water splashing from any direction has no harmful effect (EN 60529). |

3.2 Visible signals

The MyDiagnostick 1001R has 7 LEDs (Light Emitting Diode) to indicate device status, ECG (electrocardiogram) recording progress and AF (Atrial Fibrillation) detection status.

| LED | Explanation |
|---|--|
|  | Power (yellow) This LED is ON continuously during ECG recording. If the recording is completed successfully this LED is turned OFF. If the recording has failed, this LED will BLINK until the device is deactivated. When the device is connected to a computer and the batteries are being charged this LED will BLINK. When the device is connected to a computer and the batteries are fully charged this LED is ON continuously. |
|  | Progress (4x, yellow) When recording an ECG these LEDs show the progress of the recording. |
|  | No AF Detected (green) ECG recording was completed successfully and AF was <u>not</u> detected. |
|  | AF Detected (red) ECG recording was completed successfully and AF was detected. |

3.3 Audible signals

The MyDiagnostick 1001R emits audible signals to indicate ECG (electrocardiogram) recording status.

| Signal | Explanation |
|----------|--|
| 1x short | Recording Start. The device emits a single short beep when the device activates and starts an ECG recording. |
| 2x short | Recording End. The device emits two short beeps when ECG recording has been completed successfully. |
| 1x long | Error. The device emits a single long beep when an error has occurred. |

3.4 Handles

The MyDiagnostick 1001R has metal handles at both ends that serve as electrodes for ECG recording.

3.5 Computer interface

The MyDiagnostick 1001R has a USB connector (type Mini B) at one end to connect the device to a computer.

4 Information for Health Care Professionals

4.1 ECG recording

When the patient grabs the device handles with both hands (one hand per handle), the device activates automatically, emits 1 short beep and starts ECG recording. The Power LED is continuously ON during ECG recording and the Progress LEDs indicate the progress of the recording. The rightmost Progress LED will flash at the detection of a heartbeat.

When ECG recording is successful, the device emits 2 short beeps. The AF Detected LED is continuously ON if AF was detected during ECG recording. The No AF Detected LED is continuously ON if AF was not detected during ECG recording.

The device deactivates when the patient releases the device handles and at least 5 seconds have passed since the end of ECG recording.

Notes

1. ECG recording is not possible if the device is connected to a computer.
2. The device will only start an ECG recording if the device is in the deactivated state when the patient grabs the device handles.
3. Recorded ECGs and detection results can be retrieved from the device using the appropriate MyDiagnostick software.
4. The rightmost Progress LED will only flash when a heartbeat is detected if the device is configured to do so (this is the default).
5. The AF Detected LED will only be switched ON if the device is configured to do so (this is the default). If this function is disabled, the No AF Detected LED will always be switched ON at the end of a successful ECG recording. The correct detection result will however still be stored with the recorded ECG.

4.2 ECG recording errors

The device monitors the signal quality during ECG recording. If an error occurs, the device emits 1 long beep and the Power LED starts blinking.

4.3 ECG storage

The device has a storage capacity of 140 ECG recordings. When the ECG storage is full, the device will overwrite previous recordings in the following order:

1. recordings during which an error has occurred
2. recordings with no AF detection
3. recordings with AF detection

In each category the device will overwrite the oldest recording first.

4.4 Charging the device batteries

The device batteries can be charged by connecting the device to a USB power source (for example a powered USB port of a computer).

The Power LED will blink during battery charging. Charging is complete when the Power LED is continuously ON.

4.5 Preparing the device for first use

Before making the first recording with the device, the user should use the device with the appropriate MyDiagnostick software to ensure that the device clock is set correctly.

5 Information for Patients

If a patient is to use the device for a prolonged period of time, it is recommended to hand the device to the patient in the designated patient package. Symbolic instructions for use are printed on the package as depicted below. The exact symbols and format may depend on the package type.

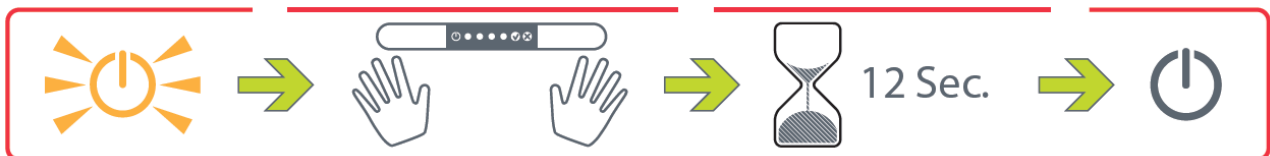
5.1 ECG recording



1. Assume a comfortable position and relax to obtain the best results. It is recommended that the forearms rest comfortably on a table.
2. Grab the MyDiagnostick device handles as indicated (but do not squeeze). The device will activate (1 short beep) and start recording. The yellow LEDs show the progress of the recording.
3. Wait until the MyDiagnostick signals the end of the recording (2 short beeps). Either the green LED or the red LED will light to indicate the detection result.
4. Release the device handles and wait until the device deactivates.

5.2 ECG recording errors

The MyDiagnostick signals a recording error with 1 long beep.



1. Release the device handles until the device deactivates and try again.

6 Maintenance, Service and Warranty

6.1.1 Maintenance

The user can clean the device with a damp cloth. The damp cloth may contain a mild soap solution or alcohol ($\leq 70\%$).

The user should charge the device batteries regularly.

6.1.2 Service

The MyDiagnostick 1001R does not contain any serviceable parts and cannot be opened.

The expected battery life at intensive use is estimated at 5 to 10 years.

6.1.3 Limited warranty

The warranty period is 2 years. The warranty only applies to failures that are the result of manufacturing faults and/or material defects.

7 Technical Specifications

Mechanical

| | |
|----------|--------|
| Length | 260 mm |
| Diameter | 22 mm |
| Weight | 180 g |

Electrical

| | |
|-----------------------------------|--|
| Batteries | 2x NiMH 1.2V 2000 mAh rechargeable (not replaceable) |
| Charge time (from depleted state) | max. 10 hours |
| Battery longevity | min. 500 recordings of 60-70 s at full charge |
| Computer connection | USB 2.0 Full Speed |
| Power consumption | max. 300 mA (charging, via USB connector) |
| Safety | type BF (EN 60601) |

Environment

| | |
|-------------------------------|------------------------------------|
| Temperature (operating) | +1 °C to +40 °C |
| Temperature (non-operating) | -10 °C to +50 °C |
| Relative humidity (operating) | 10% to 90% |
| Barometric pressure | normal atmospheric pressure ranges |
| Water resistance | IPX4 (EN 60529) |

Functional

| | |
|--------------------------|---|
| ECG storage capacity | 140 recordings of 60-70 s |
| AF detection method | R–R interval dispersion during 60 seconds |
| AF detection sensitivity | min. 90% (as a result of adjusted ROC in detection) |
| AF detection specificity | min. 95% |

Miscellaneous

| | |
|----------------|----------------------|
| Classification | class 2A (93/42/EEC) |
|----------------|----------------------|