APPLIED BIOMEDICAL SYSTEMS

MYDIAGNOSTICK

MyDiagnostick 1001R

Device Manual

CE
0344

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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. The software can be requested via the MyDiagnostick website: https://mydiagnostick.com/software_form.html.

1.3 Regulatory information

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Sales and Support
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Tel: +31 43 3885898

Internet: www.mydiagnostick.com

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.
	Batteries and electrical and electronic equipment with the symbol of a crossed-out garbage container should not be disposed of as unsorted household waste. Batteries and waste of electrical and electronic equipment (WEEE) should be disposed separately through the collection system for the return, recycling and disposal of batteries and WEEE.
	Identifies the location of the device serial number.

3 Device Description

3.1 Device label symbols

Symbol	Explanation
CE 0344	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).
	Batteries and electrical and electronic equipment with the symbol of a crossed-out garbage container should not be disposed of as unsorted household waste. Batteries and waste of electrical and electronic equipment (WEEE) should be disposed separately through the collection system for the return, recycling and disposal of batteries and WEEE.
IP24	Ingress Protection: protected against splashing water and solid foreign objects with a diameter of 12.5 mm and larger (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 and hands released 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 not 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 (electrodes)

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 connecter (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.

4.2.1 ECG recording - Points of attention

If a measurement does not start, or stops during a measurement because of an error message, this may be due to insufficiently good contact between the user and the electrodes (handles).
Causes can be:

- Hands and/or electrodes "too clean" (e.g., by disinfection);

Disinfection can make surfaces too clean/dry. The ECG signal is conducted through the hands to the electrodes, this requires a certain amount of medium.

- The contact surface may also not be sufficiently clean, please clean the electrodes as described in section 6.1.1.

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.

It is strongly advised to fully charge the batteries frequently, depending upon its use.

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, and fully charge the batteries.

4.6 Initial measurement with the Patient

In order to demonstrate and ensure the correct use of the MyDiagnostick, the health care professional shall perform an initial measurement together with the patient.

5 Information for Patients

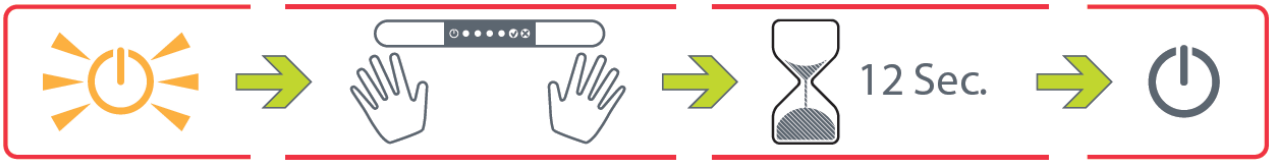
If a patient is to use the device for a prolonged period of time, it is recommended to hand the device to the patient in the designated patient package. Symbolic instructions for use are printed on the package as depicted below. The exact symbols and format may depend on the package type.

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, Warranty and Complaints

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 (≤ 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.

6.1.4 Complaints

A customer may contact MyDiagnostick Medical / Applied Biomedical Systems (see section 1.3 for contact details) in case of abnormalities, damages, etc.

7 Technical Specifications

Mechanical	
Length	260 mm
Diameter	22 mm
Weight	max. 180 g
Electrical	
Batteries	2x NiMH 1.2V 2000 mAh rechargeable (not replaceable)
Charge time (from depleted state)	max. 12 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
Ingress protection	IP24 (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)
RoHS	Complies with RoHS 3 according to directive EU 2015/863
EMC	Complies with the conditions according to - directive IEC 60601-2-1