Instructions of use Body sensor (Rev. 1)

UDI

ARES: 4260732640035
IRIS: 4260732640042

General information / safety instructions

The instructions for use must be read carefully before the first start-up and kept for future reference. Non-compliance or improper use releases the manufacturer from liability. Before each use, the medical device and its accessories must be checked for function and intactness. AthenaDiaX GmbH expressly warns against modifying the medical device and its accessories. Any change leads to the exclusion of liability. The CE mark expires with the use of non-approved spare parts. The product may only be used by medically trained personnel!

Warning notices / residual risks

Leakage currents in housings, patient leakage currents, electrical fields, ionizing radiation, high temperature, falls, renewed or cross-infection, residues, impurities, cleaning, disinfection and test agent residues, loss or degradation of function, reuse / incorrect reuse, damage to parts, Risk of explosion

Intended use

- ARES is an EKG data logger and is used to record electrocardiographic signals over several days
- The ECG data provided by ARES is available in an open format for later processing in digital systems.
- The body sensor system, consisting of ARES, ZEUS and electrodes, does not have functions that enable the recorded data to be displayed.
- The system of the body sensor, consisting of ARES, ZEUS and electrodes, does not allow direct diagnosis or control of the ECG
- ARES does not evaluate the electrocardiographic signals

Indication

Paroxysmal atrial fibrillation or for monitoring after an ablation, assessment of the extent of a cardiac arrhythmia, diagnosis of cardinal genesis, especially in patients at risk (e.g. stroke, syncope) and manual event monitoring and analysis (initiated by the patient himself)

Contraindication

The device can be damaged if an external defibrillator is used. There is no danger to the patient.

disposal

At the end of its useful life, this product must be disposed of in accordance with local regulations! The following applies to the European Union: According to the European Directive 2012/19 / EU on waste electrical and electronic equipment (WEEE), this product may not be disposed of with unsorted household waste. Prepare this product and its accessories for recycling or separate collection according to the directive. The directive does not apply to contaminated products.

Duration, frequency of use

The electrodes can stick for a maximum of 72 hours.
Use for a maximum of 7 days.

Start of signal recording

1. Clean and dry the patient's skin. If necessary, shave the left chest area. The skin should be degreased and cleaned, typical alcohol pads are suitable for this.
2. Join the two devices so that the six contacts of the ZEUS can connect to those of the ARES
3. ZEUS Attach the double ECG electrode to the ZEUS and remove the protective film

After the body sensor has been affixed to the chest, the signal recording and storage is started automatically.

Function check

If the signal is correctly recorded and saved, the green status LED flashes briefly every 4 seconds.

End the ECG recording

1. Slowly and carefully pull the body sensor including the electrodes off the skin
2. To end the recording, separate the ECG recorder (ARES) from the ECG patch (ZEUS)

Reading and analysis of the ECG data

1. Connect the reader (IRIS) to your PC using the USB cable.
2. Place the ECG recorder (ARES) in the reader and close the lid. Make sure that the ECG recorder is correctly aligned

The recorded data can be evaluated using the AthenaDiaX Themis software.

Operating states

LED signal	status displays ARES
LED flashes orange for 15 s	**Self-test**: In this state, the ECG recorder carries out an internal self-test, during which all important functions of the device are tested. In the event of skin contact, the LED then flashes at the heart rate for 10 seconds as a check. If no skin contact is detected by the ARES after the self-test, it flashes green every 1 second and requires contact with the skin in order to start the ECG measurement.
LED flashes green every 4 s	**Measure:** In this state, the ECG measurement and recording takes place.
LED lights up red continuously	**End:** This signals the end of the recording.
LED does not light up	**Fault:** Possible causes can be a full memory, empty batteries or hardware errors

Usage instructions

- The patient should sleep on their back if possible.
- To achieve correct measurement results, there must be an intact adhesive bond between the skin and the device.
- Before each use, the ECG recorder (ARES) must be checked for visible damage.
- The body sensor can be operated together with cardiac pacemakers or other stimulators if all devices involved are used according to their intended purpose.
- Portable and mobile HF devices (e.g. Bluetooth, Wi-Fi) can influence the function of the body sensor.
- If physical problems occur during the recording, e.g. severe skin irritation, the device should be removed.

Service and repairs

Unauthorized repairs or modifications of the body sensor and the accessories can impair the functions or endanger the user or patient. Repairs may therefore only be carried out by the manufacturer or by persons authorized by the manufacturer. Unlawful opening will void the guarantee. In the event of repairs or a service request, contact your distributor.

Product liability

The manufacturer of the body sensor only accepts product liability under the following conditions:
If the body sensor was operated exclusively with original accessories, if repairs to the body sensor and the accessories were only carried out by the manufacturer or by bodies authorized and trained by the manufacturer, or if these operating instructions were observed during use. In the event of improper maintenance and handling by the user of the devices, any liability is excluded.

Processing instructions

General information

The body sensor may only be cleaned with a slightly damp cloth. Do not use an aggressive solution to disinfect the body sensor. Do not clean the body sensor with organic solvents such as gasoline or ether.

Warning notices for reprocessing

The device must not be mechanically processed or autoclaved. Prevent liquids from entering (do not spray into).

Limitations and restrictions on reprocessing

The end of product life is usually determined by wear and tear and damage from use.

Cleaning preparation

Remove surface contamination with a disposable cloth / paper towel.
Cleaning / disinfection: automatic
Automatic cleaning and disinfection is not permitted.

Cleaning / disinfection: manual

Only clean the device manually. Remove surface contamination with a damp cloth.

Drying

Let the device dry for at least an hour before using it again.

Control and maintenance

After cleaning and disinfection, the parts must be checked for visible dirt. If necessary, the cleaning / disinfection must be repeated.

packaging

The device does not have to be packed in sterile packaging. Other packaging is also possible.

sterilization

Do not sterilize the device. Electronic components are destroyed by high temperatures.

Storage after processing

Store prepared products protected from dust in a dry, dark and cool room with as few germs as possible.

Technical specifications

Number of ECG channels	3
Max. Sample rate ADC	1 kS / s (per signal)
Resolution ADC	250 to 1000 S / s
Measuring range	(depending on the evaluation system)
Input impedance	0 - 40 mV
Amplitude resolution	≥ 1 MOhm
Frequency response	≤ 1µV related to the input
Measurement accuracy	0.5 - 35 Hz
Storage	According to standard (DIN EN 60601-2-47 or EN60601-1)
Data format	Micro SD card
Duration of use	MIT format

Technical specifications

Ambient temperature and relative humidity	• Operating temperature: + 10 ° C to + 45 ° C • Humidity: 10% to 95% non-condensing • Storage and transport temperature: - 25 ° C (without control of the humidity) to + 75 ° C (at a relative humidity of up to 93% without condensation)
Size	ARES: 54 x 54 x 9.6 mm
Weight	ARES: 19.0 g
Electrical supply	Exclusively via ZEUS 1D, 2D or 7D
Classification	Class I according to Annex IX, RL 93/42 EEC
Classification according to RKI	Uncritical
Article no.	ARES: 01-100 IRIS: 02-100

Symbols

Hersteller		Manufacturer
Entspricht der EG-Richtlinie „Elektro-/Elektronik-Altgeräte“ WEEE 2002/96/EG		According to the EU Directive 2002/96/EC
Um anzuzeigen, dass das Gerät nicht sterilisiert wurde		To indicate that the device has not been sterilized
Gebrauchsanweisung befolgen		Refer to instruction manual/booklet
Gebrauchsanweisung		Operating instruction

Support

If you have any questions or problems with the body sensor or accessories, please contact AthenaDiaX:


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