User Manual for Body Sensor „ARES“

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General Information

Prior to using the body sensor, the user must become familiar with the function of the body sensor through reading this manual carefully.

Intended Purpose of the Body Sensor

The AthenaDiaX body sensor is manufactured to record and store cardiac signals over long periods (up to 7 days). The body sensor consists of:

ECG recorder (ARES)
ECG patch (ZEUS)

- **ZEUS 7D: application up to 7 days**
- **ZEUS 2D: application up to 2 days**
- **ZEUS XDA: application up to 7 days with monitoring extension**

Cardiac signals are detected and recorded in the following cases:

- Paroxysmal atrial fibrillation to detect strokes or for monitoring after ablation
- Assessment of cardiac arrhythmia
- Diagnosis of cardiac genesis especially for patients at risk (e.g. after a stroke, syncope)

Safety and Patient Information for Use

- The body sensor should not be stored or used nearby strong electronic and electromagnetic fields (e.g. X-ray). This can cause errors in the recording.
- The body sensor should not be used when computer tomography or magnetic resonance systems (MR or MRI) are performed.
- Only original accessories should be used.
- The body sensor should not be used while swimming and in the sauna
- The body sensor casing should not be exposed to strong hits. After a strong hit to the casing, the product should not be used anymore.
- The body sensor should not be used on open heart.
- The evaluation of the results should be made by qualified personnel.
- The ECG recorder (ARES) should be checked prior to each use for visible damage. Defective devices or accessories should not be used on patients.

- Avoid direct sunlight on the body sensor during the wearing time.
- The compliance of the safety requirements may be guaranteed only for AthenaDiaX products and product configurations.
- The body sensor can be operated together with pacemakers or other stimulators when all participating devices are used according to their intended purpose. However, automatic ECG analysis may not be possible in this case.
- The device can be damaged by using external defibrillators. A risk to the patient does not exist.
- In case of malfunction send the device to an authorized AthenaDiaX representative.
- The patient should take off the device if a physical problem e.g. severe skin irritation occurs during the recording.
- Extreme cold and heat should be avoided.
- To obtain correct measurement results, the patient should pay attention to an intact adhesive joint between patch and body.
- The body sensor is not suitable for direct monitoring the clinical status of patients because it has no signal display or alarm functions.
- Notice the technical data limits for the ambient conditions (temperature, pressure and humidity) for storage, transportation and operation of the body sensor. Use the body sensor only within these limits.
- Portable and mobile RF communications equipment can affect the function of the body sensor. The body sensor should be installed and used according to the 'information on electromagnetic compatibility'.
- Magnetic and electric fields or ionizing radiation can affect the function of the device. Therefore, do not use the body sensor nearby equipment with high electromagnetic fields or ionizing radiation, such as X-ray apparatus or diathermy.
- Repairs should be carried out only by authorized personnel under the responsibility of AthenaDiaX.
- If the device is maintained and handled by the user improperly, AthenaDiaX has no liability.
- Showering is with ZEUS XDA not allowed. It is only allowed with ZEUS 2D and 7D.
- ZEUS 2D with monitoring extension must be used only for one patient.
- Maximum time of monitoring with ZEUS 7D, ZEUS XDA, ZEUS 2D with monitoring extension is 7 days (168h) and for ZEUS 2D without monitoring extension 2 days.
- After start of recording the body sensor must not be without skin contact for more than 1 hour. The ARES stops recording after 1 hour without skin contact.

Classification

The body sensor is a medical device class IIa, Type BF (according to EN 60601-1 and EN 60601-2-47). It is a portable device with internal power supply for continuous operation.

Product Liability

The manufacturer of the body sensor accepts product liability under the following conditions:

- If the body sensor was operated only with original accessories

- If repairs of the body sensor and its accessories are performed exclusively by the manufacturer or by persons trained and authorized by the manufacturer
- If this manual was considered in using the device
- If the safety checks were carried out

Start of Signal Recording

- If necessary, shave the respective chest area. Clean and dry the skin. For this purpose alcohol pads can be used.
- Assemble the ECG recorder (ARES) and ECG patch (ZEUS). A clicking sound is heard.
- Check to see whether all sides of the ECG recorder are snapped into the retaining rails of the ECG patch (ZEUS).
- To achieve proper assembly, notice the mark on the ECG recorder and patch. Both lines (1 and 2) must be properly aligned to each other.
- Take off the liner from the ECG patch (ZEUS) and stick the pre-assembled body sensor on the chest. Place the body sensor to the highlighted chest area in the figure below (optimal place).
- Only for ZEUS 7D: After affixing the body sensor, remove the protective foil from the top of the ECG patch.
- Only for ZEUS with monitoring extension: The monitoring extension (ECG electrode) is a single use product and it should be only used for a maximum recording of 24 hours. Make sure, that the ECG electrodes are correctly installed. A clicking sound is heard.
- After sticking the body sensor to the chest, the signal recording and storage will start automatically.
- Function Control: With proper signal recording and storage, the green LED blinks every 2s for a short time.
- Signal Control: It is possible to activate this status indicator while recording. Therefore, the body sensor needs to be firmly padded twice.

End of the Recording

- Pull off the body sensor from the skin slowly and carefully. Removing rapidly can cause skin irritation. First, loosen gently an easy accessible point of the body sensor from the skin, then remove the device from the thorax evenly.
- Disconnect the ECG recorder (ARES) from ECG patch (ZEUS).
- Send the ECG recorder (ARES) to your doctor for analysis of the recorded ECG.

Screening and Analysis of the ECG data

- Connect the reader (IRIS) to the PC via the USB cable.
- Place the ECG recorder (ARES) into the reader. Make sure that ARES is oriented correctly.
- An evaluation of the recorded signals will to be done by trained personnel.

Care and Maintenance

- The body sensor should only be cleaned with a slightly damp cloth. Use a non-aggressive solution for disinfecting the body sensor.
- Do not use abrasive materials to clean the device.
- The body sensor should not be cleaned with organic solvents such as benzene or ether.
- Prevent penetration of liquids (do not spray).
- Never insert the device into liquids / disinfectants.

Service and Repair

Unauthorized repairs or modifications of the body sensor's parts or accessories can cause impairment of the function or hazards to the user or patient. Therefore, repairs should be carried out only by the manufacturer or by an authorized person. Illegal opening causes loss of warrant. For service or repair contact your distributor.

Disposal

- The ECG recorder (ARES) and the reader (IRIS) should be properly disposed as old electrical equipment and the ECG recorder should never be disposed to the normal household waste.
- The ECG patch contains a lithium battery. Improper disposal can cause environmental hazards. Please act in accordance with local or national regulations for disposal of batteries.

Self-tests

After connecting the ECG recorder to the patch and during operation of the body sensor, a comprehensive functional test is performed automatically. All necessary functions are checked. If a result of a self-test is negative, the ECG recording will not start and the body sensor displays the 'error' status. This condition is indicated by a red LED for a period of about 1 hour. Subsequently, the body sensor switches off itself.

Internal Monitoring and Protective Measures

The body sensor includes internal protection measures:

- ESD protection according to EN 60601-2-47: / - 6 kV for contact discharge / - 8 kV air discharge
- No defibrillation strength according to DIN EN 60601-1
- Dielectric strength / test voltages applied part according to DIN EN 60601-1 and DIN EN 60601-2-47
- Leakage currents applied part according to DIN EN 60601-1 and DIN EN 60601-2-47

- EMC according to EN 60601-1-2

Support

For questions and problems with the body sensor and accessories, please contact us at:

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