CUSTOMER SUPPORT

If you have any questions regarding this product, please first refer to this guide. To obtain warranty service, you must call Sleepmed and speak with a Customer Service Representative. Be prepared to provide: 1) your name, address and telephone number, 2) the ARES model and serial numbers, and 3) an explanation of the problem.

Telephone:  (877) 710-6999
            Monday – Friday 8:00 AM to 8:00 PM Eastern Standard Time

Fax:       (561) 208-6237

Email:     info@sleeppmedinc.com

Web:       sleeppmedinc.com

SleepMed Inc.

Mailing:   1117 Perimeter Center West, Suite W1514
            Atlanta, GA 30338

MANUFACTURED FOR

Watermark Medical, Inc.
1641 Worthington Road, Suite 320
West Palm Beach, FL 33409
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SAFETY INFORMATION AND INTRODUCTION

A. About the Apnea Risk Evaluation System (ARES)

The Apnea Risk Evaluation System (ARESTM) provides an integrated approach to assist in the diagnosis of obstructive sleep apnea (OSA). The ARES design combines existing knowledge on sleep-disordered breathing with an easy-to-apply data acquisition system. The ARES employs a multivariate approach combining physiological recordings acquired during sleep with anthropomorphic and clinical information obtained from a standardized questionnaire. The ARES integrates: a) a self-applied, single site (forehead) device to record continuous full-disclosure physiological signals during sleep in any environment, b) a focused, validated questionnaire, c) automated software to recognize and quantify abnormal respiratory events, and d) an expert system which utilizes this information to identify levels of severity of OSA. By combining physiological data, questionnaire responses, and expert pattern recognition software, the ARES is designed to provide an accurate and valid assessment of sleep-disordered breathing that is easily self-administered. The ARES is a miniaturized recorder capable of recording oxygen saturation, pulse rate, snoring level, head position/movement, and nasal pressure.

The ARES is easily placed on the forehead by the user and comfortably worn for 8-10 hours. The ARES provides sufficient battery capacity for two nights of recordings (after seven continuous hours of recording the ARES conserves power by automatically going into “sleep mode”). The battery must be recharged after each use.

The ARES monitors signal quality during data acquisition, and notifies the user via a voice prompt when adjustments are required. Several disposable components must be replaced, and the forehead sensor cleaned before reuse.

The Sleepmed Medical, Inc. (Sleepmed) ARES Questionnaire is used to gather information about risk factors for sleep apnea, including gender, body mass index, neck circumference, daytime drowsiness (e.g., Epworth sleepiness score), frequency of snoring, observed apneas, and history of hypertension or diabetes. The ARES applies patented algorithms to calculate SpO2 and quantify the occurrence and severity of desideration events and associated arousals (based on changes in pulse rate, head movement, snoring sounds and/or airflow). The ARES analyzes the ARES Questionnaire responses and assigns risk levels of no, low, or high risk for OSA. A summary report provides information useful to physicians in diagnosing obstructive sleep apnea.
B. Safety

The ARES should be prepared for patient use by a trained clinician. Below are a number of warnings and cautions for the trained technician. Read them carefully: they are important to the effective and safe use of the product. The information in this guide has been carefully checked and is based on our best judgment at this time. In the interest of continued product development, Sleepmed reserves the right to make changes and improvements to this guide and the products it describes at any time, without notice or obligation.

⚠ CAUTION! Read this guide carefully before using the ARES.

Contraindications

1. Do not use the ARES in proximity to a Magnetic Resonance Imaging system.
2. Do not use the ARES as a substitute for clinical pulse oximetry.

The ARES is a recording device, not a monitoring device.

⚠ Warnings

1. Explosion Hazard. Do not use the ARES in the presence of flammable anesthetics or gases or store near high temperature such as fire or enclosed area in direct sunlight.
2. Warranty void if repairs/disassembly are performed by non approved personnel.

⚠ Cautions - General

1. The ARES should be prepared for use by a trained technician.
2. U.S. Federal law restricts this device to sale by or on the order of physician.
3. The ARES should only be worn by a patient after having read the written instructions regarding product use provided by Sleepmed.
4. Do not spray, pour, or spill any liquid on the ARES, its connectors, switches, or openings. Such application of liquids may cause permanent damage and will void the Warranty.
5. Do not use caustic or abrasive cleaning agents on the ARES, such use of cleaning agents may cause permanent damage and will void the Warranty.

6. This device has been tested and found to comply with the limits for medical devices to the IEC 60601 standards. These safety standards are designed to provide reasonable protection against harmful interference in a typical medical installation.

7. Verify that the status indicator illuminates during the startup (initialization) sequence. If any indicator is not lit, do not use the ARES. Contact Customer Support for repair or replacement (1-877-710-6999).

8. For hygienic purposes, replace all disposable components, (i.e., the enclosure strap and nasal cannula, etc) after each patient use.

9. Always inspect and then disinfect the forehead sensor according to the recommended guidelines. The forehead sensor should be replaced after approximately 60 nights of use. It should be replaced earlier if the inspection shows that the surface that comes in contact with the forehead is cracked or pitted.

10. The ARES device is a latex FREE device and suitable for patient with latex allergy.

⚠️ Cautions – Limitations of Use

1. The Apnea Risk Evaluation System (ARES) is indicated for use in the diagnostic evaluation of adult patients with possible sleep apnea. The ARES can record and score obstructive respiratory events (e.g., apneas, hypopneas, mixed apneas, and flow limited events). The device is designed for use in in-home screening of adults with possible sleep disorders.

2. The ARES is not recommended for unassisted use by patients with the following conditions:
   a. Deafness
   b. Blindness
   c. Severe arthritis which limits use of both hands
   d. Dementia
   e. Supplemental oxygen at night
   f. Cardiac arrhythmia
   g. Atrial fibrillation
   h. Tics or tremors of the head
Unassisted use of the ARES by patients with any of these conditions may result in poor signal quality that could lead to a misdiagnosis by the physician.

3. The ARES is **not recommended** for use by patients with the following conditions:
   a. Sensitivity of skin or scalp and/or open wounds on the forehead or scalp.
   b. Allergic reactions to extended exposure to synthetic fabrics (e.g., polyester, rayon).
   c. Upper respiratory infection or congestion.
   d. Inability to sleep at least 5-hours per night or a total of 8-hours over two nights.
   e. Inability to sleep with head reclined (less than 60 degree angle).
   f. Head circumference less than 21 inches or greater than 25 inches.

Use of the ARES by patients with any of these conditions may result in poor signal quality that could lead to a misdiagnosis by the physician.

4. The proper use of the ARES requires patients to be dexterous in both hands, capable of reading and comprehending instructions, and able to see and hear the audio and visual indicators. If the patient cannot meet these requirements the result may be poor signal quality leading to a misdiagnosis by the physician. Such patients require assistance in order that the ARES provides accurate data.

5. ARES use under any of the following conditions may result in poor signal quality that could lead to a misdiagnosis by the physician:
   a. Strap not adjusted properly; too loose or too tight.
   b. Forehead not prepared according to instructions (e.g., makeup, lotion or hair under the sensor).
   c. Loud snoring bed partner or significant ambient noise.

6. In less than 0.1% of patients, the ARES forehead sensor may cause a red mark to appear on the Patient’s forehead after the study. The mark is similar to a sore that sometimes occurs when a patient wears a CPAP mask. This mark is normal and usually disappears in a few hours. On rare occasions, it may remain for two or three days.

If the device causes ANY adverse reaction, discontinue use and consult your health care professional.
⚠️ Cautions - Battery

1. Device shall be fully charged prior to first use. The green indicator light on the ARES will switch off when fully charged.

2. Recharge the ARES batteries using the wall charger provided. Do not rely on the USB port on a computer for proper charging.

3. For optimal performance, use fully recharged batteries.

4. The wall charger should not be sent home with the patient.

5. Follow local ordinances and recycling instructions regarding disposal or recycling of the device and device components, including the battery. The battery might leak or explode if it is used or disposed of improperly.

Guide to Symbols:

![Warning Symbol]

Warnings are identified by the WARNING symbol shown to the left.

![Cautions Symbol]

Cautions are identified by the CAUTION symbol shown to the left.

![Attention Symbol]

Attention – See Instructions for Use is identified by the ATTENTION symbol shown to the left.
A. About Cleaning and Replacing Disposables

The forehead sensor, enclosure pad, and ARES enclosure must be disinfected and the enclosure strap, nasal cannula and EEG disposables must be replaced after each patient use. After the disposables have been replaced the ARES must be placed in a clean resealing bag. The following tasks should be performed after data have been successfully downloaded from the ARES:

1. Unscrew the Nasal Cannula Luer lock from the Enclosure Luer lock.
2. Remove the EEG sensors, enclosure strap, and nasal cannula.
3. Initialize the ARES.
4. Recharge the batteries.
5. Apply latex gloves and clean the sensor.
6. Clean the enclosure.
7. Replace the strap.
8. Apply new EEG sensors.
9. Apply new nasal cannula
10. Place the ARES in customized packaging.
B. Removing the Disposable Components with EEG

Remove the EEG sensors by grasping the Enclosure strap and the EEG flex cable with one hand and pulling on the EEG sensor with the other.

1. Unsnap the Enclosure strap from the Stabilizing Straps.
2. Unscrew the Nasal Cannula from the Cannula Luer Lock on the Enclosure.
3. The disposable components are single use and must be discarded.

C. Cleaning the ARES & Forehead Sensor

Materials:

1. Alcohol-based hand sanitizer meeting CDC hand hygiene guidelines
2. Two 70% Isopropyl Alcohol Swabs
3. Latex or nitrile gloves

Parts Reference:

| Component Description       |  |  |
|-----------------------------|--|--|---|
| 1. Black Luer Lock           | 4 |
| 2. Forehead Sensor           | 2 |
| 3. Forehead Sensor Windows   | 3 |
| 4. Sensor Enclosure Pad      |   |
Procedure:

1. Remove the clear plastic sheet covering the forehead sensor.

2. Apply a small amount of alcohol-based hand sanitizer meeting CDC hand hygiene guidelines (Isagel made by Coloplast recommended) to your index finger.

3. Push down the long edge of the forehead sensor closest to the black plastic Luer lock and gently lift up the other long side of the forehead sensor. Thoroughly rub all exposed areas of the sensor-enclosure pad underneath the forehead sensor and the underside of the forehead sensor for approximately 10 seconds. (Please see cautions below for information on lifting the forehead sensor).

4. Push down the long edge of the forehead sensor closest to the grid of speaker holes and gently lift up the other long side of the forehead sensor. Thoroughly rub all exposed areas of the sensor-enclosure pad underneath the forehead sensor and the underside of the forehead sensor for approximately 10 seconds. (Please see cautions below for information on lifting the forehead sensor).

5. Thoroughly rub the top and side surfaces of the forehead sensor and the rim of sensor-enclosure pad surrounding the forehead sensor with your index finger containing the gel for approximately 10 seconds. (Please see cautions below for information on rubbing the sensor and sensor-enclosure pad).

6. Push down the long edge of the forehead sensor closest to the black plastic Luer lock down and gently lift up the other long side of the forehead sensor. Using a 70% Isopropyl Alcohol Swab made from cotton, thoroughly rub all exposed areas of the sensor-enclosure pad underneath the forehead sensor and the underside of the forehead sensor for approximately 10 seconds.
7. Push down the other long edge of the forehead sensor closes to the grid of speaker holes and gently lift up the other long side of the forehead sensor. Using a 70% Isopropyl Alcohol Swab made from cotton, thoroughly rub all exposed areas of the sensor-enclosure pad underneath the forehead sensor and the underside of the forehead sensor for approximately 10 seconds.

8. Thoroughly rub the top and side surfaces of the forehead sensor and the rim of sensor-enclosure pad surrounding the forehead sensor with the alcohol swab for approximately 10 seconds. (Please see cautions below for information on rubbing the sensor and sensor-enclosure pad).

9. Use a new alcohol swab to thoroughly wipe the top surface of the forehead sensor and the area of the sensor-enclosure pad around the forehead sensor for approximately 10 seconds.

10. Let the unit air-dry; the alcohol drops will dry in approximately 30-60 seconds.

11. Look underneath the forehead sensor and ensure the cable is feeding directly through the hole in the sensor-enclosure pad. Gently press the forehead sensor into the sensor-enclosure pad cavity and apply a clean clear plastic cover or place the ARES in a clean plastic bag.
**CAUTION:**

Vigorous rubbing of the sensor with sufficient moisture from cleansing gel and isopropyl alcohol is required for proper cleaning.

Do not tug on the forehead sensor when lifting it to clean sides of sensor and sensor-enclosure pad underneath forehead sensor.

To avoid damaging the sensor, do not rub it with your finger when the sensor is dry.

The forehead sensor must be replaced after 60 nights of use or when the sensor surface becomes pitted or cracked.

Pulling upward too hard on the forehead sensor during cleaning can cause permanent damage to the forehead sensor and/or Unicorder connector.

The forehead sensor must be replaced after approximately 60 nights of use or when the sensor surface becomes pitted or cracked. The forehead sensor is not covered by the warranty. Use care when cleaning to maximize life of this sensor.

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**D. Replacing the Nasal Cannula**

1. Place the ARES on a flat surface with the luer lock connector pointing upward.
2. Place the two cannula tips in front of the ARES with the tips curving toward the device.
3. Begin affixing the cannula tubing into the four cannula clips on the strap. Pull down slightly on the tubing on both sides of the clip until the tubing slides into the clip.
4. Attach the Nasal Cannula luer lock to the enclosure luer lock and rotate it clockwise until it stops.
5. Check to be sure the Nasal Cannula luer lock is firmly connected to the enclosure luer lock.
E. Recharging the ARES Battery

⚠️ CAUTION: The ARES should only be recharged by trained staff.

⚠️ CAUTION: Do not touch the metal snaps on the flex circuit during charging.

1. The batteries will need to be recharged within two weeks to complete a two-night study, and every four weeks to complete a one-night study.

2. To recharge the ARES, plug the USB charger into a power outlet and confirm the light on USB charger is illuminated.

3. Insert the USB cable connector into the ARES.

4. The ARES will switch on after the USB cable is inserted. A voice message will indicate the battery is charging and the green indicator light on the ARES will blink once per second.

5. If there is a problem with the charging, the ARES will provide a voice message or chirp 4 times a second.

6. The green indicator light on the ARES will switch off when charging is finished. Remove the USB Cable from the ARES and it will shut off automatically.

7. Recharge the ARES with the USB charger supplied. Do not charge the Ares by connecting it to the USB port on a computer.

Note if the voice message does not sound and the ARES light is not flashing then the battery is completely drained and the device must be trickle charged for 5 minutes. After 5 minutes, remove the ARES from the cable and plug it back in, this time the voice message “the ARES is Charging” will sound and normal charging will continue.

Plug the wall charger into a power outlet and verify the light on the wall charger is illuminated red or green. Connect the ARES to the wall charger and confirm the ARES is ON.
The green light on the front of the ARES will flash rapidly during charging and will stop flashing when charging is complete.

F. Replacing the Enclosure Strap and EEG Sensors

⚠️ CAUTION: If the Stabilizing Straps become damaged the result can be poor signal quality with compromised test.

<table>
<thead>
<tr>
<th>Number</th>
<th>Description of Component</th>
<th>Number</th>
<th>Description of Component</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>EEC Sensor Snap</td>
<td>3</td>
<td>EEG Flex Circuit</td>
</tr>
<tr>
<td>2</td>
<td>EEG Sensor</td>
<td>4</td>
<td>EEG Flex Circuit Connector</td>
</tr>
</tbody>
</table>

1. Each side of the Enclosure Strap is labeled with the letter L or the letter R. Each Stabilizing Strap is also labeled with letters L and R.
2. Snap the L side of the Enclosure Strap to the L Stabilizing Strap.
4. Snap the EEG Sensor into the connector on the EEG Flex circuit. Repeat for the other EEG Sensor and Flex circuit.

G. Placing the ARES in a Clean Resealing Bag

After the ARES has been cleaned, the plastic sensor cover has been applied and new disposable components have been applied, the ARES must be placed in a new resealing bag so as not to contaminate any of the ARES surfaces and to protect the silicone forehead sensor during transportation.
AQUIRING AND PROCESSING A SLEEP STUDY

The ARES sleepmed device is operated through the Watermark Medical Website. The SleepMed Medical Web Portal is used to perform basic operations for completing a home sleep test, including initializing the device for user, downloading and processing the study, and retrieving study results. To login to the Watermark Web Portal the user should navigate to the Watermark website at www.watermarkmedical.com. User login information should be obtained through your Sleepmed Sales Representative or Sleepmed customer service.

The web portal requires some custom files to be installed on each computer that will initialize and process study information on the device. This software will automatically be installed the first time the computer uses the website. Administrative rights on the machine are required to do the install but after the install all users should be able to process studies on the machine.

The web portal must be run in Microsoft’s Internet Explorer and requires the Microsoft .Net 2.0 framework or higher to be installed on the system. If the framework is not installed the user will be prompted to install the framework from the Microsoft site during the first use.

A. Initiating a Study

1. The initialize device process checks the status of the device and writes some basic patient identifiers on to the device before dispensing the device to the patient.

2. The device must be attached to the machine using the provided USB cable. From the web portal main menu the user will click on the new study menu item. The user completes the patient information and clicks the initialize device button.

B. Downloading Patient Data

1. From the web portal main menu the user will click on the process study item. The device will be recognized and the initialization data will be pre-populated for the user. The user will complete additional study information and then click on the upload button.

2. The sleep study data will be retrieved from the device (this process takes several minutes) and then uploaded to the Watermark Secure Servers. After successfully uploading the device the device will be formatted and ready for charging.
C. Reviewing Sleep Study Reports

1. Completed sleep studies will be posted to the Watermark web portal and can be retrieved in a PDF format by clicking on the reports menu of the web portal.

D. Dispensing the ARES to the Patient

1. Review the ARES Dispensing instructions with the patient.

2. Measure the head circumference of the patient and adjust the strap according to the table below. (See the ARES dispensing instructions document for measurement instructions)

<table>
<thead>
<tr>
<th>Head Size</th>
<th>Strap Setting</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;21.5”</td>
<td>0</td>
</tr>
<tr>
<td>21.5”</td>
<td>1</td>
</tr>
<tr>
<td>22”</td>
<td>2</td>
</tr>
<tr>
<td>22.5”</td>
<td>5</td>
</tr>
<tr>
<td>23”</td>
<td>7</td>
</tr>
<tr>
<td>23.5”</td>
<td>9</td>
</tr>
<tr>
<td>≥24”</td>
<td>10</td>
</tr>
</tbody>
</table>

3. Show Patient How to Apply the ARES at Home:
   a. Thoroughly wash and dry your forehead.
   b. Remove the plastic covers from the electrodes and the forehead sensor.
   c. Center the ARES sensor to the forehead and gently pull the black strap into place.
   d. Remove hair from under the sensor.
   e. Adjust the slip tube to tighten the cannula. Make sure the cannula tips cannot be pulled more than 1/4 inch away from the nose.
   f. When removing the ARES, gently peel the black sensor away from your forehead prior to completely removing the ARES from your head. Failure to do so may damage the sensor connector.

   Problem to avoid: If the slip tube is not tight enough the airflow alarm will sound during the night. A 1/4 inch error in slip tube adjustment may cause poor signal quality.

Alarms: Communicate with the patient about the ARES device alarms. The different alarms displayed by the device are described in the user guide provided to the customer.
# ARES Specifications

<table>
<thead>
<tr>
<th>Environmental Conditions</th>
<th>Operation</th>
<th>Transportation</th>
<th>Storage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Temperature</td>
<td>5°C to 40°C / 41°F to 104°F</td>
<td>-20°C to 70°C / -4°F to 140°F</td>
<td>-20°C to 70°C / -4°F to 140°F</td>
</tr>
<tr>
<td>Altitude</td>
<td>-390 m to 3,012 m / -1,254 ft. to 9,882 ft.</td>
<td>-390 m to 3,012 m / -1,254 ft. to 9,882 ft.</td>
<td>-390 m to 3,012 m / -1,254 ft. to 9,882 ft.</td>
</tr>
<tr>
<td>Atmospheric Pressure</td>
<td>70 kPa to 106 kPa / 20.6 in. Hg to 31.3 in. Hg</td>
<td>70 kPa to 106 kPa / 20.6 in. Hg to 31.3 in. Hg</td>
<td>70 kPa to 106 kPa / 20.6 in. Hg to 31.3 in. Hg</td>
</tr>
<tr>
<td>Relative Humidity</td>
<td>15% to 95% non-condensing to be compliant with IEC 60601-1, sub-clause 44.5</td>
<td>15% to 95% non-condensing</td>
<td>15% to 95% non-condensing</td>
</tr>
</tbody>
</table>

# General Compliance

<table>
<thead>
<tr>
<th>Item</th>
<th>Compliant With</th>
</tr>
</thead>
<tbody>
<tr>
<td>Equipment classification</td>
<td>Safety Standards: IEC 60601-1, CSA 601.1, UL 2601-1, EN/IEC 60601-1-2 2nd edition</td>
</tr>
<tr>
<td>Type of protection</td>
<td>Class II, Internally powered battery</td>
</tr>
<tr>
<td>Degree of protection against electrical shock</td>
<td>Type BF – Applied part</td>
</tr>
<tr>
<td>Mode of operation</td>
<td>Continuous</td>
</tr>
<tr>
<td>Degree of safety in presence of flammable mixtures</td>
<td>UL 2601-1, sub-clause 5.5, Not suitable</td>
</tr>
<tr>
<td>Applied sensor label to indicate Type BF applied part</td>
<td>IEC 60601-1 Symbol 2 of Table DII of Appendix D</td>
</tr>
<tr>
<td>Attention symbol, consult accompanying documentation</td>
<td>IEC 60601-1 Symbol 9 of Table DII of Appendix D</td>
</tr>
<tr>
<td>External case made with non-conductive plastic</td>
<td>IEC 60601-1, sub-clause 16(b)</td>
</tr>
<tr>
<td>Case mechanically strong</td>
<td>IEC 60601-1</td>
</tr>
<tr>
<td>Electromagnetic compatibility</td>
<td>IEC 60601-1, sub-class 36 IEC/EN 60601-1-2 2nd edition</td>
</tr>
<tr>
<td>Electrostatic discharge immunity</td>
<td>IEC 60601-1-1-2, EN 61000-4-2</td>
</tr>
<tr>
<td>Radiated magnetic field emissions</td>
<td>IEC 60601-1-1-2, EN 61000-4-3</td>
</tr>
<tr>
<td>Magnetic field susceptibility</td>
<td>IEC 60601-1-1-2, EN 61000-4-8</td>
</tr>
</tbody>
</table>
## Audio Signals and Interpretation

<table>
<thead>
<tr>
<th>Event</th>
<th>Sounded when</th>
<th>Audio</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unicorder on - USB</td>
<td>Unicorder attached to USB, power automatically turned on.</td>
<td>ARES Unicorder has been recognized.</td>
</tr>
<tr>
<td>Unicorder off – USB</td>
<td>Unicorder detached from USB, power automatically turned on.</td>
<td>Unicorder has been turned off.</td>
</tr>
<tr>
<td>Unicorder on – study</td>
<td>Unicorder is turned on by subject.</td>
<td>Unicorder has been turned on.</td>
</tr>
<tr>
<td>Unicorder off – study</td>
<td>Unicorder is turned off by subject.</td>
<td>Unicorder has been turned off.</td>
</tr>
<tr>
<td>Power Warning</td>
<td>Unicorder is attached to USB wall charger, turned on, warning message.</td>
<td>Warning. The Unicorder is Charging.</td>
</tr>
<tr>
<td>Hardware error</td>
<td>Hardware error detected during start-up that makes recording impossible</td>
<td>“Call Tech Support. The Unicorder is not working. Code 1”</td>
</tr>
<tr>
<td>Unicorder check failed</td>
<td>Firmware check failed on study start-up that makes recording impossible: needed calibration data is missing, etc</td>
<td>“Call Technical Support. Unicorder internal check failed and study cannot be performed. Code 5”</td>
</tr>
<tr>
<td>Call Technical Support</td>
<td>Unknown hardware error, detected during study, usually related to forehead sensor not sensing enough optical signal</td>
<td>“Call Tech Support. The Unicorder is not working. Code 6”</td>
</tr>
<tr>
<td>Battery low, must be recharged</td>
<td>Battery low warning on start-up, not enough for full study</td>
<td>“The Unicorder battery is low. It must be recharged.”</td>
</tr>
<tr>
<td>Memory card full</td>
<td>Memory card is full on start-up, recording impossible</td>
<td>“Call Tech Support. The memory card is full. Code 7”</td>
</tr>
<tr>
<td>Initialization period started</td>
<td>Start up initialization period started</td>
<td>“Lie on your back, look at the ceiling and do not move.”</td>
</tr>
<tr>
<td>Initialization period completed</td>
<td>Initialization period finished, subject can sleep now</td>
<td>“Initialization successful. You can now go to sleep.”</td>
</tr>
<tr>
<td>Bad Airflow 1</td>
<td>Nasal cannula fell off alarm. Subject is instructed to place it back.</td>
<td>”Tighten the nasal cannula.”</td>
</tr>
<tr>
<td>Optical alarm</td>
<td>Off head alarm. Subject is instructed to adjust Unicorder on forehead.</td>
<td>“The Unicorder has fallen off.”</td>
</tr>
<tr>
<td>Bad optical 1</td>
<td>Optical signal is bad. Subject is instructed to adjust Unicorder on forehead.</td>
<td>“Adjust the Unicorder on your forehead.”</td>
</tr>
</tbody>
</table>
### Table 204

**Guidance and manufacturer’s declaration – electromagnetic immunity**

The ARES is intended for use in the electromagnetic environment specified below. The customer or the user of the ARES should assure that it is used in such an environment.

<table>
<thead>
<tr>
<th>Immunity Test</th>
<th>IEC 60601 test level</th>
<th>Compliance level</th>
<th>Electromagnetic environment - guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conducted RF</td>
<td>3 Vrms</td>
<td>3 Vrms</td>
<td>Portable and mobile RF communications equipment should be used no closer to any part of the ARES, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</td>
</tr>
<tr>
<td>IEC 61000-4-6 - Radiated RF IEC 61000-4-3</td>
<td>150 kHz to 80 MHz / 3 V/m 80 MHz to 2.5 GHz</td>
<td>3 V/m</td>
<td>$d = 1.2 \sqrt{P}$ MHz to 800 MHz d = $2.3 \sqrt{P}$ MHz to 2.5 GHz</td>
</tr>
</tbody>
</table>

where $P$ is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and $d$ is the recommended separation distance in meters (m).

Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range.

Interference may occur in the vicinity of equipment marked with the following symbol:

| NOTE 1 | At 80 MHz, the higher frequency range applies. |
| NOTE 2 | These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people. |

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* Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Model 603 is used exceeds the applicable RF compliance level above, the Model 603 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Model 603.

* Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.
Table 201

Guidance and manufacturer’s declaration – electromagnetic emissions

The ARES is intended for use in the electromagnetic environment specified below. The customer or the user of the ARES should assure that it is used in such an environment.

<table>
<thead>
<tr>
<th>Emissions Test</th>
<th>Compliance</th>
<th>Electromagnetic environment – guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>RF emissions CISPR 11</td>
<td>Group 1</td>
<td>The ARES does not use RF energy only for its internal function and is not likely to cause any interference in nearby electronic equipment.</td>
</tr>
<tr>
<td>RF emissions CISPR 11</td>
<td>Class B</td>
<td></td>
</tr>
<tr>
<td>Harmonic emissions IEC 61000-3-2</td>
<td>N/A</td>
<td>The ARES is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.</td>
</tr>
<tr>
<td>Voltage fluctuations/</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>flicker emissions IEC 61000-3-3</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

PATENT AND TRADEMARK ACKNOWLEDGEMENTS

- The ARES is patented in the United States (P/N 6,811,538), Australia, and other patents pending.
- ARES, ARES Manager and ARES Insight are trademarks of Watermark Medical, Inc., WPB.
- Windows is a trademark of Microsoft Corporation.
- All other products or brand names are trademarks or registered trademarks of their respective companies.
ARES LIMITED WARRANTY

1. Sleepmed’s Responsibilities. This Agreement is between Sleepmed and purchaser (the “Customer,” “you,” or “your”) for the ARES covered by this Agreement (“Product”). During the term of this Agreement, Sleepmed will provide all parts and labor except as excluded below, necessary to service and repair the Product to a condition suitable for normal use (the “Service”). “Normal use” is defined as regular, ordinary, and routine use of the Product under normal operating conditions as intended and/or recommended by Sleepmed.

2. How to Obtain Service. You may obtain Service for the Product, or request additional information, by contacting Sleepmed at (877) 710-6999. This Agreement and the ARES serial number must be provided when you request Service for the Product. All Service provided under this Agreement shall be performed by Sleepmed. If Service requires replacement of the Product or parts, Sleepmed will supply new or remanufactured product or parts on an exchange basis. Exchanged Product/parts become the property of Sleepmed.

3. Warranty Coverage.
   A. Standard Warranty. Under the 12-month “STANDARD WARRANTY” coverage, Sleepmed is responsible for all shipping and delivery of the ARES to and from Watermark. If Sleepmed is unable to resolve an included repair within 10 working days, at our option Sleepmed may replace a product with one of like kind and quality. The replaced Product or part shall become Sleepmed property and exchanged or replaced products and parts assume the remaining coverage period under this Agreement.

4. Services and Parts Excluded under Warranty.
   A. Exclusions:
      i. On-Site or in-house service and repair of the Product;
      ii. Service or repair by persons other than those trained or authorized by Sleepmed to service the Product;
      iii. Service or repair of Product on which the ARES serial number has been defaced or removed;
      iv. Service or repair made necessary by use of or damage caused by third party products.
      v. Installing more than one database or transferring/copying a database without following the specific instructions which can be obtained from ARES Client Services.
      vi. The black forehead sensor assembly is a wear item and therefore not covered in the 12 month warranty,
   B. Payment for Non-Warranty Work.
      i. If you authorize Sleepmed to perform any services excluded under this Agreement, you agree to pay Sleepmed its usual and customary fees for such work.

5. Eligibility. Sleepmed reserves the right to require an inspection of the Product at your expense prior to the acceptance of this Agreement to verify that the Product is in unaltered, operable condition and in good working order suitable for normal use. Acceptance of this Agreement is expressly conditioned upon prior payment by you. You agree to notify Sleepmed if Product is lost, stolen, or sold.

6. Return of Product. To return ARES products to Sleepmed under a warranty claim, the Purchaser must first contact Sleepmed’s Customer Support at (877) 710-6999 and receive a Return Merchandise
Authorization (RMA) number. Purchaser must place the RMA number on the outside of the package containing the products being returned and ship the package to Sleepmed’s facility, freight prepaid. The package should contain a short description of the defect and a contract number to discuss equipment concerns with the licensee. Any returned ARES Product received by Sleepmed without a RMA number shall be sent back to the Purchaser.

7. LIMITATION OF WARRANTIES. SLEEPMED DOES NOT REPRESENT OR WARRANT THAT THE ARES PRODUCT WILL MEET YOUR REQUIREMENTS OR THAT THE OPERATION OF THE SOFTWARE PRODUCT WILL BE UNINTERRUPTED OR ERROR FREE. TO THE MAXIMUM EXTENT PERMITTED BY LAW, EXCEPT AS EXPRESSLY PROVIDED IN THIS LICENSE, SOFTWARE PRODUCTS ARE PROVIDED “AS IS” WITHOUT WARRANTY. SLEEPMED DISCLAIMS ALL WARRANTIES, EXPRESS OR IMPLIED, THAT ARE NOT EXPRESSLY PROVIDED IN THIS WARRANTY INCLUDING THE IMPLIED WARRANTIES OF MERCHANTABILITY, AND FITNESS FOR A PARTICULAR PURPOSE.

8. LIMITATION OF LIABILITY. IN NO EVENT SHALL SLEEPMED, ITS RESPECTIVE PARENT OR AFFILIATE COMPANIES OR ANY OF THEIR RESPECTIVE DIRECTORS, OFFICERS, EMPLOYEES, AGENTS OR SUBCONTRACTORS, BE LIABLE UNDER ANY THEORY OF TORT, CONTRACT, STRICT LIABILITY OR OTHER LEGAL THEORY FOR LOST PROFITS, LOST REVENUES, LOST BUSINESS OPPORTUNITIES AND INFORMATION, BUSINESS INTERRUPTION, EXEMPLARY, PUNITIVE, SPECIAL, INCIDENTAL, INDIRECT OR CONSEQUENTIAL DAMAGES, EACH OF WHICH IS HEREBY EXCLUDED BY AGREEMENT OF THE PARTIES, REGARDLESS OF WHETHER SUCH DAMAGES WERE FORESEEABLE OR WHETHER SLEEPMED HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES. SLEEPMED’S CUMULATIVE LIABILITY FOR ALL LOSSES, CLAIMS, SUITS, CONTROVERSIES, BREACHES, OR DAMAGES FOR ANY CAUSE WHATSOEVER (INCLUDING, BUT NOT LIMITED TO, THOSE ARISING OUT OF OR RELATED TO THIS AGREEMENT) AND REGARDLESS OF THE FORM OF ACTION OR LEGAL THEORY SHALL BE THE AMOUNT YOU ACTUALLY PAID FOR THE SOFTWARE PRODUCT, AS EVIDENCED BY WRITTEN RECEIPTS OR OTHER WRITTEN EVIDENCE. BECAUSE SOME STATES DO NOT ALLOW THE EXCLUSION OR LIMITATION OF LIABILITY FOR CONSEQUENTIAL OR INCIDENTAL DAMAGES, THE ABOVE LIMITATION MAY NOT APPLY TO YOU.

9. GOVERNING LAW. This Warranty shall be governed by and construed in accordance with the laws of the State of Florida (without regard to its choice of law provisions). YOU IRREVOCABLY WAIVE ANY AND ALL RIGHTS YOU MAY HAVE TO A TRIAL BY JURY IN ANY JUDICIAL PROCEEDING INVOLVING ANY CLAIM RELATING TO OR ARISING UNDER THIS AGREEMENT.

10. DISPUTE RESOLUTION. Any dispute, controversy, or claim against Sleepmed arising out of or relating to this Agreement, its interpretation, or the breach, termination or validity thereof, or any related purchase shall be resolved exclusively and finally by arbitration administered by the American Arbitration Association (AAA) under its rules (www.adr.org). You may file for arbitration at any AAA location in the United States upon the payment of any applicable filing fee. The arbitration will be conducted before a single arbitrator, and will be limited solely to the dispute or controversy between you and Sleepmed. The arbitration shall be held in any mutually agreed upon location in person, by telephone, or online. Any decision rendered in such arbitration proceedings will be final and binding on each of the parties, and judgment may be entered thereon in a court of competent jurisdiction. The arbitrator shall not award either party special, exemplary, consequential, punitive, incidental or indirect damages, or attorneys’ fees and each party irrevocably waives any such right to recover such damages. The parties will share the costs of the arbitration, (including the arbitrator’s fees, if any) in the proportion that the final award bears to the amount of the Initial claim. No action, regardless of form, arising out of or in conjunction with the subject matter of this Agreement may be brought by either party more than one (1) year after the cause of action arose.

11. ENTIRE AGREEMENT. This Warranty constitutes the entire agreement between you and Sleepmed pertaining to the subject matter hereof and supersedes in their entirety all written or oral agreements between the parties pertaining to the subject matter hereof.