If you have any questions regarding this product, please first refer to this guide. To obtain warranty service, you must call Watermark Medical 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 5:00 PM Eastern Standard Time

Fax: (561) 208-6237

Web: www.watermarkmedical.com

Mailing: 1117 Perimeter Center West, Suite W514  
Atlanta, GA 30338

Watermark Medical, Inc.  
1117 Perimeter Center West, Suite W514  
Atlanta, GA 30338
SAFETY INFORMATION AND INTRODUCTION

A.  About the Apnea Risk Evaluation System (ARES)

The Apnea Risk Evaluation System (ARES™) 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 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 desaturation events and associated arousals (based on changes in pulse rate, head movement, snoring sounds and/or airflow). The ARES system software 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 technician. Below are a number of warnings and cautions. Read them carefully: they are important to the effective and safe use of the product. The information in this guide has been carefully reviewed and is based on our best judgment at this time. In the interest of continued product development, Watermark Medical 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 or store near:
   • Flammable anesthetics or gases
   • High temperatures such as fire
   • Enclosed areas 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 a physician.
3. The ARES should only be worn by a patient after having read the written instructions regarding product use provided by Watermark Medical.
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. Do not introduce the device into an environment with pest issues (ex.: bedbugs). Infestation of the device may cause permanent damage and will void the warranty. **NOTE:** Replacement cost of devices returned due to bug infestation is the responsibility of the customer.

7. The cleaning procedure for the ARES has been validated and meets agency guidelines to mitigate the transfer risk of bacteria and viruses found in illnesses such as the common cold, influenza and viruses such as COVID-19, etc. If the device comes in contact with a patient that has an active infectious disease such as MRSA or C. diff, please refer to item 3d in the “Cautions – Limitations of Use” of this manual for further instruction.

8. 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.

9. 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 (877-710-6999).

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

11. Always inspect and then disinfect the forehead sensor according to the recommended guidelines. The forehead sensor is recommended for replacement 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.

12. The ARES is a latex-free device and suitable for patients with latex allergy.

---

### Cautions – Limitations of Use

1. The Apnea Risk Evaluation System (ARES) Model 610 is indicated for use in the diagnostic evaluation of adult patients with possible sleep apnea. The ARES can record and score obstructive respiratory events during sleep (e.g., apneas, hypopneas, mixed apneas, and flow-limited events). The device is designed for 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 use 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. Active, contagious, infectious disease (ex.: MRSA, C. diff).  

   **NOTE:** If a device is used on a person with active, infectious disease such as MRSA or C. diff it cannot be used on any other patient. The customer should contact Watermark Medical Customer Support for instructions on returning the device.

e. Inability to sleep at least 5-hours per night or a total of 8-hours over two nights.  
f. Inability to sleep with head reclined (less than 60 degree angle)  
g. Head circumference less than 20 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 to ensure that the ARES records 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. The ARES device is not to be used on children.
7. In less than 0.1% of cases, patients may experience a red mark appearing on the 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 patient experiences ANY adverse reaction, they should discontinue use and consult their health care professional.

⚠️ **Cautions - Battery**

1. Device should 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 only using the wall charger provided.

3. Do not attempt to charge the ARES with a charger from another product.

4. Do not rely on the USB port on a computer for proper charging.

5. For optimal performance, use fully recharged batteries.

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

7. 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:**

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

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

- Attention – See “Instructions for Use” identified by the ATTENTION symbol shown to the left.
PREPARING THE ARES 610 FOR USE

A. About Cleaning and Replacing Disposables

The forehead sensor, enclosure pad, and ARES enclosure must be cleaned 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 has 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 non-latex gloves and clean the sensor.
6. Clean the enclosure.
7. Replace the strap.
8. Apply new EEG sensors.
10. Place the ARES in customized packaging.

<table>
<thead>
<tr>
<th>COMPONENT DESCRIPTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Enclosure Strap</td>
</tr>
<tr>
<td>2. Stabilizing Strap Snap</td>
</tr>
<tr>
<td>3. Cannula Tip</td>
</tr>
<tr>
<td>4. Cannula Clip</td>
</tr>
<tr>
<td>5. Stabilizing Straps</td>
</tr>
<tr>
<td>6. Enclosure Luer Lock</td>
</tr>
<tr>
<td>7. Nasal Cannula Luer Lock</td>
</tr>
<tr>
<td>8. Slip Tube</td>
</tr>
<tr>
<td>9. Forehead Sensor</td>
</tr>
<tr>
<td>10. On/Off Button</td>
</tr>
<tr>
<td>11. USB Cable Connector</td>
</tr>
<tr>
<td>12. EEG Flex Cable</td>
</tr>
<tr>
<td>13. EEG Sensor</td>
</tr>
</tbody>
</table>
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 Pads
3. Non-latex or nitrile gloves

Parts Reference:

|------------------------|-------------|--------------------|----------------------------|------------------------|
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 to your index finger.

3. Push down the long edge of the forehead sensor closest to the 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 on page 10 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 on page 10 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 on page 10 for information on rubbing the sensor and sensor enclosure pad).
6. Perform Steps 1—5 again using a 70% alcohol pad instead of hand sanitizer. (See photos below.)

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

8. Look underneath the forehead sensor and ensure the cable is feeding directly though 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 and place the Unicorder 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.
- 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 is recommended to 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.

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 wall charger into a power outlet and confirm the light on the charger is illuminated.

3. Insert a USB cable into the wall charger and 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. The green light on the front of the ARES will flash rapidly during charging and will stop flashing when charging is complete.

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. Call Technical Support at (877) 710-6999 if you have additional questions.
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>EEG 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.
ACQUIRING AND PROCESSING A SLEEP STUDY

The ARES device is operated through the Watermark Medical Website. The ARES 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 ARES Portal the user should navigate to the Watermark website at www.watermarkmedical.com. User login information should be obtained through your Sales Representative or customer service.

The ARES 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 ARES portal must be run in Microsoft’s Internet Explorer or Google Chrome and requires the Microsoft .Net 3.5 framework or higher to be installed on the system.

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 ARES 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 ARES 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 data, the device will be formatted and ready for charging.

C. Reviewing Sleep Study Reports

1. Completed sleep studies will be posted to the ARES portal and can be retrieved in a PDF format by clicking on the reports menu of the 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. (See the ARES Dispensing Instructions document for measurement instructions.)

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 alert will sound during the night. A 1/4 inch error in slip tube adjustment may cause poor signal quality.

Alerts: Communicate with the patient about the ARES device alerts. The different alerts displayed by the device are described in the user guide provided to the patient.
# ARES 610 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</td>
<td>-20°C to 70°C</td>
<td>-20°C to 70°C</td>
</tr>
<tr>
<td></td>
<td>41°F to 104°F</td>
<td>-4°F to 140°F</td>
<td>-4°F to 140°F</td>
</tr>
<tr>
<td>Altitude</td>
<td>-390m to 3,012m</td>
<td>-390m to 3,012m</td>
<td>-390m to 3,012m</td>
</tr>
<tr>
<td></td>
<td>-254 ft. to 9,882 ft.</td>
<td>-254 ft. to 9,882 ft.</td>
<td>-254 ft. to 9,882 ft.</td>
</tr>
<tr>
<td>Atmospheric Pressure</td>
<td>70 kPa to 106 kPa</td>
<td>70 kPa to 106 kPa</td>
<td>70 kPa to 106 kPa</td>
</tr>
<tr>
<td></td>
<td>20.6 in. Hg to 31.3 in. Hg</td>
<td>20.6 in. Hg to 31.3 in. Hg</td>
<td>20.6 in. Hg to 31.3 in. Hg</td>
</tr>
<tr>
<td>Relative Humidity</td>
<td>15% to 95% non-condensing</td>
<td>15% to 95% non-condensing</td>
<td>15% to 95% non-condensing</td>
</tr>
<tr>
<td></td>
<td>compliant with IEC 60601-1, sub-clause 44.5</td>
<td></td>
<td></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 by 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>Sound 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 device should ensure 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></td>
<td></td>
<td></td>
<td><strong>Recommended separation distance</strong></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>$d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>$d = 2.3 \sqrt{P}$ 800 MHz to 2.5 GHz</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>where $P$ is the maximum output power rating of the transmitter in watts (W) according to the manufacturer and $d$ is the recommended separation distance in meters (m).</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Interference may occur in the vicinity of equipment marked with the following symbol:</td>
</tr>
</tbody>
</table>

**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.

- 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 610 is used exceeds the applicable RF compliance level above, the Model 610 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 610.
- Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.
### 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/ ficker emissions IEC 61000-3-3</td>
<td>N/A</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.
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