







Xodus Medical
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INSTRUCTIONS FOR USE

HOT PINK PAD WARMING SYSTEM

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1.0 INFORMATION ABOUT THESE INSTRUCTIONS

- Before using this product, read the following information thoroughly.
- Correct and safe operation can only be guaranteed if the instructions for use are observed.
- Incorrect use can result in damage to the product or to other property and/or personal injury.
- Keep the instructions for use for future reference.
- Only use the device for the intended purpose as described in these instructions for use.
- Any alteration of this Patient Warming System not authorized or performed by Xodus Medical which could affect its operation voids the warranty, could jeopardize operator and patient safety and could violate national, state, or local regulations.
- Two-part system – Single Use Hot Pink Pad and Reusable Hot Pink Pad Controller.
- Notice to the User that any serious incident that has occurred in relation to this medical device should be reported to the manufacturer and competent authority in the country where the incident occurred.

2.0 DESCRIPTION

The Hot Pink Pad Warming System is an active warming system that is designed to assist in patient temperature management and prevent inadvertent hypothermia during surgical procedures. Included with the system is a reusable controller, reusable connecting signal cable, and a single use Hot Pink Pad (warming pad) with cable.

The Hot Pink Pad Controller is to be secured to an IV pole or similar. The controller has the functionality to set and regulate the desired temperature for the heating function of the system using the front panel display. The controller also detects faults and provides alarming via an audible source and the controller LCD display. The controller is a reusable device that remains in the OR when not being used.

The Hot Pink Pad Controller has one fifteen-foot cable that connects to the single use warming pad. The set-temperature of the connected warming pad can be selected between a range from 36.0°C to 40.0°C in 0.5°C increments.

The warming pad of the Hot Pink Pad Warming System is a single use device. It uses Xodus Medical's Pink Pad foam that provides patient protection and safety during surgical procedures when positioning a patient on the OR table.

The Hot Pink Pad Warming System is not intended to regulate the patient's body temperature and does not display associated patient temperature data. The display indicates current temperature of the warming pad's heated core. Temperature regulation of the Hot Pink Pad's warming function is measured using several integrated sensors located on the pad.

The Hot Pink Pad Warming System offers a combination of assistance in patient temperature management and prevent inadvertent hypothermia during surgical procedures. The Hot Pink Pad is a single use device and must be discarded following use in accordance with hospital policy.

The single-use warming pad materials are X-ray compatible.

Patient safety of the Hot Pink Pad Warming System is ensured by the following measures for each output:

- Multiple sensors on the warming pad for software driven temperature regulation
- Independent sensor monitoring with one dedicated mechanical sensor for overtemperature detection
- Visual and audible alarm signals

3.0 INDICATIONS FOR USE

The Hot Pink Pad Warming System is a non-sterile, electrically conductive Patient Warming System with adjustable temperature in a pre-defined range. The Hot Pink Pad Warming System is to be used during surgical procedures to assist in patient temperature management and prevent inadvertent hypothermia.

The Hot Pink Pad Warming System is intended for use in hospitals and surgery centers.

The Hot Pink Pad Warming System's patient population includes adult and pediatric patients, but excludes neonatal patients.

4.0 INTENDED PURPOSE AND USER

This device is intended for use by trained healthcare professionals only.

5.0 CONTRAINDICATIONS

This device is not designed, sold, or intended for use except as indicated. This device is contraindicated for use with neonatal patients.

6.0 KNOWLEDGE AND USE

Device is to be used by prescription only. Professional use requires knowledge of this instruction for use. Device use limited to the surgical operating room in a hospital or surgery center.

7.0 CLINICAL BENEFITS

- 7.1 Provides assistance in patient temperature management and preventing inadvertent hypothermia during surgical procedures

8.0 MODE OF OPERATION

- 8.1 Operating mode is continuous as determined by device design risk and functionality.

9.0 PREPARATION AND USE

Important Note:

- No need for periodic service or calibration during controller service life.
- Compact packaging with no parts to lose

9.1 Product Inspection Prior to Use:

9.1.1 When opening the Controller

9.1.1.1 Open the package only at the time of use and remove the contents which include (1) Controller, (1) signal cable, (1) AC power cord.

9.1.1.2 Visually Inspect all parts for any damage.

9.1.1.3 Do not use any product that is considered damaged.

9.1.2 When opening the Warming Pad

9.1.2.1 Open the package only at the time of use and remove the contents which include (1) Warming Pad.

9.1.2.2 Visually Inspect the warming pad for any damage.

9.1.2.3 Do not use any product that is considered damaged.

9.2 MOUNTING THE CONTROLLER:

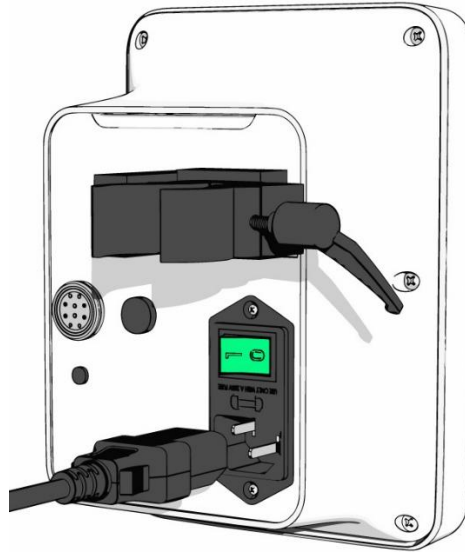
9.2.1 Mount the controller onto an IV pole (or similar) using the mounting bracket on the back of the controller.

9.2.2 The Hot Pink Pad controller is outfitted with a universal mounting clamp. The clamp can be securely fixed to (IV) poles with diameters between 1.0" (25.4mm) and 1.5" (38mm).

9.2.2.1 Open the bracket by rotating (turning) the handle counter-counterclockwise. Seat the open bracket around the IV pole between the rubber pads inside the jaws of the mounting bracket. Sufficiently tighten the mounting bracket to the IV pole by rotating (turning) the handle in the clockwise direction. Once the handle has been sufficiently tightened, add ¼ turn to the rotation of the handle to assure the mounting bracket is tight.

9.2.3 Plug the female end of the electrical power supply cord into the controller female receptacle. Do not plug the electrical cord male end into the electrical outlet (wall) at this time. See Figure 1.

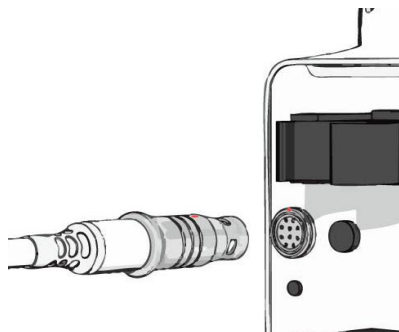
FIGURE 1



9.3 CONNECT CABLE:

- 9.3.1 Plug the 15' (4.6 m) male end of the signal cable connector into the female cable connection on the rear left side of the controller. See Figure 2.
- 9.4.1. The reusable 15' (4.6 m) signal cable male connector has a red mark that aligns with the red mark on the controller female connector.
- 9.4.2. Once the red marks are aligned, press the male shielded cable connector directly into the female connector until a clicking sound is heard. This sufficiently seats the connectors together.

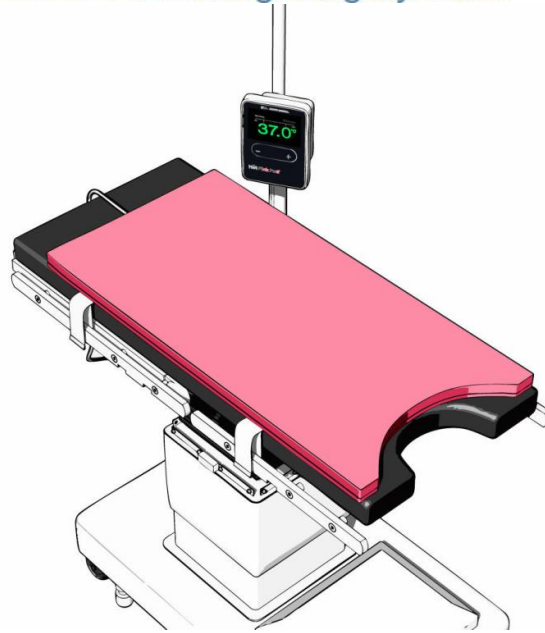
FIGURE 2



9.4 PLACING WARMING PAD:

- 9.4.1 Place the warming pad on the OR table with the 'This Side Up' tags on the white straps visible and facing upward.
- 9.4.2 The warming pad shall be at the very edge of the middle table segment nearest the perineal cutout, positioning the white Velcro straps on the underside of the warming pad in direct contact with the table pad surface. See Figure 3.
- 9.4.3 DO NOT use the warming pad in conjunction with table covers or other materials.
- 9.4.4 The warming pad must contact the surface of the OR table mattress.

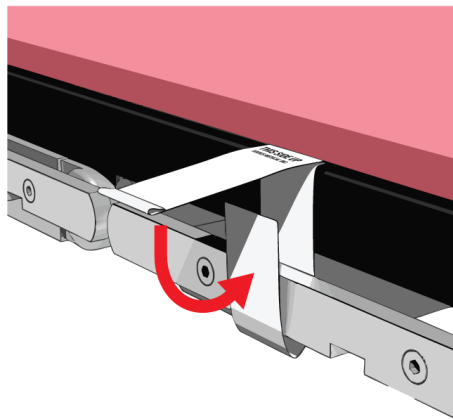
FIGURE 3



9.5 ATTACH WARMING PAD STRAPS

- 9.5.1 Attach the white Velcro straps of the warming pad to the OR table rails by looping under the rail, as shown, and affixing the ends of the Velcro to each other. See Figure 4.

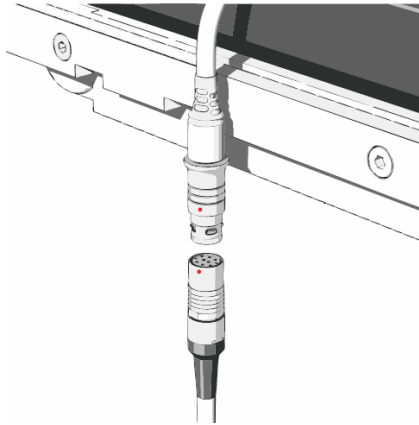
FIGURE 4



9.6 CONNECTING THE WARMING PAD:

- 9.6.1 Remove the cap from the distal end of the cable. Allow cap to hang from lanyard.
- 9.6.2 Plug the warming pad stub cable male connector (attached to the warming pad) into the reusable 15' (4.6 m) signal cable female connector (attached to the controller), forming a complete connection between the Hot Pink Pad controller and warming pad. See Figure 5.
- 9.6.2.1 Align the red dots on the male and female connector ends and press inward to connect.
- 9.6.3 Route the 15' (4.6 m) shielded signal cable off of the OR table and down toward the floor, near the head-end of the OR table safely to the controller location. Ensure the cable is not creating a trip hazard.
- 9.6.4 Do not route the cable above or beneath the warming pad.
- 9.6.5 Follow hospital protocol for routing of cables on the floor.

FIGURE 5



9.7 CONNECTING CONTROLLER TO AC MAINS POWER:

- 9.7.1 Plug the controller male end of the electrical power cable into the appropriate (wall) electrical outlet.
- 9.7.2 Verify the mains voltage used at the facility (typically 110/220VAC) to assure the male plug end is appropriate to plug into the electrical outlet. See Figure 6.

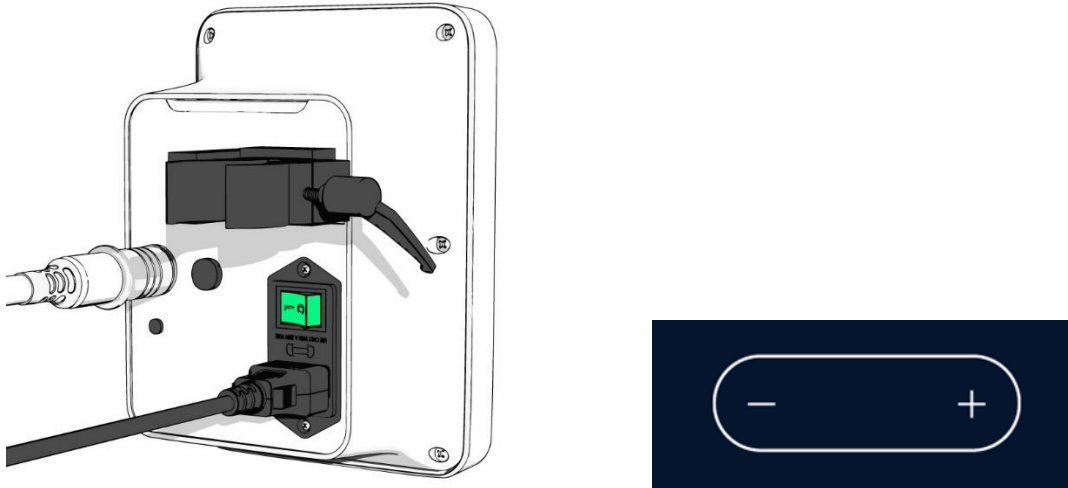
FIGURE 6



9.8 POWERING ON THE CONTROLLER:

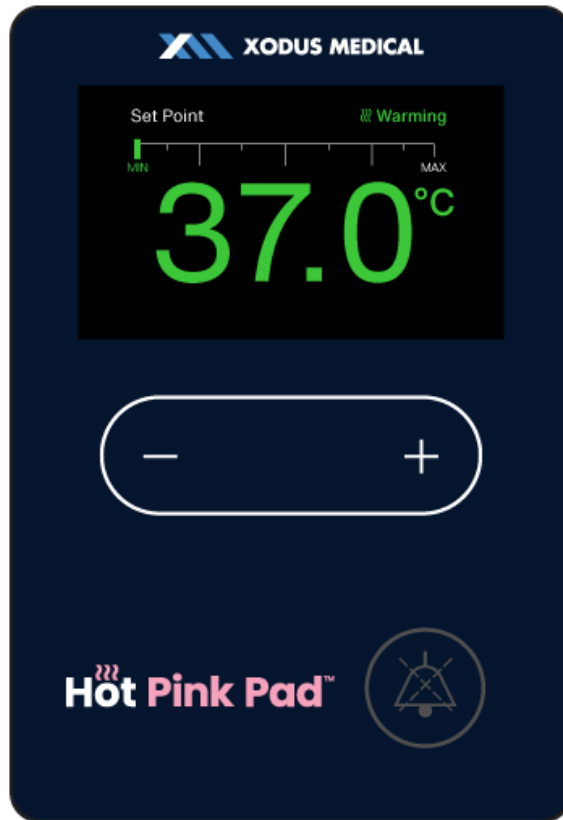
- 9.8.1 Turn on the controller at the rear of the controller housing using the rocker switch. The + (plus) and - (minus) buttons will backlight in white and the Power indication button on the rear of the controller will be backlit with a green color. See Figure 7.
- 9.8.2 Note: Turn on the controller at least 10 minutes prior to patient placement on the warming pad.

FIGURE 7



- 9.8.3 The controller shall “boot up” and display a default temperature of 36°C in green colored text. “Warming” will also appear to indicate the system is warming toward the set temperature.
- 9.8.4 Adjust the temperature setting to the desired set temperature using the + (plus) and - (minus) buttons on the front of the controller in 0.5°C increments. These are illuminated with a white outline as shown below. The set temperature range is 36°C to 40°C. See Figure 8.

FIGURE 8



- 9.8.5 The warming pad will have reached the set temperature within 10 minutes.
- 9.8.6 If the set temperature of the controller needs to be adjusted during the surgical procedure, use the + (plus) and - (minus) buttons on the front of the controller to raise or lower the selected set temperature.

9.9 PATIENT POSITIONING:

- 9.9.1 Properly position the patient on the warming pad and follow hospital protocol for patient prep and intubation.

IMPORTANT: THE PATIENT'S SKIN MUST MAKE DIRECT CONTACT WITH THE WARMING PAD. The skin of the Scapula Region and Sacrum must contact the pad surface. Do not drag patient on or across the Pink Pad. Make sure the Pink Pad remains completely flat at all times assuring no folds or creases.

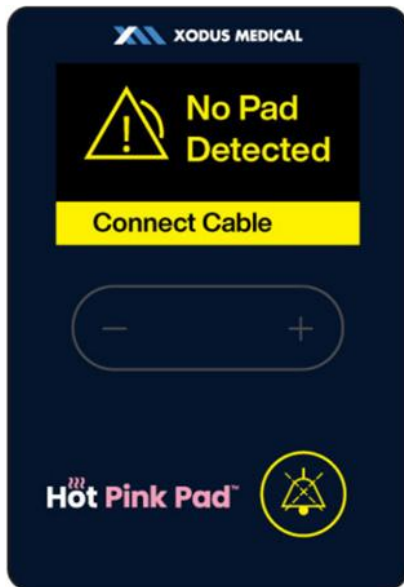
9.10 ALARMING

- 9.10.1 The Hot Pink Pad Controller is equipped with independent alarming functions.
- 9.10.2 System alarms are provided with the system and are an indication of an issue related to either the controller, cabling, or warming pad.
- 9.10.3 Alarms will automatically trigger when an error is encountered.
- 9.10.4 Alarms have a visual indicator and an audible indicator of the priority of the alarm.

- 9.10.5 The Hot Pink Pad has low priority alarms and medium priority alarms.
- 9.10.6 Any alarm audio may be paused by pressing the alarm button at the bottom right on the front of the controller.
 - 9.10.6.1 The paused alarm audio will present a reminder audible alert at the 10 minute mark from the time it was paused.
 - 9.10.6.2 The alarm indication on the display screen shall remain during this time.
- 9.10.7 Alarms can be reactivated at any time by pressing the alarm button after the act of pausing an alarm.
- 9.10.8 *This line Left Intentionally blank*
- 9.10.9 In the event of a loss of power, it is recommended that the Hot Pink Pad be connected to an uninterruptible power supply for continued operation.
- 9.10.10 During power up, there is a system check that verifies that all features are operational. There is no requirement for operator on how and when to verify the functionality of the alarm system.
 - 9.10.10.1 As part of this system check, the independent thermal cut-out is verified as operational.
- 9.10.11 The following alarm descriptions are accompanied by a depiction of the controller display.
 - 9.10.11.1 **“Connect Cable”**: Low priority alarm with a visual and audible signal. Visual display in yellow on the display of the controller when the warming pad cable is not plugged into the controller cable connection. This alarm is accompanied by an appropriate audible sequence of a single beep tone. Figure 9 & 10.
 - 9.10.11.1.1 Recommended action:
 - 9.10.11.1.1.1 Plug warming pad cable into the controller cable connection.
 - 9.10.11.1.2 Plug controller cable into the controller.

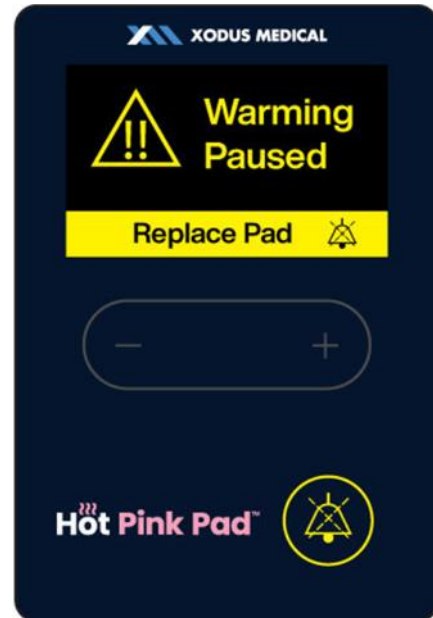
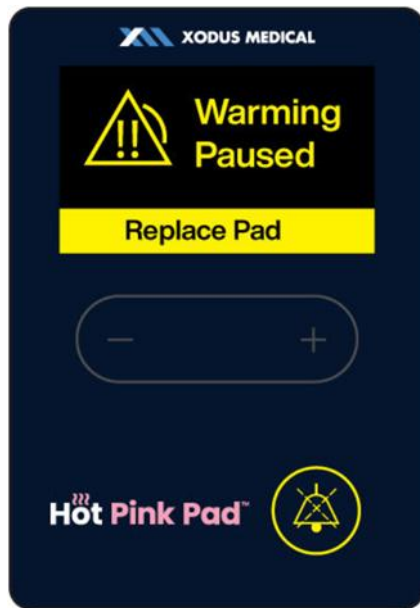
Figure 9: ALARM VISUAL and AUDIBLE

Figure 10: ALARM VISUAL with AUDIBLE PAUSED



- 9.10.11.2 **“Replace Pad”**: Medium priority alarm occurs prior to patient placement on the warming pad, a visual display in yellow when a fault is encountered during the initial warm up period. The alarm is accompanied by an appropriate audible sequence of a single beep tone with a reminder tone every 15 seconds.
 - 9.10.11.2.1 Recommended action: Replace the warming pad.

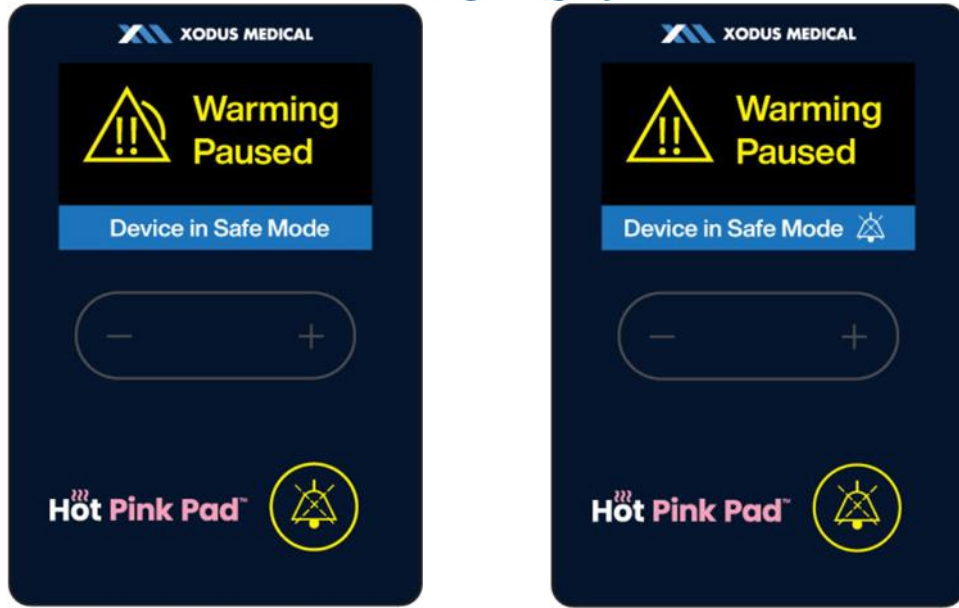
Figure 11: ALARM VISUAL and AUDIBLE Figure 12: ALARM VISUAL with AUDIBLE PAUSED



9.10.11.3 “Safe Mode Warming Paused”:

- 9.10.11.3.1 Medium priority alarm with a visual display in yellow when there is a system issue related to the warming pad. The alarm is accompanied by an appropriate audible sequence of a three beep with a siren. If this message appears, the warming of the warming pad has been paused. The alarm is accompanied by an appropriate audible sequence with a reminder tone every 15 seconds.
- 9.10.11.3.2 The issues related to this alarm include an over temperature condition where the thermal cut-out is operational and the pad will no longer continue to heat.
- 9.10.11.3.3 It is not recommended to replace the warming pad during the surgical procedure.
- 9.10.11.3.4 Recommended action: Alternative methods for patient temperature management must be used.

Figure 13: ALARM VISUAL and AUDIBLE Figure 14: ALARM VISUAL with AUDIBLE PAUSED

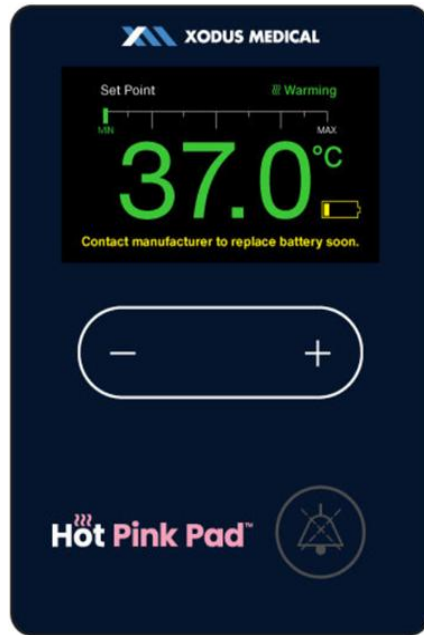


9.10.11.4 **“Contact Manufacturer to replace battery soon”:**

9.10.11.4.1 Low priority messaging occurs with visual display on the controller when the internal clock battery is nearing its end of life. There is no audible alarm with this alarm condition. Warming is not stopped with this alarm.

9.10.11.4.2 Recommended action: Contact Xodus Medical at 1-724-337-5500 for further instructions regarding battery replacement.

Figure 15: ALARM VISUAL ONLY



9.10.11.5 **“Battery Life Expired Contact Xodus Medical 1-724-337-5500”:**

- 9.10.11.5.1 A medium priority alarm with a visual display on the controller when the internal clock battery is imminently due to be changed, due to low charge.
- 9.10.11.5.2 The system stops warming with this alarm.
- 9.10.11.5.3 The alarm is accompanied by an appropriate audible sequence of a single beep tone with a reminder tone every 15 seconds.
- 9.10.11.5.4 Recommended action: Contact Xodus Medical for further instructions regarding battery replacement at 1-724-337-5500.

Figure 16: ALARM VISUAL and AUDIBLE

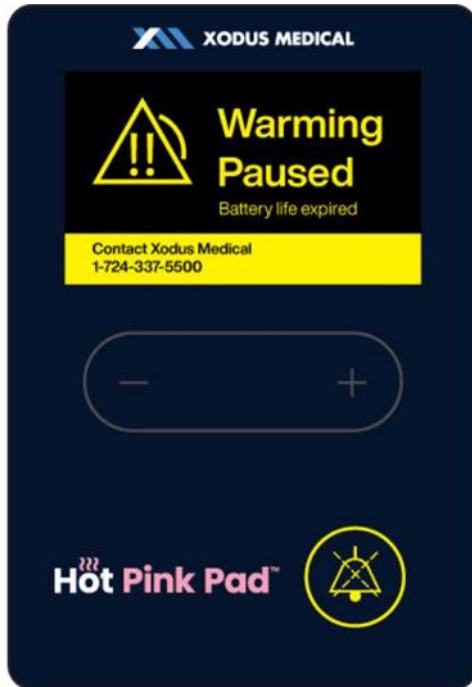
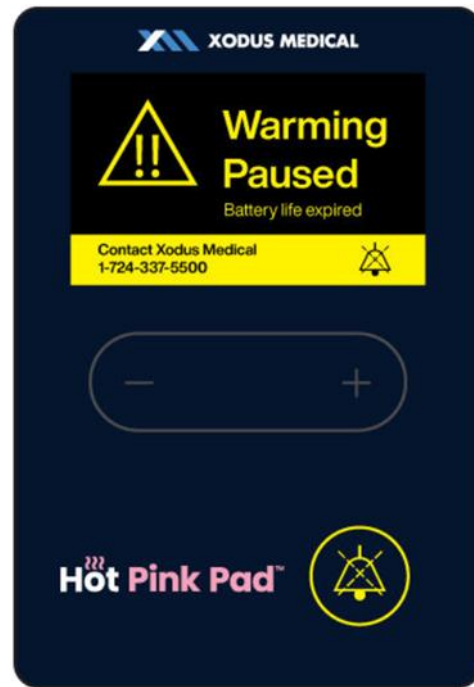


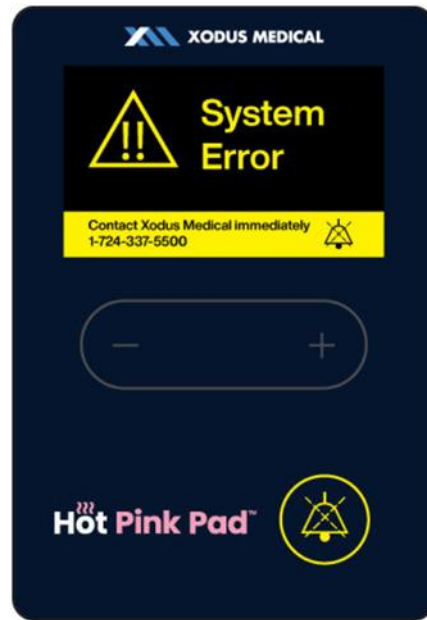
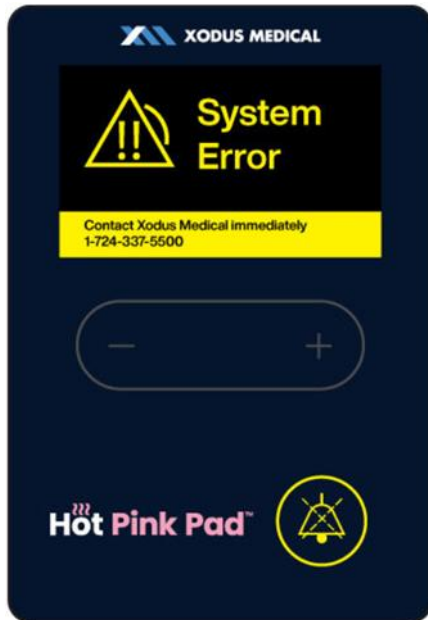
Figure 17: ALARM VISUAL with AUDIBLE PAUSED



- 9.10.11.6 **“System Error Contact Xodus Medical Immediately 1-724-337-5500”:**
- 9.10.11.6.1 A medium priority alarm with a visual display on the controller when a system bootup error is encountered.
 - 9.10.11.6.2 The alarm is accompanied by an appropriate audible sequence with a reminder tone every 15 seconds.
 - 9.10.11.6.3 Recommended action: Contact Xodus Medical for further instructions regarding battery replacement.

Figure 18: ALARM VISUAL and AUDIBLE

Figure 19: ALARM VISUAL with AUDIBLE PAUSED



- 9.10.12 Any alarm may be paused, including the visual alarm and the audio alarm, by pressing the alarm button at the bottom right on the front of the controller.
- 9.10.13 The alarm will present a reminder audible alert at the 10 minute mark from the time it was paused.
- 9.10.14 Alarms can be reactivated at any time by pressing and holding the alarm button after the act of pausing an alarm.
- 9.11 When finished using the Hot Pink Pad system, turn off the controller using the green rocker switch at the back of the unit and disconnect the power supply (wall) cable, as well as, the cable connection at the warming pad.
- 9.12 The warming pad is a single use device and shall be discarded according to hospital protocol for single use surgical products.

10.0 CLEANING AND DISINFECTION

The controller, AC power cord, and 15' Signal cable are reusable components. They may become contaminated during the course of operation. As a result, they shall be cleaned and disinfected prior to and following surgical procedures.

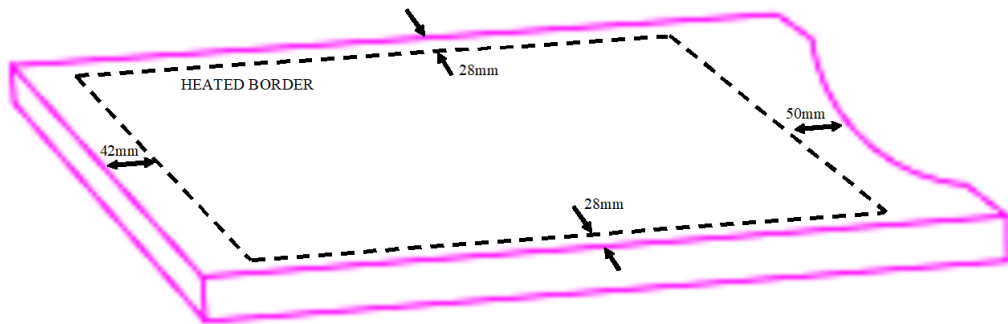
- 10.1 When cleaning components, always work from top to bottom and from clean to dirty areas.
- 10.2 When using wipes, only use for as long as they leave a closed film of fluid on the surface.
- 10.3 Please observe the defined contact time of the disinfectant.
- 10.4 Work methodically to disinfect all areas of the components.
- 10.5 To prevent damage:
 - 10.5.1 Do not immerse the controller, AC power cord or 15' Signal Cable in liquid.
- 10.6 Do not disinfect the controller, AC Power cord or 15' Signal Cable with:
 - 10.6.1 Steam (e.g. in autoclaves)
 - 10.6.2 Hot Air
 - 10.6.3 Thermochemical cleaning solutions
- 10.7 Please observe the specific instructions for using the disinfectant.
- 10.8 Make sure the controller's AC power cord is disconnected from electrical (AC outlet) power and the 15' Signal Cable is disconnected from the controller and warming pad.
- 10.9 Wear gloves when cleaning and disinfecting (chemical-resistant).
- 10.10 Follow hospital protocol and instructions for cleaning reusable equipment with standard operating room cleaning agents and disinfectants.
- 10.11 Cleaning agents and disinfectants shall be applied to a cloth or wipe before cleaning and not directly on the controller, AC power cord, and 15' Signal Cable.
- 10.12 Thoroughly wipe clean all sides of the controller using the cloth working from top to bottom.
- 10.13 Thoroughly wipe clean the 15' Signal Cable and AC power cord outside of the connector/plug ends and subsequently down the cable around its full diameter.
 - 10.13.1 Do not wipe inside of any connector/plug ends. If there are any contaminants in the connector ends, discard the 15' Signal cable or AC power cord and obtain a new one.
- 10.14 Please observe the defined contact time of the cleaning agents and disinfectants.
- 10.15 Inspect the controller, AC power cord, and 15' Signal Cable for any remaining contaminants.
 - 10.15.1 Visually inspect all sides, connectors, plugs, and adapters for cleanliness.
 - 10.15.1.1 Inspect to assure all areas have been thoroughly cleaned.
 - 10.15.1.2 Inspect for any remaining contamination.
 - 10.15.1.3 If any contamination still exists on any of the components, repeat the instructions for cleaning on that component and re-inspect for complete cleanliness.
- 10.16 Allow all components to fully air dry before continuing use or storage.
- 10.17 When the Hot Pink Pad Warming Pad is used on an OR table, the OR table must be prepared according to the customary national regulations and guidelines.
- 10.18 Damage to the Hot Pink Pad system during cleaning may result in overheating.
- 10.19 Only disinfect the Hot Pink Pad controller, AC power cord, and 15' Signal Cable with an alcohol-based disinfectant or one of the approved disinfectants.
- 10.20 Do not use bleach solution containing hypochlorite (or other agents containing chlorine) to disinfect any component of the Hot Pink Pad system.
 - 10.20.1 Chlorine and all other oxidizing disinfectants have a negative effect on the materials. Therefore, the use of these disinfectants is not recommended. Product life will be significantly shortened by disinfectants of this kind.
- 10.21 Do not carry out cleaning or disinfection procedures other than those specified in this manual without the express permission of the manufacturer.
- 10.22 Do not use cleaning or decontamination methods other than those recommended by Xodus Medical.

11.0 TEMPERATURE CONTROL

- 11.1 Important Note: The temperature control of the Hot Pink Pad system regulates and monitors the temperature of the warming pad, not the patient's body temperature.
- 11.2 When the Hot Pink Pad system is used, the patient's body temperature must be monitored at regular intervals by qualified clinical OR staff.
- 11.3 If the Hot Pink Pad system is not operational, or if the patient's temperature is insufficient, consider using alternative warming methods for patient temperature management.
- 11.4 Margins of unheated Border:
 - 11.4.1 The limits of the heated area and unheated margins of the warming pad are identified in diagram below. The heated area is visually and functionally apparent during normal use. Correct placement of the patient in accordance with this IFU assures patient positioning on the heated portion of the pad. Risk analysis per ISO 14971 has determined that additional permanent marking on the device is not necessary to ensure safe use. See Figure 20.



Figure 20:



12.0 MISINTERPRETATION

Shadows of the internal cables and sensors may be captured in diagnostic images (CT, X-ray) taken when the patient is using the Hot Pink Pad system. Diagnostic images should be assessed by clinical experts to determine their quality and diagnostic suitability.

13.0 DISPOSAL

- 13.1 The Hot Pink Pad warming pad shall be discarded after use per international regulations.
- 13.2 The controller and associated cables are reusable and should not be discarded.
- 13.3 Electrical devices are recoverable waste and should not be disposed of as domestic waste at the end of their service life.
- 13.4 Please follow the local rules for the disposal of used products.

14.0 GROUNDING CONDUCTOR


The grounding stud on the back of the controller may be used as a grounding point connection for leakage current testing. The grounding stud is for ease of attaining ground connection during electrical safety testing. Clip to the grounding stud during test.

15.0 RETURN OF USED PRODUCT

A report must be sent together with the equipment, detailing the precise reasons, circumstances, and, if known, the cause of the return. To prevent transportation damage, the equipment should be shipped either in the original packaging or in other, well-protected packaging.

Transport regulations for returning devices with a built-in battery:

When returning the Hot Pink Pad control units, it is essential to ensure that the control unit is in a state in which it can be stored/transported. The customer is responsible for the proper packaging and labelling of returns.

 WARNING
Risk of infection! Clean and disinfect the equipment after every use and before you return the equipment for repairs.

NOTICE
The customer is responsible for the proper packaging and labeling of returns.

16.0 SERVICE INFORMATION

There are no serviceable parts for the Hot Pink Pad system.

For service or technical support, please contact your local Xodus Medical representative or Customer service at:

XODUS MEDICAL, INC
702 Prominence Drive
New Kensington, PA 15068 USA

PH: +1-724-337-5500
FAX: +1-724-337-0055
EMAIL: INFO@XODUSMEDICAL.COM



17.0 PRECAUTIONS

- 17.1 Use under the direct supervision of a clinician. The Hot Pink Pad system may only be used by appropriately trained and medically qualified specialists.
- 17.2 This product should be used in accordance with the instructions for use and any contraindications, warnings or precautions provided by the manufacturer.
- 17.3 The skin of the patient's scapula region and sacrum must contact the warming pad surface.
- 17.4 Operator should monitor the temperature of the patient at regular intervals.
- 17.5 Utilize a lift sheet to carefully lift the patient up and off of the pad to reposition as needed for safe and proper positioning. Do not drag the patient on the warming pad. Make sure the warming pad remains flat at all times.
- 17.6 Before using the warming pad, ensure the OR table mattress is securely affixed to the OR table.
- 17.7 Be sure to follow your facility's policies and guidelines for frequency of patient monitoring. Check for skin integrity and proper circulation.
- 17.8 Do not carry or move the Hot Pink Pad warming pad by the connected cable as this may damage the warming pad. Carry or move the warming pad by handling the warming pad only.
- 17.9 Notify the user and/or patient that any serious incident that may occur in relation to the device should be reported and the competent authority of the Member State in which the user and/or patient is established, as well as, Xodus Medical and its Authorized Representative.
- 17.10 The Hot Pink Pad warming pad may be operated only with the Hot Pink Pad controller.
- 17.11 When installing the Hot Pink Pad controller on an IV pole, please observe the instructions from the manufacturer of those products regarding maximum load and tilting stability.
- 17.12 Never insert pointed or sharp objects into any component of Hot Pink Pad system or damage the surface of the components in any other way.
- 17.13 The Hot Pink Pad system may be temporarily affected if portable or mobile RF communications equipment is used in close proximity.
- 17.14 Use only Xodus Medical parts designated for use in the Hot Pink Pad system.
- 17.15 The Hot Pink Pad system has been tested and found in compliance with:
 - 17.15.1 BS EN IEC 60601-1-2:2015 Medical Electrical equipment – Part 1-2: General requirements for basic safety and essential performance-Collateral Standard: Electromagnetic Disturbances-Requirements and Tests;
 - 17.15.2 IEC 60601-1-2: Edition 4.1 2020-09 Medical Electrical Equipment-Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic Disturbances – Requirements and Tests.
- 17.16 When the mains is interrupted, there is no alarm to indicate this. The system is designed to retain the settings of the unit for 10 minutes following a power interruption.
- 17.17 Do not position the Hot Pink Pad Controller in a way that makes it difficult to operate the disconnection device (i.e. unplugging the Mains cord).
- 17.18 Hot Pink Pad system is not designed for use in an aircraft.



18.0 WARNING: Risk of Injury

- 18.1 **EXPLOSION HAZARD – DO NOT** use the Hot Pink Pad System in the presence of flammable anesthetics or highly oxygen- enriched environments such as hyperbaric chambers, oxygen tents, etc.
- 18.2 Read and observe all instructions, stickers, and accompanying documentation that came with the Hot Pink Pad system. Failure to observe the instructions, including warnings and safety information, can result in incorrect handling, patient injury, injury to users or medical personnel, damage to the device, or material damage.
- 18.3 Operate and service the Hot Pink Pad system only in accordance with the procedures described in these instructions and with the applicable standards, rules, and guidelines. The manufacturer shall not be responsible for the safety of users or patients if any actions/procedures other than those published are carried out during operation, servicing, or repeated inspections.
- 18.4 When high frequency (HF) or RF instruments or endocardial catheters are used, risk of electrical shock, burns or electromagnetic interference may occur.
- 18.5 With transdermal drug applications (patches), the additional heat can increase the uptake of the drugs and result in injury to the patient.
- 18.6 The Hot Pink Pad system does not contain any parts the user can repair. Therefore, do not attempt to repair the Hot Pink Pad system yourself. Contact Xodus Medical for support.
- 18.7 Any repairs to the equipment may only be carried out by people authorized and qualified by the manufacturer.
- 18.8 Do not use the Hot Pink Pad system on neonates.
- 18.9 Do not use the Hot Pink Pad system with hyperthermic patients.
- 18.10 Modifications to the Hot Pink Pad system are not permitted.
- 18.11 Do not use Hot Pink Pad system until the following error conditions have been remedied through appropriate corrective action:
 - 18.11.1 Damaged or worn cables, plugs, or connecting socket.
 - 18.11.2 Damaged controller housing, damaged or loose control panel.
 - 18.11.3 Damaged or missing labels/safety signs/warnings.
 - 18.11.4 Damaged Hot Pink Pad warming pad
 - 18.11.5 No visual or audible alarm activated after switching on the unit (self-test defective).
 - 18.11.6 Button(s) which do not function correctly.
 - 18.11.7 Hot Pink Pad system has been exposed to mechanical impact or extreme exposure to a liquid.
 - 18.11.8 Hot Pink Pad system has given someone an electric shock.
 - 18.11.9 Hot Pink Pad system appears to have overheated.
 - 18.11.10 Hot Pink Pad system has triggered an alarm shutdown.
- 18.12 The warming pad connection cable and mains (wall power supply) cable should not touch the patient and should not hinder the treating personnel.
 - 18.12.1 Keep the Hot Pink Pad system outside the MRI area. The Hot Pink Pad system is not designed for use in an MRI environment.
- 18.13 Never operate the Hot Pink Pad warming pad when folded, bent or creased under the patient.
- 18.14 When using the Hot Pink Pad system, please ensure that the warming pad is placed flat underneath the patient, is secured, and is not creased.
- 18.15 In all surgical procedures, it is important to ensure that sufficient measures are taken to avoid pressure injuries in accordance with patient positioning protocols.
- 18.16 The risk of skin irritation caused by an accumulation of surgical preparation solutions under the

patient may increase with warming; please ensure that the instructions for use for surgical preparation solutions are followed.

- 18.17 The use of materials with good thermal conductivity, such as water, gel, and similar substances, with the heating device not switched on can decrease the temperature of the patient's body.
- 18.18 Reduce or eliminate the risk of skin warming under pressure-loaded bony protrusions.
- 18.19 Ensure highly insulative materials do not partially cover the warming pad.
- 18.20 Do not fold or crease the warming pad during storage.
- 18.21 Do not place ANY hard objects (such as connection cables, ECG cables, hard reusable neutral electrodes, patient fluid lines, etc.) between the Hot Pink Pad warming pad and the patient.
- 18.22 Hot Pink Pad warming pad internal components that are visible in x-ray images:
 - 18.22.1 Copper materials
 - 18.22.2 Temperature sensors
- 18.23 Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- 18.24 This device complies with the EMC requirements according to IEC 60601-1-2. Radio transmitting equipment, cellular phones, etc. shall not be used in the close proximity of the device since this could influence the performances of the device. Particular precaution must be considered during use of strong emission sources such as High Frequency surgical equipment.



19.0 WARNING: Radio Interference

- 19.1 Use of accessories other than those specified by the manufacturer of the Hot Pink Pad system may cause increased electromagnetic interference or reduced electromagnetic immunity and result in incorrect operation.
- 19.2 Do not use portable RF communication devices (radio equipment) (including their accessories such as antenna cables and external antennas) within 30 cm (12 inches) of the parts of the Hot Pink Pad system and cables stipulated by the manufacturer. Failure to observe this may cause a reduction in the performance of the Hot Pink Pad system.
- 19.3 Use of accessories, transducers, and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.



20.0 WARNING: Electric Shock

- 20.1 To prevent the risk of an electric shock, only connect the Hot Pink Pad system to a main power supply with a protective earth conductor.
- 20.2 Do not use mains adapters that interrupt the protective earth conductor.
- 20.3 Do not open the Hot Pink Pad system controller housing.
- 20.4 If several pieces of equipment are combined or connected (e.g., in multiple socket outlets), the sum of the leakage currents may not exceed the permissible limits (please see the respective national regulations). Observe the requirements as stipulated in IEC/EN 60601-1 regarding medical electrical equipment.
- 20.5 All electrical installations must conform to the applicable electrical standards and the specifications defined by the manufacturer.
- 20.6 Before every use, check to make sure that the Hot Pink Pad system controller and the Hot Pink Pad warming pad are not damaged.
- 20.7 The mains plug must be removed from the socket to fully disconnect the Hot Pink Pad system from the mains.
- 20.8 The Hot Pink Pad system is designed to operate at a certain voltage and other electrical characteristics. Use of any other power supply could result in serious personal injury or system damage.
- 20.9 Do not touch the Hot Pink Pad controller and patient simultaneously
- 20.10 Do not touch the Hot Pink Pad cable connectors and patient simultaneously.

21.0 NOTICE

- 21.1 The specified moisture resistance IPX2 for the Hot Pink Pad system controller and warming pad is ensured only when the connector:
 - 21.1.1 is connected to the Hot Pink Pad 15' connection cable and warming pad.
 - 21.1.2 The attached protective cap for the signal cable port of the controller is used.
- 21.2 Actions to avoid damaging the Hot Pink Pad system:
 - 21.2.1 Do not immerse the Hot Pink Pad system controller, the warming pad or the cables in liquid.
 - 21.2.2. Do not disinfect the Hot Pink Pad system controller and/or the warming pad with:
 - 21.2.2.1. Steam (e.g. in autoclaves)
 - 21.2.2.2. Hot air
 - 21.2.2.3. Thermochemical cleaning solutions
- 21.3 The Hot Pink Pad system controller and cables must not be disinfected with bleach solution (hypochlorite or other agents containing chlorine).
- 21.4 Do not use any cleaning or decontamination methods other than those recommended by hospital protocol.
- 21.5 The customer is responsible for the proper packaging and labeling of returns.

22.0 TECHNICAL SPECIFICATIONS

- 22.1 Electrically powered device - protection against electric shock: externally powered
- 22.2 Classification of applied part: Hot Pink Pad warming pad only as applied part
- 22.3 Mode of operation: continuous
- 22.4 Not intended for use with flammable anesthetics or in conjunction with flammable agents
- 22.5 Ingress protection – Controller and Warming Pad: IPX2 (ordinary equipment)
- 22.6 Product complies to IEC 60601-1-2 Electromagnetic Disturbances: device has not been evaluated against other equipment used in surgical setting
- 22.7 Finished products are non-sterile
- 22.8 Shelf-life: Controller-10 years; Warming Pad-Single Use; Signal Cable-7.5 years; AC Power Cord-10 years.

TABLE 1:

Physical Characteristics	
Controller Dimensions	190mm high x 69.5mm deep x 137.5mm wide (7.5" high x 2.75" deep x 5.4" wide)
Controller Weight	1.1 kg (2.43 lbs.) with the mounting clamp
Controller Mounting	Shall be clamped to an IV pole only
Warming Pad Dimensions	1016mm high x 38.1mm deep x 508mm wide (40" high x 1.5" deep x 20" wide)
Warming Pad Material	Polyurethane Viscoelastic Foam
Temperature Characteristics	
Temperature Control	Micro-processor
Operating Temperatures	Adjustable in 0.5°C increments: 36°C to 40°C ± 1.0°C accuracy (98.6°F to 109.4°F ± 1.8°F)
Safety System	
Alarm conditions may be classified as Low Priority Technical Alarms or Medium Priority Technical Alarms	
Auditory Alarms	Minimum SPL of 60-70 dB(A) at 3m (from front of controller) for medium level alarming; Minimum SPL of 55-65dB(A) for low level alarming. with a back ground SPL not to exceed 55dB(A)
Primary Over-temp Alarm	Independent electronic circuit shuts the heater off if the warming pad temperature sensor reaches maximum temperature not to exceed 41°C. Medium Priority Alarm sounds.
Over-current limits	Medium Priority Alarm sounds in over current condition.
System Over-current Protection	Input / Output fused line. Medium Priority Alarm sounds.
Electrical Characteristics	
Leakage Current	Meets UL 60601-1 and IEC 60601-1 requirements for Class I, Type BF equipment.
Power Consumption	440W maximum

Power Cord	4.6 m (15 ft)
Controller to Pad Cord	4.6m (15ft)
Device Ratings	Input: 100VAC-264 VAC, 50/60Hz; 1.5A Output: 48 VDC, 2A
Fuses	5.250.1250A (48VDC output fuse) T4AL250V (AC Power Input fuse)
Defibrillation	In the event a defibrillation pulse is experienced, the system may have a momentary decay in performance and either recover manually or automatically within sixty seconds.
Environmental Conditions	
Environmental Conditions for Transport and Storage	Temperature: -20°C to 70°C Humidity: 15% to 95% non-condensing
Environmental Conditions for Use	Temperature: 5°C to 40°C (41°F to 104°F) Humidity: 15% to 95% Atmospheric Pressure: 70kPA to 106kPA
Expected Operating Life	
Controller	The expected operating life is 10 years from the date of first use, providing the product has not been subject to misuse, negligence, damage or inappropriate use and the equipment is used and serviced properly and as intended.
Warming Pad (Applied Part)	Single Use; Dispose of the Warming Pad following single use.
Signal Cable	The expected operating life is 7.5 years from the date of first use, providing the product has not been subject to misuse, negligence, damage or inappropriate use and the equipment is used and serviced properly and as intended.
AC Power Cord	The expected operating life is 10 years from the date of first use, providing the product has not been subject to misuse, negligence, damage or inappropriate use and the equipment is used and serviced properly and as intended.
Classification and Standards	
Certifications	IEC 60601-1; EN 60601-1-2; IEC 60601-1-8; IEC 60601-2-35; IEC 62304
Classification	Classified under IEC 60601-1 Guidelines (and other national versions of the Guidelines) as Class I, Type BF, Ordinary equipment, Continuous operation. Not suitable for use in presence of flammable anesthetic mixtures with air or with oxygen or nitrous oxide. Classified by Underwriters Laboratory (UL).
Diagnostics	The Controller and warming pad have no user serviceable parts.
Important Information	This device complies with the EMC requirements according to IEC 60601-1-2. Radio transmitting equipment, cellular phones, etc. shall not be used in the close proximity of the device since this could influence the performances of the device. Particular precaution must be considered during use of strong emission sources such as High Frequency surgical equipment and similar so that, e.g., the HF-cables are not routed on or near the device. If in doubt, contact a qualified technician or your local representative.
Essential Performance	
	<ol style="list-style-type: none"> 1. Overtemperature protection and automatic shutoff at temperatures greater than 41C. 2. Visual and audible alarming 3. Safe failure behavior

23.0 Electromagnetic Compatibility (EMC)

- The Hot Pink Pad system is intended for use in the electromagnetic environment specified in Table 2 through Table 5. The user should ensure this system is used in such an environment.

23.1 Warning



23.1.1 Warning per IEC 60601-1-2 Standard:

23.1.1.1 Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

23.1.1.2 Use of accessories, transducers, and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

23.1.1.3 Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches), including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

23.1.2 This device complies with the EMC requirements according to IEC 60601-1-2, Edition 4.1, Medical Electrical Equipment- Part 1; General Requirements for Safety; Electromagnetic Compatibility (EMC). There is potential for electromagnetic or other interference between this equipment and other devices. Should user experience interference, relocate this device or minimize the use of the affected equipment while this device is in operation.

23.1.3 Hot Pink Pad system operation may be temporarily affected if portable or mobile RF communications equipment is used in close proximity.

23.1.4 Hot Pink Pad system operation may be temporarily affected if the guidelines for EMC in this IFU are not followed.

23.1.5 Medical Electrical Equipment needs special precautions regarding EMC. Put Hot Pink Pad system into service according to the EMC information provided in this IFU.

23.1.6 This device complies with the EMC requirements according to IEC 60601-1-2. Radio transmitting equipment, cellular phones, etc. shall not be used in the close proximity of the device since this could influence the performances of the device. Particular precaution must be considered during use of strong emission sources such as High Frequency surgical equipment and similar so that, e.g., the HF-cables are not routed on or near the device.

TABLE 2:

Guidance and Manufacturer's Declaration – Electromagnetic Emissions		
The Hot Pink Pad system is intended for use in the electromagnetic environment specified below. The customer or user of the Hot Pink Pad system should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic Environment – Guidance
RF emissions, CISPR 11	Group 1	The Hot Pink Pad system uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions, CISPR 11	Class A	NOTE The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A).
Harmonic emissions, IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions, IEC 61000-3-3	Complies	


TABLE 3:

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The Hot Pink Pad system is intended for use in the electromagnetic environment specified below. The customer or the user of the Hot Pink Pad system should assure that it is used in such an environment.			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2, 4, 8, 15 kV air	±8 kV contact ±2, 4, 8, 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	+/-0.5kV, +/-1kV, +/-2kV L-G +/-0.5kV & +/-1kV L-L	+/-0.5kV, +/-1kV, +/-2kV L-G +/-0.5kV & +/-1kV L-L	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% UT for 0,5 cycle @0°, 45°, 90°, 135°, 180°, 225°, 270°, 315° (45° angle steps) Dwell Time: 1 min between events 0% UT (100 % dip in UT) for 1 cycles 70 % UT	0% UT for 0,5 cycle @0°, 45°, 90°, 135°, 180°, 225°, 270°, 315° (45° angle steps) Dwell Time: 1 min between events 0% UT (100 % dip in UT) for 1 cycles 70 % UT	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Hot Pink Pad system requires continued operation during power mains interruptions, it is recommended that the Hot Pink Pad system be powered from an uninterruptible power supply or a battery.

	(30 % dip in UT) for 25/30 cycles	(30 % dip in UT) for 25/30 cycles	
	0 % UT (100 % dip in UT) for 5 sec	0% UT (100 % dip in UT) for 5 sec	
	0% Ut; 250/300 cycles 50Hz and 60Hz Dwell time: 1 minute between events	0% Ut; 250/300 cycles 50Hz and 60Hz Dwell time: 1 minute between events	
Power frequency 50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE UT is the AC mains voltage prior to application of the test level.			

TABLE 4:

Guidance and Manufacturer's Declaration – Electromagnetic Immunity (cont'd)			
The Hot Pink Pad system is intended for use in the electromagnetic environment specified below. The customer or the user of the Hot Pink Pad system should assure that it is used in such an environment.			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the Hot Pink Pad system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1,2 \sqrt{P}$ $d = 0,35 \sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$

Conducted RF IEC 61000-4-6	3 Vrms with 6 Vrms in ISM bands 150 kHz to 80 MHz	3 V, and 6 Vrms	$d = 0,7 \sqrt{P}$ 800 MHz to 2.7 GHz 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, ^a should be less than the compliance level in each frequency range. ^b Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF IEC 61000-4-3	Enclosure Port; SIP/SOP 3V/m 80 MHz to 2.7 GHz	3 V/m	

NOTE 1 At 80 MHz and 800 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.

TABLE 5:



















Recommended separation distances between portable and mobile RF communications equipment and the Hot Pink Pad system			
The Hot Pink Pad system is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Hot Pink Pad System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Hot Pink Pad System as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d = 1,2 \sqrt{P}$	80 MHz to 800 MHz $d = 0,35 \sqrt{P}$	800 MHz to 2,5 GHz $d = 0,7 \sqrt{P}$
0,01	0,12	0,04	0,07
0,1	0,37	0,11	0,22
1	1,2	0,35	0,70
10	3,7	1,1	2,2
100	12	3,5	7,0
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.			
NOTE 1 At 80 MHz and 800 MHz, the separation distance for 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.			












25.0 STORAGE, TRANSPORT, AND OPERATIONAL CONDITIONS

The Hot Pink Pad system should be stored in a clean, dry location at room temperature prior to use. Avoid prolonged exposure to elevated temperatures.

26.0 SYMBOLS

TABLE 6:

Where applicable, these symbols appear at the appropriate location on the Hot Pink Pad system, on the packaging, on the type plate or in the accompanying documentation.	
	Type BF Applied Part; Defibrillation Protected in accordance with IEC 60601-1
IPX2	Protected against dripping water in accordance with IEC/EN 60529
	Follow the instructions for use
	General caution/warning symbol
REF	Reference (part) number
LOT	Batch designation
MD	Medical device
	Manufacturer
	Do not reuse
Rx ONLY	Prescription use only
	Not made with natural rubber latex
	Consult instructions for use or consult electronic instructions for use (xodusmedical.com/eifu)
	Margins of the heated area.
	Prohibited: Keep the Hot Pink Pad outside the MRI area.
	Additional information.
	Increase temperature setting
	Decrease temperature setting
	Batteries and rechargeable batteries are recoverable waste and should not be disposed of in domestic waste at the end of their service life.
	Electrical Devices are recoverable waste and should not be disposed of in domestic waste at the end of their service life.
	Symbol for the permitted temperature range for storage and transport.
	Symbol for the permitted moisture range for storage and transport.
	Symbol for the permitted atmospheric pressure range for storage and transport.
	Low priority technical alarm condition

	Medium priority technical alarm.
	Audible Alarm Paused
	Keep dry.
	Packaging labelling for transporting lithium metal batteries according to ADR SV 188 or IATA - DGR International Dangerous Goods Regulations, Packing Instruction 965, II. SECTION II 43416.
	Equipment not suitable for use in the presence of a flammable anesthetic mixture with air or oxygen or nitrous oxide.
	Powered by AC
	Electric Shock Hazard
	Protective Earth Ground
VA	Volt Amperes
W	Watts
Hz	Frequency Rating of the Unit in Hertz
	Hot Surface Warning
	Do not use if package is damaged
	Unique Device Identifier

27.0 REORDERING

40670 – Hot Pink Pad Controller

40671 – Hot Pink Pad

40795 - 15' AC Power Cord

40796 - 15' Signal Cable

Patent: 11,266,525

Additional Patents Pending