

AXsys™ TORIC MARKERS



USER GUIDE AND DIRECTIONS FOR USE (DFU)

Includes:

Sterilization
Guidelines

Manual
Cleaning

Troubleshooting
Steps

Product Information for the KATENA Electronic Toric markers

AE-2929: AXsys® 0-180 Ref Electronic Toric Marking Device, complete

AE-2930: AXsys® One Step Electronic Toric Marking Device, complete

AE-2930M: AXsys® One Step Electronic Toric Marking Device With 5.5 mm CCC marker, complete

AE-2939: AXsys® Electronic Head

AE-2929H: AXsys® 0-180 Ref Electronic Toric Marking (handle only)

AE-2930C: AXsys® One Step Electronic Toric Marking Device With 5.5 mm CCC Marker (handle only)

AE-2930H: AXsys® One Step Electronic Toric Marking Device (handle only)

⚠ Caution: Federal (U.S.A) law restricts the sale of this device only to or by the order of a physician. The device can only be used by a trained and certified Physician, Surgeon, Ophthalmologist, or a nurse specifically trained to operate this device.

Description:

These marker Handles are autoclavable and reusable, made of stainless steel and intended to assist with the precise implantation of Toric IOLs. The electronic toric head of the device is NOT meant to be sterilized under any circumstances. It can be cleaned by alcohol wipe.

Operating and maintenance instructions

Opening note: The package is provided with the batteries removed from the electronic head (AE-2939). To start working with the device, please install the batteries (2 quantity) in the device. Please refer to "**REINSTALLING OR CHANGING THE BATTERIES**" section for the instructions on the same.

⚠ Caution: For any model of the electronic toric marker, always reset the electronic toric head by following the procedure laid out in this document. This is to confirm that the device is set to 0-180 horizontal.

⚠ WARNING: *Modification of this equipment in any form or function, without authorization of the manufacturer, is strictly prohibited. The Manufacturer will take no responsibility in an event of an event of tampering with the electronic element of the device.*

Directions for use – video:

Please also refer to the video outlining the directions for use for the device here:

Video link: <https://youtu.be/R9m161tkm0g>

Scannable QR code



Figure 1: AE-2929 (AXsys™ Electronic Toric Pre-op Reference Marker)



Figure 2: AE-2930 (AXsys™ Electronic One-step Marker)

Acceptable range of operating conditions:

The Electronic Toric Head (AE-2939) can be used in the following environmental conditions.

- Temperature: -40°C to 85°C
- Humidity: 20% to 60%
- Keep away from high humidity atmosphere.

Do not clean the electronic toric head with water under any circumstances.

Handling before and after each use:

The markers are provided unsterile and must be cleaned and sterilized before use. Before the first time use, the instrument needs to be cleaned with distilled water and sterilized in an autoclave using the directions in this document. **The AXsys® Electronic Head(AE-2939) SHOULD NOT be sterilized under any circumstances.** For cleaning of the stainless steel body of the marker, in an ultrasound cleaner, to reduce or avoid endotoxin contamination, it is recommended to change the distilled water from the cleaner after each and every use. The use of ultrasound baths and strong cleaning fluids (alkalis pH > 9 or acids pH < 5) can reduce the life span of products. The manufacturer accepts no liability whatsoever in such cases. They should also undergo manual cleaning and sterilization immediately after each surgery. Please ensure that before the first use or subsequent uses that the hand piece is undamaged. Do not use the instrument if it appears to be damaged.

Whenever the device (AXsys® Electronic Head AE-2939) has not been in use for an extended period of time (more than 2 weeks or 14 calendar days), it must be checked that the device batteries are fully functional [that is, all the light, sound, and sensitivity settings are fully functional]. Please refer to the "IMPORTANT NOTE" in the above section. If batteries are removed, and re-installed OR replaced with new batteries, ensure to set the 'factory-reset' action on the AXsys® Electronic Head (AE-2939). The process to do this is mentioned and detailed in the section "**RESETTING THE DEVICE:**" on page 13.

IMPORTANT NOTE: whenever the device is not in use, the batteries should be removed, and stored separately.

Manual Cleaning and General care:

- The markers are provided non-sterile and only the stainless steel body(s) must be ultrasonically cleaned and sterilized prior to initial use.
- On the day of surgery or the day device is to be used, ultrasonically clean the markers at least once before and after use **without the electronic head**
- The Intra-Op Toric Axis Marker (AE-2930) should be ultrasonically cleaned in order to allow the barrel to easily rotate on a continuous basis.
- Always use new, unused distilled water for cleaning the stainless steel (body) of the toric marker after every case.
- Rinse the body of the stainless steel toric marker with distilled water.
- Dry the body with a lint free cloth or by using compressed air. Do not let any water droplets remain on the body.
- **Do not use water to clean the Electronic Toric Head.** Only use an alcohol wipe and wipe off all surfaces.
- Do not allow blood, tissue, or saline to dry on the markers.
- Do not use saline (balanced salt solution) for rinsing the instrument.
- Always use de-ionized water for final rinsing.
- Do not use metal brushes or abrasive powders to clean the markers.
- Store instrument in protective silicone finger mat of a sterilization tray .
- Special care must be taken when handling these delicate instruments to avoid breakage, especially at the fine connection between marker head and handle. This fine connection is necessary for optimal visualization.
- The AXsys™ Electronic Head cannot be thrown, dropped or generally mishandled. This may cause potential damage to the functionality of the instrument. CAREFUL HANDLING of the AXsys™ Electronic Head is strongly recommended.

- The AXsys™ Electronic Head can be removed from the marker by simply pulling the electronic device from the steel body of the marker (as pointed by arrow 1) **OR** by sliding the AXsys™ Electronic Head away from the marking point of the body (arrow 2)

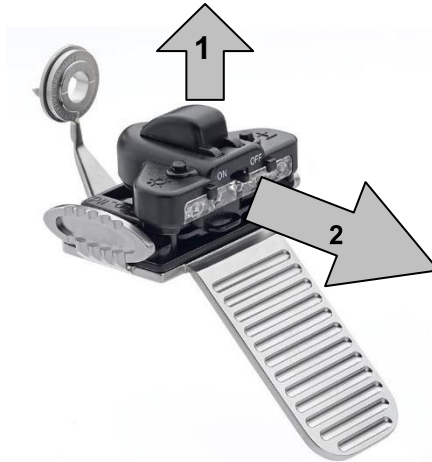


Figure 3: Apply a pull in one of the two directions as indicated by arrows to easily detach the AXsys™ Electronic Head from the steel body

- The AXsys™ Electronic Head is held in position by magnets. Both the magnetic base and head of the AXsys™ Electronic Head must be removed. See "[Parts of the AXsys™ Electronic Head Device](#)" for details.

Sterilization

Only the stainless steel body of the marker must be sterilized. The AXsys™ Electronic Head **SHOULD NOT** be sterilized under any circumstances.

DO NOT STERILIZE WITH AXsys™ ELECTRONIC HEAD ON HANDLE.



NOTE: Due to the variation found in steam autoclaves and the variable bioburden on instruments in clinical use, it is not possible for KATENA to provide specific parameters to ensure an adequate sterility assurance level. The appropriate parameters to be used and the sterility assurance level achieved with these parameters must be validated by each hospital. Please refer to current ANSI/AAMI standards or your hospital's standard procedures for the most appropriate specifications. The below parameters/cycles have been validated. If other methods, times, and temperatures are used, the user should validate these methods.

Steam Cycle	Preparation	Temperature	Exposure Time (Minimum time in minutes)	Drying Time (Minimum time in minutes)
Gravity Displacement	Wrapped	132 ° C/270 ° F	15	30
Dynamic air removal **	Wrapped	132 ° C/270 ° F	4	20
Dynamic air removal	Wrapped	132 ° C/270 ° F	3	20
Immediate Use (Flash)(Gravity or Dynamic Air Removal)	Unwrapped	132 ° C/270 ° F	3	N/A

** Pre-Vacuum or Steam Flush Pressure Pulse (SFPP) is classified as Dynamic Air Removal Steam Cycle by AAMI.

AXsys™ Electronic Head– Basic Operations:

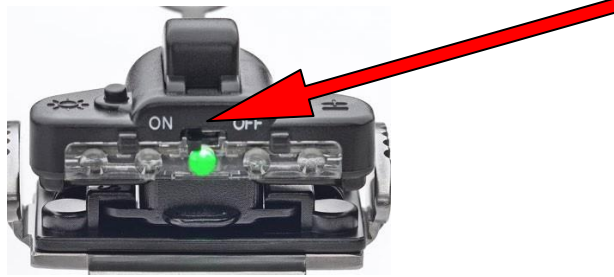


Figure 4: AE-2939 AXsys™ Electronic Toric Head: On-Off Switch (Red arrow – indicates location of on-off switch)

- To turn on the electronic leveling device, simply flip the switch from the 'off' to 'on' position on the front of the device.
- Lights
 - The electronic head is a leveling device with 5 LED lights (2 Red, 2 Orange and 1 Green)
 - Red light indicates extreme tilt
 - **Note: Red light does not indicate a warning on the instrument. It only indicates an extreme tilt in the 0-180 degree line (horizontal).**
 - Orange light indicates a slight tilt
 - Green light indicates a perfectly horizontal axis.
- This device sits on the toric marker handle like in the picture below:



Device is switched 'On'

or



Device is switched 'Off'

- To ensure that the device is fully functional, tilt the device in a horizontal plane like below and check whether all the lights are working.



Figure 5: Sequence indicates right tilt



Figure 6: Sequence indicates left tilt

- This can be done without placing the AXsys™ Electronic Head on the marker as well.
- If the lights do not work, or if using the sound setting, if it does not beep, a change of batteries may be required. If a change of batteries does not fix the problem, contact KATENA.
- To turn off the device, flip the switch on the front to on to off.

PARTS OF THE AXSYS™ ELECTRONIC HEAD DEVICE:

- The AXsys™ Electronic Head consists of two components – the head part and base part.
- The head part is indicated by the Red Arrow below in Figure 7.
- The base part is indicated by the Green Arrow below in Figure 7.
- The base part has four magnets (indicated by arrows (x4) in Figure 8.) The base is made of plastic (indicated by 2 in Figure 8.)
- The head part and base part can be separated by sliding in and out of the base jacket.

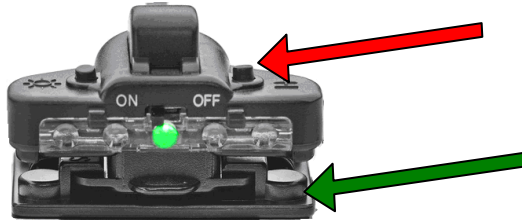


Figure 7: Components of the AXsys™ Electronic Head (Red arrow – indicates head; Green arrow – indicates base)

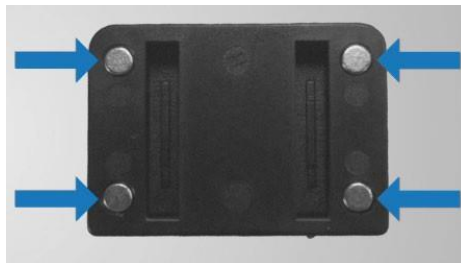


Figure 8: Base part of the AXsys™ Electronic Head (magnets location pointed out)



Figure 9: Picture of the AXsys™ Electronic Head part and base part separated




- The KATENA Electronic Toric Markers (AE-2929, AE-2930) can only be used with the AXsys™ Electronic Head when the head part and base part are connected to each other as a single unit.
- Do not separate the head part and base part, unless for cleaning. After cleaning, put the head part and base part (attached back together) and store the electronic head as a single unit.
- If either the base part or the head part gets separated or lost or damaged, please contact KATENA.
- Both the base part and head part CANNOT BE STERILIZED.

DO NOT STERILIZE WITH ELECTRONIC TORIC HEAD – BASE PART OR HEAD PART.



AXsys™ Electronic Head– Sensitivity Settings:

Legend for the Arrows in pictures/diagrams:

	Arrow to indicate location		Single (quick) press of the button indicated		Long (2 second) press of the button indicated
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- The sensitivity of the leveling device can be adjusted to 5 sensitivity levels.
- Setting one (1) is the most sensitive and setting five (5) is the least sensitive.
- To adjust the sensitivity of the device, use the sensitivity adjustment button, which is located on the top of the device and labeled with a plus minus symbol (\pm) . (See below.)




Figure 10: AE-2939 AXsys™ Electronic Toric Head: Sensitivity button location

- When the sensitivity adjustment button is pushed, a light will flash to indicate the sensitivity level (one of the five LED's.)
- When the left-most red light flashes, this indicates a sensitivity level of 1, the most sensitive level on the device. This level is sensitive to 0.2 degrees.
- When the middle-left orange light flashes, it indicates a sensitivity level of 2, which is sensitive to 0.4 degrees.
- When the green light flashes, this indicates a sensitivity level of 3, which is sensitive to 0.6 degrees.
- When the middle-right orange light flashes, this indicates a sensitivity level of 4, which is sensitive to 0.8 degrees.
- When the right-most red light flashes, this indicates a sensitivity level of 5, the least sensitive level, which is sensitive to 1 degree.
- Once you have selected your sensitivity level, this setting will save when the device is turned on or off and will not change until it is manually altered.
- The tolerances for this device are given below:

The angle values for each step					
Step\ Level	●○○○○○	○●○○○○	○○●○○○	○○○●○○	○○○○●●
1st	Over 0.4° (± 0.16°)	0.2° - 0.4° (± 0.16°)	Within 0.2° (± 0.10°)	0.2° - 0.4° (± 0.16°)	Over 0.4° (± 0.16°)
2nd	Over 0.8° (± 0.20°)	0.4° - 0.8° (± 0.20°)	Within 0.4° (± 0.12°)	0.4° - 0.8° (± 0.20°)	Over 0.8° (± 0.20°)
3rd	Over 1.2° (± 0.24°)	0.6° - 1.2° (± 0.24°)	Within 0.6° (± 0.15°)	0.6° - 1.2° (± 0.24°)	Over 1.2° (± 0.24°)
4th	Over 1.6° (± 0.30°)	0.8° - 1.6° (± 0.30°)	Within 0.8° (± 0.18°)	0.8° - 1.6° (± 0.30°)	Over 1.6° (± 0.30°)
5th	Over 2.0° (± 0.40°)	1.0° - 2.0° (± 0.40°)	Within 1.0° (± 0.20°)	1.0° - 2.0° (± 0.40°)	Over 2.0° (± 0.40°)
(Unit : Degrees) (± °) : Tolerance					

AXsys™ Electronic Head– Sound & Brightness Settings:

- The sound settings on the electronic leveling device can also be altered based on surgeon's preference.
- To adjust the sound setting on the device, sound/brightness adjustment button located on top of the device can be used. This button is labeled with a sun-like symbol  .

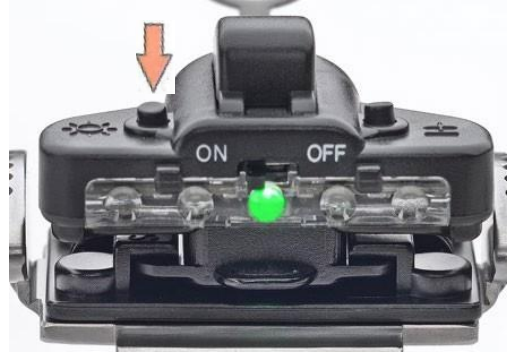


Figure 11: AE-2939 AXsys™ Electronic Toric Head: Location of Sound & brightness button

- There are 3 sound settings on the device.
- When the adjustment button is pressed, a light will flash to indicate the sound setting that has been selected.
- Sound setting one is indicated with a flash of the left-most red light. In sound setting 1, the device will remain silent, regardless of the tilt of the device.
- Sound setting two is indicated with a flash of the middle green light. In sound setting two, the device will only beep when it reaches a perfectly horizontal axis, which is also confirmed by the green light.
- Sound setting three is indicated with a flash of the right-most red light. In sound setting 3, the device will beep quickly when it is held with extreme tilt and show a red light. The device will beep at a slower rate when held with a slight tilt and show the orange light. For this sound setting, the device will only stop beeping when it is held perfectly horizontal. This is again confirmed by the green light.
- The brightness level on the electronic head can be adjusted.

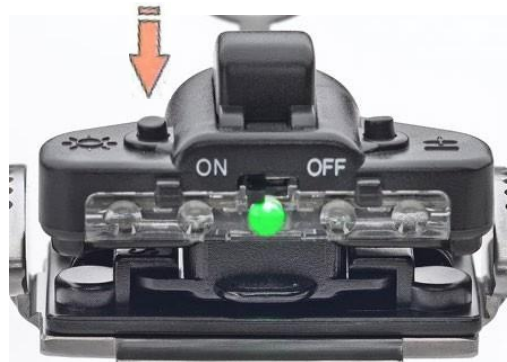


Figure 12: Brightness level can be adjusted by 2-second press of the Sound/brightness adjustment button

- For adjusting the setting, the sound/brightness adjustment button on the top of the device will be used. It needs to be pressed and held down, rather than just press it.
- When the sound/brightness adjustment button is held, a light will indicate what level of brightness you have selected.
- The right-most red button indicates the least bright level of the lights.
- The middle green light indicates an average brightness level for the lights.
- The left-most red light indicates the brightest level for the lights.



Figure 13: Indications of the brightness level setting in the Electronic Toric head

Remember push the sound/ brightness adjustment button with a quick press and release to adjust the sound setting. To adjust the brightness setting, press and hold the button for two seconds.

RESETTING THE DEVICE:

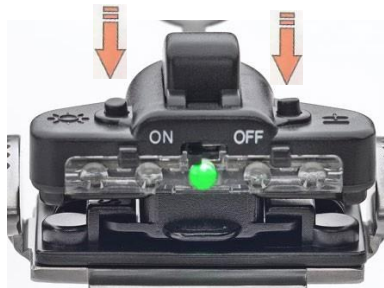


Figure 14: Resetting the device

- The device can be reset by holding both the sensitivity adjustment button and sound/brightness adjustment button at the same time, until all the lights start flashing. This resets the device to the Default Factory Setting.

Default Factory Setting:

- This is when the AXsys™ Electronic Head is working with the following settings – the device only beeps when it is in perfect horizontal (green light) and lights are set to medium brightness.
- In other words, factory setting is the level in which AXsys™ Electronic Head is set to the following settings:

Sound: Makes a beep sound only when centered. Sensitivity: Level 3 (0.4 degrees sensitivity)

Brightness: Level 3



Figure 15: After a successful reset, the five LED lights sequentially illuminate until device is tilted to horizontal.

REINSTALLING OR CHANGING THE BATTERIES:

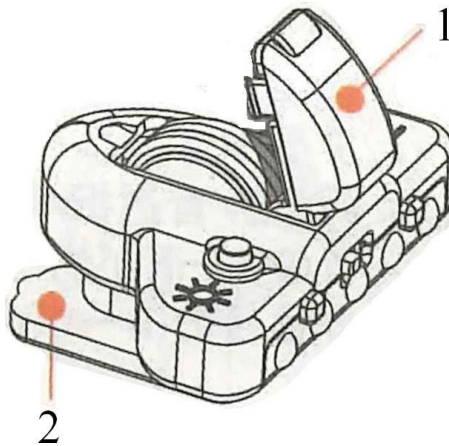
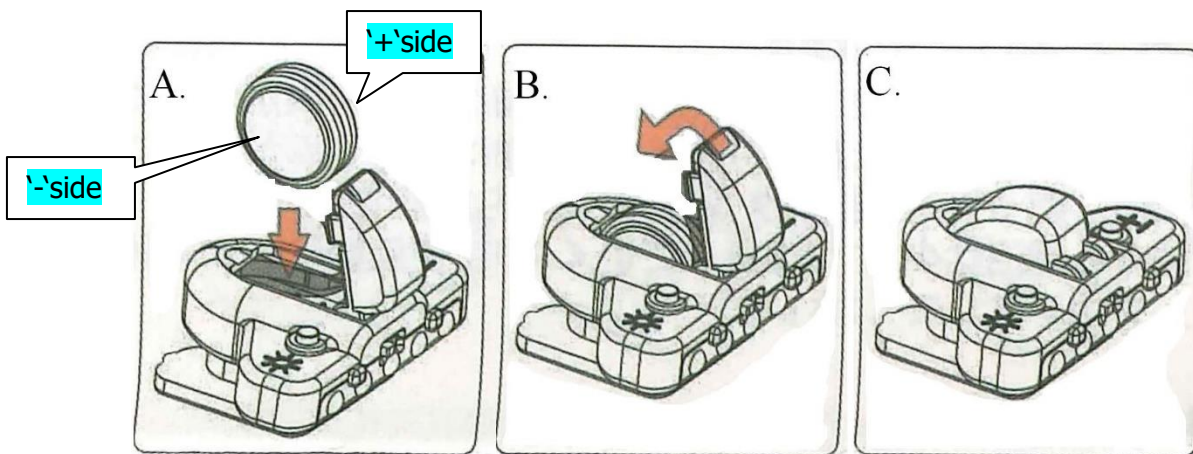


Figure 16: Battery compartment details

- The device has a battery compartment located on the top.
 - Number **1** – indicates the cover of the battery.
 - Number **2** – indicates the magnetic base of the AXsys™ Electronic Head (AE-2939).
- The batteries in this device are two 3V **coin cell CR1220 or ECR1220** .
- **Note:** The battery type is not mentioned on the device body itself. The 'Refer to Manual' sticker points out the instructions on the battery replacement process.
- For convenience, there are additional batteries provided with every purchase of a complete KATENA Electronic Toric marker (AE-2929 or AE-2930). The batteries can be removed by hand or using small forceps- like instruments.
- Ensure that the two batteries are put together as follows – orientation of the + / - sides is important, as shown:



- A. Open the battery cover – remove the old/expired batteries.
- B. Put the 2 pieces of CR1220 batteries in series, and inside the compartment.
- C. Close the battery cover.

- The batteries in a unit will last for six hours in a continuously switched on mode. The unit is also designed to turn off automatically after 20 minutes if it is completely stationary and not used.
- KATENA strongly recommends that the device is turned off immediately after use.
- KATENA recommends that the batteries be checked an hour before the surgery to ensure they are in good working condition. If the light or sound outputs are low or weak, it is recommended that the batteries be changed.

- **IMPORTANT NOTE ON BATTERIES:** whenever the device is not in use, the batteries should be removed, and stored separately. Whenever the device (AXsys® Electronic Head AE-2939) has not been in use for an extended period of time (more than 2 weeks or 14 calendar days), it must be checked that the device batteries are fully function [that is, all the light, sound and sensitivity settings are fully functional]. Please refer to the "IMPORTANT NOTE" in the above section. If batteries are removed, and re-installed OR replaced with new batteries, ensure to set the 'factory-reset' action on the AXsys® Electronic Head (AE-2939). The process to do this is mentioned and detailed in the section "**RESETTING THE DEVICE:**" on page 13.
- If there is a visible battery leak, they must be changed immediately or the AXsys™ Electronic Head must be replaced.

ACCEPTABLE STORAGE CONDITIONS:

The KATENA Electronic Toric Markers (AE-2929 and AE-2930) and AXsys™ Electronic Head (AE-2939) can be stored in the following methods. They can be stored in the box provided by KATENA or any similar tray free of moisture, water, contaminants, particulates, or biomaterials. The storage box should not be exposed to direct sunlight. Ideal dry conditions should be maintained.

Following are the recommended environmental conditions for storage: Temperature: 18°C to 35°C / Humidity: 20 to 50%

Environmental protection

On the end of life of the electronic device's batteries, care must be taken to ensure proper disposal of the batteries as per local, state and federal laws. If the electronic device is damaged, broken, or has reached the end of its useful life, it must be carefully disposed in the correct manner of disposal of electronic devices.

Frequently Asked questions:

Q) What is the sensitivity of the device?

A) Sensitivity is 0.2°. It can be adjusted to 0.4°, 0.6°, 0.8°, and 1.0° by following guidelines for "AXsys™ Electronic Head– Sensitivity Settings".

Q) How do I turn off the device?

A) To turn off the device, flip the switch on the front to on to off.

Q) How sensitive is the electronic toric head?

A) It is as sensitive as 0.2 degrees or 1.0 degree depending on the setting used. The sensitivity of the leveling device can be adjusted to 5 sensitivity levels. Refer to instructions in the "AXsys™ Electronic Head– Sensitivity settings" section on how to change the settings.

Q) What is the life of the battery?

A) The batteries in a unit will last for six hours in a continuously switched on mode. The unit is also designed to turn off automatically after 20 minutes if it is completely stationary and not used. KATENA strongly recommends that the device is turned off immediately after use.

Q) How can the batteries be disposed of after the end life of the battery?


A) Once they are completely used, the batteries in a unit can be removed, and disposed of as per the local laws regulating the disposal of used/exhausted electronic batteries and power cells.

Troubleshooting Steps:

Q) Device is not on a horizontal but shows a green light. Why? [or] The Device is not pointing to the correct horizontal position.

A) If you notice that the electronic head is not leveling to a horizontal plane, this is because someone has manually changed the plane it is supposed to align to. They did this by holding the sensitivity button for two seconds on a tilted plane. To reset the device and align the horizontal plane; we hold both the sensitivity adjustment button and sound/brightness adjustment button at the same time, until all the lights start flashing. This resets the device to the factory setting.

Q) The device is silent. The lights respond to motion, and only one light turns on at a time.

A) The device is set to a sound setting that is silent. Using the Sound/Brightness adjustment button (), change the setting to include beeping sound. Refer to the instructions in the "AXsys™ Electronic Head– Sound & Brightness Settings" section.

Q) The device is not working even when it is turned on. What is the problem?

A) The batteries in the device may have run out. Try replacing the batteries as mentioned above. Remember, the battery compartment is located as pointed out by pink arrow in the below picture.



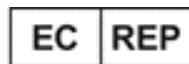
Figure 17: Location of battery compartment on the electronic head

REGULATORY INFORMATION

Any serious incident that occurs in relation to this product should be reported to the manufacturer, and to the healthcare authority of the country in which the incident occurred.



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