PrevisEA™

Instructions for Use

ENTAC MEDICAL

TABLE OF CONTENTS

LIST OF FIGURES

LIST OF TABLES

1. SYMBOLS

Symbol	Symbol Description
	Caution
	Not Sterilized
	Serial Number
	Catalogue Number
	Batch Code

Symbol	Symbol Description
	Humidity Limitation
	Manufacturer
	Temperature Limit
	Atmospheric Pressure Limitation
Rx ONLY	Prescription Use Only
	Do not use if package is damaged
	Fragile, handle with care
	Keep dry
	Type B Applied Part
	ESD susceptibility

BEFORE USE

- Read and understand these Instructions for Use and either watch the provided instructional video at www.entacmedical.com/PrevisEA or take in-person training provided by Entac personnel. A Quick Reference Guide is also provided.
- This device is intended to be used by properly trained health care providers in hospital settings only. Improper use could render the device ineffective.

2. GENERAL INFORMATION

Read all instructions and warnings before use. Receive in-person training or watch instructional video provided by Entac Medical at www.entacmedical.com/PrevisEA. Keep these instructions for reference. A Quick Reference Guide is also provided.

If you have questions regarding this product contact Entac Medical Inc. at 845-773-8473 (845-PREVIS3).

If there is any problem with the device contact Entac Medical Inc. at 845-773-8473 (845-PREVIS3).

3. PREVISEA DEVICE DESCRIPTION

PrevisEA™ is a non-invasive, self-contained, medical device with a proprietary algorithm used to assess the digestive health of postoperative patients. PrevisEA detects an acoustic biomarker, MH4, and quantifies

the number of detections over a 4-minute interval at postoperative hour 12 to determine the Previs™ Index. This is compared to a predefined threshold to determine the presence of abnormal digestive health in patients following intestinal surgery, such as gastrointestinal impairment (GII). GII is defined as emesis, the need for diet reversal, or the need for nasogastric intubation beyond 24 hours from the completion of surgery. GII generally develops between postoperative day 2 and postoperative day 10. The definition of GII is intended to exclude nausea and vomiting within the first 24 hours following surgery, which is defined as early postoperative nausea and vomiting. GII is mostly commonly associated with postoperative ileus, but can result from other causes, such as early postoperative bowel obstruction.

Postoperative care decisions that the use of PrevisEA™ may assist with are:

1. Can the patient successfully undergo early oral re-feeding within 24 hours of surgery without concern for GII developing 2–7 day after surgery?
2. When can the patient be discharged without concern for GII developing as a result of a postoperative ileus or other causes, after discharge?

The PrevisEA device is a convenient, single-use, disposable unit, which attaches to the abdomen of the patient via an adhesive wafer on the back of the device. The PrevisEA is a single-use, disposable unit, which avoids the need for cleaning and disinfection.

PrevisEA utilizes the Previs Index to assist a physician in determining when it is safe to begin oral refeeding of a patient following surgery. The PrevisEA™ algorithm counts the number of acoustic biomarker

detections that occur at postoperative hour 12 to determine the Previs™ Index. If the the Previs Index is above a pre-specified threshold, clinical data has shown that the patient is at low risk for developing GII. If the the Previs Index is less than or equal to the pre-specified threshold, clinical data has shown that the patient is at high risk for developing GII.

The device is intended to be used by properly trained health care providers in hospital settings such as hospital operating rooms, surgical recovery areas, and inpatient rooms. The device shall be used by physicians, surgeons, nurses or other medical personnel qualified to monitor intestinal surgery patients for POI.

Clinical users of the PrevisEA™ apply the device to the patient, turn the device on, view/record information from the device display, and remove the device from the patient. The clinical user of the PrevisEA device will contact the membrane overlay buttons to operate the device and contact the plastic device enclosure. The clinical user is in contact with the device daily for a period of less than 30 seconds to view/record information from the display. The clinical user of the device uses the screen to determine if the Previs Index of the patient is "High Risk" or "Low Risk".

4. INTENDED USE AND INDICATIONS FOR USE

PrevisEA™ is intended for analyzing intestinal sounds following intestinal surgery. PrevisEA displays information which assists physicians in assessing the digestive health of postoperative patients.

PrevisEA is a compact, non-invasive device placed on the abdomen to capture the digestive sounds of patients. PrevisEA displays information, the Previs™ Index, which assists physicians in assessing the digestive health of patients. This device is for prescription use only and should be used under the direction of a licensed healthcare practitioner. The PrevisEA device has not been tested for and it is not intended for pediatric use.

5. CONTRAINDICATIONS, WARNINGS, AND PRECAUTIONS

5.1. CONTRAINDICATIONS

1. Do not use if the patient has any known sensitivities or allergies to the adhesive used in the PrevisEA device.
2. Do not wear the PrevisEA device while bathing.

5.2. WARNINGS

WARNING

1. Do not submerge the PrevisEA™ device in any type of liquid or solvent.
2. Immediately discontinue use if patient exhibits signs of infection including redness, swelling or fever.
3. Device is not intended to be used outside of these Instructions for Use (IFU).
4. No modifications of the device outside these Instructions for Use (IFU). Unauthorized modifications of the device can result in Shock, Burn, and/or laceration injuries including surgical site reinjury.

5.3. PRECAUTIONS

The PrevisEA device is placed on the abdomen after abdominal surgery.

- Take caution when placing the device to avoid directly placing the adhesive on top of any surgical incisions or surgical dressings. Avoid placement over bony prominences.

- Do not apply force directly on any incision when placing the device.
- When removing, do not use excessive force.

ESD Caution—ESD (electrostatic discharge) sensitive device. Although this product features patented or proprietary protection circuitry, damage may occur on devices subjected to high energy ESD. Therefore, proper ESD precautions should be taken to avoid performance degradation or loss of functionality. If performance degradation from ESD occurs it is anticipated that the device will lose clinical functionality, the clinician shall revert to standard of care. To prevent this performance degradation operators shall consider grounding themselves prior to and while interacting with the device. Facilities shall consider instituting an electrostatic control program as described in IEC 61340-6-1:2018.

When operating at the maximum specified operation temperature the applied part exceeds 41°C. The maximum temperature of the applied part is 41.4°C. The conditions for safe use are indicated in **sections 8 DEVICE PLACEMENT AND START UP, 9 DEVICE USAGE AND OUTPUT,** and **10 DEVICE REMOVAL AND DISPOSAL.**

6. PrevisEA™ DEVICE

The PrevisEA device is approximately 3.25 inches (length) x 3.25 inches (width) x 0.75 inches (depth) with a weight of less than 0.5 lbs.

6.1. PrevisEA DEVICE DESCRIPTION

The PrevisEA device is a non-sterile, single use device. It is activated following device placement. The PrevisEA device is a single packaged unit with a copy of these Instructions for Use and a desiccant.

7. DEVICE PREPARATION

The PrevisEA™ device will be shipped in low-power consumption mode. The device has a shelf life of six months.

Before use, inspect the PrevisEA device for any signs of damage. If the PrevisEA appears damaged, contact Entac Medical Inc. at 845-773-8473 (845-PREVIS3). **See section 13 Return of Damaged or Defective Device.**

Ensure adherence to sterility precautions and procedures per hospital policy.

1. Remove the white box containing the PrevisEA device from the shipping package. Open the white box and remove the Instructions for Use. Read thoroughly.

2. Remove the grey dye-cut foam insert that secures the device in the white box.

3. When ready for placement, proceed to **Section 8 Device Placement and Start Up.**

8. DEVICE PLACEMENT AND START UP

The device may be placed in any quadrant of the abdomen where there is clean, dry, intact skin with hair removed. Recommended placement for the PrevisEA™ device is in the left upper quadrant of the abdomen (when feasible). See **Figure 1** for example placement. If the device cannot be placed in the left upper quadrant of the abdomen, alternative placement in the right upper quadrant is permitted. If neither upper quadrant is available, either lower quadrant is permitted for placement.

When ready to place PrevisEA:

1. Open the pink transparent plastic sleeve by *pulling the two open edges of the sleeve apart* to remove the device. Scissors may be used to open the package, but **user must avoid cutting the device's adhesive.** Discard the pink plastic sleeve and desiccant (silica gel pack) according to institutional practices.

2. Remove the paper backing from the adhesive wafer on the back PrevisEA™ starting with the inner, round paper backing first. Then, remove the outer, square paper backing from the adhesive wafer.

3. Place on left upper quadrant of the abdomen of the patient by placing the adhesive wafer to clean, dry, intact skin that has hair removed. Alternative locations include the right upper quadrant of the abdomen or either of the lower quadrants, in that order of preference. Device may face any direction. For ease of use, placing bottom edge of device toward the near side of patient is recommended (perpendicular to the midline). See **Figure 1.**

Figure 1: PrevisEA Placement (Left)

4. Once placed on the patient, activate the PrevisEA™ device by pressing the "**A**" button for 5–6 seconds **Figure 2** until the PrevisEA logo appears on the screen **Figure 3.** User may wish to hold the device with one hand while activating it with the other hand. Once activated, peel away the Power On label revealing the "A" button.

Figure 2: PrevisEA™ Device Activation

Figure 3: PrevisEA Logo upon startup

5. Once activated, the PrevisEA device listens to and records intestinal sounds for a specific acoustic MH4 biomarker.
6. Clinical users should inform patients not to touch the PrevisEA device buttons or remove it from their abdomen while in use. Patients should tell their care providers if the device irritates them or is causing any other concern while in use.

9. DEVICE USAGE AND OUTPUT

During usage, do not expose the device to liquid. Take caution when cleaning around the wound. An Aquaguard or similar device may be used to cover the device for showering as needed.

To view data while the PrevisEA™ device is attached to the patient, use the "**B**" button to display desired display screens. See **Table 2** for sequences and display screens.

NOTE: All button presses after the device has been turned on can be short in duration. They should be firm enough to feel the depression of the button. **It will take 2–3 seconds after the button press for the screen to respond.**

10. DEVICE REMOVAL AND DISPOSAL

The PrevisEA device is a single use device. Do not reuse.

PrevisEA is designed to be used for at least 12 hours from completion from surgery. It has an operating life of at least 48 hours.

To remove the PrevisEA device from the patient, gently peel the adhesive wafer away from the abdominal skin where it is adhered. Do not use excessive force, peel, or pull the abdominal skin.

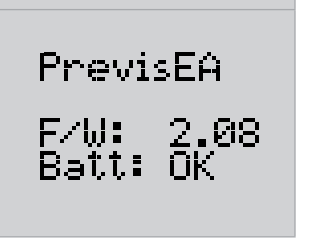
If needed, a medical adhesive remover can be used to aid in device removal.

Upon removal, the device should be disposed of as biological waste per institutional policies and procedures, unless it is determined to return it back to the manufacturer for a malfunction, defect or other similar issue.

11. CLEANING

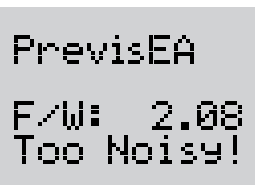
- The PrevisEA™ device is a single-use device and provided clean. It is not intended to be routinely cleaned or disinfected by the user.
- Do not immerse the PrevisEA device under water. For showering, the device may be covered with a water impermeable barrier (i.e., Aquaguard or similar device).

TABLE 2: PrevisEA DISPLAY SCREENS

PrevisEA – Power On Press and hold the "**A**" button for 5-6 seconds until PrevisEA logo appears, indicating the unit is powered and activated.	
Status Screen Once activated, device will default to sleep mode unless taking a reading or awakened by a user. While the device is in sleep mode, press the "**B**" button once to access the status screen which displays the Firmware Version Number ("F/W: x.xx") and battery ("Batt: xx").	

Time to Previs™ Index While device is displaying the Status screen, press the "**B**" button once. If in sleep mode, press "**B**" button once to reach Status screen and press the "**B**" button a second time to see time until the Previs Index is available.	
The Previs Index From the status screen, press the "**B**" button again. This will display the Previs Index risk assessment. This value only becomes available after the 12-Hour measurement has been successfully completed. If the device is in sleep mode, three presses of the "**B**" button are required.	

12. TROUBLESHOOTING

Error	Potential Cause	Solution
Device will not turn on.	Firmware does not load completely or has a detectable problem.	**Do not use the device.** Contact Entac Medical Inc. at 845-773-8473 (845-PREVIS3).
Environmental noise too high canceling Previs™ Index calculation. 	Ambient noise level is above 83 dB.	Minimize environmental noise. Device shall retry a canceled Previs Index calculation automatically after one minute of notifying the user that the ambient noise in the environment is too high. User of the device should make an effort to take control of noise level in the patient environment when possible.
Unable able to determine Previs Index. 	Device malfunction other than excess environmental noise.	Physician should use protocol as they deem appropriate. Contact Entac Medical at 845-773-8473 (845-PREVIS3).

Previs Index Error not available.	Environmental noise.	If a Previs Index is not available, the clinician should use protocol-based care as they deem appropriate.
The PrevisEA™ device does not adhere or loses adhesiveness to the patient.	Skin may be wet.	Lightly press down on the areas the adhesive wafer is lifted to reattach wafer.
The adhesive backing on the PrevisEA device fails to properly adhere the device to the patient.	Faulty adhesive, non-adherent skin surface .	The adhesive wafer may be reinforced with hospital-approved medical tape. The reinforcement should not contact the plastic enclosure. Only apply a new PrevisEA device if it is within one hour of completion of surgery.
There is difficulty when removing the PrevisEA device from the patient.	Device left on skin longer than recommended or sensitive skin.	Medical adhesive remover can be used to aid in device removal.

13. RETURN OF DAMAGED OR DEFECTIVE DEVICE

In the event that the PrevisEA device is either damaged prior to use on a patient or found defective at any time from the point of device receipt through the use on a patient, contact Entac Medical Inc. at 845-773-8473 (845-PREVIS3) for authorization. Entac Medical will provide for pre-paid shipping label, return packing slip and any other required instructions.

To return the device, use either the original shipping box or similar shipping container. Secure the device within the container using a protective barrier such as the original foam insert, bubble wrap or other cushioning material for stability within the shipping container. Place a completed copy of the return packing slip in the shipping container. Carefully seal the shipping container. Place the pre-paid shipping label on the outside of the packaged container along with any other required labels (if applicable). The pre-paid shipping label will be addressed to;

Address: Entac Medical Inc.
680 Oakleaf Office Lane, Suite 201
Memphis, TN 38117

14. PRODUCT SPECIFICATIONS

The PrevisEA™ device contains the following parts.

Unit Description	Part Number
PrevisEA Unit	944-12-451011-01
Adhesive Wafer	944-12-453522-01

Package Description	Part Number
Instructions for Use	944-08-455406-01
Bottom White Foam	944-12-453597-01
Label	944-12-453605-01
Pink Poly Pouch	944-12-453606-01
White Box	944-12-453604-01
Grey Dye-Cut Foam	944-12-453598-01
Desiccant	944-12-453618-01

Shipping Description	Part Number
Shipping Box	944-12-453703-01
Shipping Label	944-12-453638-01
Safe Handling Label	944-12-453649-01
Battery Label	944-12-453650-01
Bubble Wrap	944-12-453744-01
Shipping Tape	944-12-453648-01

Parameter	Specification
Battery Operating Life	48 hours
Shelf Life	6 months
Data Storage Capacity	32 GB
Weight	0.5 lbs
PrevisEA Dimensions	3.23 x 3.09 x 0.75 in.
Adhesive Wafer	4.5 x 4.5 in.
Battery Voltage	3.7V
Battery Type	Lithium Ion
Operating Temperature	10 – 40˚ C
Operating Humidity	30 – 75% RH, non-condensing
Operating Barometric Pressure	70,0kPa to 106,0 kPa
Applied Part Type	Type B Applied Part
Storage Temperature	10 – 40˚ C
Storage Humidity	30 – 75% RH, non-condensing
Storage Barometric Pressure	70,0kPa to 106,0 kPa
Transit Temperature	-35˚C – 60˚C
Transit Humidity	30 – 85% RH
Transit Barometric Pressure	50,0kPa to 106,0kPa

15. SAFETY DECLARATION GUIDANCE

PrevisEA™ was tested for electrical safety, electromagnetic compatibility using the following standards;

1. IEC 60601-1 Edition 3.1 2012-08 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
2. IEC 60601-1-2 Edition 4.0 2014-02 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
3. AIM 7351731 Rev. 2.00 2017-02-23 Medical Electrical Equipment and System Electromagnetic Immunity Test for Exposure to Radio Frequency Identification Readers

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944-08-455406-01 REV. D Effective date: 17 February 2021