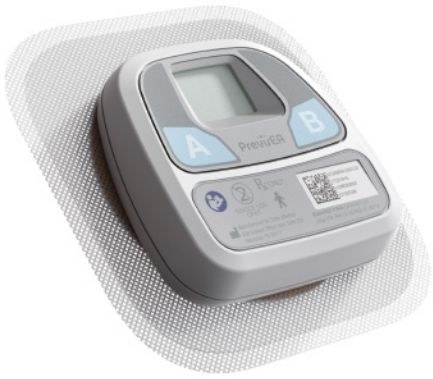
PrevisEA™

A Vital Sign For Postoperative Digestive Health



Question and Answer

Does PrevisEA™ diagnose postoperative ileus?

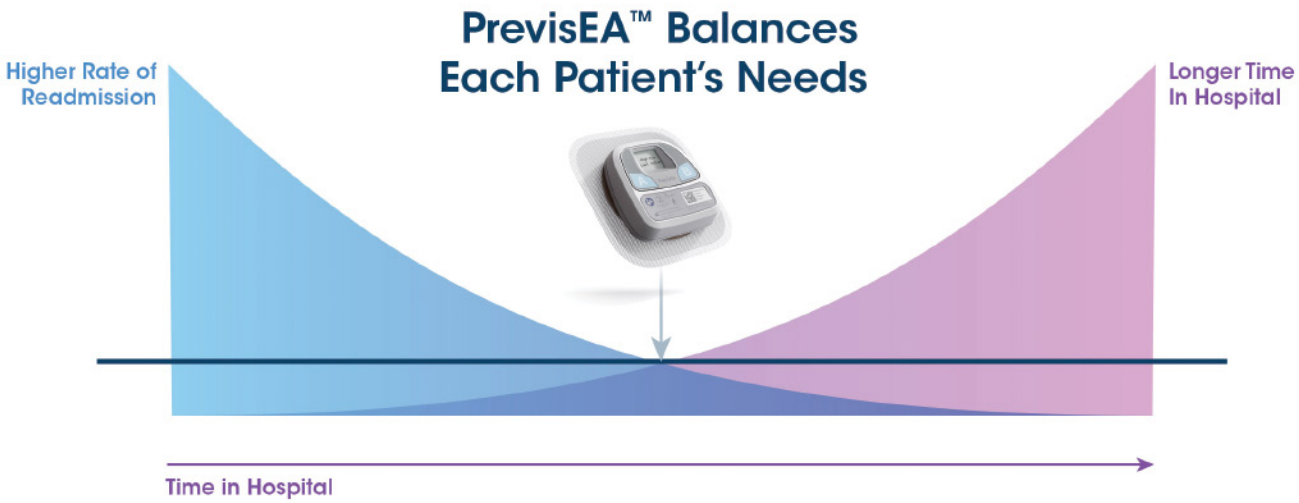
No, PrevisEA is a wearable device that is used to assess digestive health immediately following surgery and days before gastrointestinal impairment (GII) occurs, primarily due to postoperative ileus (POI)[1].The physiologic derangements that ultimately lead to POI begin in the hours following surgery, but don't manifest as clinical symptoms for days.The magnitude and duration of these derangements determine if patients will develop GII due to POI. PrevisEA analyzes a validated acoustic biomarker for these early changes and can help clinicians determine whether digestive health is sufficient to support early oral refeeding as part of an enhanced recovery protocol.

Why use PrevisEA?

In care pathways that involve early oral refeeding, up to 25% of patients undergoing major abdominal surgery develop GII primarily due to POI. Prior to developing GII, many patients appear to be tolerating a diet and appear ready to be discharged to home.[2,3] POI that develops following discharge to home can lead to vomiting, abdominal distention, dehydration, and acute kidney injury in this setting, thus requiring readmission to the hospital for treatment. Gastrointestinal impairment is responsible for more than 20% of readmissions in many major abdominal surgeries.[4]

Care pathways that involve delayed oral refeeding often avoid high readmission rates at the expense of longer length of stay. Patients do not undergo oral re-feeding until it is believed there is a return to normal bowel function as evidenced by flatus or bowel movements.This often unnecessarily delays oral re-feeding and discharge by several days for the 75% of patients who do not develop GII.

PrevisEA addresses both readmission and length of stay by determining if the patient is at risk for GII at postoperative hour 12. In high risk patients, oral re-feeding and discharge can be delayed until resolution of GII while the patient remains safely in the hospital. In low risk patients, oral re-feeding can be initiated earlier and the patient can be confidently discharged without concern for GII due to POI happening at home (see figure).



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When is the PrevisEA™ device placed on a surgical patient?

The device must be placed on the patient within 1 hour following completion of surgery to produce a valid assessment.

Where on the surgical patient can the PrevisEA device be placed?

PrevisEA may be placed in any quadrant of the abdomen following surgery. It should be placed on intact or sealed skin, similar to an ostomy wafer.

When does PrevisEA perform an assessment of digestive health in the surgical patient?

PrevisEA detects a validated acoustic biomarker of intestinal health during the first 12 hours following surgery. It performs an assessment of digestive health at the end of that 12-hour period. The Previs™ Index that is generated at that time is a measure of digestive health and suitable for making decisions regarding early oral refeeding and discharge.

What is the Previs™ Index?

The Previs Index is a vital sign for the postoperative digestive health of a patient. PrevisEA measures the presence of an acoustic biomarker, known in the literature as MH4,[5] over a specified time interval. **At 12 hours following the completion of surgery, the patient's MH4 count is known as the Previs Index,** which is a validated measure of digestive health following surgery that is highly correlated with the risk of GII 2–7 days after surgery. A patient's Previs Index value above a predetermined MH4 count threshold, established in clinical trials, represents intestinal health that will support early oral refeeding. PrevisEA will display **"Low Risk"** for these patients. A value below or equal to the threshold represents suboptimal intestinal health and suggests a high risk of developing GII 2–7 days after surgery. PrevisEA will display **"High Risk"** for these patients. PrevisEA is calibrated to maximize the sensitivity for identifying patients at high risk of GII, while maintaining high confidence when a low risk is identified (95% negative predictive value).

How long must a patient wear PrevisEA?

The Previs Index at postoperative hour 12 is the summary assessment of digestive health. Once this value has been obtained and recorded, the device is removed and disposed of according to hospital policies for disposing devices with lithium ion batteries.

What patient populations are appropriate for using PrevisEA?

PrevisEA is designed for use following major abdominal surgeries where the risk of gastrointestinal impairment due to POI or other causes is greatest. Patients undergoing intestinal resection surgery (open or laparoscopic) is an example of such a high-risk population.

Is PrevisEA reusable?

No, PrevisEA is designed to be used by a single patient following a single episode of surgery and then disposed of. There is no need for hospital staff to clean or process the device following use or maintain a fleet of reusable devices.

For more information visit www.entacmedical.com or call 845-773-8473.

References

1 Kim et al. Journal of Laparoendoscopic & Advanced Surgical Techniques. Part A, 24(8), 543–549.

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3 Grass, F., Slieker, J., Jurt, J., Kummer, A., Solà, J., Hahnloser, D., Demartines, N., & Hübner, M. (2017). Postoperative ileus in an enhanced recovery pathway—a retrospective cohort study. *International Journal of Colorectal Disease* (Vol. 32, Issue 5, pp. 675–681).

4 Merkow, R. P. et al. (2015). Underlying reasons associated with hospital readmission following surgery in the United States. *JAMA: The Journal of the American Medical Association,* 313(5), 483–495.

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