Entarik™ G2-N Feeding Tube System

Operator's Manual

IFU-04-2408 Rev A

Introduction

Please read carefully.

This manual covers the function and proper use of the Entarik G2-N Feeding Tube System (Entarik G2-N System). The Entarik G2-N Feeding Tube System refers to the combined use of the Entarik G2 Monitor and the specified Entarik G2 NI Feeding Tubes. **NOTE: The feeding tube has its own accompanying Instructions for Use, which is found inside the feeding tube packaging.** Both IFUs must be referenced for proper usage of the Entarik G2-N Feeding Tube System. Refer also to the separate IFU for additional warnings, precautions, and contraindications.

Do not use or operate the Entarik G2 Monitor until you have read and understood this manual and the separate instructions included with the Entarik G2 NI Feeding Tube.

CAUTION: The Entarik G2-N Feeding Tube System is only intended for use by a physician, or on the order of a physician.

Background

Operator's Manual Scope

This manual covers the function and proper use of the Entarik G2-N Feeding Tube System. The Entarik G2-N Feeding Tube System refers to the combined use of the Entarik G2 Monitor and the Entarik G2 NI Feeding Tubes. **NOTE: The Feeding Tube has its own accompanying Instructions for Use, which is provided with the feeding tube.** Both IFUs must be referenced for proper usage of the Entarik G2-N Feeding Tube System.

Definitions

Entarik G2-N Feeding Tube System (Entarik G2-N System, System)	Combined usage of the Entarik G2 Monitor with the Entarik G2 NI Feeding Tubes.
Entarik G2 Monitor (Monitor)	Portable electronic device which, when used with the Entarik G2 NI Feeding Tube, measures and records impedance, temperature, and cardiac electrical (not displayed) data from the sensors on the feeding tube and provides information to the operator to aid in initial placement of feeding tube followed by continuous monitoring for dislodgement, gastric and esophageal temperature, gastrointestinal impedance, and reflux.
Entarik G2 NI Feeding Tubes (Feeding Tube, FT)	Disposable, single-use feeding tube (available sterile, with or without an optional stylet). The feeding tube has one lumen for the administration of nutrition, fluids and medications. The catheter (applied part) has embedded temperature sensors and outer electrode rings which come into physical contact with the patient and connect to the monitor to perform its sensing functions.

Part Numbers of Entarik G2-N System

Entarik G2 Monitor: FGN-04-2064

Extension Cable: MSP-04-1959

Entarik G2 NI Feeding Tubes – *With* Stylet

Product Line	Feeding Tube		Sterility	Part Number
	Size (Fr)	Length (cm)		
Neonatal Products (NI) For patients < 110 cm tall *(With* Stylet)	5	90	Sterile	FGS-04-2065
	8	109	Sterile	FGS-04-2069

Entarik G2 NI Feeding Tubes – *Without* Stylet

Product Line	Feeding Tube		Sterility	Part Number
	Size (Fr)	Length (cm)		
Neonatal Products (NI) For patients < 110 cm tall *(Without* Stylet)	5	90	Sterile	FGS-04-2366
	8	109	Sterile	FGS-04-2370

Overview

Indications for Use

Entarik G2 NI Feeding Tubes (FTs) are intended for the administration of nutrition, fluids and medications by the nasoenteric, or orogastric route for neonatal patients who have an intact gastrointestinal tract but are physically unable to manage nutritional intake through normal mastication and deglutition.

The Entarik G2-N Feeding Tube System (Entarik G2-N System) is designed to aid, in conjunction with institutional protocols, qualified operators in the placement of the Entarik G2 NI Enteral Feeding Tubes (FT) into the stomach of neonatal patients requiring enteral feeding. The Entarik G2 NI FT is equipped with sensors designed to provide information about the location of the tube tip relative to the stomach, thus assisting in reducing the incidence of misplacement during first positioning. The Entarik G2 NI Feeding Tubes are provided sterile.

The Entarik G2-N System also monitors the feeding tube position continuously during the course of feeding and automatically and in real time alerts of tube migration.

The Entarik G2-N System provides continuous monitoring of gastric and esophageal temperature. The Entarik G2-N system can be used solely for the purpose of monitoring gastric and esophageal temperature in situations where invasive monitoring is indicated.

The Entarik G2-N system is intended to record, store, view and analyze impedance in the pharynx, esophagus and stomach.

Functional Description

The Entarik G2 Monitor (monitor) is a standalone monitoring unit with an integrated IV pole clamp and a separate AC adapter. The monitor is to be used exclusively with the Entarik G2 NI Feeding Tube (FT). The Entarik G2 NI Feeding Tube is a single-use device intended for short term use (less than 30 days). The components together are known as the Entarik G2-N Feeding Tube System and are designed to provide the following functions:

- Aids in the proper positioning of the feeding tube during initial placement
- Monitors feeding tube position during ongoing use
- Monitors patient temperature (gastric and esophageal)
- Monitors pharynx, esophagus and stomach impedance
- Enables the delivery of enteral nutrition and/or medication
- Provides user-friendly operating controls via touch-screen display with optional battery power mode for portability

NOTE: Brief instructions for operation of the Entarik G2-N Feeding Tube System as well as a brief explanation of each warning will be displayed on the Entarik G2 Monitor screen during use. These are not intended to be used in place of the Operator's Manual. They are simply a quick reference guide. The user must read the Operator's Manual before operating the Entarik G2-N Feeding Tube System.

The Entarik G2-N System is not suitable for use in the presence of electrosurgery. The monitor stays in the current operating mode without loss of any stored data.

Intended Users and Training Requirements

The Entarik G2-N System is indicated for neonatal patients in need of nasoenteric, or orogastric enteral feeding and/or administration of medications. The Entarik G2 NI Feeding Tube will be inserted into patients by medical staff qualified to insert commercially available feeding tubes. Apart from a short overview of the Entarik G2-N System, no special training is required for use of the Entarik G2-N System in the clinical setting.

The Entarik G2-N System is intended to be used by anyone qualified to insert commercially available feeding tubes who have read the Operator's Manuals for both the Entarik G2-N Feeding Tube System and the Entarik G2 NI Feeding Tube.

Contraindications

- Use caution with patients who have anomalies or disease of the nose, throat, or esophagus.
- The use of this product is contraindicated in patients with known sensitivities or allergies to the feeding tube components.
- The use of this product is contraindicated in patients with basilar skull fracture.

Warnings

Entarik G2-N Feeding Tube System

- No modification of any kind is allowed for this equipment. Do not attempt to open, repair, or modify the unit or replace broken parts. Attempting to do so could result in bodily injury or harm. If the unit or any parts are not working, please contact Gravitas Medical Customer Service. Repairs should only be made by Gravitas Medical trained personnel. The Entarik G2 NI Feeding Tube System has no serviceable parts.
- The Entarik G2 Monitor has a USB port for firmware upgrades and live data streaming and an SD Card for data access using proprietary Gravitas applications or Gravitas approved applications and equipment. The monitor has no other accessible wired or wireless communication ports, and thus cybersecurity risk is low. To maintain a secure environment for cybersecurity and confidentiality, do not attempt to open, repair, or modify the unit or replace broken parts. Do not plug unauthorized devices into the USB port. Do not use the Entarik G2 Monitor if the SD card door is not installed.
- Do not touch connector ports and the patient simultaneously. Doing so could result in bodily injury or harm to you and/or the patient.
- Avoid contact between the monitor and water and/or fluids. Do not immerse or submerge the monitor in water and/or fluids.
- A hazard can exist if different alarm presets are used for the same or similar equipment in any single clinical area, e.g. an intensive care unit (ICU) or a cardiac operating theater.
- Do not steam autoclave, EO sterilize, immerse the monitor, or allow fluids to enter the housing.
- Do not spray fluids directly into the monitor, especially into any connector port.
- The Entarik G2 Monitor and Entarik G2 NI Feeding Tube are MR unsafe. Do not take the monitor or feeding tube into an MRI unit.
- Do not use in the presence of flammable anesthetics or oxygen rich environment.
- Do not use in the presence of electrosurgery.
- As with all medical electronic equipment, care must be exercised to avoid exposing the Entarik G2 Monitor to powerful sources of electromagnetic interference. Using the Entarik G2 Monitor near operating equipment which radiate high-energy radio frequencies (such as electro-surgical/cauterizing equipment, diathermy, two-way radios, - cellular telephones or wireless power transfer) may cause false readings. If interference is observed, avoid concurrent use of Entarik G2 Monitor with other high energy equipment. Please reference Appendix D: Guidance and Manufacturer's Declaration, for additional steps to mitigate such interferences.

- The monitor uses a Lithium-ion battery. Leakage of the Lithium-ion batteries can occur. Discontinue use if leakage occurs.
- Use ONLY with provided Entarik G2 Monitor DC 5V power supply.
- The battery capacity indicator is an approximation. If you are unsure about whether enough capacity remains for your intended use, plug in power supply to recharge the monitor battery.
- To avoid electrical shock, never clean the monitor with the power supply plugged into the monitor or when the monitor is on.
- Make sure power supply is completely dry before plugging into an electrical outlet.
- During placement, there is a general risk for malposition in the respiratory tract. Delivery of fluids into the airway may result in serious injury, ALWAYS confirm appropriate positioning of the feeding tube using institutional protocol (e.g., X-ray) prior to initiating fluid delivery. Should the feeding tube enter the tracheobronchial tree during a tube placement, damage to the lung or esophagus could occur. Use caution when placing the device.
- The Entarik G2 NI Feeding Tube is intended for enteral feeding, fluids and medication administration, but has the potential to misconnect with small bore connectors of other healthcare applications. This nasoenteric/orogastric feeding tube should not be used with connectors from other healthcare applications.
- Avoid leaving tubing and cords where infants, children, or those deemed at high risk for medical line entanglement, can become entangled. Be aware that if these items become wrapped around a patient's neck, there is an increased risk of strangulation or death. Caregivers of patients who are at risk for entanglement should discuss with their health care provider how to properly manage their lines and properly monitor patients based on their needs while in use.

Cautions

Entarik G2-N Feeding Tube System

- Use only with Entarik G2 NI Feeding Tubes. The Entarik G2 NI Feeding Tube has ENFit connectors which were designed to prevent misconnections between enteral devices and other devices used in various medical applications. However, the design of the ENFit connector cannot overcome all chances of misconnection. There is a possibility of misconnection of the feeding tube connector with the following types of connectors: the sockets of anesthetic and respiratory equipment (including cones and sockets of ISO 5356-1:2004 and ISO 5356-2:2006 as well as Nipples of EN 13544-2:2002), conical oxygen tubing, connectors for breathing systems and driving gas applications, connectors for intravenous applications, connectors for urethral/urinary applications, connectors for neuraxial applications and conical connectors for limb cuff inflation applications.
- Esophageal and gastric temperature reported by the Entarik G2-N System can be affected by the administration of medications or nutrition.
- Esophageal and gastric temperature reported by the Entarik G2-N System must not be used for servo control of body temperature, such as during whole body hypothermia.
- Handle the Entarik G2-N Monitor carefully. Do not drop.
- As with all temperature and impedance probes, in the presence of RF energy sources, local heating, measurement errors, and probe damage may occur. In medical use, disconnect all connections between the Entarik G2 NI Feeding Tube and the Entarik G2 Monitor before activating electrosurgical or other types of directly-coupled RF energy sources.
- Unplug 5V Power Supply before moving the monitor. Failure to do so could damage the cord, the monitor, or the external device(s) to which the monitor is attached.
- During cleaning, do not use strong solvents (e.g., acetone or trichloroethylene) or abrasive material. Mild detergents are appropriate for cleaning.
- Do not position the monitor so that it is difficult to disconnect the 5V Power Supply from the monitor.
- In the event of an automatic power off or reset due to ESD vulnerability, the Entarik G2-N System can be restarted for continued use.

Package Contents

Each Entarik™ G2 Monitor package contains:

- One Entarik™ G2 Monitor (with integrated IV pole clamp)
- One 5V Power Supply
- One Reusable Extension Cable

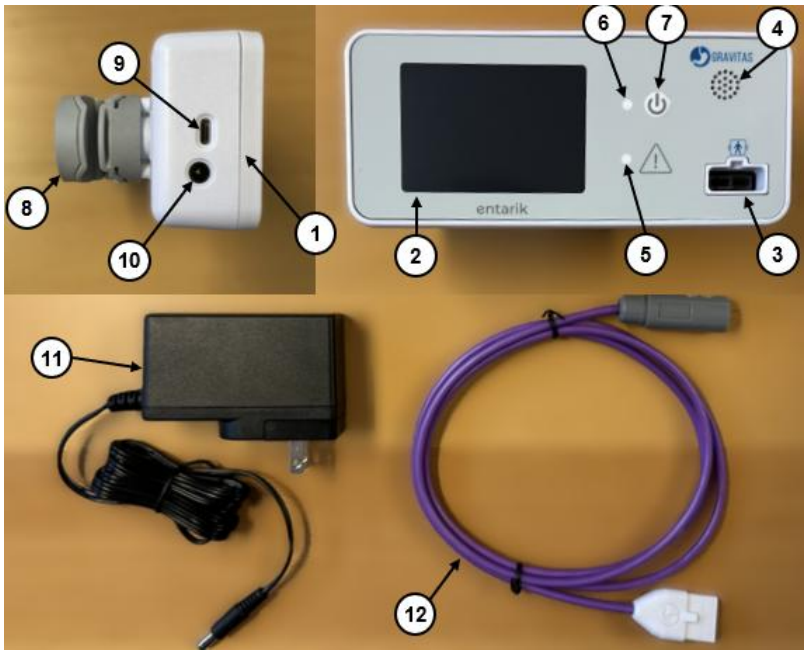


Figure 1: Entarik G2 Monitor

Entarik G2 Monitor - Detailed Components

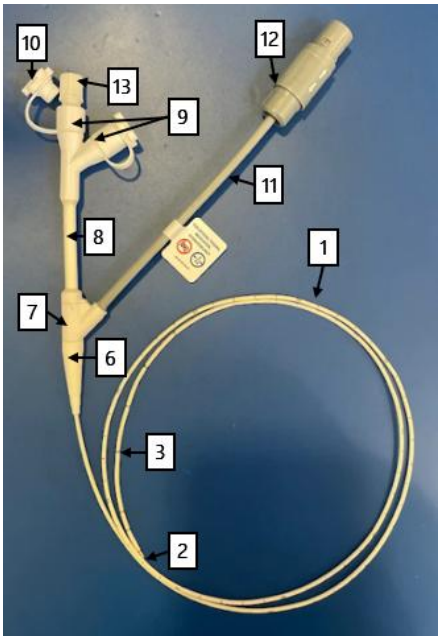
1. Electronic housing box made from medical grade Polycarbonate ABS blend
2. Touch screen that presents the user with information and allows for user input
3. Extension cable connector receptacle
4. Speaker to alarm the user
5. LED to alert the user
6. LED to indicate Entarik G2 Monitor has Power
7. Power button
8. IV pole clamp which allows connection of the monitor to a standard IV pole
9. USB connection for firmware upgrades and live data stream
10. Power supply connection
11. Wall Power Supply
12. Extension Cable which allows connection of Feeding Tube to Monitor

Not Shown in Figure 1:

- SD card access door
- Internal battery to allow usage for several hours when not plugged into the wall

Entarik G2 NI Feeding Tube

The Entarik G2 NI Feeding Tube is a nasoenteric/orogastric feeding tube made of a radiopaque polyurethane material that includes an array of stainless-steel electrode sensors on its external surface. The feeding tube is a single use device intended for short-term use (less than 30 days). A detailed description of the device is provided below in Figure 2.



Not Shown:

(4): Temp sensors in shaft wall

(5): Wires in shaft wall

Figure 2: Entarik G2 NI Feeding Tube

The G2 NI Feeding tube is comprised of the following components:

1. Shaft with depth markers consisting of polyurethane exterior, PTFE inner liner, and internal braided wire encapsulated in shaft wall.
2. Atraumatic stainless steel electrode tip
3. Impedance and ECG sensing electrodes made from passivated 316 L grade stainless steel
4. Temperature sensors (internal, not shown).
5. Internal braided wires encapsulated in shaft wall (internal, not shown).
6. Polyurethane shaft strain relief.
7. Cable Break-off made of ABS.
8. Kinkable polyurethane shaft.
9. ENFit Feeding Port made of ABS.
10. ENFit Feeding Port cap made of ABS.
11. Electrical cable with thermoplastic polyurethane outer jacket.
12. Electrical connector.
13. Optional Stylet.

Setup and Operation

NOTE: Read all warnings and cautions prior to initiating use of the Entarik G2-N System or inserting the Entarik G2 NI Feeding Tube.

Setup

The monitor should be mounted on an IV pole using the pole mount included with the Entarik G2 Monitor. The operator may stand by the monitor while powering up, changing settings on the device, and inserting the feeding tube to enable easy access to the touchscreen controls. For monitoring after feeding tube placement, the operator does not need to remain next to the device. The monitor runs on either wall power or internal battery. Interruption of wall power exceeding 30 seconds is not an issue since the monitor will automatically switch to internal battery power.

1. Mount the monitor on the pole using the pole mount.
2. Connect the monitor to wall power via the provided 5V Power Supply and the Power Connection (10, in Figure 1). Note: The Entarik G2-N System shall only be used with the provided power supply.
3. Set up the feeding tube according to the IFU packaged with the Entarik G2 NI Feeding Tube. Connect the feeding tube electrical connector (12, in Figure 2) to the monitor extension cable (12, in Figure 1), then plug extension cable into the monitor connector (3, in Figure 1).

Operation

Turn on Monitor

Press the Power Button (7, in Figure 1). The display screen will turn on, the Power Indicator Light (6, in Figure 1) will illuminate, and the Patient Data Entry screen will be displayed (Figure 3).

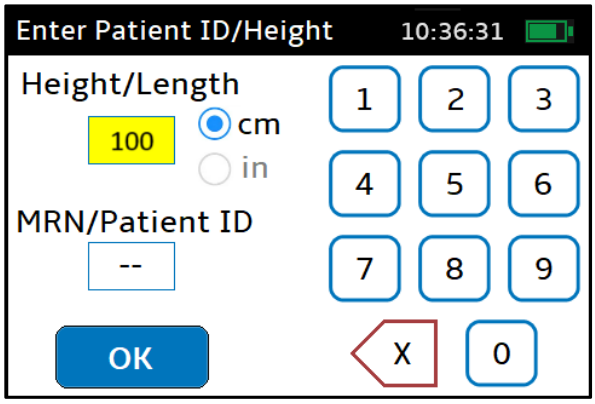


Figure 3: Patient Data Entry Screen

Patient Height and ID Entry

A valid height value must be entered before any further screens can be accessed. Height is needed for Safety Check and Stomach Check insertion depth calculations. The OK button is grayed out and disabled until height is entered. The Height field is selected for editing by default at startup; enter the 2 or 3-digit height value (in centimeter or inch units) using the keypad, then the OK button will light up blue as shown in Figure 3.

MRN/Patient ID is not required for monitor operation, but an appropriate value may be entered for patients if desired. To edit this field, tap on the blue (--) box then use the keypad to enter a number (up to 3 digits max). Tap OK when finished, then the Feeding Tube/Placement Mode Selection screen will be shown (Figure 4).

The recommended safety check depth and initial stomach depth are based on the following equations:

Safety Check Depth:

Nasogastric placement: Safety Check depth (cm) = 0.155 x height (cm) + 4

Orogastric placement: Safety Check depth (cm) = 0.145 x height (cm) + 3

Stomach Check Depth:

Nasogastric placement: Initial Stomach Check depth (cm) = 0.32 x Height (cm) + 5.5

Orogastric placement: Initial Stomach Check depth (cm) = 0.31 x Height (cm) + 4.5

Feeding Tube and Placement Mode Selection

If the feeding tube is not already connected to the monitor, a range of compatible feeding tube sizes will be indicated as shown in Figure 4 (left side):

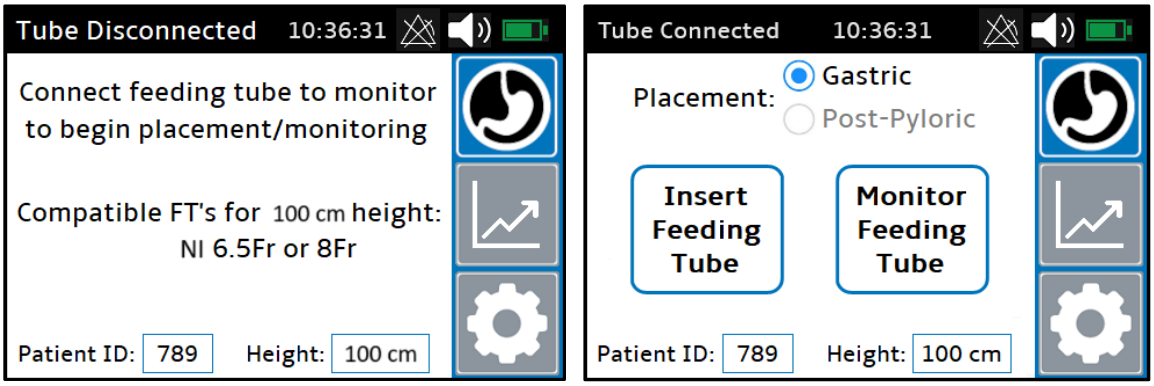


Figure 4: Feeding Tube Selection (left) and Placement Mode Selection (right)

Note that the compatible feeding tube list depends on the Height value entered on the previous screen. If the Height was entered incorrectly, tap on the blue Height box at the bottom of the screen to go back and re-enter the corrected value.

Plug a compatible feeding tube into the monitor and the Placement Mode selection screen will be shown (Figure 4, right side). "Tube Connected" will be displayed in the top Status bar. If a feeding tube that is incompatible with the patient's height is connected, the monitor will notify the user to plug in a compatible feeding tube or edit the Patient Height before proceeding.

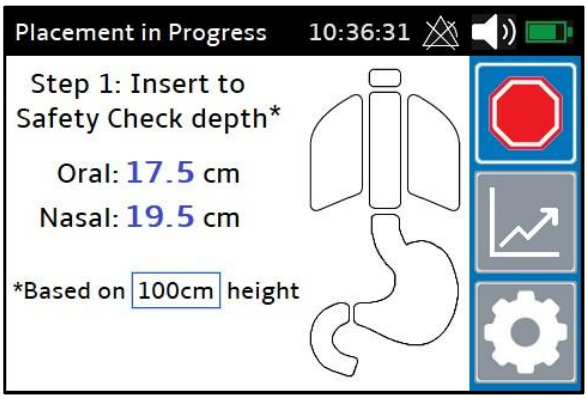
If you intend to insert the feeding tube to post-pyloric depth (or if the feeding tube is already at post-pyloric depth), select the Post-Pyloric radio button option at the top of the screen; otherwise, select Gastric (default). This selection can be changed later at any time during Insertion or Monitoring.

If the feeding tube has already been inserted to final feeding depth, tap on "Monitor Feeding Tube" button to skip guided insertion and proceed straight to monitoring. Otherwise, tap "Insert Feeding Tube" for guided insertion.

Insertion Mode – Placement Procedure

Step 1: Safety Check

When "Insert Feeding Tube" is selected, the Placement screen is shown:



User selects **Insert Feeding Tube** from Placement Mode Selection screen.

User checks that height value is correct and begins inserting feeding tube to indicated depth from nasal or oral entry point.

Figure. 5: Placement Screen (Insert to Safety Check Depth)

The monitor prompts the user to insert the feeding tube to the Safety Check depth calculated from the patient's height. Two depth options are shown: One for insertion through the Nasal cavity, and one for Oral insertion. The depth is calculated such that the tip of the feeding tube should be in the upper esophagus while stopping for the Safety Check. If the Height used for depth calculation is incorrect, the user can tap on the blue Height box to go back to the Height Entry screen. In case the "Insert Feeding Tube" option was pressed in error and the FT is already at final gastric/post-pyloric depth, the user can press the Stop button (top right) to go back to the Placement Mode selection screen. If everything looks correct, the user should then begin inserting the feeding tube to the recommended depth.

Note: The user must review the Entarik G2 NI Feeding Tube Operator's Manual including all **Warnings** and **Cautions** prior to inserting feeding tube into patient. **Standard feeding tube insertion techniques are used.**

As the feeding tube is inserted, the monitor will detect the feeding tube as "in-body" and activate a button for the user to confirm when the calculated Safety Check depth is reached:

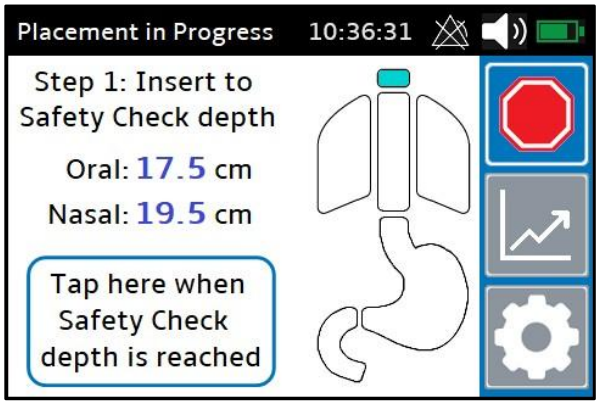
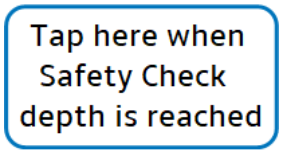


Figure 6: Placement Screen (Confirm Safety Check Depth)

Monitor detects that the feeding tube is in-body.

When the user has finished inserting the feeding tube to the indicated depth, the user starts the Safety Check by pressing this button:



When the user taps the button to confirm that Safety Check depth has been reached (Figure 6), the monitor starts the Safety Check (Figure 7).

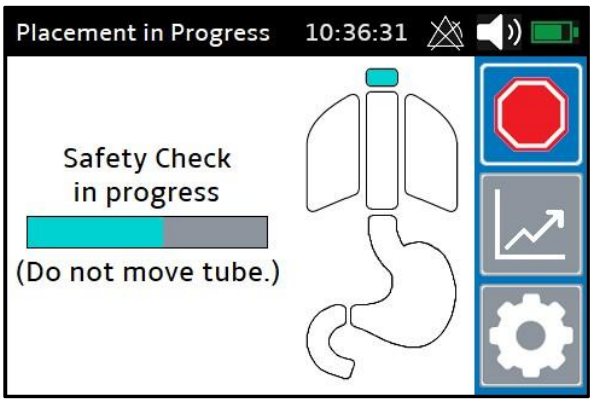


Figure 7: Safety Check in Progress

User actuates the Safety Check for misplacement detection and monitor displays a progress bar during check.

Do not move tube during safety check.

Caution: If misplacement is indicated at conclusion of Safety Check, do not advance feeding tube.

The Safety Check takes 10-30 seconds to complete. During this time, the monitor analyzes temperature and impedance data at the tip of the feeding tube to distinguish between misplacement in the trachea/pharynx vs expected positioning in the esophagus. One of 3 possible results is then shown to the user:

- If significant respiratory-related temperature cycling is detected or abnormal impedance levels are observed, the monitor shows a "Misplacement Detected" alert (Figure 8), and the user should withdraw the feeding tube from the patient and start over.
- If the initial data is inconclusive, a "Retry Safety Check" message is shown (Figure 9), which prompts the user to advance the feeding tube slightly deeper than the initial estimate and then start a 2nd Safety Check attempt.

- If the feeding tube appears to be properly placed in the esophagus, the monitor instructs the user to continue insertion to the stomach at the recommended depth calculated from the patient's Height (Figure 10).

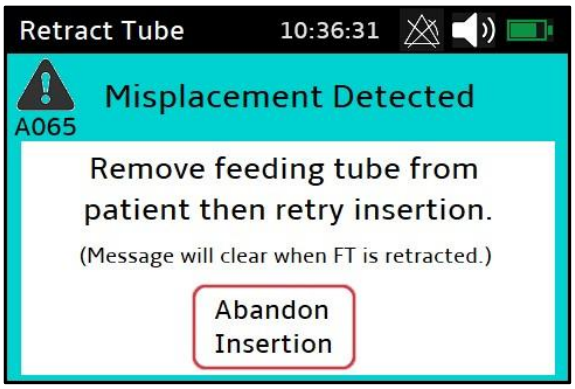


Figure 8: Safety Check Misplacement Alert

Monitor detected temperature/impedance activity indicative of misplacement in airway.

User must withdraw the feeding tube before retrying guided insertion. The alert self-clears when the FT is detected out of body. The user can choose to manually clear the alert via the "Abandon Insertion button", but the Insert Feeding Tube workflow will be disabled until the FT is detected out of body.

Caution: User must not advance tube further due to potential risk of airway injury.

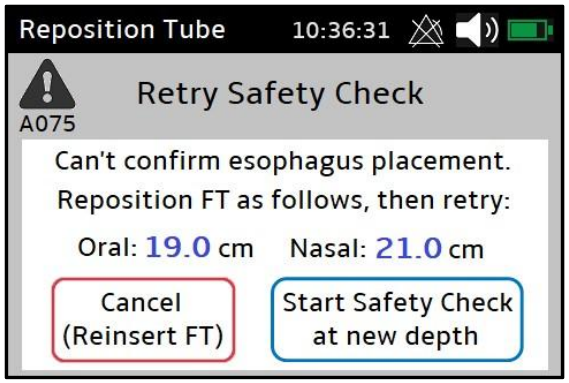
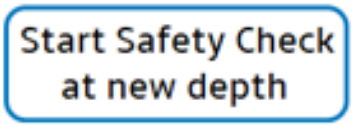


Figure 9: Retry Safety Check at New Depth

Safety Check at initial depth was inconclusive.

User should carefully advance the feeding tube to the new recommended depth and press this button to restart the Safety Check:



Caution: Do not advance feeding tube past the indicated depth.

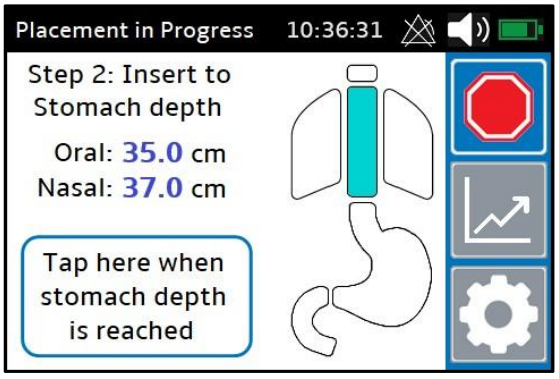
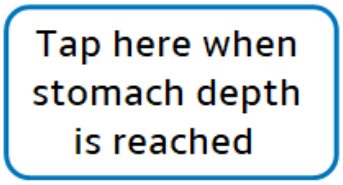


Figure 10: Insert to Stomach Depth

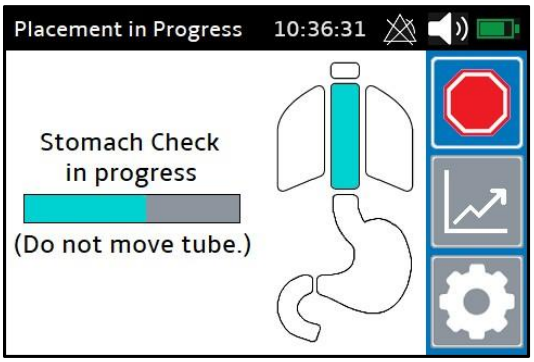
Safety Check passed: Anatomy diagram indicates the feeding tube is positioned in the esophagus as expected.

User should advance the feeding tube to the indicated stomach depth then press this button to start the Stomach Check:



Step 2: Stomach Check

After the Safety Check passes, the user is instructed to insert the feeding tube to stomach depth. The indicated depth is calculated from the patient's Height. (Note that even if post-pyloric final placement is desired, the monitor still requires a pause at stomach depth to help verify that the feeding tube did not get stuck/curled in the esophagus during insertion.) After inserting to the indicated depth, the user should press the button to start the Stomach Check:



User actuates the **stomach detection check** and monitor displays a progress bar during check.

Do not move tube during stomach check

Figure 11: Stomach Check in Progress

The Stomach Check requires 6-30 seconds to complete. During this time, the monitor measures and analyzes impedances to determine if the tip of the feeding tube is inserted sufficiently deep within the stomach. (The monitor requires some safety margin to help avoid future dislodgements from normal patient movement). For ideal placement, the monitor expects to see low impedances indicative of gastric tissue in the distal section of the tube and higher impedances indicative of esophagus tissue in the mid-proximal section of the tube. Several results are possible:

- If the feeding tube is too shallow (tip is in the esophagus, or tip is in the stomach but with insufficient safety margin), the monitor tells the user to insert slightly further and retry the Stomach Check (Figure 12).
- If Gastric Insertion mode is selected and the feeding tube is inserted too deeply into the stomach, the monitor tells the user to retract the FT slightly then retry the Stomach Check (Figure 13). This retraction is intended to position the tip at ideal depth for feeding and for reflux detection. However, if the clinician is confident that the placement depth is fine as-is and retraction is undesirable, the "Accept As-Is" button allows the user to bypass further stomach check attempts and continue to the final step (standard of care verification).
- If very high impedances are observed in the distal section of the tube, "Gastric Air" is indicated (Figure 14). The user should use standard of care methods to remove air from the stomach before retrying the Stomach Check. Removing the air helps the feeding tube make better contact with stomach tissue, which allows the monitor to make a more definitive stomach placement determination. Alternatively, if aspiration is undesirable and the clinician is confident that the placement is correct, the "Accept As-Is" button allows the user to continue to the final step (standard of care verification) without further stomach checks.

- If the feeding tube appears to be curled or stuck in the esophagus (i.e., stomach tissue is still not detected after 3 consecutive "too shallow" results), a notification is shown indicating that placement cannot be confirmed (Figure 15). In this scenario, the user should retract the feeding tube out of body and restart the Insert Feeding Tube procedure.
- If the tip of the feeding tube is detected at proper depth within the stomach, the "Stomach Detected" message is shown (Figure 16). This is presented as an alert to emphasize that the user should independently verify proper placement via Standard-of-Care methods.

WARNING: FINAL FEEDING TUBE POSITION MUST BE CONFIRMED BY INSTITUTIONAL PROTOCOL (e.g., X-RAY) PRIOR TO FEEDING OR FLUID ADMINISTRATION.

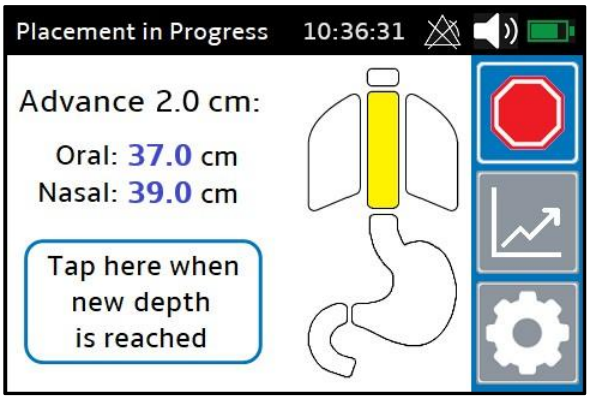
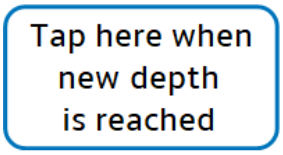


Figure 12: Advance FT & Retry Stomach Check

Monitor detects feeding tube as too shallow and prompts user to insert slightly further.

User advances the feeding tube to the new indicated depth and taps this button to restart the Stomach Check:



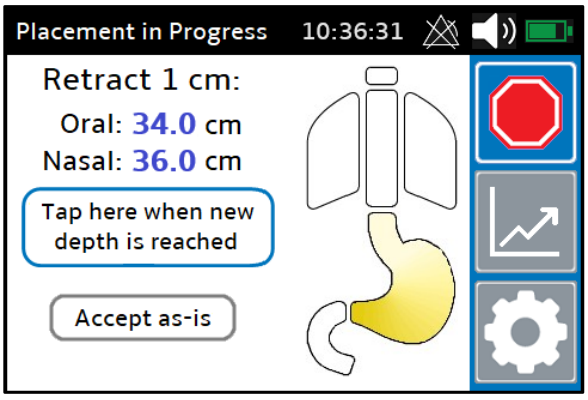
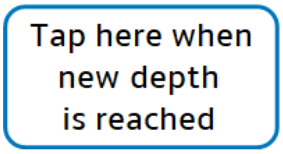


Figure 13: Retract FT & Retry Stomach Check

Monitor detects feeding tube as too deep and prompts user to slightly retract feeding tube.

User retracts the feeding tube to the new indicated depth and taps this button to restart the Stomach Check:



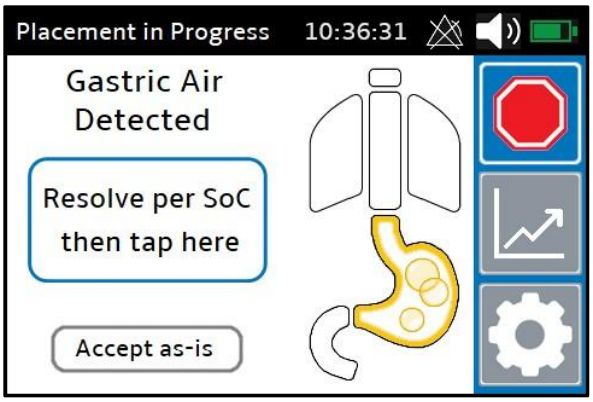
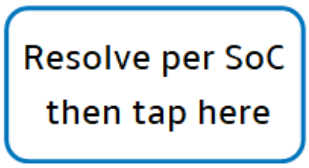


Figure 14: Stomach Check - Gastric Air Detected

Monitor detects gastric air and prompts user to resolve per Standard-of-Care.

User aspirates air (if desired), and then taps this button to restart the Stomach Check:



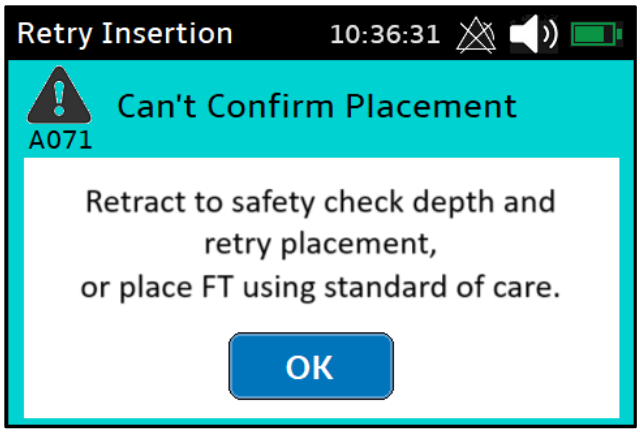


Figure 15: Placement Failure Alert

Unable to Confirm Placement:

Monitor is still unable to detect the feeding tube in stomach after 3 prior "too shallow" results or feeding tube appears to be curled in esophagus.

User can clear alert by tapping OK or by fully withdrawing the feeding tube, and the monitor goes back to the Insert to Safety Check depth screen.

User should then retry monitor-guided insertion or use independent standard-of-care protocol to place and verify the feeding tube.

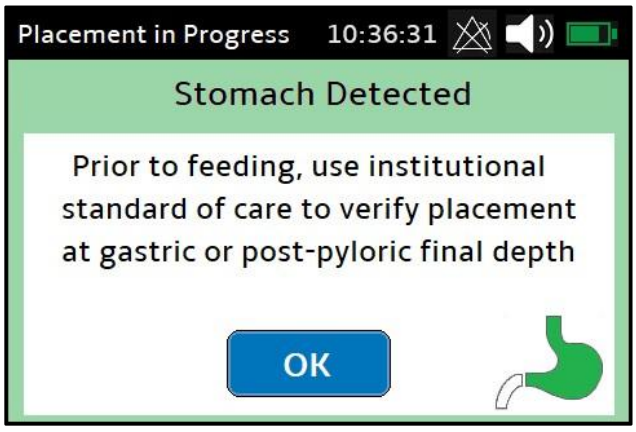


Figure 16: Stomach Detection Notification

Monitor detects the feeding tube tip at proper stomach depth.

The monitor notifies the user to use standard-of-care protocol to verify final gastric or post-pyloric placement position.

Step 3: Verify Final Placement per Standard of Care

Prior to feeding or fluid administration through the feeding tube, the user must use institutional standard-of-care protocols (e.g., X-ray) to independently verify gastric placement or to continue insertion to post-pyloric depth. **Note: The Entarik G2 Monitor does not provide further guidance for post-pyloric placement.** Note that regardless of whether the "Gastric" or "Post-Pyloric" preference was previously selected in the Placement Mode Selection screen, the user is free to end placement at either depth.

After independently verifying proper placement at desired gastric or post-pyloric positioning, the user should then enter the final depth (relative to the nasal/oral opening) as shown in Figure 17. The Depth value defaults to the last recommended depth when the Stomach Check passed; if any further adjustments were made during standard-of-care verification, use the **+/-** buttons to update the final depth in the monitor.

If the final placement depth is verified in the stomach per SoC, press the **Confirm: Gastric** button to accept the final depth and proceed to Gastric Monitoring mode.

If the final placement depth is verified post-pyloric per SoC, press the **Confirm: Post-Pyloric** button to proceed to Post-Pyloric Monitoring mode.

If the standard-of-care evaluation indicates that the feeding tube needs to be withdrawn and reinserted, press the Stop button to restart guided insertion.

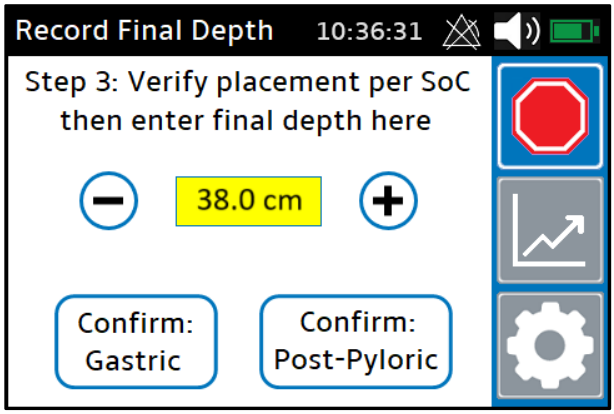


Figure 17: Verify Final Placement Depth per SoC

Monitor prompts user to evaluate proper gastric or post-pyloric position using standard of care (e.g., X-ray).

If the standard-of-care evaluation indicates that the feeding tube needs to be reinserted, press the Stop button to restart guided insertion.

If standard-of-care evaluation is successful, user adjusts depth (if necessary) and presses Confirm: Gastric or Confirm: Post-Pyloric.

Caution: User must independently verify proper feeding tube final placement prior to initiation of feeding or fluid administration.

If the stylet was used to assist with insertion, it should be removed from the feeding tube. Connect the ENFit male connector on the feeding tube to an enteral feeding syringe or an enteral feeding set. Only the syringe or feeding set designed with an ENFit connector can be securely connected to the feeding tube. Confirm that the feeding tube is connected to an enteral port only and NOT an I.V. set.

Monitoring Mode

Monitoring mode (Figure 18) is reached by following the above guided insertion procedure or by pressing the "Monitor Feeding Tube" option from the Placement Mode Selection screen (Figure 4). Note: If the feeding tube is not detected in-body when the "Monitor Feeding Tube" button is pressed, the monitor will prompt the user to select the "Insert Feeding Tube" option instead.

If the Gastric option is selected, the Safety Check will be skipped, but the monitor will still conduct a Stomach Check to verify that the feeding tube tip is in the stomach with sufficient safety margin to help avoid future dislodgements. This Monitoring-mode Stomach Check follows the same process as the Insertion-mode Stomach Check.

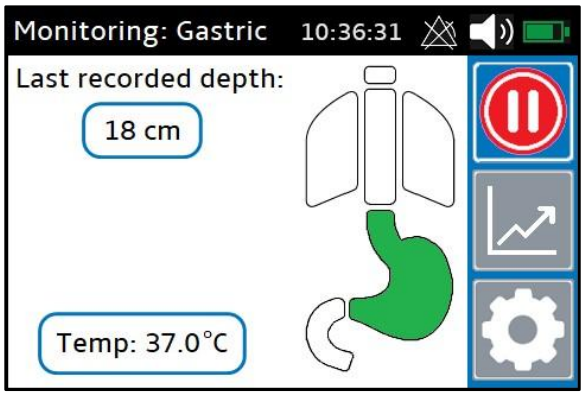


Figure 18: Gastric Monitoring Mode

Gastric Monitoring: Monitor continuously evaluates feeding tube position and updates the Anatomy diagram accordingly. The monitor also continuously updates the temperature value based on measurements from the feeding tube sensors.

If the feeding tube position needs to be adjusted, tap the Depth button to show the Modify Depth screen.

Press the Pause button to stop monitoring. After pausing, an option will be shown to end monitoring.

Press the Graph button to view Temp, Reflux, or Impedance history plots.

Press the Settings button to enable/disable alerts, adjust monitor time, etc.

If the Post-Pyloric option is selected, the monitor prompts the user to confirm that the feeding tube is already placed at post-pyloric depth; if affirmative, the monitor skips to Post-Pyloric Monitoring mode without a Safety Check or Stomach Check. The Monitor does not provide guidance for post-pyloric insertion; the user must independently verify placement via institutional standard of care protocols.

The following features are available in Monitoring mode:

- Depth display/update. The most recently confirmed feeding tube depth is shown at the top of the Monitoring screen (Figure 18); the user can update this depth and/or switch between Gastric vs Post-Pyloric Monitoring mode by following the instructions on the ensuing screen.
- Continuous placement evaluation/dislodgement detection.
- Gastrointestinal temperature monitoring. The current temperature is displayed in the Monitoring screen (Figure 18) and historical temperature plots are available in the Graph screen.
- Gastroesophageal reflux detection. (Only available in Gastric Monitoring mode.) Tap the Graph button to access historical reflux plots.
- Impedance monitoring. Tap the Graph button to access historical impedance plots.
- Event logging. The user may enter events such as emesis, desaturation, medication administration, etc. which are annotated in the Reflux and Impedance graphs.

Depth Display/Update

The most recent user-confirmed feeding tube insertion depth is always displayed at the top of the Monitoring screen. The user can periodically visually inspect the feeding tube to make sure that it hasn't deviated from this depth value.

If the feeding tube depth needs to be updated or the user would like to switch between Gastric vs Post-Pyloric Monitoring mode, tap on the Last Recorded Depth button to show the Modify Depth screen (Figure 19):

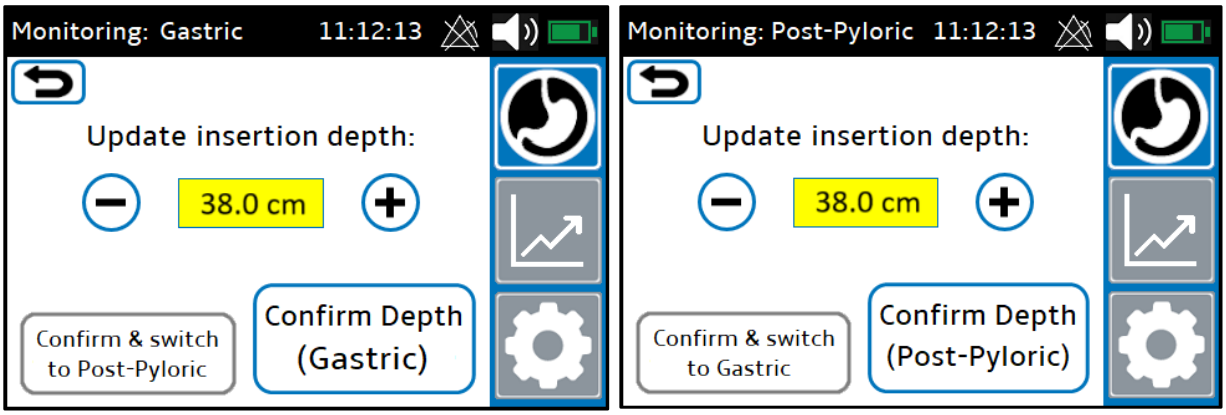


Figure 19: Modify Monitoring Depth

Press the +/- buttons to adjust the depth and then press the blue "Confirm Depth" button on right to accept the new depth and remain in the same operating mode. To switch from Gastric Mode to Post-Pyloric mode (or vice versa), press the gray "Confirm & switch" button on the left and then follow the instructions on the next screen to confirm or cancel the switch. To exit without making any changes, press the Back button on the top left.

Continuous Placement Evaluation

The monitor continuously checks the feeding tube position and notifies the user if significant movement is detected. The following movement notifications/alerts are possible:

- Major Dislodgement Alarm (Figure 20): Monitor detects that a significant length of the feeding tube has been pulled out-of-body. In this scenario, the user should repeat the guided insertion procedure (including the Safety Check and Stomach Check) to navigate back to the stomach. If Major Dislodgement Alerts are disabled by the user in the Settings screen, a smaller "Check for Dislodgement" message is displayed in the Placement screen instead (Figure 22).
- Minor Dislodgement Alarm (Gastric Mode only, Figure 21): Monitor observes moderately high impedances suggestive of esophageal tissue contact at the tip of the feeding tube. These high impedances can also be caused by shallow gastric feeding tube placement and/or intermittent gastric air buildup during fasting periods; therefore, the user should visually inspect the feeding tube to confirm whether the feeding tube has moved from the last recorded depth. If the feeding tube appears to be positioned correctly, the user can choose the "Clear Notification" option and snooze further Minor Dislodgement notifications for 1 hour. Otherwise, if the feeding tube has retracted from the last known depth, the user should choose, "Yes, Dislodged"; the monitor will then instruct the user to insert back to the correct depth and conduct a Stomach Check to re-verify placement. If Minor Dislodgement alerts are disabled by the user, a shallow placement message is shown in the Placement screen instead (Figure 23).
- Gastric Air Detected notification (Gastric Mode only, Figure 24): Monitor detects consistently very high impedances throughout the distal end of the feeding tube. If desired, the user can use standard-of-care methods (e.g. aspiration) to clear the gas. If successful, the monitor will detect proper stomach contact, clear the Gastric Air message, and show a green stomach again on the Anatomy diagram.
- Deep migration notification (Figure 25): Monitor detects consistently low impedances indicative of stomach tissue contact across the reflux sensors that are normally expected to be in the esophagus. Deep placement does not pose a significant risk to the patient, but it does prevent reflux detection. If reflux monitoring is desired and the standard-of-care placement verification result indicates that the feeding tube is inserted into the stomach with sufficient margin to safely tolerate slight retraction, the user can carefully retract the feeding tube 1 cm and then wait 1 minute to see if the monitor detects the feeding tube at proper depth (as indicated by a green stomach in the Anatomy diagram). The user should then use standard-of-care protocols to verify that the feeding tube was not retracted out of the stomach. If the monitor still detects that the tube is too deep after the 1-minute wait time, the user can repeat the process (retract 1 cm and wait 1 minute) if the clinician deems it still safe to retract further.

  If the user does not wish to retract the tube, these messages can be manually disabled by tapping the "Reflux Detection Disabled" button and confirming the option to "Hide these notices" on the ensuing screen.

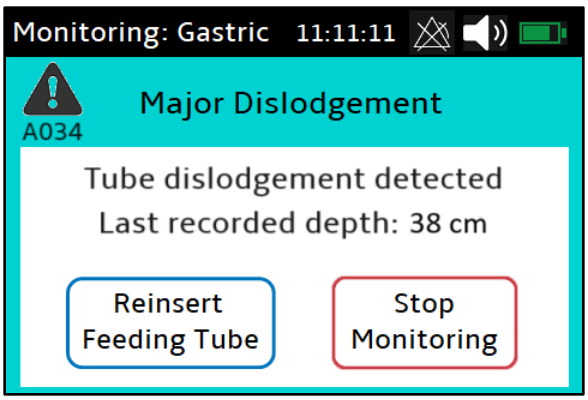


Figure 20: Major Dislodgement Alarm

Major dislodgement alarm: The monitor detects the feeding tube has been retracted from the stomach by a significant distance.

User can choose "Reinsert Feeding Tube" to restart the guided insertion process, including the Safety Check and Stomach Check.

Otherwise, press Stop Monitoring to go back to the Placement Mode Selection screen.

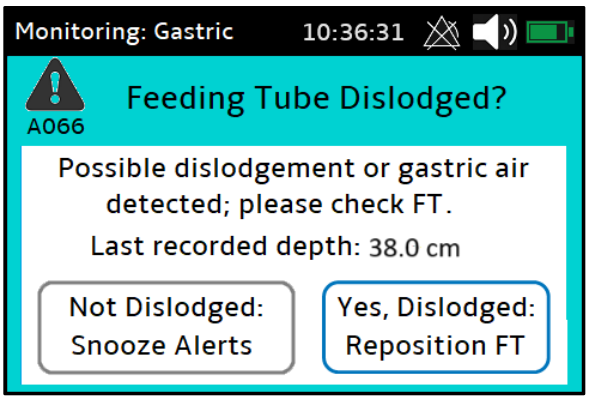


Figure 21: Minor Dislodgement Alarm

Minor dislodgement alarm: The tip of the feeding tube is detected in the esophagus.

User visually inspects the feeding tube and confirms or rejects the dislodgement.

To confirm the dislodgement, tap the "Yes, Dislodged" button then advance the feeding tube back to the last verified depth.

To reject the dislodgement, tap the "Not Dislodged" button; further Minor Dislodgement notifications will be disabled for 1 hour.

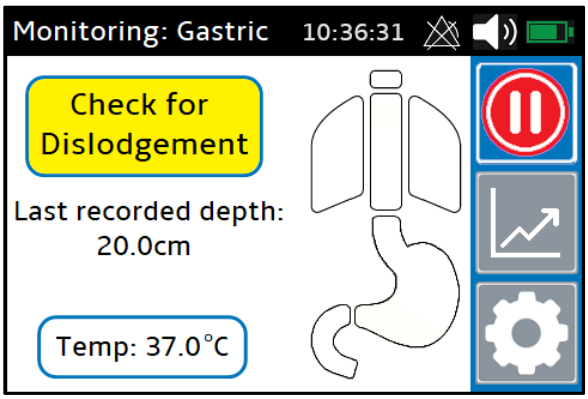


Figure 22: Major Dislodgement Message

If Major dislodgement alarms are disabled by the user, this "Check for Dislodgement" message will be shown instead of an alert when dislodgements are detected.

The user can tap the Check for Dislodgement button to confirm or reject the dislodgement and clear the message.

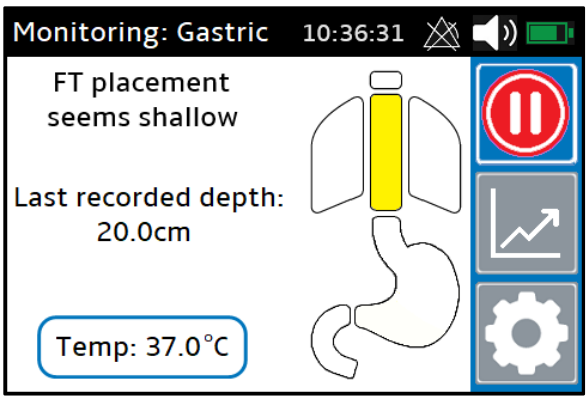


Figure 23: Minor Dislodgement Message

If Minor dislodgement alarms are disabled by the user, this "FT placement seems shallow" message is shown instead of an alert when the tip of the FT is detected in the esophagus.

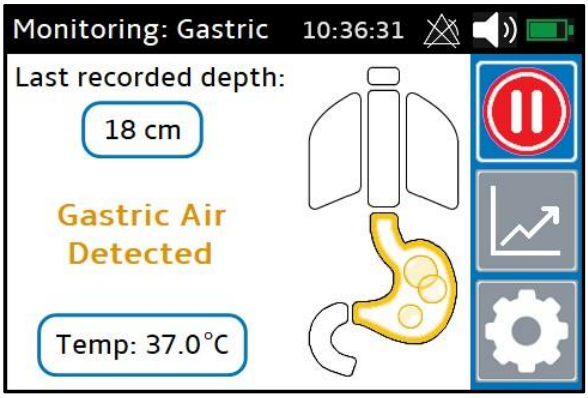


Figure 24: Monitoring - Gastric Air Message

Gastric Air Detected message is shown if very high impedances are consistently observed near the tip of the feeding tube.

The user can resolve the gastric air per SoC if desired, and the message will automatically clear if/when the feeding tube makes better contact with stomach tissue and low impedances are observed again.

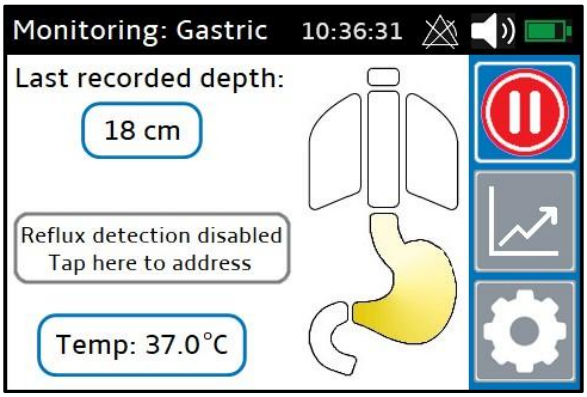


Figure 25: Monitoring - Deep Message

FT Too Deep message is shown if the feeding tube has migrated deeply enough such that the esophageal reflux monitoring sensors are now situated within the stomach.

The user can carefully retract the feeding tube to get the tip back to ideal depth within the stomach to clear the message.

Alternatively, the user can tap the button and follow the prompt to disable these messages.

Caution: Do not retract feeding tube out of stomach.

Reflux Detection

Gastroesophageal reflux monitoring is only available in Gastric Monitoring mode. Several reflux-sensing electrodes are situated in a section of the feeding tube that is expected to remain in contact with esophageal tissue while monitoring, assuming the feeding tube is inserted to a proper depth. If the feeding tube is inserted too deeply into the stomach (or migrates too far into the stomach over time via peristalsis), the reflux sensors will end up in the stomach and reflux detection will be disabled. If deep placement is detected (see Figure 25) but reflux monitoring is required, the user should follow the protocol mentioned above for safely repositioning the feeding tube.

The monitor uses industry-standard Multichannel Intraluminal Impedance measurements for detecting reflux events. The reflux events are then summed and displayed as "Events per Hour" in the Reflux graph (Figure 26):

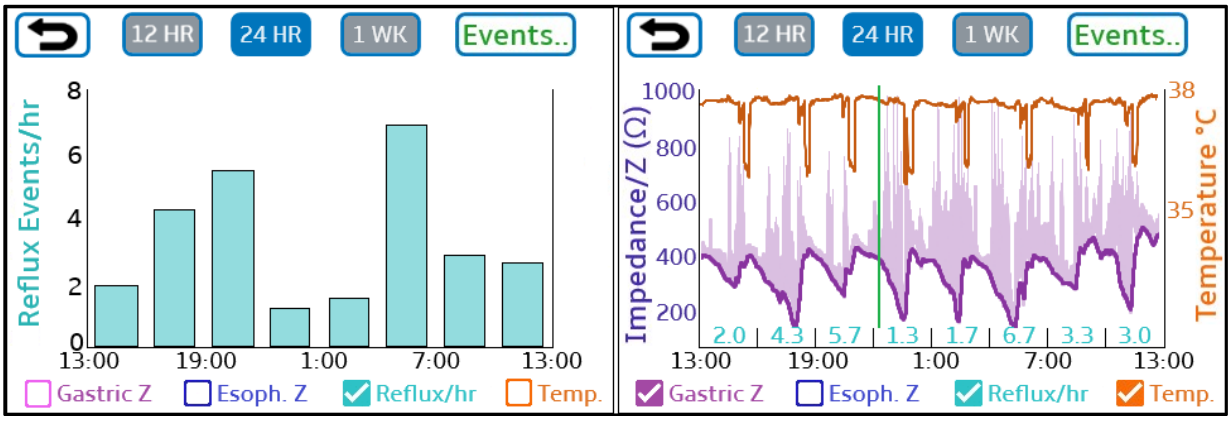


Figure 26: Reflux-Only Bar Graph (left) and Reflux Values (right)

The Reflux graph displays reflux activity as teal bars. If Impedance plots are enabled by the user, reflux values are shown as text instead of bars; the combined display of Impedance & Reflux allows the user to observe potential correlations between reflux activity and gastric filling/emptying during and after feeding. Three viewing options are available: The 12-Hour view is divided into 1-Hour reflux blocks, the 24-Hour view is divided into 3-hour time blocks, and the 1-Week view is divided into 24-Hour time blocks. (For all view options, the reflux values are normalized as hourly rates.)

Note: If the feeding tube is inserted too deep, reflux events will be missed; and if the feeding tube is too deep for a significant amount of time, the corresponding reflux bars/values may be omitted from the graph.

The green vertical lines on the graph represent user-entered Events; these are detailed in the Patient Events section.

Temperature Monitoring

The monitor processes data from several temperature sensors located along the feeding tube to continuously update the temperature value displayed on the Monitoring screen (Figure 18) and

reported to the Temperature graph (Figure 27). Note that the observed temperature can be affected by feeding or fluid administration. If a significant fast drop in temperature is detected, the monitor will recognize this as likely feeding activity; in this scenario, it will show dashes (--) for the temperature value in the Monitoring screen.

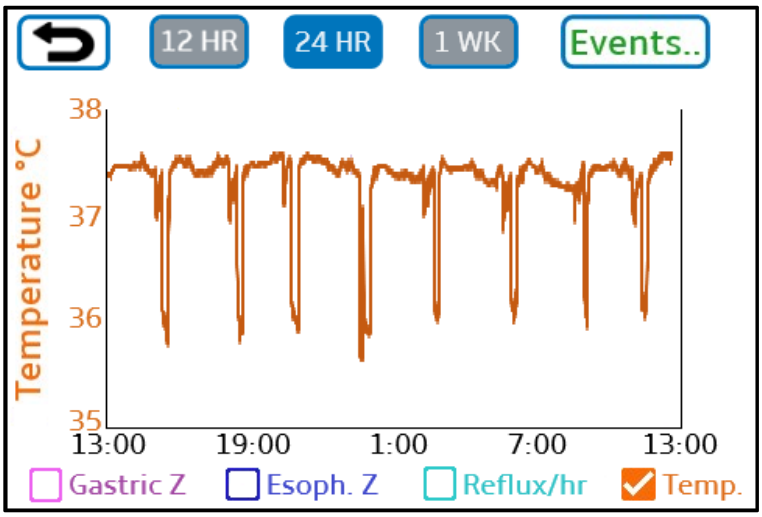


Figure 27: Temperature Graph

The user can navigate to the Temperature Graph by pressing the Graph button or the Temperature value button on the Monitoring screen. The graph is available in 12-Hour, 24-Hour, or 1-Week views. The orange dashed lines in the graph represent the temperature high/low alert thresholds chosen in the Settings screen.

Impedance Monitoring

Impedance-sensing electrodes are spaced throughout the gastric and esophageal-facing regions of the feeding tube. Impedances are processed and displayed in the Impedance graph (Figure 28):

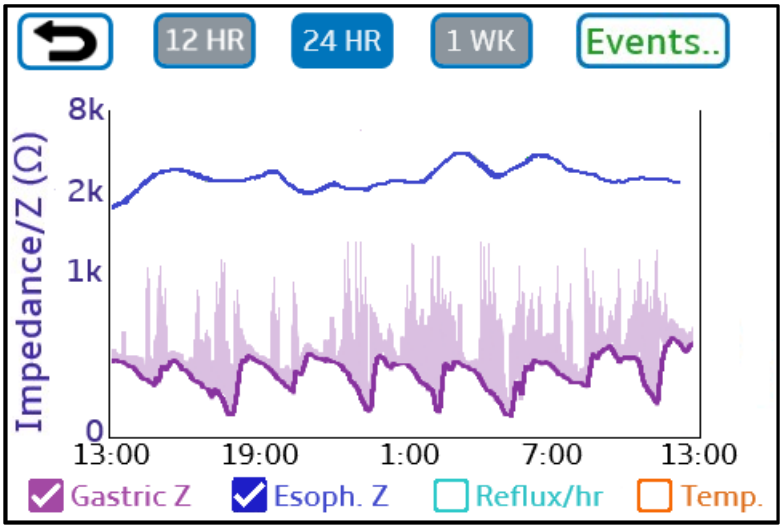


Figure 28: Impedance History Graph

The Impedance graph is available in 12-Hour, 24-Hour, or 1-Week views. Gastric impedance is the purple plot and Distal Esophageal impedance is blue. Note that for Post-Pyloric mode, these plots are relabeled as Distal (purple) and Proximal (blue). If the user switches between Gastric vs Post-Pyloric Monitoring modes, previous impedance graph data is cleared.

Patient Events

The user can add annotations to the Reflux and Impedance graphs when important events are observed. These events are represented as green vertical lines. The user can access the Patient Event screen (Figure 29) in several ways:

a) Pressing the "Events.." button at the top right of the graph (Figure 26-28)

b) Navigating to the Settings screen and pressing the "Patient Events ..." button (Figure 38)

c) Pressing the "Add Event" button from the Monitor Inactivity lock screen (Figure 33)

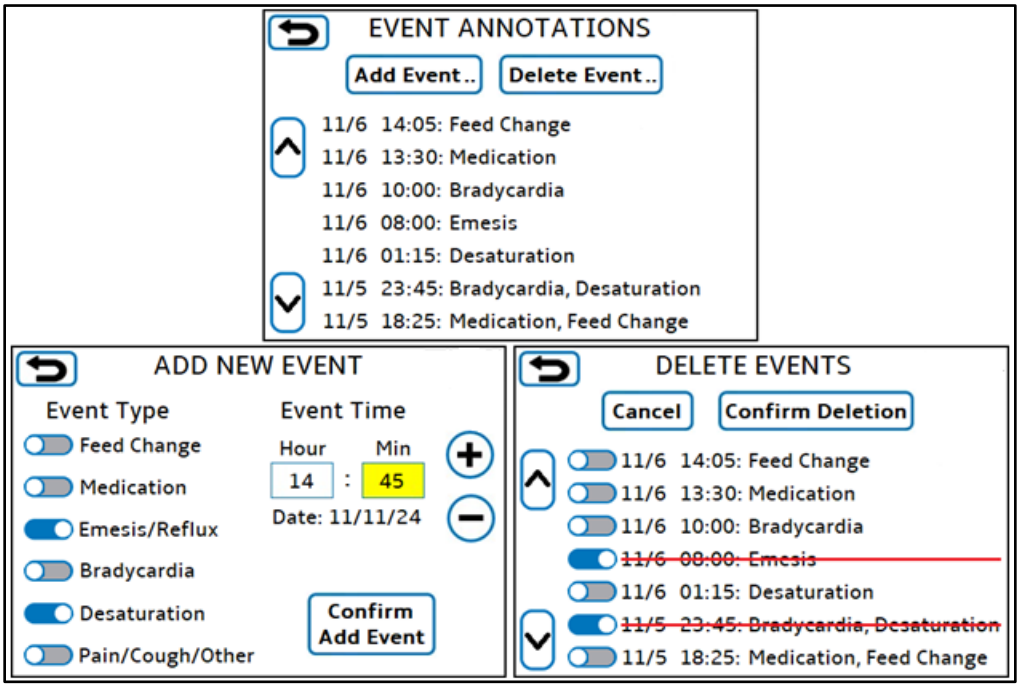


Figure 29: Patient Event Dialog

Follow the Patient Event dialog instructions to add event annotations with corresponding timestamps to the Reflux and Impedance plots. Up to 24 events can be added; the oldest event in the list is deleted if additional events are added. The user can also manually delete events if desired. The Event history is automatically cleared if the user selects the "New Patient" option when connecting a new feeding tube.

Pause or Stop Monitoring

The user can either pause or end Monitoring as needed. To pause Monitoring mode, press the red "Pause" button on the Monitoring screen and disconnect the feeding tube from the monitor. Alternatively, Monitoring mode can be paused by disconnecting the feeding tube and tapping "Pause Monitoring" on the next screen (Figure 30). When it is time to resume monitoring, connect the feeding tube to the monitor and tap "Resume Monitoring" on the screen (Figure 31).

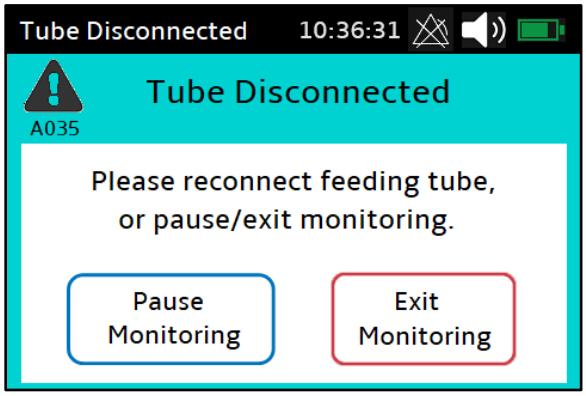


Figure 30: Tube Disconnected (Monitoring Mode)

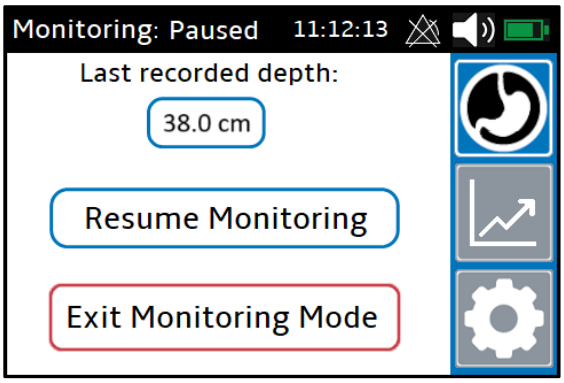


Figure 31: Monitoring Paused: Resume or Exit

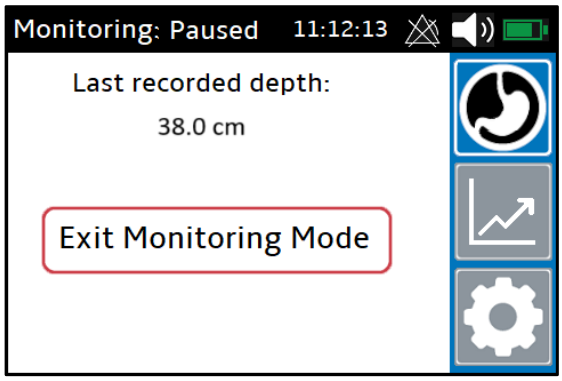


Figure 32: Monitoring Paused (FT Disconnected)

The user can end Monitoring mode by pressing the "Exit Monitoring Mode" button (Figure 31 & Figure 32) after pausing the monitor.

To resume monitoring after pausing, reconnect the feeding tube (if not already connected) and press the "Resume Monitoring" button (Figure 31).

Monitor Inactivity Lock Screen

If the screen is inactive for over five minutes, the screen will become locked and the user must select "Unlock" to access the user interface (Figure 33). This screen also provides the option to directly add new patient event annotations without navigating to the graph screens.

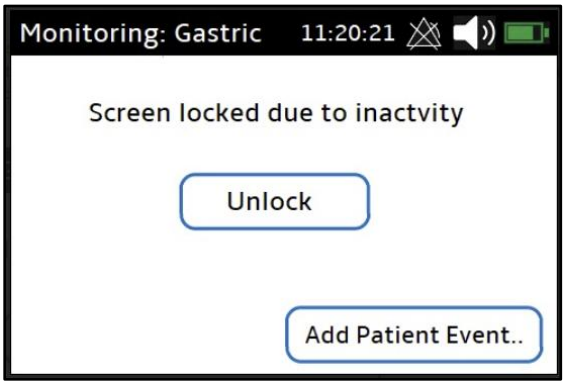


Figure 33: Inactive Screen

Charging the Internal Battery

Plug the unit into wall power according to the setup instructions. Only use the provided 5V Power Supply unit. If the monitor is charging, a lightning symbol will appear within the battery symbol on the status bar.

Power off Monitor

To power off the monitor, press the power button located on the front of the monitor. Acknowledge the power off alert on the screen and the monitor will power down. The Entarik G2 Monitor will continue to charge the internal battery while powered down and plugged into wall power.

General Monitor Features

Additional features of the Entarik G2 Monitor include:

- Status bar
- Selection bar
  - Placement/Stop button
  - Graph button
  - Settings button
- Settings

Status Bar

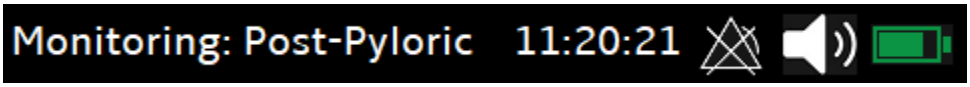


Figure 34: Status Bar

The Status Bar is visible on most screens (always at the top of the screen) and contains the following information:

1) Monitor Status (top left): Text to inform the user of the Insertion/Monitoring status.
2) Current Time: Monitor local time, which can be adjusted in the Monitor Settings screen.
3) Alert Icon: The Alerts Enabled icon is displayed if all Dislodgement alerts are enabled in the Alert Settings screen; otherwise, the Alerts Disabled icon is displayed.
4) Speaker Icon: The Speaker Enabled icon is displayed if audible alerts are enabled in the Monitor Settings screen; otherwise, the Speaker Disabled icon is displayed.
5) Battery Icon: The Battery Icon will be green if the battery charge is above 50%, yellow if between 25% and 50%, and red if below 25%. If the power supply is connected to the monitor, a charging icon is shown in the battery icon.

Selection Bar

The **Selection Bar** (Figure 35) is always on the right side of the placement screen and allows the operator to switch views. The selected view is blue and the unselected icons are gray:

The Placement button navigates to the Placement/Monitoring screen. If feeding tube placement/verification is still in progress, the Stop Insertion button is shown on the Placement screen; otherwise, while in Monitoring mode, a Pause button is shown instead.

The Graph button navigates to the Graph Menu (**Error! Reference source not found.**). The Settings button navigates between several Settings screens.

Figure 35: View Selection Bar

Graph Button

The Graph button navigates to the graphs (Figures 26-28)

Settings

Tap the Settings button to scroll between the Alert Settings, Monitor Settings, and Patient Settings screens (Figures 37-39):

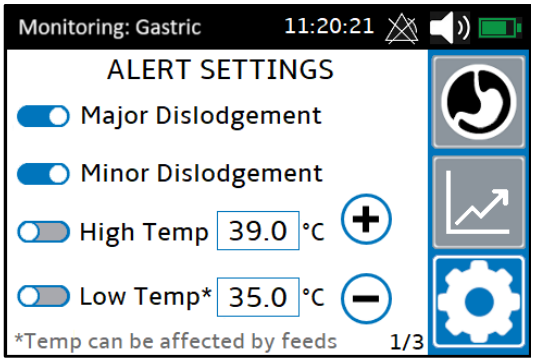


Figure 36: Alert Settings

Tap the toggle buttons to enable or disable the Temperature and Dislodgement alerts.

Dislodgement alerts are enabled by default upon start up and when switching to a new patient. Temp alerts are disabled by default.

To change the Temp alert thresholds, tap on the number to highlight it yellow then tap the +/- buttons to increment/decrement the value.

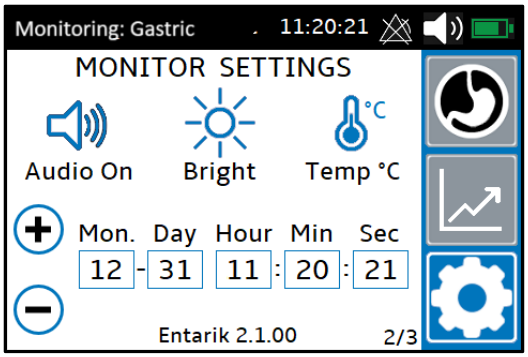


Figure 37: Monitor Settings

Tap the Audio button to toggle between enabled/disabled Audible Alert Notifications.

Tap the Brightness button to toggle screen brightness between Dim/Medium/Bright.

Tap the Temp button to toggle between temperature display units (°C and °F)

To update the monitor time, tap the desired value to highlight it yellow then tap the +/- buttons.

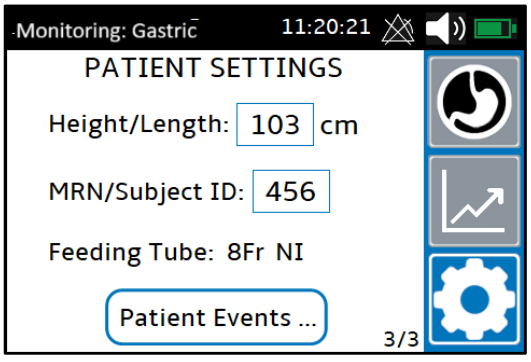


Figure 38: Patient Settings

This screen shows the Patient Height and Patient ID values and feeding tube in use.

To revise the Height/ID values, tap on either of the blue boxes to navigate back to the Patient Data Entry screen (

Figure 3).

The Event Annotations screen (Figure 29) can be accessed by pressing the Patient Events button.

Placement Indicators

In placement or monitoring mode, the monitor will indicate the location of the tip of the feeding tube with one of several potential Anatomy diagrams (Figure 39):

A. Not In Body: The anatomical drawing is blank if the feeding tube is not detected in body yet.
B. Initial Insertion: The upper segment of the anatomical drawing is blue if the Entarik G2-N System has detected initial tube insertion in the patient, but the Safety Check has not been completed yet.
C. Safety Check Success: The esophagus is blue if the monitor detected the tip of the feeding tube in the esophagus during the Safety Check.
D. Misplacement (Safety Check Failure): The lungs/pharynx are yellow if the monitor detected the tip of the feeding tube in the lungs or airway during the Safety Check.
E. Very Shallow Insertion or Confirmed Dislodgement: The esophagus is yellow if the monitor detects the tip of the FT in the esophagus during the Stomach Check or while Monitoring.
F. Slightly Shallow Insertion or Possible Dislodgement: The lower esophagus and upper stomach are yellow if the monitor detects that the FT is not inserted deeply enough into the stomach during the Stomach Check or while Monitoring.
G. Too Deep (Reflux Disabled): The stomach is yellow if the monitor detects that the esophageal reflux sensors are within the stomach.
H. Gastric Air: The stomach is hollow with a yellow outline if the monitor has detected abnormally high impedances indicative of gastric air in the distal section of the feeding tube.
I. Good Gastric Placement: The stomach is green if the monitor detects that the tip of the Feeding Tube is placed at the proper depth within the stomach.
J. Post-Pyloric Placement: The intestine is green if the user confirms that the feeding tube is placed post-pyloric.

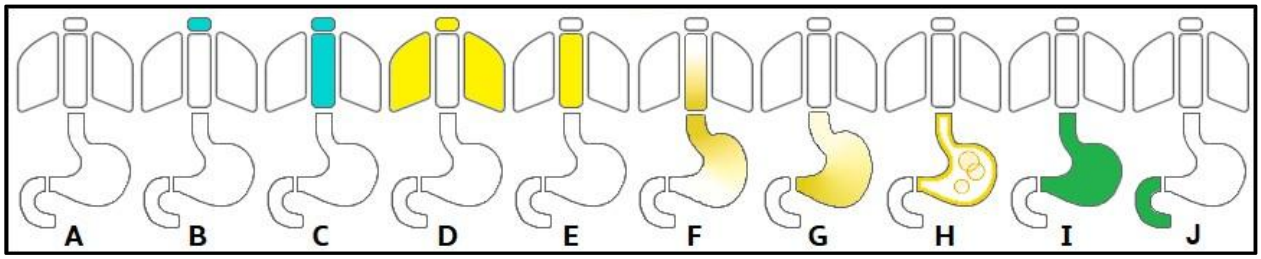


Figure 39: Anatomy Diagram

Environment and Cleaning

Use and Storage Environment

The Entarik G2 Monitor is intended to be used between 50°F and 86°F (10°C to 30°C) and stored between 50°F and 104°F (10°C to 40°C) in a hospital environment, relative humidity of 15-90%, non-condensing. Please refer to Appendix D for guidance on conditions impacting electromagnetic performance of the device.

MRI Safety Information

The Entarik G2 Monitor and Entarik G2 NI Feeding Tubes are MR unsafe. Do not take the monitor into an MRI unit and remove the Entarik G2 NI Feeding Tube prior to MR imaging.

Cleaning and Disinfecting

The monitor shall be cleaned after every use to reduce the risk of infections to patients. The monitor shall also be inspected after every cleaning procedure to ensure proper function by powering the monitor on and ensuring no errors.

Before cleaning, turn the monitor off and unplug the 5V Power Supply from AC power. The exterior surfaces of the monitor may be cleaned with a soft, non-abrasive cloth dampened with warm water/mild detergent, or a non-staining chemical disinfectant.

Always dilute cleaning agents according to manufacturer's instructions, or lowest possible concentration.

Clean by spraying cleanser directly onto a soft lint-free cloth and then wiping surfaces dry.

Take extra care when cleaning the screen of the monitor because it is more sensitive to rough cleaning methods than the housing. Wipe around, not over, connector sockets when possible. Do not use bleach inside the connector sockets.

Inspect monitor for visible contaminants. If visible contaminants are present, repeat the cleaning of the monitor until it is visually clean.

Recommended cleaning and disinfecting agents are listed below. In addition, follow institution's guidelines for cleaning and disinfecting of devices.

Recommended cleaning agents are:	Mild soaps
	Common bleach 10% solution diluted with water.
	Mild detergent mixed with water.
Recommended disinfecting agents are:	Alcohol based [e.g. Ethanol 70%[1], Isopropyl 70%[1], Cutasept®, Hospisept®, Kodan®Tinktur forte, Sagrosept®, Spitacid®, Sterilium fluid®.]
	Aldehyde based [e.g. Dilution of formaldehyde (3-5%), Cidex®, Gigasept®.]
	Bleach [e.g. Dilution of sodium hypochlorite (laundry bleach): concentration ranging from 500ppm (1:100 dilution of household bleach), Hydrogen peroxide 3%[1], Clorox (1:10 dilution), Dakin's Solution.]
	Phenol based [e.g. Wofasept®, Sporicidin®.]

[1] Agents have been tested and qualified.

Disposal

The Entarik G2 Monitor is considered electrical and electronic equipment (EEE) and has a lithium-ion battery inside. The monitor cannot be thrown away and shall be returned to Gravitas Medical, Inc. for disposal.

Servicing, Troubleshooting, and Technical Support

Servicing and Periodic Maintenance

All servicing and/or repairs are to be completed by Gravitas Medical trained personnel only. Daily basis or scheduled basis activity to be performed by a clinical operator to test visual and auditory alarm signals is not required.

Troubleshooting

A list of common problems and possible solutions is below. Please consult Gravitas Medical Customer Service if the problem cannot be resolved even after referring to the list below.

Problem	Potential Solution
No parameter readings are displayed	Ensure that the feeding tube connector is firmly connected to the monitor.
Cannot press buttons or select parameters (touch screen non-responsive)	Press the desired button firmly a few times. If this does not work, refer to the Setup and Operation section of this manual to check if the button is one that the user can press and/or select. If all buttons are unresponsive, press and hold the power button for several seconds until the system powers down, then press the power button again to power on the monitor back on.
Unit is plugged into wall power but is not charging	Ensure that the 5V Power Supply is plugged into a functioning wall outlet.
Clock not accurate	Clock may be adjusted in the Settings menu.
Alarm sound is annoying	Audio and alarm may be adjusted in the Settings menu.

Technical Support

For technical support, please call Gravitas Medical, Inc. at +1 (650) 516-6508 or send an email to support@gravitasmedinc.com.

Appendix A: Alarms and Alerts

The Entarik G2 Monitor has several types of cues for Entarik G2-N System errors, including a display message on the screen, an LED error indicator, and an auditory cue. Alarms/alerts are checked several times per second in a periodic loop.

Alerts are denoted by a blue popup message box and must be acknowledged by pressing a button (or restarting the Entarik G2-N System) as indicated by the alert content. See alert table below for more information.

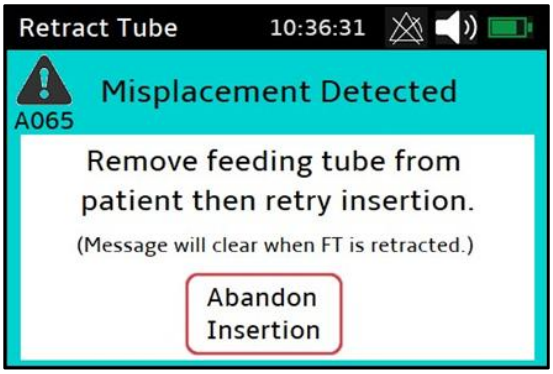


Figure 40: Alert Example

The Entarik G2-N System has 4 alarms: Major Dislodgement, Minor Dislodgement, Low Patient Temperature, and High Patient Temperature. All of these alarms are low priority. These alarms are denoted by a blue popup message box and will beep every 30 seconds until acknowledged by the user. See the Visual Alarms/Alerts table below for more detail.

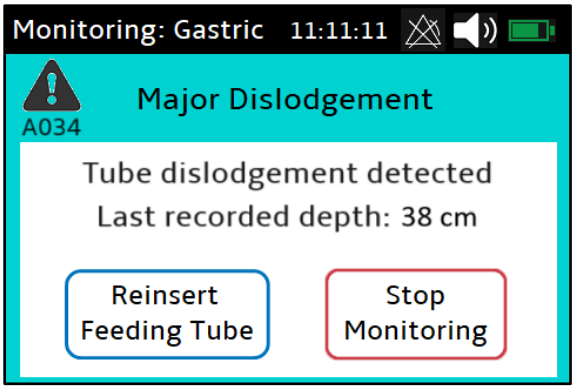


Figure 41: Low Priority Alarm Example

Visual Alarms/Alerts – Technical and Physiological Alarm Conditions

Alerts

Displayed Message	Description	What to Do
Alert Change Disable dislodgement alert?	The user disabled dislodgement alerts and the monitor displays a message to confirm.	Confirm dislodgement alert setting.
Alert Change Disable High Temperature Alerts?	Confirmation to disable high temperature alerts when the alert is disabled in the settings screen. See Setup and Operation – Settings section for more detail.	Confirm by pressing "OK" or cancel by pressing "Cancel".
Alert Change Disable Low Temperature Alerts?	Confirmation to disable low temperature alerts when the alert is disabled in the settings screen. See Setup and Operation – Settings section for more detail.	Confirm by pressing "OK" or cancel by pressing "Cancel".
Alert Change Mute all alerts? All alerts will be silenced.	The user muted audio and the monitor displays a message to confirm.	Confirm audio setting.
Battery Alert Battery Critically Low. Please plug in AC power.	Less than 20% of battery power remains.	Plug in the DC 5V power supply.
Battery Alert Battery Low. Please plug in AC power.	Less than 40% of battery power remains.	Plug in the DC 5V power supply.
Battery Error Use monitor with power supply only	An error with the battery inside the monitor has been detected.	Use the monitor with the power supply plugged in.
Can't Confirm Placement Retract to safety check depth and retry placement, or place FT using standard of care	The monitor is unable to confirm proper placement: Tube is possibly curled in esophagus or gastric air is preventing stomach tissue detection.	Retract feeding tube back to Safety Check depth and retry insertion, or confirm placement using institutional standard of care.

Displayed Message	Description	What to Do
Feeding Tube Cal Error	A problem has been detected with the calibration data stored in the Feeding Tube memory.	Unplug and reconnect the feeding tube to the monitor. If the message repeats, use a new feeding tube. Alternatively, the feeding tube can be used without Monitoring guidance.
Feeding Tube Change, Is this the same or new patient?	When a new feeding tube is plugged in, the system asks the user whether it should erase or preserve temperature/impedance/reflux monitoring data from the previous tube.	If this is the same patient with a new tube, and you would like to preserve the temp/impedance/reflux graphing data, select Same Patient. Otherwise, select New Patient to clear graphs and avoid unintentionally mixing the previous patient's chart data with the new patient's chart data.
Feeding Tube Error	An error with the feeding tube has been detected.	Unplug and reconnect the feeding tube to the monitor. If the message does not clear, use a new feeding tube or continue without Monitoring guidance.
Feeding Tube Temp Fault	The feeding tube's temperature sensors are reporting erroneous values.	Unplug and reconnect the feeding tube to the monitor. If the message does not clear, use a new feeding tube or continue without Placement guidance.
FT Placement Incomplete?	The user has selected "Monitor FT", but the monitor senses that the feeding tube is not fully inserted in the body yet.	If the FT has not been inserted to final depth yet, switch to Insertion mode and initiate insertion. Otherwise, the FT connection might be bad; unplug and firmly reconnect the feeding tube to the monitor and try "Monitor FT" again. If the error repeats, the tube may need to be replaced. Alternatively, the user can continue to use the feeding tube without monitor guidance.
FT Not Supported Please replace feeding tube with a supported feeding tube	The feeding tube that has been inserted is not recognized as a tube that is supported by this monitor (e.g. a non-Entarik tube or damaged tube).	Replace the feeding tube with a supported feeding tube.

Displayed Message	Description	What to Do
Incompatible FT	The feeding tube connected to the monitor is not compatible with the patient's height. G2 NI FT's may only be used for patients up to 110 cm.	Update the patient height entry if it is incorrect; otherwise, connect an appropriate G2 NI feeding.
Low Battery	The battery backup power supply is running low. (~1 hour remaining.)	Plug the monitor into the DC 5V power supply.
Monitor Error Please restart monitor	A monitor error has been detected.	Restart the monitor. If the problem persists, call Gravitas Medical customer service.
Patient Movement or electrical noise. Press OK and try again or confirm via SoC	Patient movement or electrical noise was detected during the safety check.	Remove the source of movement or noise if possible and try again, or insert the tube using the institution's standard of care.
Power Alert Power off?	The user pressed the power button and the monitor displays a message to confirm power off.	Confirm power off.
Power Alert Powering Off...	The monitor is powering off.	Wait for power off.
Stomach Detected, Prior to feeding, use standard of care to verify gastric placement or to continue post-pyloric	The monitor has detected gastric placement, but the user must also independently confirm feeding tube placement using their standard methods.	Confirm feeding tube placement using institutional standard of care (e.g. x-ray). If desired, you may continue insertion to post-pyloric depth. (The monitor does not provide further guidance for post-pyloric).
Temperature Error Please move monitor to ambient temperature less than 30C.	Ambient temperature is high, which prevents accurate measurements from feeding tube temperature sensors.	If room temperature is in normal range, try unplugging/reconnect FT. If error persists, replace FT.
Temperature Error Please restart monitor	An error with the temperature measurement system has been detected.	Restart the monitor. If the problem persists, call Gravitas Medical customer service.
Temperature Error Please power off and wait for system to cool down.	The monitor has overheated.	Wait for the system to cool down prior to turning the monitor on.

Displayed Message	Description	What to Do
Temp Sensor Error Try unplugging/reconnecting FT. If error persists, replace FT.	The feeding tube temperature sensors are outside of expected range.	Reconnect feeding tube to monitor to make sure the connector is fully inserted. If error persists, the feeding tube is faulty and cannot be used in Insertion mode. (Feeding tube can be used in Monitoring mode instead, but Temperature display will be disabled).
Tube Disconnected Please connect Feeding Tube	The feeding tube was unplugged while the monitor was in Insertion or Monitoring mode.	If in Insertion mode, connect the feeding tube to the monitor or abandon insertion. If in Monitoring mode, connect the feeding tube to the monitor or pause/exit monitoring, as applicable.
Tube inserted without monitor guidance, Bypass placement guidance and proceed to monitoring?	When user inserts tube without Entarik G2-N System guidance and enables monitoring mode, the system alerts the user that they are bypassing the safety check.	Press OK to confirm that the FT is already placed at gastric/post-pyloric depth, or Cancel to go back to home screen.

Alarms

Displayed Message	Description	Priority Level	What to Do
Feeding Tube Dislodged? Possible dislodgement or gastric air detected; please check FT.	Minor Dislodgement: Monitor detected that the tip of feeding tube has retracted into the esophagus (or to very shallow depth within stomach). Alternatively, Gastric air build-up may be limiting stomach tissue contact with feeding tube.	Low	Visually inspect the feeding tube position. If this was a legitimate dislodgement, tap "Yes, Dislodged" to confirm and the monitor will guide the user through the Stomach Check process. Otherwise, if the FT still appears to be at the proper depth, tap "Not Dislodged" to clear the alert and snooze further notifications for 1 hour.
Major Dislodgement Tube Dislodgement Detected	The monitor has detected a dislodged feeding tube for 30 consecutive seconds. See Setup and Operation – selection bar, IFU section for more detail.	Low	Adjust the feeding tube position (or remove tube) by following screen instructions.
Temperature Alert Temperature is above set threshold	The measured temperature has exceeded the high threshold in the settings menu. See Setup and Operation – Settings section for more detail.	Low	Observed temperatures can be affected by feeding. Verify temperature and proceed per clinical judgement.
Temperature Alert Temperature is below set threshold	The measured temperature is below the low threshold in the settings menu. See Setup and Operation – Settings section for more detail.	Low	Observed temperatures can be affected by feeding. Verify temperature and proceed per clinical judgement.

Appendix B: Technical Specifications

Performance Specifications

Component	Specification
Power Supply (Entarik G2-N System only to be used with provided power supply)	5V±5%, DC, 2.5A EN55032 Level B, EN61000, IEC60601-1-2 Ed 4.0 2014, EN61204-3, EN60601-1-2, UL60950-1, UL62368-1, ANSI/AAMI ES 60601-1, EN60601-1, IEC60950-1, IEC62368-1, IEC 60601-1, CSA C22.2 no 60601, CE, UKCA Manufacturer: XP Power Manufacturer part number: ACM18US05
Full battery	3 hours capacity
Battery type	Li-Ion
System Temperature (Rated output range)	Range: 32°C to 46°C Accuracy: ±0.3°C
Impedance Measurements	Range: 0-29999 ohms Accuracy: 0 ohms to 500 ohms: +/- 50 ohm 500 ohms and greater: +/- 10%

General Characteristics

Parameter	Specification
Dimensions	2" x 7.5" x 3.5" (W x L X H) (Monitor only)
Weight	1 lb.
Mobility	Portable
Protection against ingress of liquid	None
Environmental Storage and Transport Conditions	Ambient temperature: 23°F to 140°F (-5°C to 60°C) Relative humidity: 15%-90%, non-condensing Altitude: less than 2000 meters Pressure: 50 kPa to 101 kPa
Use Conditions	Ambient temperature: 23°F to 140°F (-5°C to 60°C) Relative humidity: 15%-90%, non-condensing Altitude: 0 to 2000 meters Pressure: 50 kPa to 101 kPa
Electrical Utility Requirements	100-240V~ 50-60 Hz 0.21A at 230V~
Electromagnetic Compatibility	See Appendix D
Patient Connected Circuits	Type BF (IEC 60601-1) classification NOT ESU Compatible (Electro-Surgical/Electro-Cautery)
Electrical Safety Designations	Class II Medical Equipment, Type BF Applied Parts
Means of isolation	Disconnect power supply
Mode of operation	Continuous
Alarms, Alerts	See Appendix A
Alarm Sound Level	62.9 to 71.6 dB
Alarm Details	Meets IEC 60601-1-8 requirements Volume: 80 dB at 10cm Frequency: 795 Hz ± 24 Hz Voltage Range: 5.0 ± 0.5 V DC Max Current: <250 mA
Data Recording	Data written to internal SD card
Sampling	Temperature: 12x every second Impedance: 6x every second
Screen Update (Graphs)	4x per minute

Appendix C: Patient Risks

Per FDA Guidance, general nasogastric/orogastric feeding tubes for short-term use (<30 days) are considered non-significant risk (NSR) devices. The device is not intended as an implant, nor is it purported or represented to be for use supporting or sustaining human life, nor is it of substantial importance in diagnosing, curing, mitigating, or treating disease or otherwise preventing impairment of human health.

The Entarik G2 NI Feeding Tube is single use only. It has not been tested or designed for cleaning and re-sterilization.

The potential risks associated with using or re-using this device are:

- Lung perforation/pneumothorax
- Esophagus perforation
- Stomach perforation
- Impaired ventilation
- Sinusitis
- Hypoxic respiratory failure
- Pneumonia
- Mucosal irritation or abrasion
- Electric shock
- Allergic reaction

Appendix D: Guidance and Manufacturer's Declaration

The Entarik G2 Monitor complies with the requirements of IEC 60601-1-2:2014 + A1 (2020). The Entarik G2-N System was tested to the following standards.

Emissions (Class A, Group 1)	CISPR 11:2015 +AMD1:2016+AMD2:2019 (Radiated Emissions)
	CISPR 11:2015 +AMD1:2016+AMD2:2019 (Conducted Emissions)
	IEC 61000-3-2:2018 +AMD1:2020 (Harmonic distortion)
	IEC 61000-3-3:2013 +AMD1:2017 +AMD2:2021 (Voltage fluctuations and flicker)
The EMISSIONS characteristics of this equipment make it suitable for use in hospitals only. If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.	
Immunity	IEC 61000-4-2:2008 – ESD immunity (± 2, 4, 8 & 15kV Air discharge; ±8kV Contact discharge)
	IEC 61000-4-3:2020 – Radiated immunity (3V/m f) (80 Mhz to 2.7 GHz); IMMUNITY to RF wireless communications 9-28V/m, see table 9 for additional
	IEC 61000-4-4:2012 – EFT immunity (± 2 kV)
	IEC 61000-4-5:2014 +A1:2017 – Surge immunity (L-L: ± 0,5 kV, ± 1 kV; L-G ± 0,5 kV, ± 1 kV, ± 2 kV)
	IEC 61000-4-6:2013 – Conducted immunity (3V m; 0.15 MHz - 80 Mhz; 6V m 0.15 MHz - 80 Mhz)
	IEC 61000-4-8:2009 – Magnetic immunity (30 A/m)
	IEC 61000-4-39:2017 - Radiated fields in close proximity immunity: tested at CW 8A, 134.2KHz 65A, 13.56MHz 7.5A
	IEC 61000-4-11:2020 –Voltage dips, short interruptions and voltage variations immunity: tested at 0 % UT; at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°; and 0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0°
	IEC 61000-4-11:2020 –Voltage dips, short interruptions and voltage variations immunity: tested at 0 % UT; 250/300 cycle
Deviations taken during Immunity testing: No deviations noted	
The normal test levels for Professional Healthcare equipment as specified in tables 4, 5, 7, 8 and 9 of IEC 60601-1-2 were applied for the immunity tests noted above.	

Immunity to RF Wireless Communications Equipment				
Test Frequency (MHz)	Band (MHz)	Service	Modulation	Immunity Test Level (V/m)
385	380 –390	TETRA 400	Pulse Modulation: 18Hz	27
450	430 – 470	GMRS 460, FRS 460	FM ± 5 kHz deviation 1kHz sine	28
710	704 – 787	LTE Band 13, 17	Pulse Modulation: 217Hz	9
745				
780				
810	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse Modulation: 18Hz	28
870				
930				
1720	1700 – 1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse Modulation: 217Hz	28
1845				
1970				
2450	2400 – 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse Modulation: 217Hz	28
5240	5100 – 5800	WLAN 802.11 a/n	Pulse Modulation: 217Hz	9
5500				
5785				

The system is designed for use in a hospital non-protected electromagnetic environment. If used in a hospital, it should not be located in parts of the hospital where there are any HF Surgical or magnetic resonance systems used.

During EMC testing, the unit should function normally throughout its useful life.

Essential Performance description: The Entarik G2-N System's essential performance is defined as its ability to detect the amplitude and frequency of temperature fluctuations in a patient's airway, measure impedance properties of a patient's anatomy and measure ECG, without detecting erroneous heartbeats, for proper placement of the Entarik G2 NI Feeding Tube.

Should these functions fail to work as intended, discontinue use and contact Gravitas Medical Inc. To help ensure the system functions as intended as it pertains to electromagnetic performance, follow all

the instructions in this manual and contact Gravitas Medical Inc. for any repairs. Do not modify the system. Simple troubleshooting measures as it pertains to EMC are noted at the end of this section.

The limits above are designed to provide reasonable protection against harmful interference[1] in a typical hospital environment. This equipment generates, uses, and can radiate radio frequency energy, and if not installed and used in accordance with the manufacturer's instructions may cause harmful interference to other devices in the vicinity. There is no guarantee that interference will not occur in a particular installation.

To maintain proper functioning of the Entarik G2 Monitor as it pertains to EMC, all the instructions in this manual should be followed throughout the useful life of the product. Only use the battery charger supplied by Gravitas.

Interference from electronic sources may result in the following observations or Entarik G2-N System messages. The operator should be aware of the following; however, they do not pose hazards to the patient or operator.

- See Appendix A alert list for potential hardware failure alerts
- In the event of an automatic power off or reset due to ESD vulnerability, the Entarik G2-N System can be restarted for continued use.

If this equipment causes interference with other devices or if other equipment is causing interference with this equipment, which may be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the device receiving the interference.
- Increase the separation between the equipment (minimum 30cm is recommended)
- Connect the equipment into an outlet on a circuit different from that to which the other device(s) are connected.
- Replace unshielded cables with shielded ones.
- Consult the manufacturer or field service technician for help.

The operator should be aware of the following; however, they do not pose hazards to the patient or operator.

- In the event of an automatic power off, restart or error message due to ESD vulnerability, the Entarik G2-N System can be restarted for continuous use.
- Avoid use of the system when in close proximity to an RFID device. Impedance or temperature signal may be affected, but will return to normal working condition immediately following exposure to RFID.

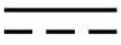
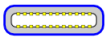
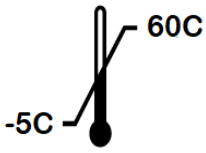
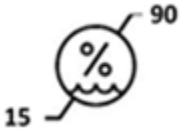
[1] NOTE: "Harmful interference" is defined in 47 CFR §2.122 by the FCC as follows: Interference which endangers the functioning of a radionavigation service or of other safety services or seriously degrades, obstructs, or repeatedly interrupts a radio communication service operating in accordance with the [ITU] Radio Regulations.

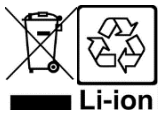
WARNINGS:

- 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.
- 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.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of Entarik G2-N System, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Symbols Glossary

The required symbols below relate to the labeling for the Entarik G2-N Feeding Tube System. Explanations of the symbols are included in this glossary.

Symbol	Description
	Refer to Instruction Manual Indicates a requirement to read and understand the Operator's Manual and other accompanying instructions before use of the device. ISO 7010-M002
	General Warning General caution or warning sign. Also indicates referral to accompanying documents. ISO 7010-W001
	Type BF Applied Part Indicates low risk conductive contact between device and body. IEC 60417-5334
	Direct Current Indicates a direct current connection. IEC 60417-5031
	USB Type C Indicates a type C USB port.
	Class II Indicates protection against electric shock does not rely on basic insulation only. Additional safety precautions such as double insulation or reinforced insulation are provided, there being no provision for protective earthing or reliance upon installation conditions. IEC 60417-5172
	Temperature Limit The device can be safely exposed to temperatures between -5ºC to 60ºC. ISO 7000-0632
	Humidity Limitation The device can be safely exposed to a range of humidity between 15% and 90%. ISO 7000-2620

Symbol	Description
	Keep Dry Indicates the device needs to be protected from moisture. ISO 7000-0626
	Fragile, Handle with Care Indicates the device can be broken or damaged if not handled carefully. ISO 7000-0621
	Do Not Use if Package is Damaged Indicates the device should not be used if the package has been damaged or opened. ISO 7000-2606
	Positive Polarity Indicates that the center (tip) of the output plug is Positive (+) and the barrel (ring) of the output plug is Negative (-). IEC 60417-5926
INPUT: 5VDC 2.5A	Power supply specific Indicates that only power supply cable provided with the Entarik G2 Monitor can be used to provide power to the monitor.
	Power ON/OFF Press this button to turn the monitor on and off. IEC 60417-5009
	Waste, and Li-ion Battery inside Indicates that unit cannot be thrown away, and that there is a lithium-ion battery inside. Return unit to manufacturer for disposal. BS EN 50419, IEC 60417-1135
	Serial Number (Batch code) Indicates serial number and lot number of the Entarik G2 Monitor. IEC 60417-2498
	Catalog Number Indicates the model number of the Entarik G2 NI Feeding Tube or the Entarik G2 Monitor. IEC 60417-2493
	Rx Only Federal law restricts this device to sale by or on the order of a physician (licensed healthcare practitioner). 21 CFR Part 801 § 801.109(b)(1)

Symbol	Description
	MR Unsafe Indicates that a component may be hazardous if introduced into magnetic resonance (MR) environments. ASTM F 2503
	Non-Sterile Indicates that the device has not been sterilized ISO 7000-2906
	Date of manufacture Indicates year and month the monitor was manufactured. IEC 60417-2497
	Manufacturer Indicates the manufacturer of the device. IEC 60417-3082
IPX0	Protection against solid particle No special protection Protection against ingress of liquid The Entarik G2 Monitor is considered IPX0 for ingress protection as defined by IEC 60601-1

Entarik™ is a trademark of Gravitas Medical, Inc.

Patent: www.gravitasmedinc.com/patents

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