GRAVITAS MEDICAL, INC.

Entarik™ Feeding Tube System

Operator's Manual

IFU-04-1404 Rev C

Introduction

Please read carefully.

This manual covers the function and proper use of the Entarik Feeding Tube System (Entarik System). The Entarik Feeding Tube System refers to the combined use of the Entarik Monitor and the Entarik Feeding Tube. 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 Feeding Tube System. Refer also to the separate IFU for additional warnings, precautions, and contraindications.

Do not use or operate the Entarik Monitor until you have read and understood this manual and the separate instructions included with the Entarik feeding tube.

CAUTION: The Entarik 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 Feeding Tube System. The Entarik Feeding Tube System refers to the combined use of the Entarik Monitor and the Entarik Feeding Tube. **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 Feeding Tube System.

Definitions

Entarik Feeding Tube System (Entarik System)	Combined usage of the Entarik Monitor with the Entarik Feeding Tube.
Entarik Monitor Monitor Model: FGN-04-1539	Portable electronic device which, when used with the Entarik Feeding Tube, measures and records impedance and temperature data from the sensors on the Feeding Tube and provides information to the operator to aid in initial placement and monitoring of feeding tube position.
Entarik Feeding Tube 8Fr FT Model: FGN-04-1294 10Fr FT Model: FGN-04-1333 12Fr FT Model: FGN-04-1329	Disposable, single-use feeding tube (provided with optional-use Stylet). The Feeding Tube has one lumen for the administration of nutrition, fluids and medications and additional lumens for impedance and temperature sensor wires. The catheter (applied part) has electrode rings on the surface and comes into physical contact with the patient and is connected to the Monitor to perform its function.

Overview

Intended Use

The Entarik Feeding Tube is intended for the administration of nutrition, fluids and medications by the nasoenteric route for patients who have an intact gastrointestinal tract but are physically unable to manage nutritional intake through normal mastication and deglutition.

The Entarik Feeding Tube System is designed to aid, in conjunction with institutional protocols, qualified operators in the placement of the Entarik Feeding Tube (Entarik FT) into the stomach of patients requiring enteral feeding. The Entarik 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 Monitor (Monitor) also monitors the feeding tube position continuously during the course of feeding and automatically and in real-time alerts of tube migration.

Functional Description

The Entarik 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 Feeding Tube. The Entarik Feeding Tube is a single-use device intended for short term use (less than 30 days). The two components together are known as the Entarik 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 positioning during ongoing use.
- 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 Feeding Tube System as well as a brief explanation of each warning will be displayed on the Entarik 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 Feeding Tube System.

The Entarik 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 System is indicated for the same population as other commercially available feeding tubes, patients in need of nasogastric/enteral feeding and/or administration of medications. The

Entarik FT will be inserted into patients by medical staff qualified to insert commercially available feeding tubes. Apart from a short overview of the Entarik System, no special training is required for use of the Entarik system in the clinical setting.

The Entarik 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 Feeding Tube System and the Entarik 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 environments with an ambient temperature above 30°C (86°F).
- The use of this product is contraindicated in patients with basilar skull fracture.

Warnings

Entarik 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 Feeding Tube System has no serviceable parts.
- The Entarik monitor has a USB port for firmware upgrades and live data streaming using proprietary Gravitas applications accessible to Gravitas personnel only. 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. If the tamper proof seal is broken stop the use of the Entarik monitor and contact Gravitas Medical Customer Service. Do not plug unauthorized devices into the USB port.
- 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 Monitor is MR unsafe. Do not take the Monitor 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 Monitor to powerful sources of electromagnetic interference. Using the Entarik Monitor near operating equipment which radiate high-energy radio frequencies (such as electro-surgical/cauterizing equipment, two-way radios, or cellular telephones) may cause false readings. If interference is observed, avoid concurrent use of Entarik 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 Monitor 5VDC 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 and/or 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.
- 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.
- The Entarik 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 nasogastric feeding tube should not be used with connectors from other healthcare applications.

Cautions

Entarik Feeding Tube System

- Use only with Entarik Feeding Tubes.
- Handle the Entarik 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 Feeding Tube and the Entarik Monitor before activating electrosurgical or other types of directly-coupled RF energy sources.

- Unplug 5V Power Supply and USB Type C cable 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., as 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 System can be restarted for continued use.

Package Contents

Each Entarik™ Monitor package contains:

1 Entarik™ Monitor (with integrated IV pole clamp)
1 5V Power Supply

FIG. 1: Entarik Monitor

Entarik 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. Feeding tube connector receptacle
4. Speaker to alarm the user
5. LED to alert the user
6. LED to indicate Entarik System 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

Not Shown in Figure 1

- SD card access door (not shown in picture)
- Internal battery to allow usage for several hours when not plugged into the wall (not shown in picture)
- Wall power supply (See Figure 2)

FIG. 2: 5V Power Supply that attaches to Power Connection 10 in FIG 1.

Referenced Features in Entarik Feeding Tube

Entarik Feeding Tube

The Entarik Feeding Tube is a nasogastric 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 and features is provided below in Figure 3.

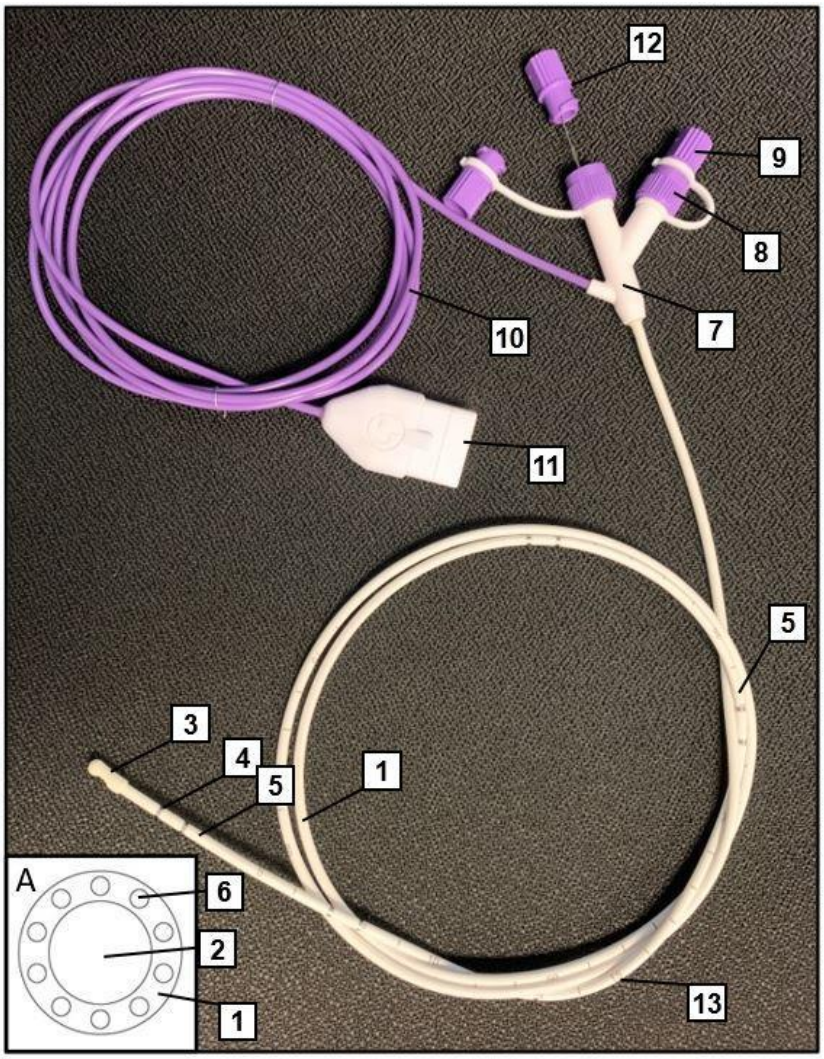


FIG. 3: Entarik Feeding Tube

- Multi-lumen shaft (1) with central feed lumen (2) and atraumatic feed tip (3)
- Impedance electrodes x 10 (4) and temperature sensors x3 in tube wall (5)
- Isolated wire lumens in the feeding tube wall (6)
- Y connector (7) joins feeding tube shaft, feeding/stylet ports and electrical cable
- ENFit feeding/stylet ports x 2 (8) with caps (9)
- Electrical cable (10) and electrical connector/plug-in for Entarik Monitor (11)
- Stainless steel Stylet (12) is included to assist with insertion (optional use).
- External depth markings on the tube (13) to track/record insertion depth

Setup and Operation

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

Setup

The Monitor should be mounted on an IV pole using the pole mount included with the Entarik 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 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). Note: The Entarik System shall only be used with the provided power supply.
3. Set up the feeding tube according to the IFU packaged with the Entarik Feeding Tube. Connect the feeding tube electrical connector (11) to the feeding tube connector on the monitor (3).

Operation

To Turn on Monitor

Press the Power Button (7, in Figure 1). The display screen will turn on and the Power Indicator Light (6, in Figure 1) will illuminate and the start-up/home screen will be displayed (Figure 4).

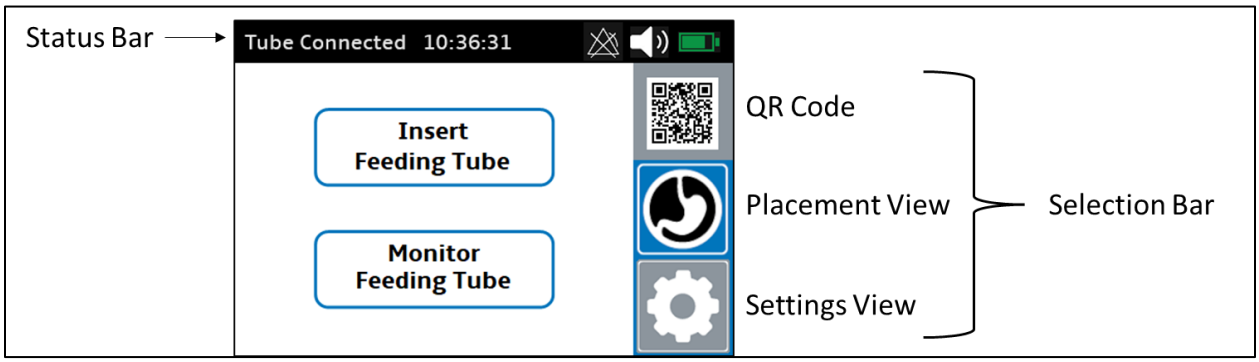


FIG 4: Monitor Start-up/Home Screen

Status Bar

The **Status Bar** is always at the top of the screen and contains the following information

1) Feeding Tube Status – The feeding tube status has two different options
    a. **Tube Connected** – The feeding tube is connected to the monitor but has not been inserted in the patient
    b. **Tube Disconnected** – The feeding tube is disconnected from the monitor
2) Current Time – The current time, which can be adjusted in the Monitor Settings screen.
3) Alert Icon – The alert enabled icon  is displayed if all alerts are enabled. The alert disabled icon  is displayed if any alert is disabled. Alerts can be enabled/disabled in the Alert Settings screen.
4) Speaker Icon – The speaker enabled icon  is displayed if the speaker is enabled. The speaker disabled icon  is displayed if the speaker is disabled. The speaker can be enabled/disabled in the Monitor Settings screen.
5) Battery Icon – The battery icon will be green  if the battery charge is above 50%, yellow  if the battery charge is between 25% and 50%, and red  if the battery charge is below 25%. If the power supply is connected to the monitor, a charging icon  will be present on the battery icon.

Selection Bar

The **Selection Bar** is always on the right side of the screen and allows the operator to switch views. The selected icon is blue and the unselected icons are gray. The Selection Bar has three icons to choose from.

1) QR Code

    The QR code can be scanned and will direct the user to a website that will provide more information about the device.

2) Placement View

    The Placement View (Figure 5) is accessed by pressing the Placement icon  , and is the default selection upon start-up and is the base view for feeding tube placement and monitoring.

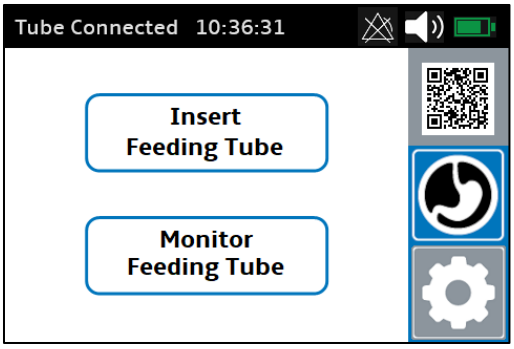


FIG 5: Placement View

3) Settings View

Tapping the Settings icon  toggles between the monitor and clock settings screens (Figures 6-7), where the user can activate/deactivate alerts and choose monitor settings.

Monitor Settings Screen

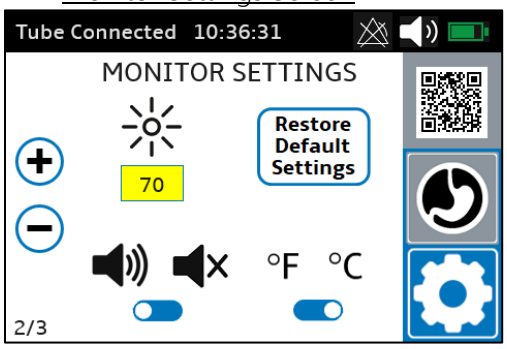


FIG 6: Monitor Settings

From the Monitor Settings screen, the user may adjust **screen brightness** by tapping the number below the brightness icon and then tapping the "+" or "-" buttons located to the left of the screen.

User may also select **Restore Default Settings** which will restore the Entarik System to factory alert and brightness settings.

The user may tap on a toggle button On or Off to activate or deactivate **Audible Alert Notifications**.

The user may tap on a toggle button On or Off to activate or deactivate **Dislodgement Alerts**.

It is recommended that alert settings be reset to default value when a new patient is connected to the monitor to prevent unintentionally disabling dislodgement alerts.

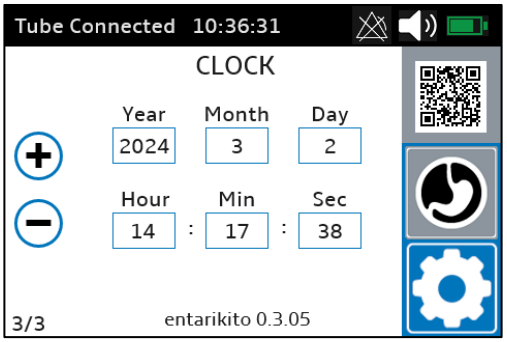


FIG 7: Clock Settings

From Clock Settings screen, the user may set **date and time** by tapping the number in the desired field and then tapping the "+" or "-" buttons located to the left of the screen.

Placement Indicators

In placement or monitoring mode, the Monitor will display the location of the tip of the feeding tube and has 5 options (Figure 8):

A. No Color - The anatomical drawing will be only black and white if the feeding tube is not connected to the monitor, not inserted in the patient, or the location is unknown.
B. Initial Insertion – The upper segment of the anatomical drawing will be blue if the Entarik System has detected initial tube insertion in the patient, but has not run the safety check to detect esophagus or airway insertion path (performed at 28cm insertion depth).
C. Esophagus - The esophagus will be blue if the monitor has detected that the tip of the feeding tube is in the esophagus.
D. Stomach – The stomach will be green if the monitor has detected that the tip of the feeding tube is in the stomach
E. Lungs – The lungs will be yellow if the monitor has detected that the tip of the feeding tube is in the lungs or airway.
F. Too Far in Stomach – The stomach will be yellow if the monitor has detected that the tip of the feeding tube is too far in the stomach

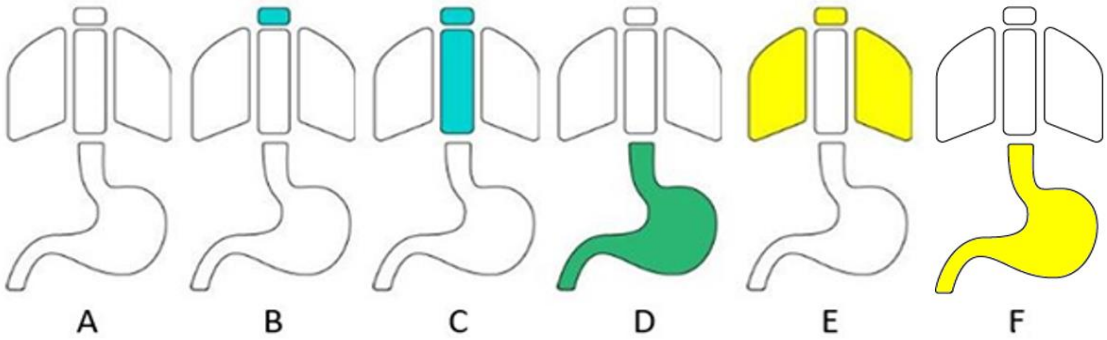


FIG. 8 Placement Indicators

Operating Modes and Procedures:

Start-Up and Operating Mode Selection

Upon power up, the Monitor will display the Start-Up/Home Screen (Figure 9). This screen allows the user to decide whether to operate in Insertion Mode or Monitoring Mode. Insertion mode is used for initial placement or repositioning of the feeding tube. Monitoring mode allows the user to monitor/confirm feeding tube position if the tube has already been placed. The Start-Up/Home Screen is accessible by tapping the Home icon or the Stop icon in the upper left of the screen. The Stop icon will be displayed if positioning/monitoring has begun. After pressing the Stop icon, a confirmation message will be displayed (Figure 10), and the user can proceed to stop monitoring and remove the feeding tube.

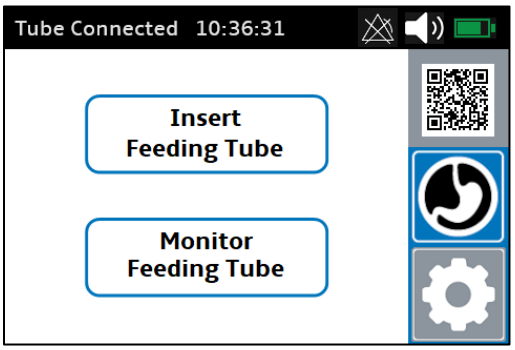
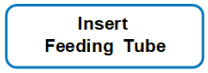


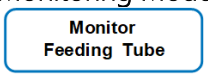
FIG 9: Start-Up/Home

From **Start-Up/Home Screen** user selects operating mode by tapping desired box:

Insertion Mode



Monitoring Mode



(Note: Entarik Feeding Tube has already been connected to Monitor in FIG. 9, as shown in Status Bar)

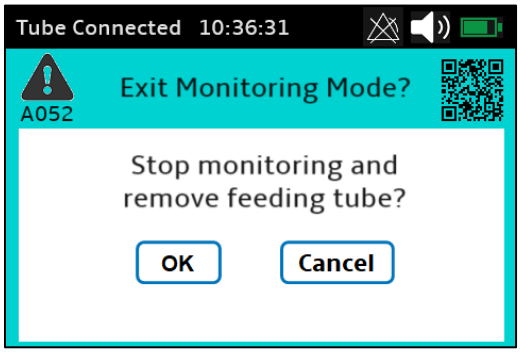


FIG 10: Stop Button confirmation

Feeding Tube Monitoring Mode

Monitoring Mode selection prompts user to initiate a positional check on the tip location of a feeding tube that has already been fully-inserted (and previously confirmed to be in proper position). Once completed the location of the feeding tube tip is displayed. In some cases, feeding tube re-insertion may be required and Monitor will convert to Insertion Mode.

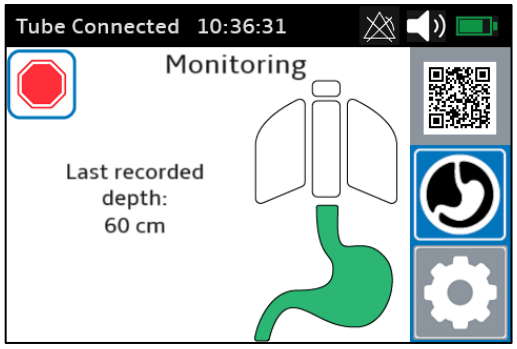


FIG 11: Monitoring

User selects **Monitor Feeding Tube** from Start-Up/Home screen:

The Entarik System checks feeding tube tip position, which is then displayed using the Placement Indicator after the Entarik System performs a placement check.

If **Monitor Feeding Tube** button is pressed after an Entarik Feeding Tube is placed without Entarik System guidance, the user must confirm that they are skipping the 28cm safety check.

FIG 11 shows the feeding tube tip is located in the stomach.

Feeding Tube Insertion Mode – Feeding Tube Placement Procedure

Insertion Mode selection will perform an initial check to determine if an Entarik Feeding Tube has been connected to the Monitor. If no tube is connected, the Monitor will prompt user to "Connect a Feeding Tube".

Once a feeding tube is connected (NOTE: Entarik System is for use with Entarik Feeding Tubes ONLY), the monitor will prompt user to insert the feeding tube to 28cm depth (from the nasal opening) for a safety check (Figure 12).

- User must review Entarik Feeding Tube Operator's Manual including all **Warnings** and **Cautions** prior to inserting feeding tube into patient. **Standard feeding tube insertion techniques are used.**
- Use caution when inserting feeding tube.

Once the feeding tube is inserted to 28cm (Figure 13), the user actuates the safety check, which monitors temperature at the tip of the feeding tube to detect the presence of temperature cycling that may be associated with respiration indicating a potential insertion into the airway.

- If no airway insertion is detected, the Monitor will instruct user to continue insertion to 60cm or NEX for stomach detection and guide user through subsequent depth adjustments until proper positioning is detected (Figures 14-19)
- If airway insertion is detected (Figure 22), the Monitor will prompt the user to retract the feeding tube to <10cm depth and re-initiate the insertion procedure.

After feeding tube positioning is completed and the stomach is detected, the Monitor prompts the user to record final insertion depth (Figure 20) and **Confirm Feeding Tube Position** (Figure 21) using standard of care (e.g., x-ray) prior to initiating feeding or administration of fluid.

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

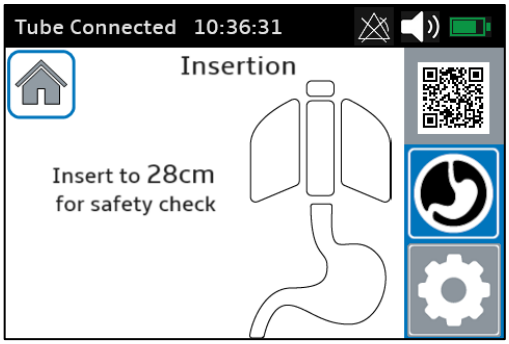


FIG. 12: Initial Insertion

User selects **Insert Feeding Tube** from Start-Up/Home Screen.

User inserts Entarik Feeding Tube to a depth of ~28cm from the nasal opening.

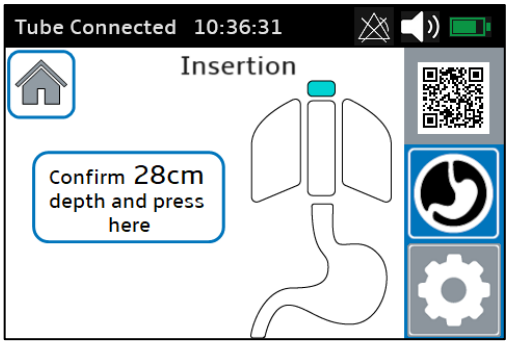
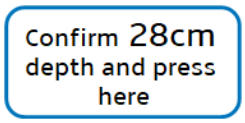


FIG 13: Safety Check Prompt

The Monitor detects when the feeding tube is inserted to 28cm, and displays a prompt for the user to actuate the Safety Check by tapping:



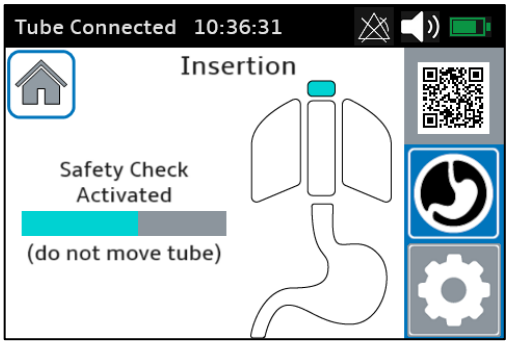


FIG 14: Safety Check

User actuates the **Safety Check** for respiratory/airway detection and Monitor displays a progress bar during check.

Do not move tube during safety check

Safety Check detects respiratory temperature cycling indicating potential airway insertion.

Caution: If airway is detected, do not advance feeding tube.

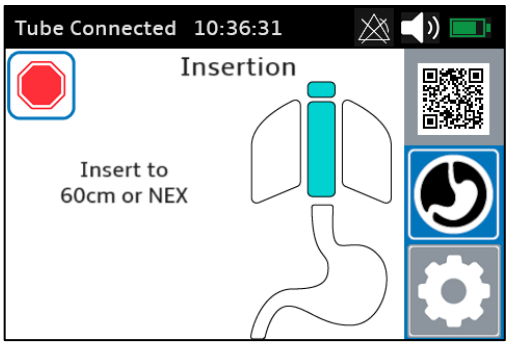
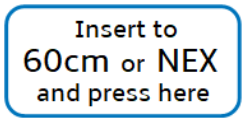


FIG 15: No Airway Detected

Safety Check completed and **no airway detected** (Figure 14). Monitor displays tube tip position in esophagus and instructs user to insert tube to a depth of 60cm or NEX. The stomach will flash green when the stomach is detected and the user can initiate the stomach detection check by tapping:



Caution: If airway is detected (See Figure 22), do not advance feeding tube.

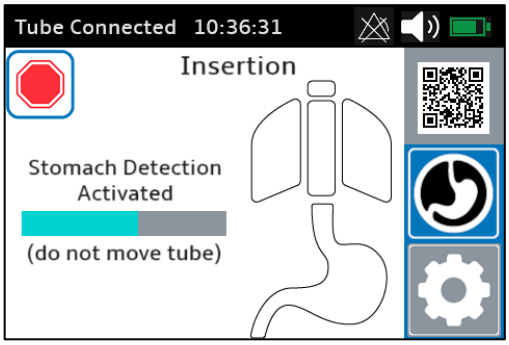


FIG 16: Stomach Check

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

Do not move tube during stomach detection check

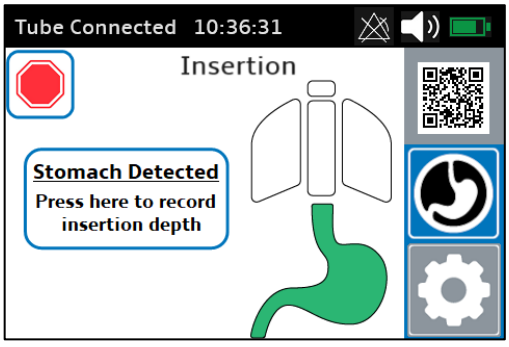
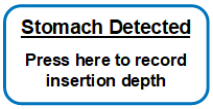


FIG 17: Stomach Detection Prompt

If proper feeding tube position is detected, monitor displays **Stomach Detected**, and prompts user to move to record insertion depth step by tapping:



If additional depth adjustments are necessary, monitor prompts adjustment or retraction and recheck (Figures 18 or 19) until stomach detected.

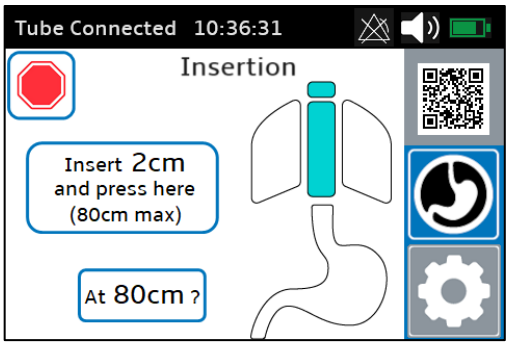
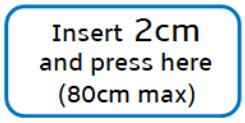


FIG 18: Insertion Adjustment

FT too shallow: Monitor prompts user to insert further. Once the tube is repositioned, the Monitor recheck for stomach placement is initiated by tapping. The Entarik System also shows a live green blinking stomach when it detects correct stomach placement (yellow stomach indicates too deep) to guide the user when to press the button. If the user reaches 80cm without stomach confirmation, the Entarik System asks the user to restart at 60cm or NEX. IF this occurs twice, the Entarik System indicates it cannot confirm placement and standard of care should be used to confirm stomach placement.



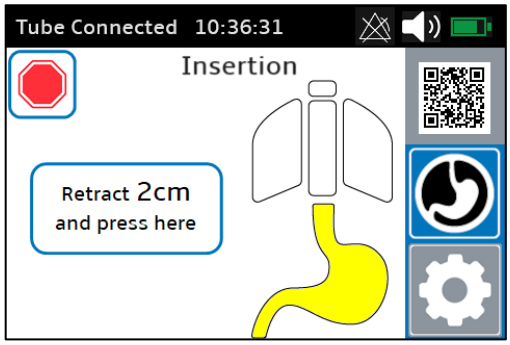
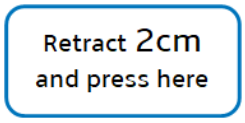


FIG 19: Retraction Adjustment

FT too deep: Monitor prompts user to retract feeding tube. Once the tube is repositioned, the Monitor recheck for stomach placement is initiated by tapping:



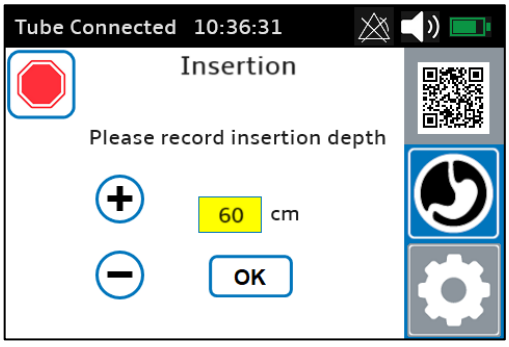


FIG 20: Record Insertion Depth

Monitor tracks insertion depth and adjustments based on user prompts. User confirms final insertion depth once stomach is detected.

If adjustments to final insertion depth are needed (based on external depth markers) user modifies depth (+ or -) and taps OK.

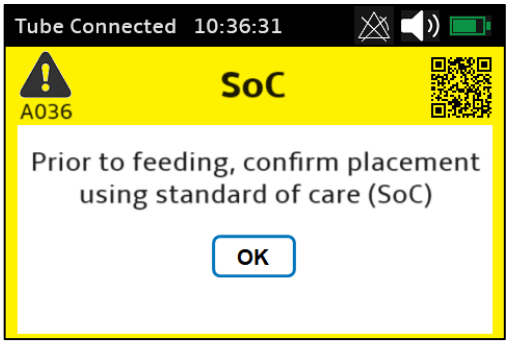


FIG 21: Tube Position Confirmation

Once feeding tube final position is determined, monitor prompts user to **confirm proper position using standard of care** (e.g., x-ray) prior to initiation of feeding.

Caution: User must confirm Tube Position in stomach 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 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.

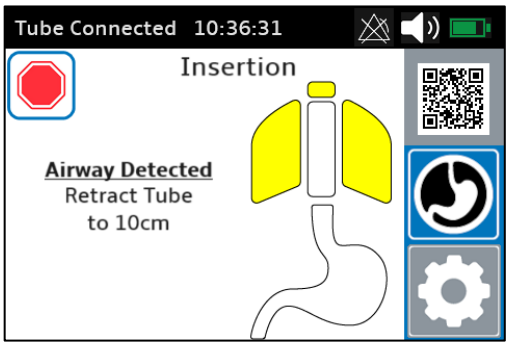


FIG 22: Airway Detected

If at any point the Monitor registers **Airway Detection,** user must not advance tube further due to potential risk of airway injury.

Monitor prompts user to retract tube to 10cm depth and reinitiates insertion procedure (Figure 22)

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 System will continue to charge the internal battery while powered down and plugged into wall power.

Ability to Connect to Non-Enteral Medical Devices

The Entarik 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.

Environment and Cleaning

Use and Storage Environment

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

Cleaning and Disinfecting

Turn the Monitor off and unplug the 5V Power Supply from AC power before cleaning. 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.

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 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.
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 quality@gravitasmedinc.com.

Appendix A: Alarms and Alerts

The Entarik Monitor has several types of cues for Entarik System errors, including a display message on the screen, an LED error indicator, and an auditory cue. In normal operation, the LED error indicator will be off and there should be no auditory cue. Alarms/alerts are checked on a 10 ms periodic loop.

Alerts are denoted by a blue or yellow popup message box and must be acknowledged by pressing a button (or restarting the Entarik System) as indicated by the alarm content. If the condition persists another alert will be triggered 20-30 seconds later. See alert table below for more information.

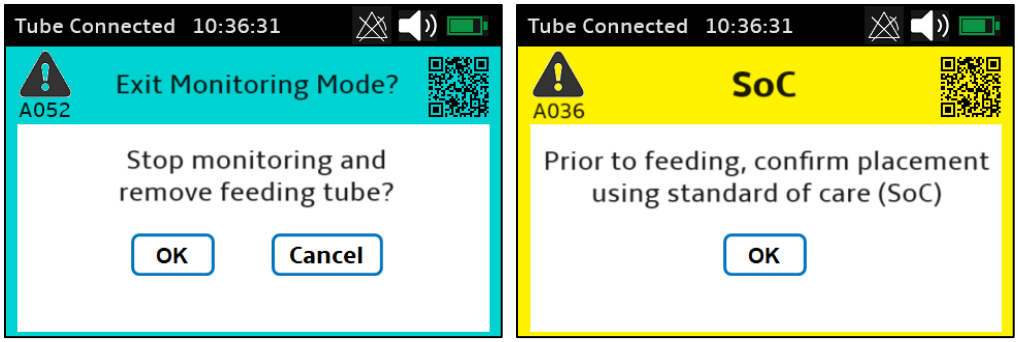


FIG. 23: Alert Example

The Entarik System has only one alarm, the feeding tube dislodgement alarm (low priority). This alarm is denoted by a blue popup message box and is acknowledged by selecting to either re-position the feeding tube or remove the feeding tube, and the Entarik System will then guide the user how to proceed. See the alarm table below for more detail.

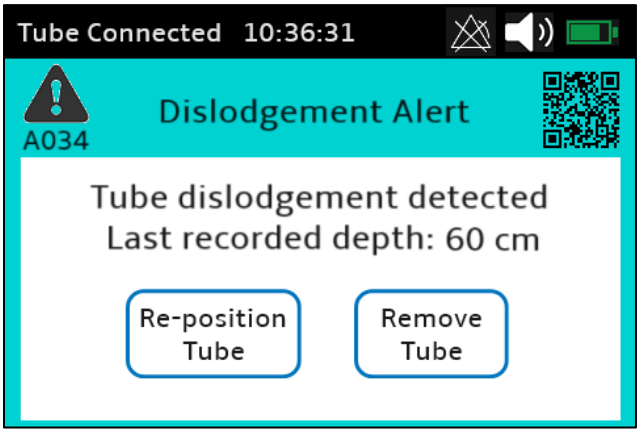


FIG. 24: Low priority alarm example

Visual Alarms/Alerts – Technical and Physiological Alarm Conditions

Alerts

Displayed Message	Description	What to Do
Monitor Error Please restart monitor	A monitor error has been detected	Restart the monitor. If the problem persists, call Gravitas Medical customer service.
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.
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.
Temperature Error Please move monitor to ambient temperature less than 30C	The monitor has detected that ambient temperature is greater than the specified 30C.	Move the monitor to an area where ambient temperature is less than 30C
Feeding Tube Error Please replace Feeding Tube	An error with the feeding tube has been detected	Replace the feeding tube
Battery Alert Battery Critically Low. Please plug in AC power.	Less than 20% of battery power remains	Plug in the AC power supply
Battery Alert Battery Low. Please plug in AC power.	Less than 50% of battery power remains	Plug in the AC power supply
FT not connected Please connect Feeding Tube	The user has initiated a feeding tube placement on the monitor, but the feeding tube is not connected to the monitor	Connect the feeding tube to the monitor
SoC, Prior to Feeding, confirm placement using standard of care	The monitor is reminding the user to confirm feeding tube placement using their standard methods	Confirm feeding tube placement using institutional standard of care

Displayed Message	Description	What to Do
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
Restore Alert Restore settings to default?	The user pressed the settings reset button and the monitor displays a message to confirm	Confirm settings reset and restore to default settings
Alert Change Mute all audio? All audio will be silenced.	The user muted audio and the monitor displays a message to confirm	Confirm audio setting
Alert Change Disable dislodgement alert?	The user disabled dislodgement alerts and the monitor displays a message to confirm	Confirm dislodgement alert setting
Feeding Tube Change, Is this the same or new patient?	When a new FT is plugged in, the system will erase temperature and impedance data if FT is connected to new patient	Confirm new or existing patient
Tube inserted without monitor guidance, Bypass placement guidance and proceed to monitoring?	When user inserts tube without Entarik system guidance and enables monitoring mode, the system alerts the user that they are bypassing the 28cm safety check	Press OK to confirm, or Cancel to go back to home screen
Patient Movement or electrical noise. Press OK and try again or confirm via SoC	Patient movement or electrical noise was detected during the 28cm safety check.	Remove the source of movement or noise if possible and try again, or insert the tube using the intitution's standard of care.

Alarms

Displayed Message	Description	Priority Level	What to Do
Dislodgement Alert 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.

Appendix B: Technical Specifications

Performance Specifications

Component	Specification
Power Supply (Entarik 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: 50°F to 86°F (10°C to 30°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
Mains 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: 6-12x every second

Appendix C: Patient Risks

Per FDA Guidance, general nasogastric 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 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 Monitor complies with the requirements of IEC 60601-1-2:2014 + A1 (2020). The Entarik 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 details.
	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: 1. In the event of an automatic power off, restart or error message due to ESD vulnerability, the Entarik System can be restarted for continuous use.	

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.

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 System's essential performance is defined as its ability to detect the amplitude and frequency of temperature fluctuations in a patient's airway and measure impedance properties of a patient's anatomy for proper placement of the Entarik 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 trouble shooting measures as it pertains to EMC are noted at the end of this section.

The Entarik Feeding Tube System is intended for the administration of nutrition, fluids and medications by the nasoenteric route for patients who have an intact gastrointestinal tract but are physically unable to manage nutritional intake through normal mastication and deglutition.

The Entarik Feeding Tube System is designed to aid, in conjunction with institutional protocols, qualified operators in the placement of the Entarik Feeding Tube (Entarik FT) into the stomach of patients requiring enteral feeding. The Entarik 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 Monitor (Monitor) also monitors the feeding tube position continuously during the course of feeding and automatically and in real-time alerts of tube migration.

The limits above are designed to provide reasonable protection against harmful interference 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 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 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 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.

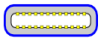
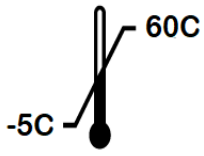
- In the event of an automatic power off, restart or error message due to ESD vulnerability, the Entarik System can be restarted for continuous use.
- Avoid use of the system when in close proximity to an RFID device. Impedance or temperature signal may be affected, but will return to normal working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

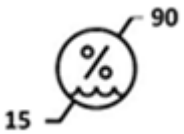
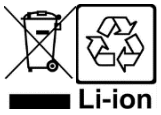
WARNINGS:

- 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.

Symbols Glossary

The required symbols below relate to the labeling for the Entarik 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 accompany 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
 Type C	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
	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 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, ISO 60417-1135
	Serial Number (Batch code) Indicates serial number and lot number of the Entarik Monitor. ISO 60417-2498
	Catalog Number Indicates the model number of the Feeding Tube or the Monitor. ISO 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)
	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. ISO 60417-2497
	Manufacturer Indicates the manufacturer of the device. ISO 60417-3082
IPX0	Protection against solid particle No special protection Protection against ingress of liquid The Entarik 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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