

**IFU Creation Form	
Artwork #: 501145836 Rev. A Component Drawing #: P000021P01	Project information: DC002871/CR20021
Product codes: ETHCM, ETHUSC, ETHCRT	

ETHICON™ Communications Module, ETHICON™ User Screen, and ETHICON™ Energy Cart

Operator's Manual

For use with Software Version 1.0.x



ETHICON™
Johnson & Johnson SURGICAL TECHNOLOGIES

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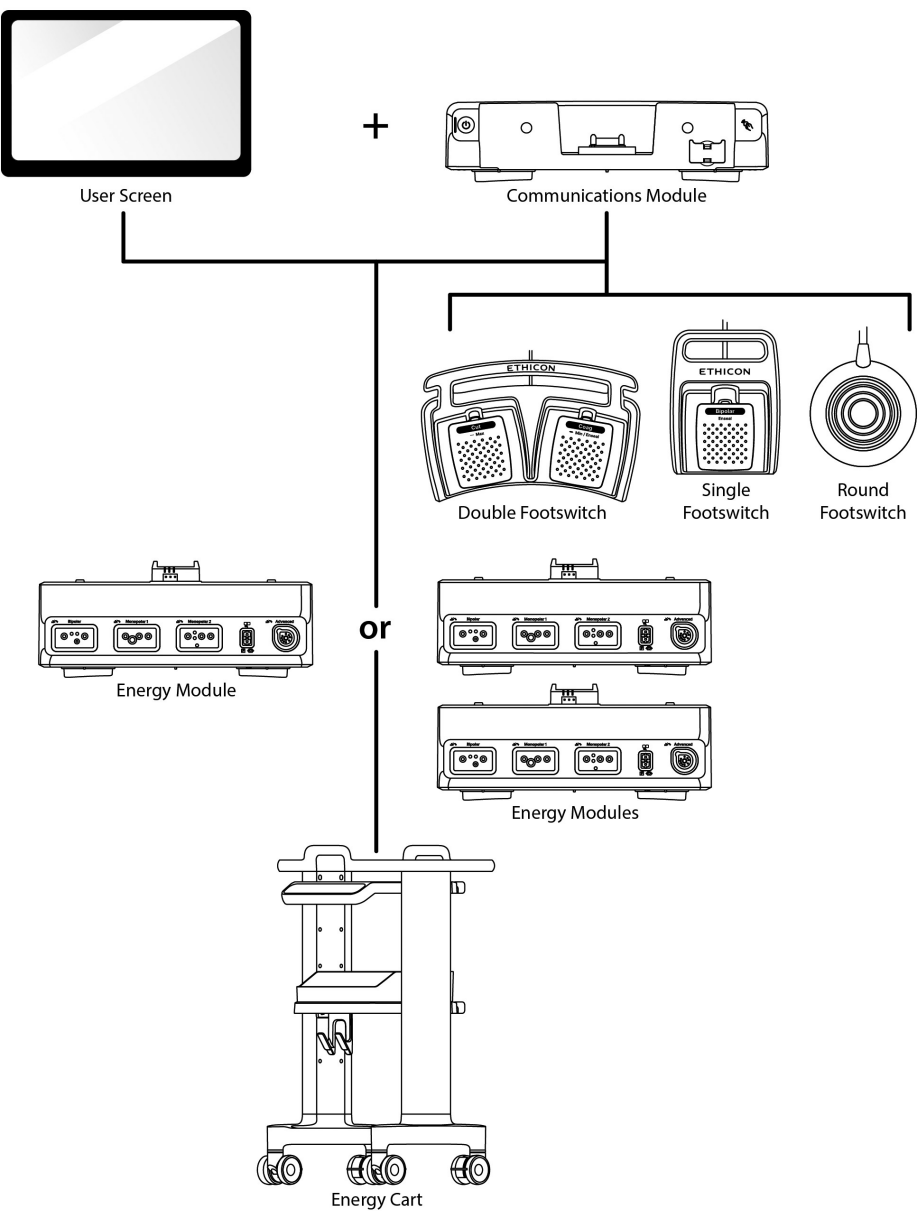
1 – General Information

Introduction

The ETHICON™ Total Energy System is a modular system that can be configured in various recommended combinations (see Section 3). This manual is designed to provide instructions for use with the following components of the ETHICON™ Total Energy System: ETHICON™ Communications Module (ETHCM), ETHICON™ User Screen (ETHUSC), and ETHICON™ Energy Cart (ETHCRT). The instructions for use for other components of the ETHICON™ Total Energy System can be found in the manual associated with that specific component.

One of the configured combinations that will be periodically referenced in this manual is a module stack consisting of the Communications Module, User Screen, and ETHICON™ Energy Module (ETHEM). This configuration is referenced as the ETHICON™ Total Energy System.

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1.1 Total Energy System

Please read all information carefully.
 This manual is valid for the major software release listed on the cover page and all subsequent ‘x’ releases.
 Failure to properly follow the instructions may lead to serious surgical consequences. This manual contains important information for operation of the Total Energy System.

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Important: This manual is designed to provide instructions for use of the User Screen, Communications Module, and Energy Cart. It is not a reference to surgical techniques. The manual is available electronically on www.e-ifu.com.

The third-party trademarks used herein are the trademarks of their respective owners.

Indications

The ETHICON™ Total Energy System is an electrosurgical generator that provides power to monopolar, bipolar, and ultrasonic surgical instruments. It is indicated for any surgical procedure requiring cutting or coagulation of tissue.

The Total Energy System is indicated for use in an operating theatre/room or surgical setting only by healthcare professionals with experience and training in the use of electrosurgical equipment.

Refer to instrument instructions for use for the specific use information of the individual devices.

Contraindications

The use of the Total Energy System and the attached instruments are contraindicated when, in the judgment of the physician, radiofrequency or ultrasonic surgery would be contrary to the best interest of the patient.

The instruments are not indicated for incising bone.

Undesirable Side Effects/Residual Risk

Undesirable side effects and risks associated with electrosurgical and ultrasonic devices that are powered through the Total Energy System include the potential for bleeding, tissue injury via mechanical or thermal damage, nerve injury, introduction of non-sterile surfaces or pathogen transfer leading to infection, inflammatory or unintended tissue reaction, electrical shock, electrical interference, arrhythmia, foreign body retention or magnetic resonance incompatibility, and property or environmental damage. Also, unintended harm, extended surgery, or altered surgical approach may result from issues related to device activation, damaged devices, electromagnetic interference, or an attempt to alter the device. Due to use of the integrated system, burn injury is possible in an oxygen rich environment with flammable materials.

System Description/Performance Characteristics

The Total Energy System is intended to supply energy to surgical instruments.

The Total Energy System is compatible with Ethicon HARMONIC™, Ethicon ENSEAL™, and Ethicon MEGADYNE™ monopolar and bipolar instruments.

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All devices compatible with the Total Energy System and provided by Ethicon and authorized manufacturers undergo an extensive verification and validation process. The Total Energy System is not designed to operate unauthorized devices. Such use is not in accordance with the design and use parameters, instructions, and guidelines for the product. See the Approved Accessories list in the ETHICON™ Energy Module and Energy Footswitches Operator’s Manual for compatible instruments and compatibility criteria.

Total Energy System components (see Section 3 for recommended component combinations):

- Communications Module (ETHCM) - The Communications Module always sits at the top of the System. It contains the power button and speakers, controls the User Screen, distributes power for the System, and provides external interfaces for other connectivity to external devices. External interfaces include Ethernet and USB. It also includes four footswitch ports and a digital accessory port, which can be used for interfacing to wired accessories of the System. The Communications Module communicates with other modules of the System via the downstream connector.

Note: Network connectivity is suspended during clinical operation as a cybersecurity mitigation.



1.2 Communications Module

- User Screen (ETHUSC) - The User Screen serves as a single point of user control for all module and system-related settings. It includes a touchscreen interface for customization of settings by the user.

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1.3 User Screen

- **Energy Module (ETHEM)** - The Energy Module receives power from the Communications Module and uses power amplifiers to provide energy to electrosurgical and ultrasonic instruments. The Energy Module contains four ports for connection of Bipolar, Monopolar, and Advanced Energy (ENSEAL™ or HARMONIC™) instruments as well as a port for connection of a patient return electrode, for use with monopolar instruments. The Energy Module delivers Monopolar Radiofrequency (RF), Bipolar RF, Ultrasonic, and Advanced Bipolar RF energy to connected instruments. Refer to the ETHICON™ Energy Module and Energy Footswitches Operator's Manual for additional information.

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1.4 Energy Module

- Energy Cart (ETHCRT, optional) - Cart to be used for transportation and storage of the Total Energy System. Contains adjustable shelves to accommodate the height of different system configurations and features for cord management and accessory storage.

The Energy Cart is intended to store and transport the Total Energy System and its accessories.

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1.5 Energy Cart

- ETHICON™ Energy Footswitches (ETHEF1, ETHEF2, ETHERF, optional) – Footswitches may be used to control power delivery to connected instruments. Up to four footswitches can be connected to the Total Energy System at once.

The Energy Footswitches are intended to control power to the connected instrument when connected to the Communications Module within the Total Energy System.

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1.6 Energy Footswitches

How Supplied

The components of the Total Energy System are supplied separately. This includes separate packaging for the Communications Module, User Screen, and the Energy Module.

The power cable is supplied with the Communications Module.

The Energy Footswitches, the Energy Cart, the Energy Output Verification Key (ETHOVK), and all compatible HARMONIC™, ENSEAL™, monopolar, and bipolar instruments are purchased separately.

Standard Conventions Used

The Use of WARNING, Caution, and Note Statements

Information relative to the completion of a task in a safe and thorough manner will be supplied in the form of a WARNING, a Caution, or a Note statement. These statements are found throughout the documentation.

These statements should be read before continuing to the next step in a procedure.

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WARNING: A Warning statement indicates an operating or maintenance procedure, practice, or condition that, if not strictly observed, could result in personal injury or loss of life.

Caution: A Caution statement indicates an operating or maintenance procedure, practice, or condition that, if not strictly observed, could result in damage to or destruction of the equipment.

Note: A Note statement indicates an operating or maintenance procedure, practice, or condition that is necessary to accomplish a task efficiently.

Warnings

- This equipment is for use only by qualified medical personnel.
- Non-flammable agents should be used for cleaning and disinfection wherever possible. Flammable agents used for cleaning or disinfecting, or as solvents of adhesives, should be allowed to evaporate before use.
- Do not operate the Communications Module and User Screen in a moist environment as a shock hazard may exist. If liquids have entered the Communications Module or User Screen, the unit(s) must be returned to the manufacturer for testing prior to use.
- Interference produced by the operation of high-frequency surgical equipment may adversely affect the operation of other electronic medical equipment such as monitors and imaging systems. Avoid use of the Total Energy System adjacent to or stacked with other non-compatible capital equipment and separate cables within the room from the RF carrying cables. If adjacent or stacked use is necessary, monitor the Total Energy System and the other equipment to assure normal operation.
- For patients with cardiac pacemakers, electrically conductive or other active implants, a possible hazard exists due to the concentration or re-direction of HF currents. The pacemaker or other active implant may become non-functional due to the interference of HF currents. In case of doubt, approved qualified advice should be obtained from the implant device manufacturer.
- Use of accessories and cables other than those specified may result in unpredictable performance, increased electromagnetic emissions, or decreased electromagnetic immunity.
- No customer modification of this equipment is allowed; modification of this equipment could have a negative impact on electrical safety and electromagnetic emissions.
- Other than fuses, the Communications Module contains no operator-serviceable parts. For service, return the module to an authorized Ethicon service facility.
- To avoid the risk of electric shock, this equipment must only be connected to a supply main with protective earth.
- To isolate the Communications Module from supply mains power, disconnect the power cord either from the back panel of the Communications Module or from the wall. Ensure that access to these points is kept clear.
- This device is neither MR safe nor MR compatible.
- In case of system failure, ensure availability of the appropriate backup equipment relevant to the specific procedure.

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- Replace fuses only with the appropriate type and rating. See System Specifications.
- Do not operate the Communications Module with the cover removed. Removing bottom screws or opening of this device invalidates the warranty and could create hazardous conditions.
- Portable RF communications equipment that are not part of the Total Energy System (including peripherals such as antenna cables and external antennae) should be used not closer than 12 inches (30 cm) to any part of the Total Energy System including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
- Do not lift entire system at once. Lift and carry each module individually when transporting if a cart is not utilized.
- Do not operate the unit in close proximity to volatile solvents such as methanol or alcohol as combustion may occur.
- Spilling or spraying fluids on or into the Communications Module, User Screen, or connectors or immersing the module may result in damage to the device and creates a risk of shock or fire.

Precautions

- Do not use if the Energy Cart or any of the Total Energy System components are damaged.
- The Total Energy System is not designed to operate unauthorized devices. See the Approved Accessories List in the Operator's Manual for the Energy Module for compatible instruments and compatibility criteria.
- The touch screen display of the User Screen is very sensitive. Do not use sharp metal objects on the touch screen.
- Do not sterilize the System. Sterilization will damage the unit.
- Do not restrict the openings on the bottom, side, and the back panel of the Communications Module, as they provide the required airflow for cooling. At least one inch (2.54 cm) of air should separate sides and back of the Communications Module from any ventilation-obstructing surface.
- If electromagnetic interference with other equipment is suspected, reorient the device or remove possible sources of interference (for example, cellular phones, radios, etc.) from the room.
- The Energy Cart is recommended if the Total Energy System is moved out of the operating room. Maintain control of the Total Energy System and Energy Cart when moving over thresholds.
- Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the local competent authority of the country in which the user and/or patient is established.
- Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.
- Do not place containers of fluids on the System or allow fluids to spill on the System.
- All associated equipment and active accessories should be inspected to determine the rated accessory voltage prior to use.
- This module is authorized for use where the antenna may be installed such that 20 cm may be maintained between the antenna and the users.

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Warranty

Limited Warranty. Ethicon Endo-Surgery warrants the following Equipment (the “Covered Equipment”) to be free from defects in material and workmanship (and its embedded software shall meet its specifications) for a period of one (1) year from date of delivery:

ETHICON™ Communications Module (ETHCM)
 ETHICON™ User Screen (ETHUSC)
 ETHICON™ Energy Module (ETHEM)
 ETHICON™ Energy Single Footswitch (ETHEF1)
 ETHICON™ Energy Double Footswitch (ETHEF2)
 ETHICON™ Energy Round Footswitch (ETHERF)
 ETHICON™ Energy Cart (ETHCRT)
 ETHICON™ Output Verification Key (ETHOVK)

A purchaser’s sole and exclusive remedy, and Ethicon Endo-Surgery’s sole and exclusive liability, for any breach of the limited warranty will be to repair or replace the Covered Equipment (or any of its components), so that it functions in accordance with the specifications at the time of original purchase. Replacement parts may be new or rebuilt to perform as new.

This warranty does not apply to: (1) materials, equipment or accessories not furnished by Ethicon Endo-Surgery, (2) any Covered Equipment use involving Ethicon Endo-Surgery instruments which have been reprocessed, refurbished, repaired, or altered by anyone other than us or our authorized representatives, (3) components, parts, and accessories lost by the purchaser, (4) any Covered Equipment which has been modified, altered or repaired by anyone other than Ethicon Endo-Surgery or its authorized representative, (5) any Covered Equipment stored, used, or handled in any manner inconsistent with its operating instructions, (6) any Covered Equipment damaged due to accident, negligence, misuse, abnormal use, or use with products not manufactured or distributed by Ethicon Endo-Surgery or its authorized representatives, (7) damage due to fire, accident, vandalism, sabotage, terrorism, riots, abuse, water, smoke, lightning, natural disasters, war, embargoes, labor disputes, other calamities commonly defined as “Acts of God,” or anything external to the Covered Equipment, including building structural deficiency or power supply, heating, humidity, temperature, ventilation, or air conditioning fluctuation or failure, (8) communications with Ethicon Endo-Surgery or its affiliates systems, and all software, systems or hardware used by the purchaser in connection with the Covered Equipment that contains bugs, viruses, or other malware that alter, infect, disrupt, or damage the Covered Equipment or related computer systems, networks, infrastructures, websites, databases, software or other data, (9) damage due to use of the Covered Equipment on systems modified by anyone other than Ethicon Endo-Surgery or its authorized agents, or on systems which include subsystems or components not certified by Ethicon Endo-Surgery or its authorized agents.

THIS WARRANTY IS IN LIEU OF ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING THE WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE, AND OF ALL OTHER OBLIGATIONS OR LIABILITIES ON THE PART OF ETHICON ENDO-SURGERY AND IS A PURCHASER’S EXCLUSIVE REMEDY. IN NO EVENT SHALL ETHICON ENDO-SURGERY BE LIABLE FOR SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES INCLUDING, WITHOUT

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LIMITATION, DAMAGES RESULTING FROM LOSS OF USE, DATA, PROFITS, BUSINESS OR GOODWILL. Ethicon Endo-Surgery neither assumes nor authorizes any other person to assume for it any other liability in connection with the sale or use of any of Ethicon Endo-Surgery products. Ethicon Endo-Surgery reserves the right to make changes to products built and/or sold at any time without incurring any obligation to make the same or similar changes on products previously built and/or sold.

Warranty Claim Process. To arrange for service, call the Ethicon Resource Department at any time at 1-877-ETHICON (384-4266).

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Customer Service

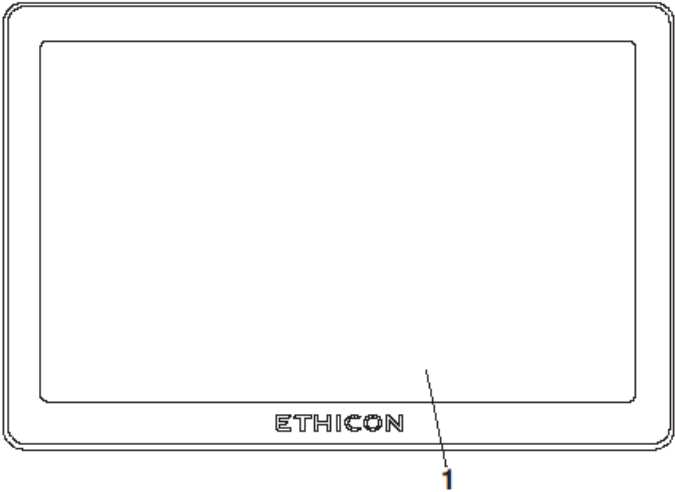
Contact the Ethicon Customer Service Department or your local representative for any customer or technical support.

1-877-ETHICON

+1-513-337-8901 (English)

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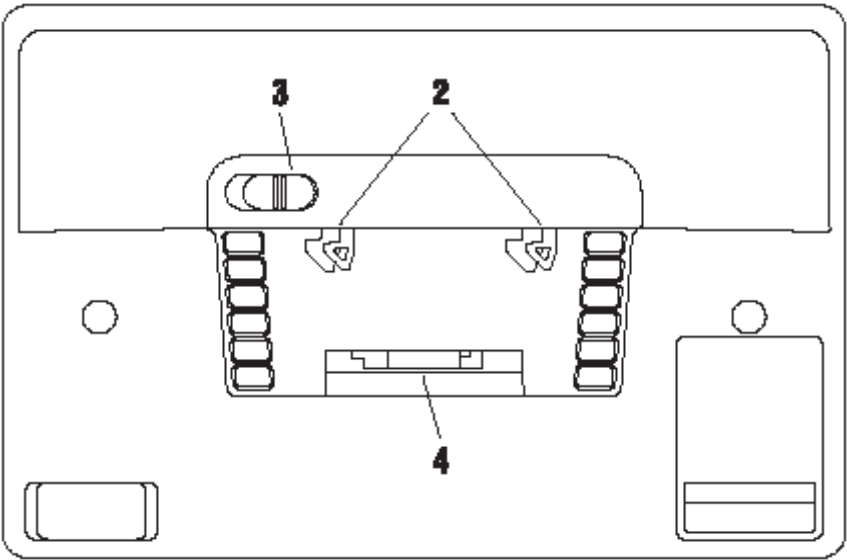
2 - System Components



2.1 User Screen – Front

1	TOUCH SCREEN	Used to control the Total Energy System
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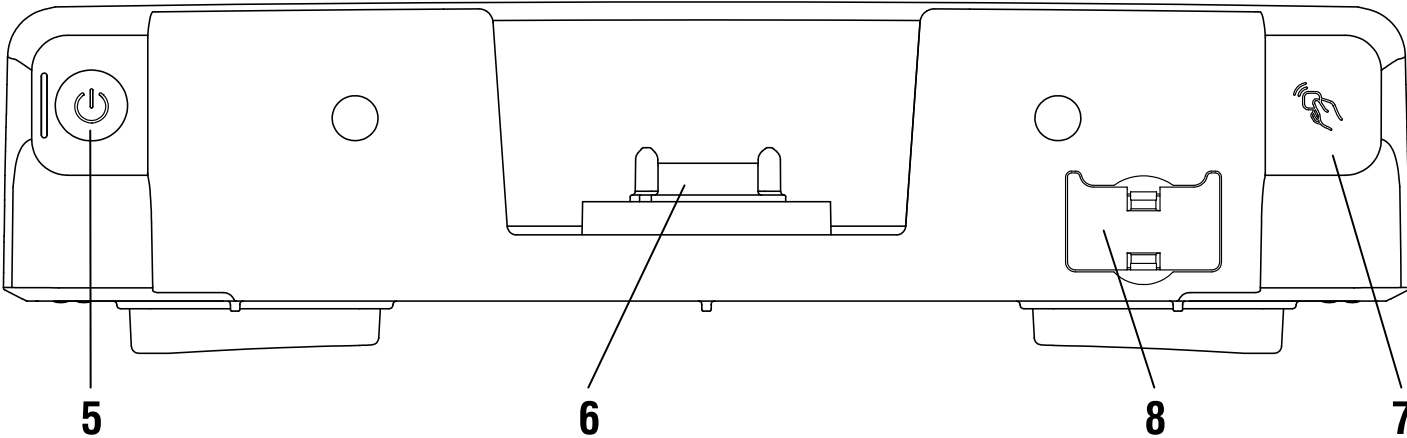
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2.2 User Screen – Back

2	RETENTION LATCHES	Used to connect the User Screen to the Communications Module. An audible click will be heard when correctly assembled to the Communications Module.
3	RETENTION LATCH SLIDER	Used to detach the User Screen from the Communications Module
4	USER SCREEN DOWNSTREAM CONNECTOR	Provides connection to the Communications Module. Attaches to the Communications Module ‘User Screen Upstream Connector.’

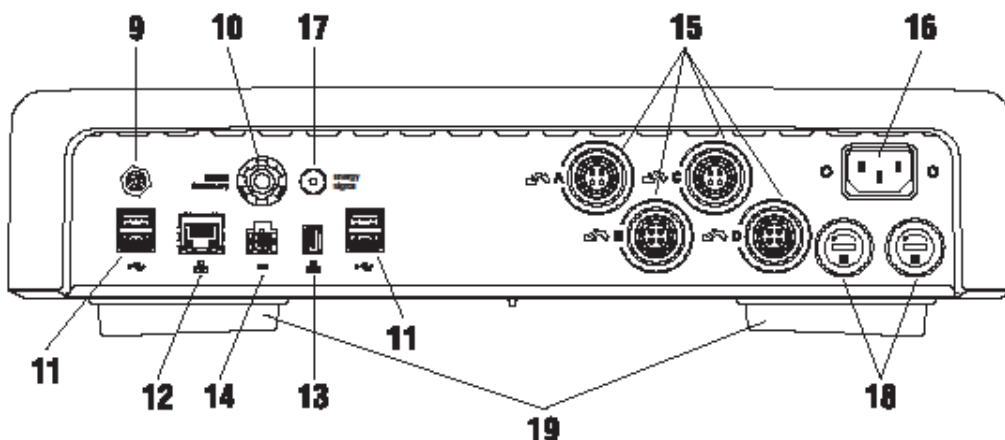
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2.3 Communications Module - Front

5	POWER ON/OFF BUTTON	Illuminates white when the Total Energy System is powered on. The light dims when the Total Energy System is powered off.
6	USER SCREEN UPSTREAM CONNECTOR	Provides connection to the User Screen. Attaches to the 'User Screen Downstream Connector.'
7	NFC READER	For use with compatible NFC-enabled products. This is a future state capability and is not currently enabled.
8	SD CARD ACCESS COVER	Removable cover to access SD Card. Note: The Total Energy System will not function without an SD card. Only use the Ethicon-provided SD card. If there are any issues with your SD card, contact your Service Department or Ethicon Representative.

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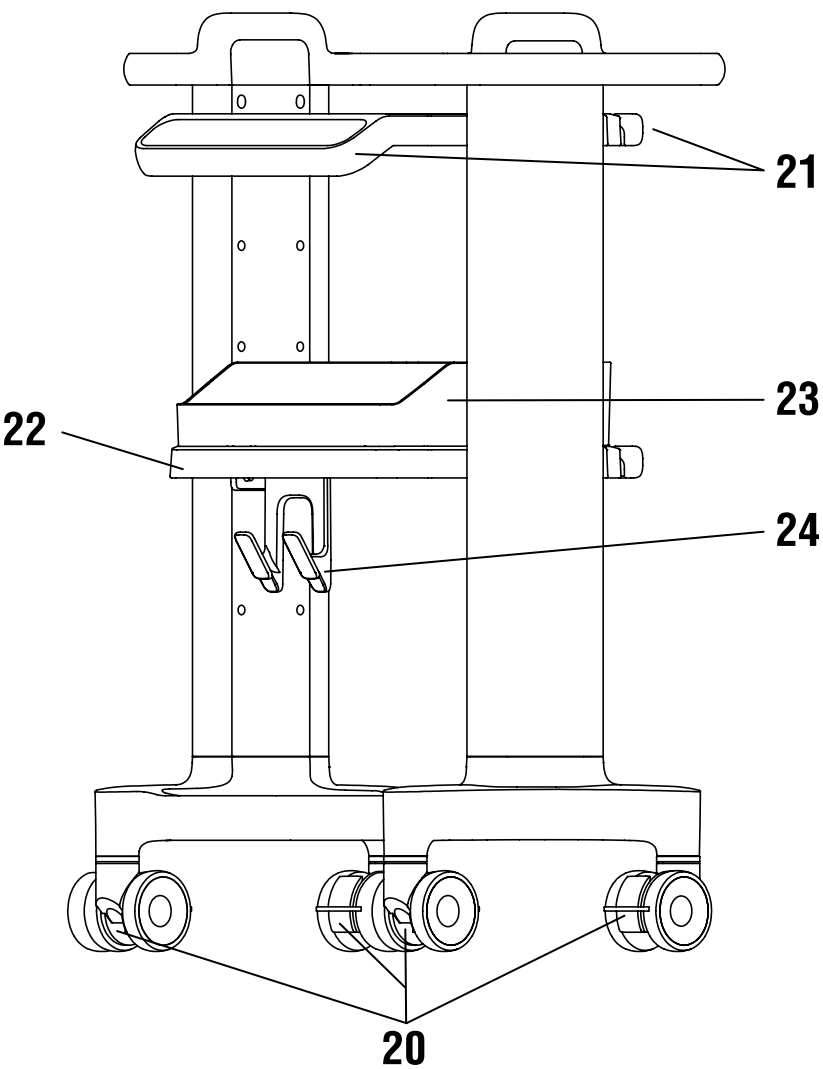
2.4 Communications Module - Back

9	EQUIPOTENTIAL LUG	Used to connect the Total Energy System to a potential equalization conductor.
10	DIGITAL ACCESSORY PORT	Used to connect compatible accessories to the Communications Module. There are currently no compatible accessories or cables that can be used with this port.
11	USB PORTS	Used to attach up to four USB devices to the Communications Module. Only USB Mass Storage Device types are supported. The Total Energy System will only recognize a physically connected USB Mass Storage Device while performing a Software Update or Event Log Export.
12	PUBLIC NETWORK ETHERNET PORT	Used to connect the Total Energy System to a hospital network.
13	ETHERNET PORT	Used to connect compatible equipment.
14	I/O PORT	Used to connect compatible equipment.
15	FOOTSWITCH PORTS	Ports used to attach up to four footswitches to the Communications Module.
16	POWER CORD RECEPTACLE	Used to attach supplied power cord to the Communications Module.
17	ENERGY SIGNAL	Used to connect blanking EKG machines or signaling smoke evacuation during energy activation.

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18	FUSE HOLDERS & FUSE MARKING AREA	The fuse holders can be accessed by using a flat tool to unscrew the holder from the housing. If a fuse has been damaged, replace with the properly rated fuse. The fuse rating for the supplied fuses is printed above the fuse holders.
19	RUBBER FEET	Provides stability for the Communications Module and alignment when connecting to other modules.

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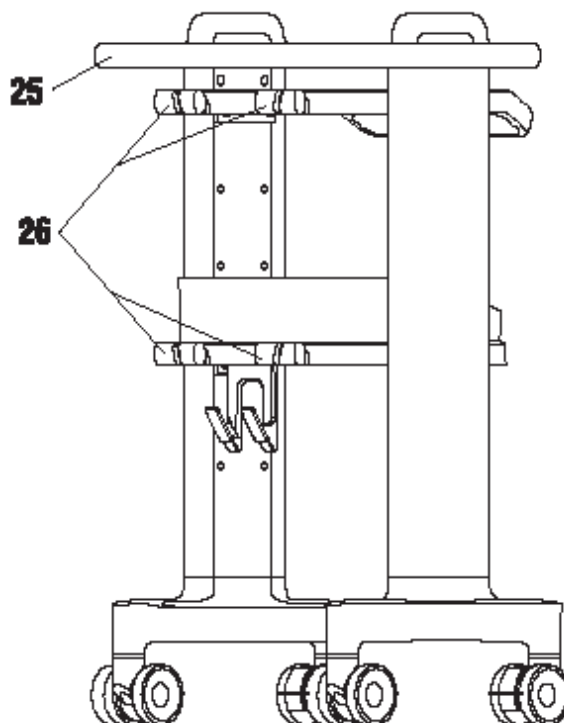


2.5 Cart - Front View

20	CASTERS	Casters provide 360° mobility. Locking tabs are used to lock casters to prevent unwanted cart movement.
21	ADJUSTABLE TOP SHELF	Used for placement of the System. Contains cut-out features in the shelf for alignment of the rubber feet on the modules. Also contains front handlebar for cart maneuvering.

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22	ADJUSTABLE MIDDLE SHELF	Used for module stacking and plastic bin placement.
23	PLASTIC BIN	Used to store instruments and accessories. Bin can be removed by the user if desired.
24	FOOTSWITCH HANGER	Used to hang footswitches when not in use. Footswitch hanger can be removed by the user if desired.



2.6 Cart – Back View

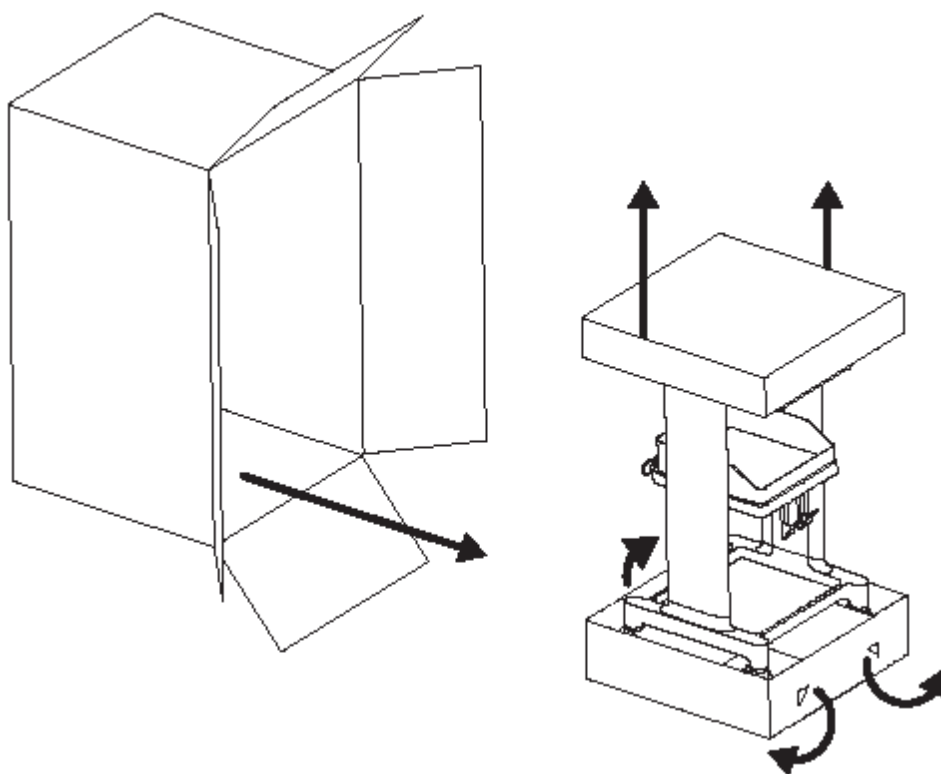
25	HANDLEBAR	Used to maneuver cart.
26	CORD MANAGEMENT FEATURES	Features on the back of the top and middle shelves for cord management and storage.

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3 – System Set-up and Initial Start-up

Energy Cart Set-up

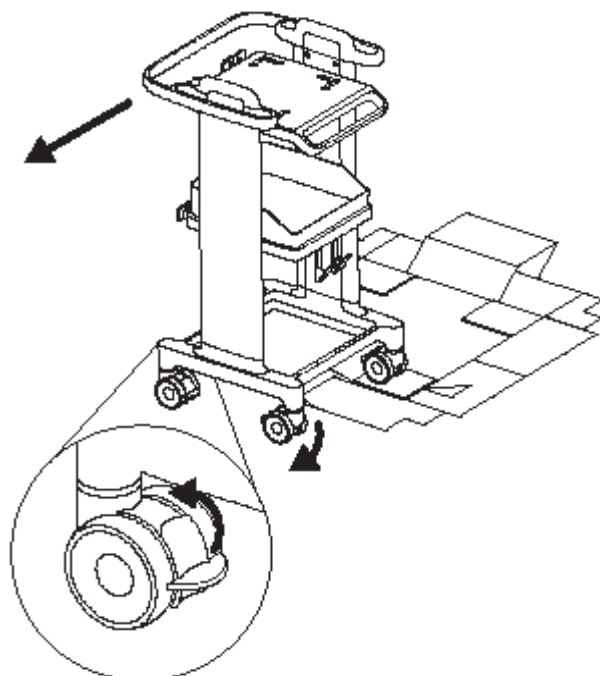
1. Remove cart from packaging in upright direction by opening the box and sliding the cart and tray from the box.



3.1 Cart Removal from Box

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2. Undo tabs on the base of the tray and roll cart off tray.



3.2 Rolling Cart off Tray

3. Inspect cart and cart components for damage prior to use.

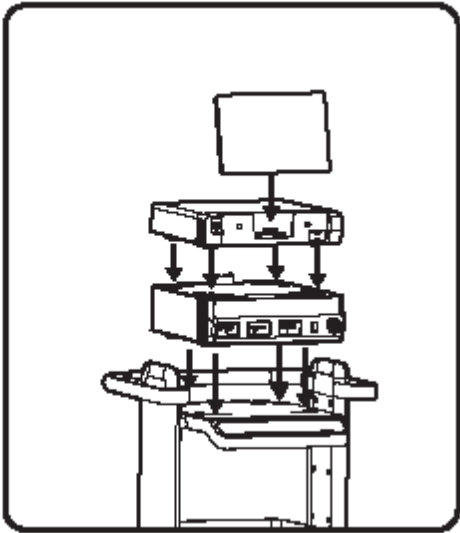
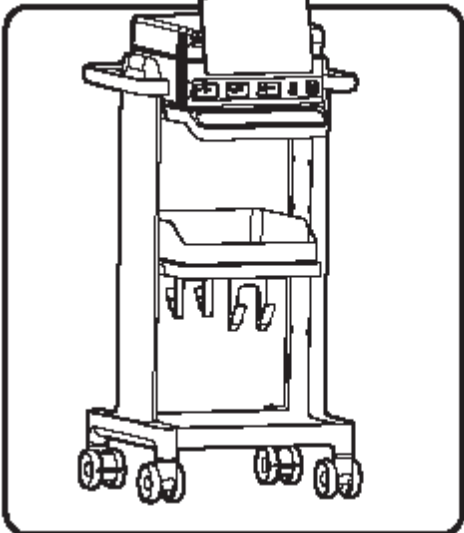
Caution: Do not use if cart is damaged.

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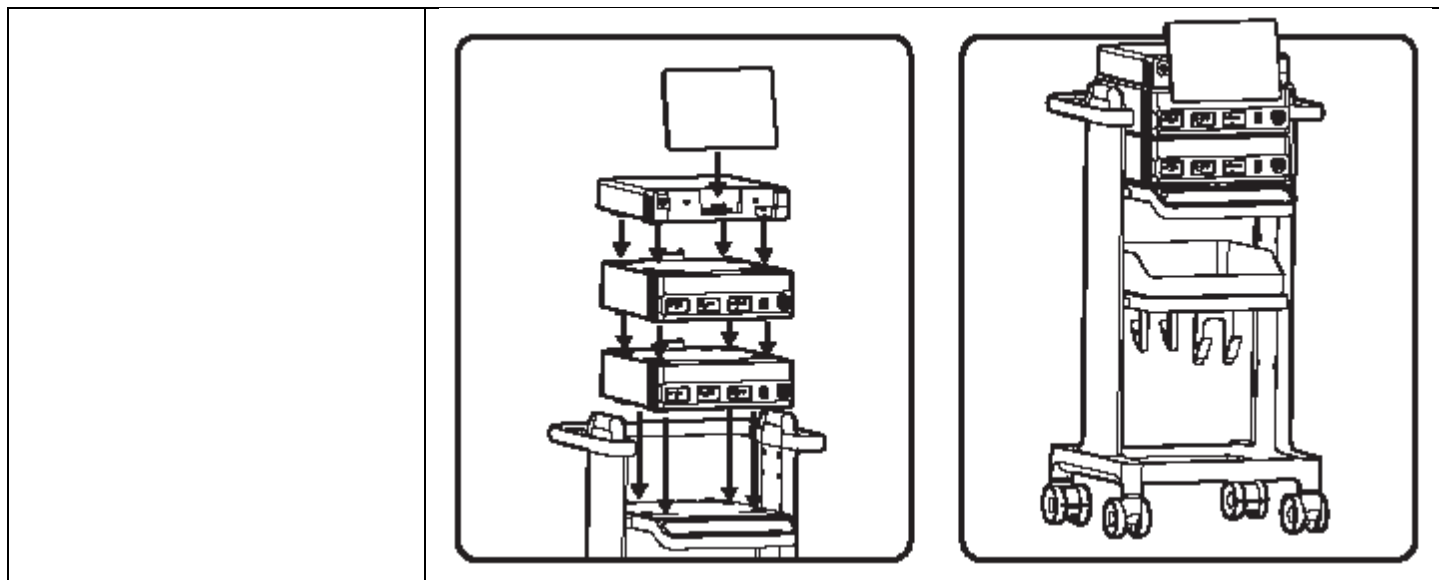
4. The cart is shipped with the top shelf installed at a height that is based on the optimal height for a system that has one additional module. The height of the shelves can be adjusted if multiple modules are used or if it is necessary to alter the position of the User Screen.



Note: The total weight of the Energy Cart, including the safe working load, is 95 kg (208 lbs.). Each shelf is equipped to hold 43.1 kg (95 lbs.). Ensure the cart does not exceed its total labeled weight limit when fully loaded.

Available Module Configurations	Energy Cart Shelf Position
One (1) – User Screen One (1) – Communications Module One (1) – Energy Module	Top Shelf Position  
One (1) – User Screen One (1) – Communications Module Two (2) – Energy Modules	Second Shelf Position

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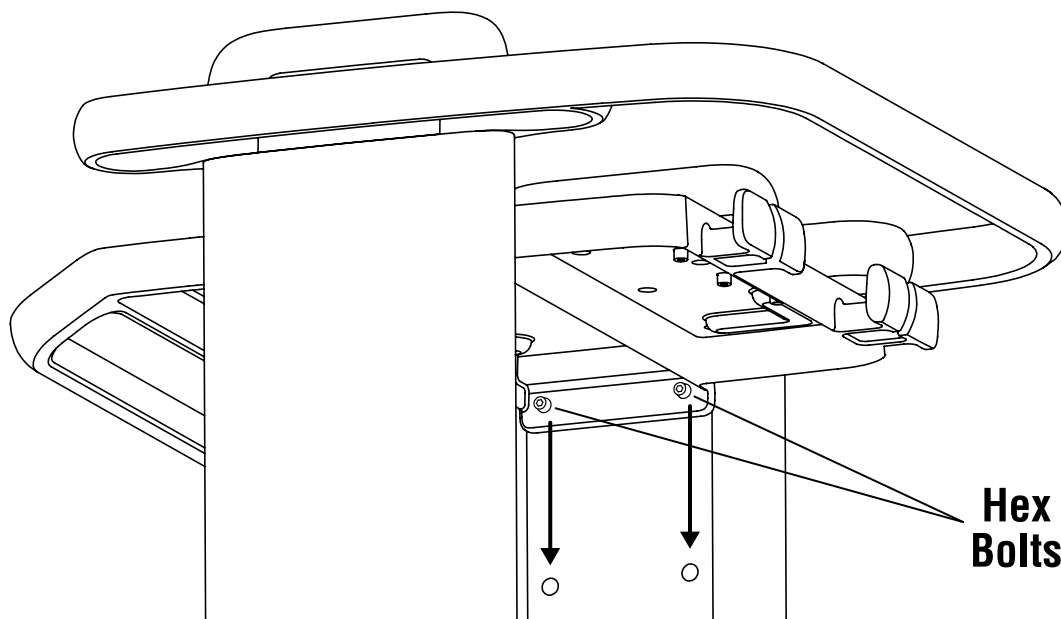
3.3 Energy Cart Shelf Positions

5. To adjust the shelf height, use a 4 mm hex wrench to remove the hex bolts (4) from underneath the shelf. Remove the white stickers covering additional threaded insert locations. Slide the shelf to the desired height and use the hex wrench to reattach bolts.

Note: Loosen the hex bolts (4) on the lower shelf before moving the top shelf to the desired position. This allows more space between the uprights to adjust the shelf position.

Caution: Ensure shelves are secure before placing the Total Energy System on the cart.

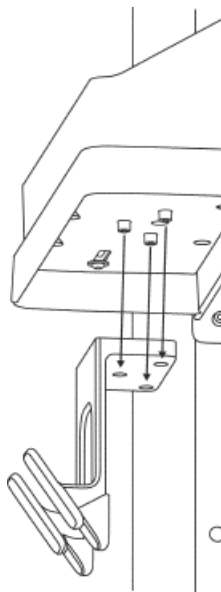
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3.4 Adjusting Shelf Position

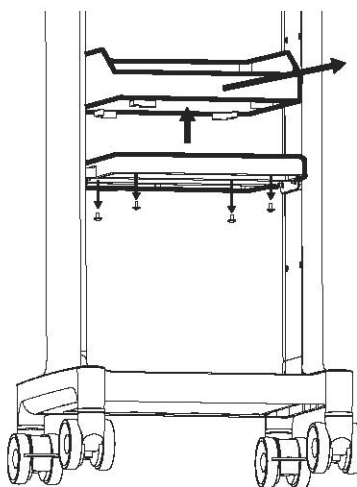
6. The cart comes with two (2) footswitch hangers installed that can be used to store any of the footswitches when not in use. The cart will come with the footswitch hangers already assembled to the front and back of the cart. If a footswitch hanger needs to be removed, use a 4 mm hex wrench to remove the hardware and detach the footswitch hanger.

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3.5 Removing the Footswitch Hanger

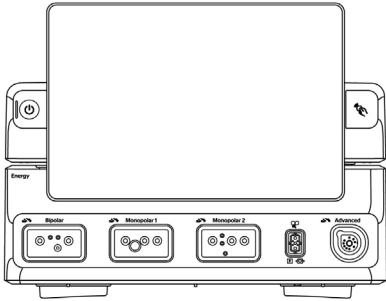
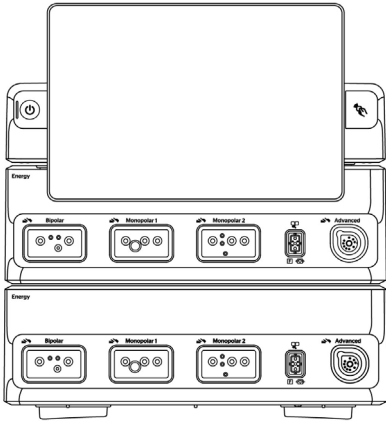
7. The cart also contains a removable plastic bin on the adjustable middle shelf that is used for storage. If the plastic bin needs to be removed, use a 4 mm hex wrench to remove the washers and screws from the bottom of the shelf and detach plastic bin.



3.6 Removing the Plastic Bin

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Module Set-up

Available Module Configurations	Images
One (1) – User Screen One (1) – Communications Module One (1) – Energy Module	
One (1) – User Screen One (1) – Communications Module Two (2) – Energy Modules	

3.7 Available Module Configurations

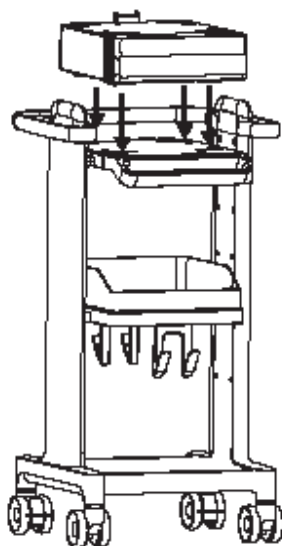
1. Remove Communications Module, User Screen, and any other modules from their respective packaging. Inspect devices for damage prior to use.

Caution: Do not use if device is damaged.

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Product codes: ETHCM, ETHUSC, ETHCRT	

2. If using the Energy Cart, place the module on the top shelf of the cart ensuring that the bottom, rubber feet of the module are aligned with the cut-outs on the top shelf. If not using a cart, place module on a stable surface such as a table.

Note: The Communications Module must always be at the top of the Total Energy System assembly.



3.8 Aligning Bottom Module with the Cart Shelf

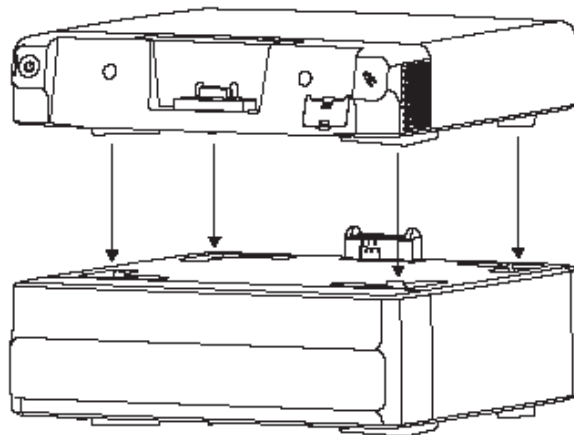
Caution: Prior to placing Total Energy System on cart, ensure casters are locked and shelves are properly installed.

3. Place other modules according to available module configurations table. When a module is placed, ensure the rubber feet are aligned with the pockets on the top of the bottommost module and the upstream and downstream connectors on both modules are aligned. Ensure the upstream and downstream connectors are fully seated by pushing down on the top module.
4. Place the Communications Module on top of the module(s), ensuring the upstream connector on the module is in line with the back of the Communications Module, and the bottom rubber feet are aligned with the pockets on the top of the module.

WARNING: Do not lift entire Total Energy System at once. Lift and carry each module individually when transporting, if a cart is not utilized.

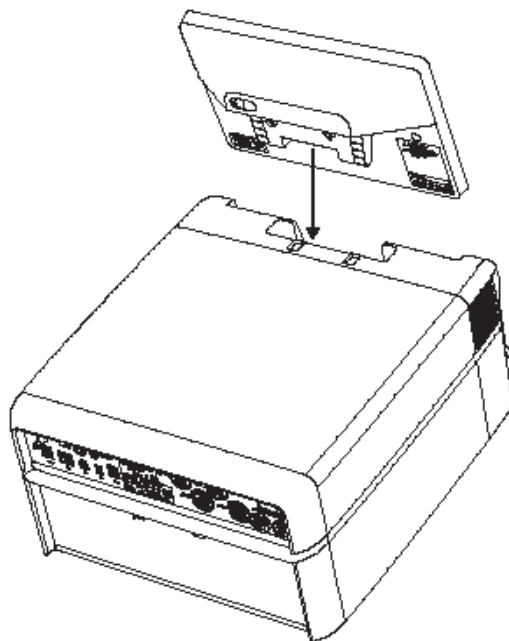
Note: The Communications Module must always be at the top of the Total Energy System assembly.

**IFU Creation Form	
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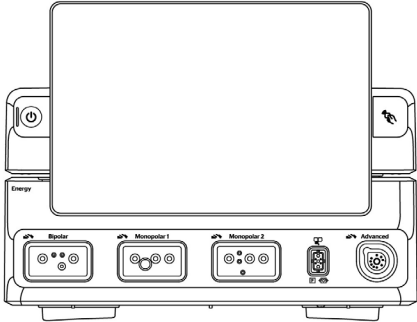
3.9 Attaching the Communications Module to the Lower Module

5. Attach the User Screen to the front of the Communications Module and snap in place. An audible click will be heard.



3.10 Attaching the User Screen to the Communications Module

**IFU Creation Form	
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Product codes: ETHCM, ETHUSC, ETHCRT	



3.11 Assembled Single Module System

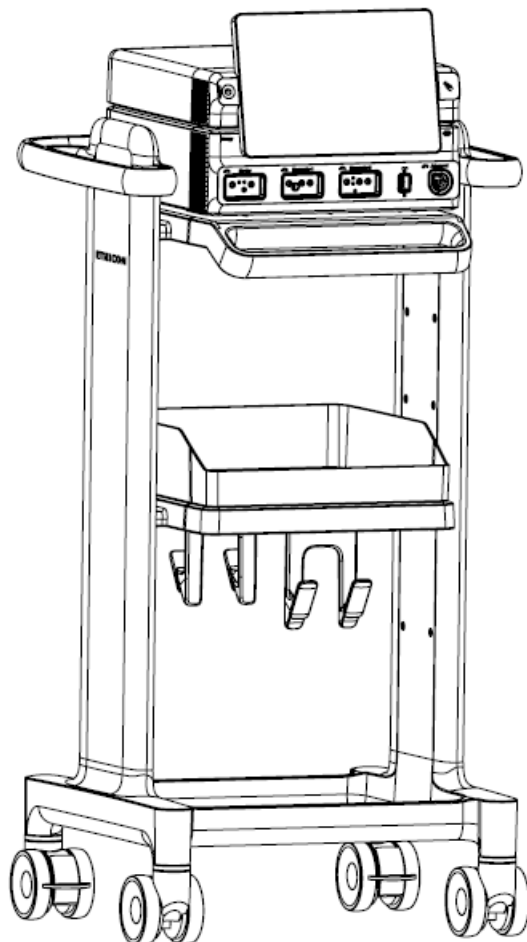
Energy Cart Positioning and Transport

The Energy Cart is recommended if the System needs to be moved.

If the Energy Cart is being used with the System, follow the instructions below for cart positioning and transport. If another cart is being used, follow the manufacturer’s instructions for use.

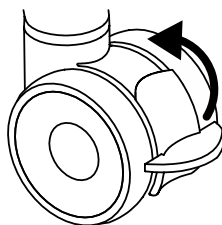
- 1. Verify the System was placed securely within the defined cut-out features on the top shelf of the cart.

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Product codes: ETHCM, ETHUSC, ETHCRT	



3.12 Single Total Energy System on Cart

- The cart has 4 wheels with lockable casters. Unlock the casters by pushing the tabs on the caster locks up.



3.13 Unlocking the Casters

Caution: Verify that the Total Energy System components are placed securely on the cart prior to positioning or moving the cart.

**IFU Creation Form	
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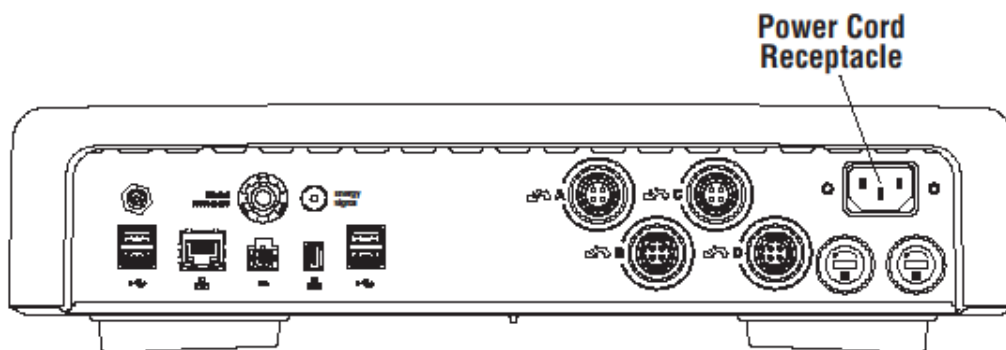
- Using the cart handlebars, move the cart to the desired location.
- Once the cart is positioned, re-lock all casters by pushing the tabs down.

Initial Start-up



- Connect the power cord from the back panel of the Communications Module to a dedicated, grounded electrical outlet. **A dedicated outlet means that no other medical equipment is plugged into the same electrical outlet as the Ethicon Total Energy System.** Plugging the System into a dedicated outlet avoids overloading the circuit and reduces the risk of interference with other medical equipment. Position the Total Energy System in a manner that provides access to the power cord for easy disconnection as needed. The power requirements are listed on the label on the back panel of the Communications Module and in the System Specifications section of this manual.

WARNING: To avoid the risk of electric shock, this equipment must only be connected to a supply main with protective earth.



3.14 Connecting the Power Cord to the Communications Module

Caution: Verify that the Total Energy System components are secured to the cart, or any other suitable fixture, before powering on.

- Turn on the Total Energy System by touching the power on/off button on the front of the Communications Module.

Note: Powering the System on for initial set-up or for the first time after reconfiguring modules included in the System may take up to 5 minutes for the System to boot.

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- Once powered on, the user will be prompted to select a language.

Select Language

English
Français
Deutsch
Español
Italiano
Português
Svenska

Next ►

3.15 Language selection screen

- Once the language is selected follow on-screen prompts for initial guided set-up. Guided set-up will walk through the steps required to prepare the System for use. Refer to the Service Manual for information on how to connect.

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Hello.
You are a few
steps away from
being ready for
surgery.



◀ Back

Let's Begin ▶

3.16 Guided set-up screen

**IFU Creation Form	
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Product codes: ETHCM, ETHUSC, ETHCRT	

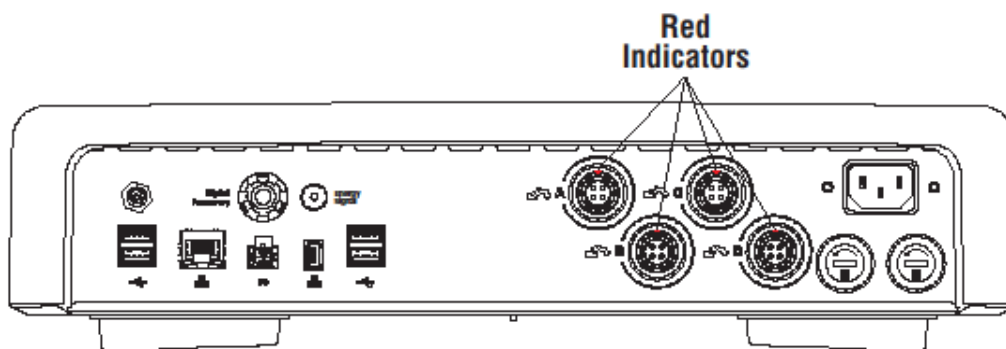
Clinical Use Set-up

Once the Total Energy System is initially configured and the unit is powered on, the footswitch(es) can be connected, if desired.

1. Remove the footswitch from the packaging.
2. Inspect the footswitch for damage prior to use.

Caution: Do not use if footswitch is damaged.

3. Insert the footswitch connector into any footswitch port on the back of the Communications Module. Up to four footswitches can be connected to the System at any given time. There are red indicators on the top of the footswitch connector and on the footswitch port for proper alignment. See the Energy Module and Energy Footswitches Operator's Manual for information on the use of the footswitches.



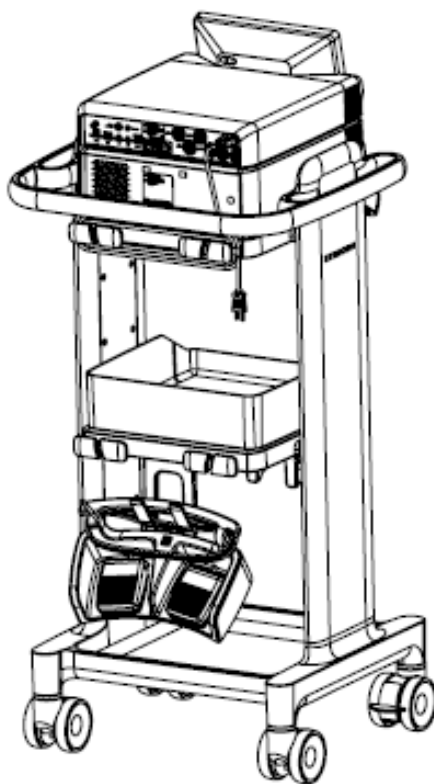
3.17 Connecting the Footswitches to the Footswitch Ports

**IFU Creation Form	
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Product codes: ETHCM, ETHUSC, ETHCRT	

4 – Shut Down and Storage

1. Turn off the System using the power on/off button on the front of the Communications Module.
2. When the on/off button is touched, the User Screen will display a message to confirm Shut Down. Once shut down is complete, the on/off button will dim.
3. If using the Energy Cart, store power cables on the cord management features on the back of the cart shelves and place footswitches within the plastic bin, shelves, or on the footswitch hangers, as applicable.

Note: A notification will display after 4 hours of nonuse and will automatically shut the System down if the notification is not dismissed.



4.1 Cables and Footswitch Storage on Cart

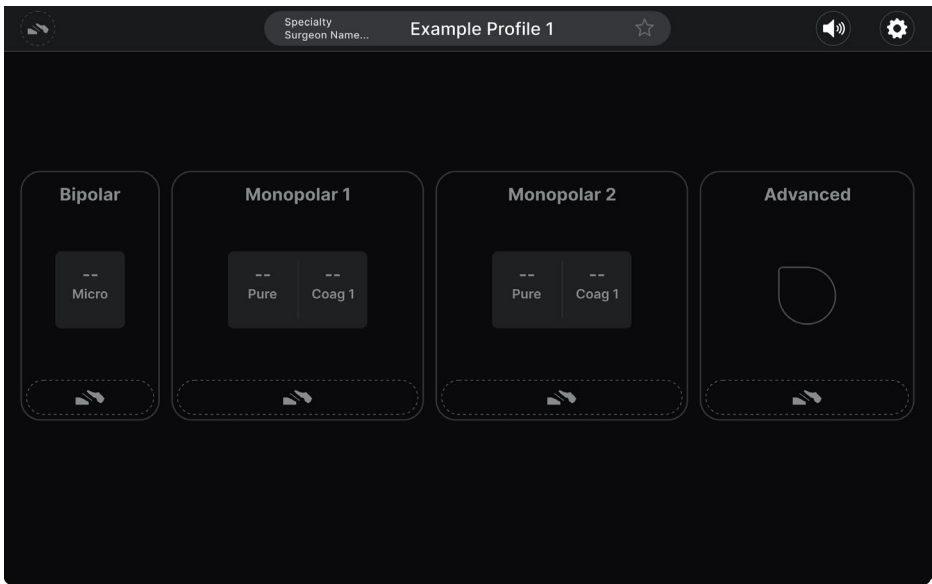
**IFU Creation Form	
Artwork #: 501145836 Rev. A Component Drawing #: P000021P01	Project information: DC002871/CR20021
Product codes: ETHCM, ETHUSC, ETHCRT	

5 - System Settings

From the Main screen, the user can access the Volume and other Settings.

Note: To minimize interferences, the touch screen may not respond when electrosurgical cables from other electrosurgical systems are in close proximity.

Note: The touch screen will be disabled during energy activation.



5.1 Main Screen – Single Energy Module Configuration

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Product codes: ETHCM, ETHUSC, ETHCRT	

Volume Settings

To adjust the volume of system sounds, select the volume icon in the upper right-hand corner of the screen. Drag the slider to the left to decrease volume or to the right to increase volume. To comply with international regulations, alarms and activation tones must maintain a minimum decibel level and will not go below a predetermined threshold.

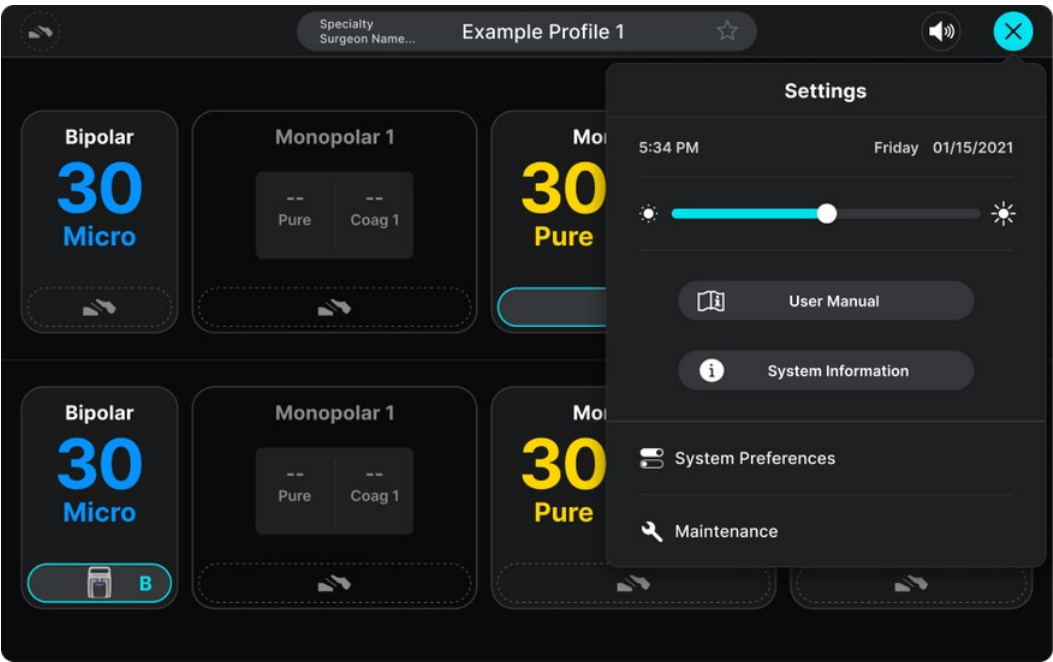


5.2 Volume Settings Screen – Double Energy Module Configuration

Settings Menu

Selecting the settings icon in the upper right-hand corner of the screen will display the Settings drop-down menu.

**IFU Creation Form	
Artwork #: 501145836 Rev. A Component Drawing #: P000021P01	Project information: DC002871/CR20021
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5.3 Settings Menu Screen – Double Energy Module Configuration

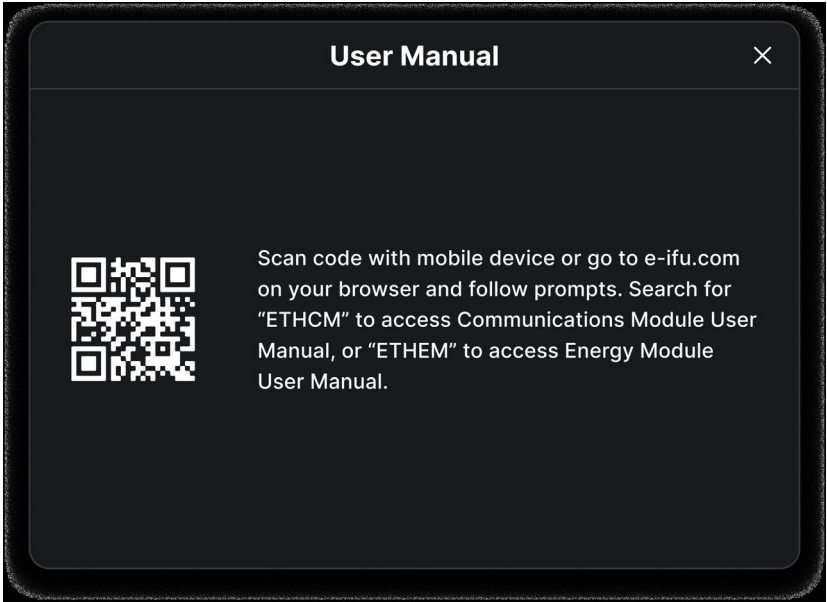
User Interface Screen Brightness

Screen brightness can be adjusted from the Settings menu by dragging the scroll bar to the left to decrease brightness or to the right to increase brightness (see brightness scroll bar in image 5.3).

User Manual

Selecting 'User Manual' displays a screen with a barcode that can be scanned to obtain access to the module Operator's Manuals.

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5.4 User Manual Screen

System Information

Selecting 'System Information' displays information about the Total Energy System, including the System serial number, software version, and a link to check for software updates. It also includes information on the modules that are connected in the System, Hand Pieces that are connected to the Energy Module(s), and Hand Piece uses remaining, as applicable.

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5.5 System Information Screen

System Preferences

Selecting 'System Preferences' displays options for modifying various system settings.

Language

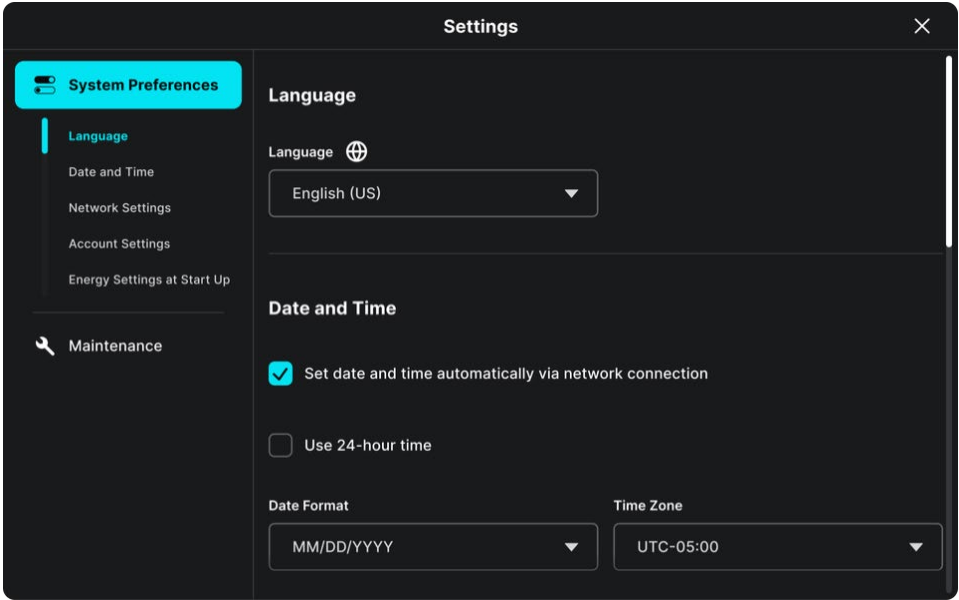
The preferred language can be selected from the pull-down menu. There are multiple language options. Once the user selects the language, that language becomes the new system default.

Date and Time

The date and time can either be set automatically by using a network connection or set manually.

If 'Use 24-hour time' is selected, the time will be displayed with a 24-hour format instead of a 12-hour format. The 'Date Format' and 'Time Zone' can be selected from the pull-down menus.

**IFU Creation Form	
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Product codes: ETHCM, ETHUSC, ETHCRT	

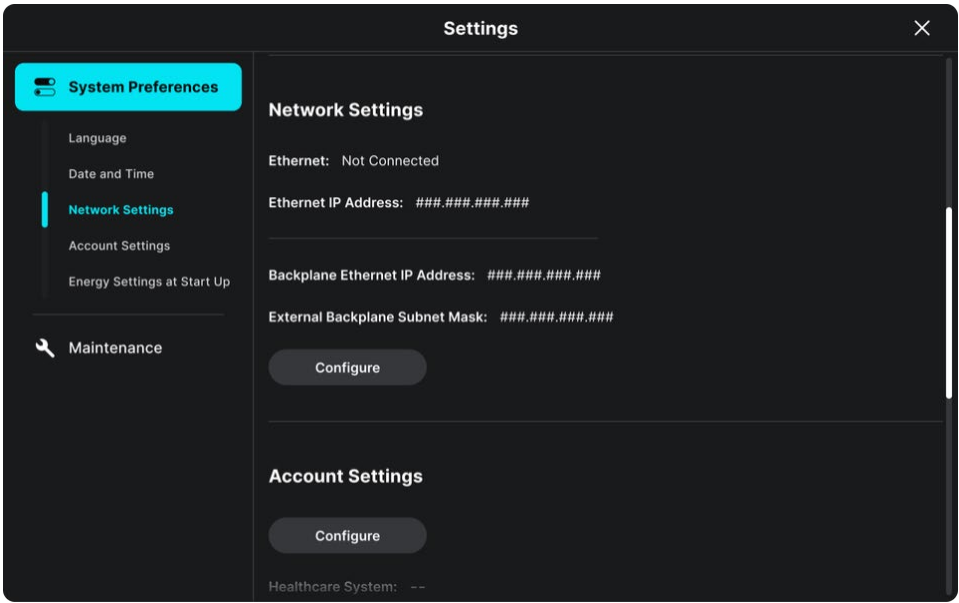


5.6 System Preferences Screen

**IFU Creation Form	
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Product codes: ETHCM, ETHUSC, ETHCRT	

Network Settings

Network Settings includes Ethernet connection and network configuration settings. Consult the Service Manual and hospital IT for additional information on Network Settings.

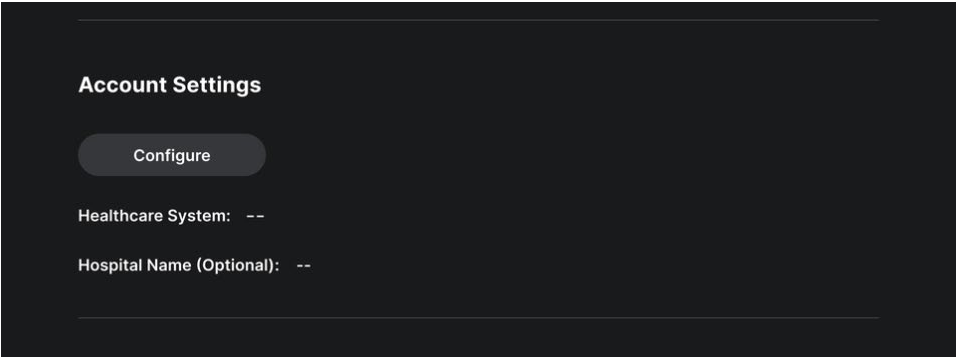


5.7 Network Settings Screen

Account Settings

Account Settings allows the user to configure identifying information specific to the System (e.g., Hospital Name). For information about Account Settings, please refer to the Service Manual.

**IFU Creation Form	
Artwork #: 501145836 Rev. A Component Drawing #: P000021P01	Project information: DC002871/CR20021
Product codes: ETHCM, ETHUSC, ETHCRT	



5.8 Account Settings Screen

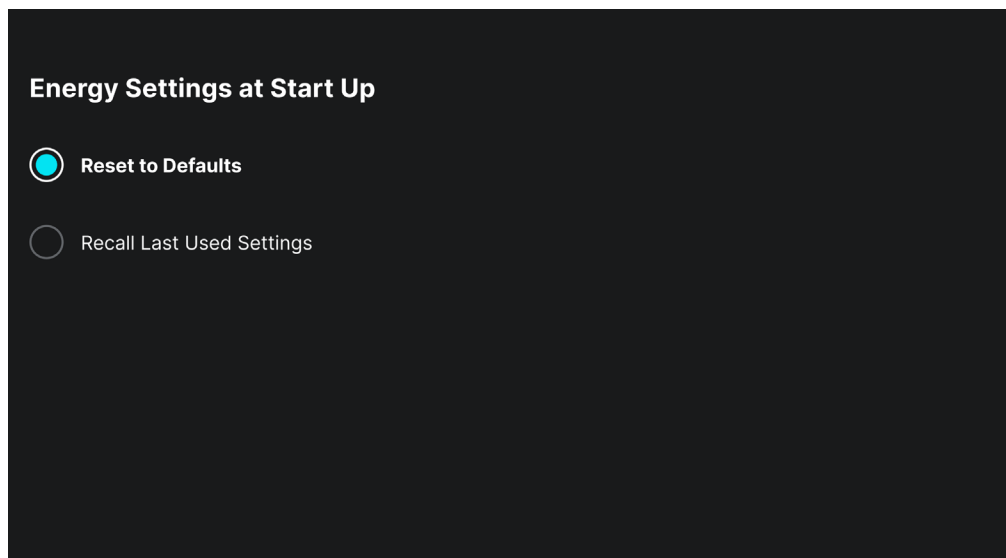
**IFU Creation Form	
Artwork #: 501145836 Rev. A Component Drawing #: P000021P01	Project information: DC002871/CR20021
Product codes: ETHCM, ETHUSC, ETHCRT	

Energy Settings at Start Up

Selecting 'Energy Settings at Start Up' displays options for resetting system settings at the next start-up or recalling the last used energy settings.

- 'Reset to Defaults' option — resets to the default system settings prior to shut down. Power levels will be returned to dashes (no power will be delivered upon activation).
- 'Recall Last Used Settings' option — displays the last used system settings prior to system shutdown.

Note: This will only be displayed if using the Communications Module in conjunction with an Energy Module. The Energy Settings at Start Up feature does not apply to the Advanced Energy port settings.

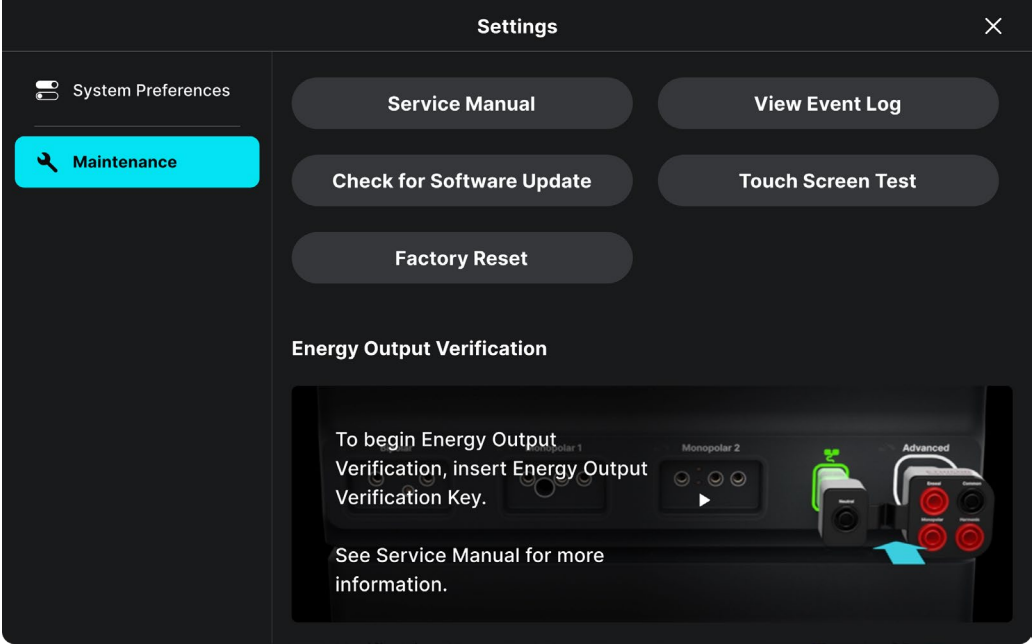


5.9 Energy Settings at Start Up Screen

Maintenance

Selecting the 'Maintenance' icon from the Settings menu provides information and settings for technicians to perform routine maintenance and to access information about errors that may have occurred. Refer to the Service Manual for additional maintenance information.

**IFU Creation Form	
Artwork #: 501145836 Rev. A Component Drawing #: P000021P01	Project information: DC002871/CR20021
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5.10 Maintenance Screen

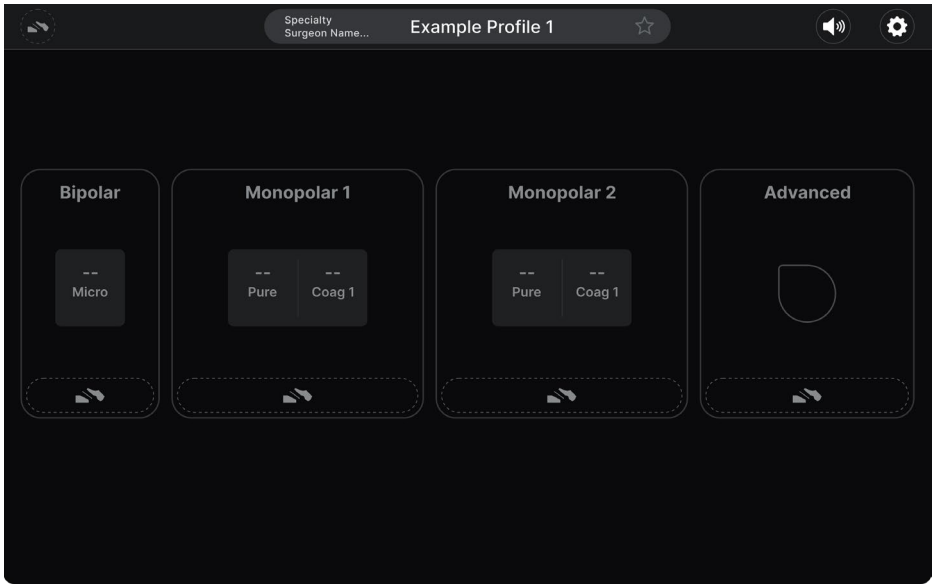
Use the 'X' button in the top right corner to exit out of the Settings menu and return to the previous screen.

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Product codes: ETHCM, ETHUSC, ETHCRT	

6 – Creating a Profile

The System has the ability to create and save Surgeon profiles on the User Screen. Specific profiles can be created based on the connected modules and are used to save settings and preferences for different cases in the Operating Room.

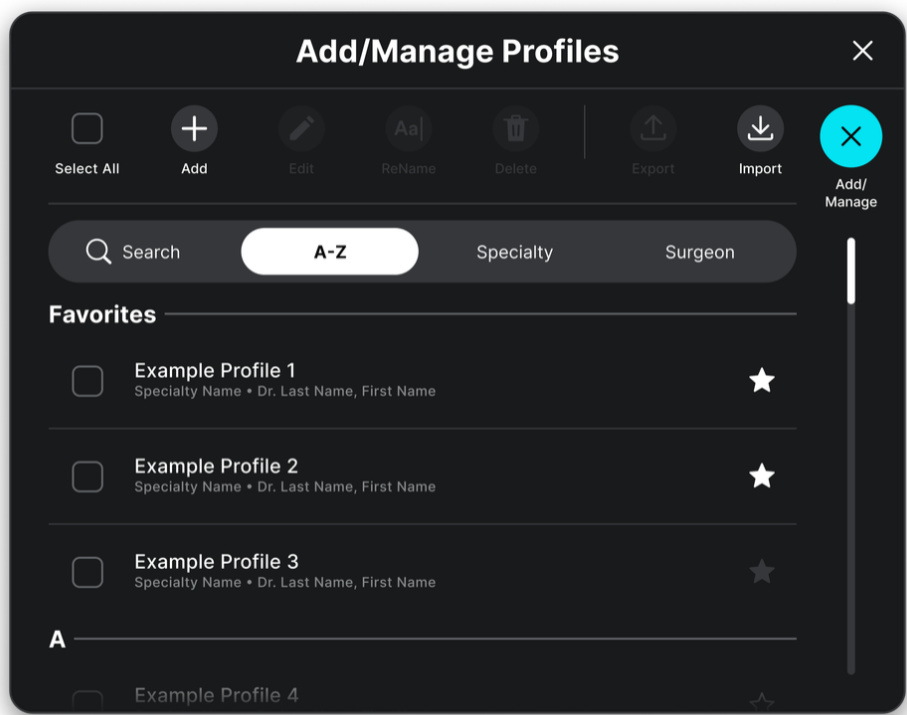
- 1. Tap in the Profile Name field centered at the top of the Main Screen.



6.1 Main Screen

**IFU Creation Form	
Artwork #: 501145836 Rev. A Component Drawing #: P000021P01	Project information: DC002871/CR20021
Product codes: ETHCM, ETHUSC, ETHCRT	

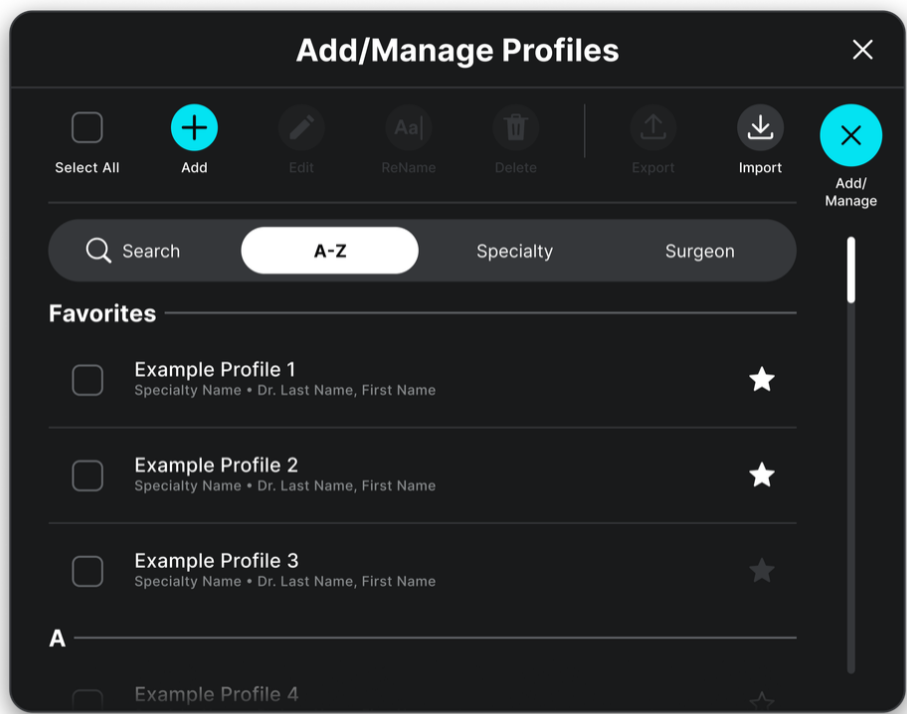
2. Select ‘Add/Manage’ icon above the scroll bar.



6.2 Add/Manage Profiles Screen

**IFU Creation Form	
Artwork #: 501145836 Rev. A Component Drawing #: P000021P01	Project information: DC002871/CR20021
Product codes: ETHCM, ETHUSC, ETHCRT	

3. Select the ‘Add’ icon to create a new profile.



6.3 Add/Manage Profiles Screen – Add New Profile

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Product codes: ETHCM, ETHUSC, ETHCRT	

- The following screen will be displayed to enter profile settings. Refer to the Energy Module and Footswitches Operator's Manual for information on creating and maintaining profiles for use with the Energy Module.

Note: The screen highlights blue when the profile is being edited, as shown below.

The screenshot displays the 'Profile Settings Screen - Double Energy Module Configuration'. The interface features a top navigation bar with a blue background. On the left, there is a 'Cancel' button. In the center, the text 'Specialty Surgeon Name' is followed by 'Untitled Profile' and a pencil icon. On the right, there is a 'Save & Exit' button. Below the navigation bar, the screen is divided into two rows of four panels each. Each panel represents a different energy mode: 'Bipolar', 'Monopolar 1', 'Monopolar 2', and 'Advanced'. The 'Bipolar' panel shows a 'Micro' setting. The 'Monopolar 1' and 'Monopolar 2' panels show 'Pure' and 'Coag 1' settings. The 'Advanced' panel shows a diagram of a footswitch. Each panel has a 'Use Footswitch' toggle at the bottom, which is currently turned on (indicated by a white circle). The entire screen is highlighted in blue, indicating that the profile is being edited.

6.4 Profile Settings Screen - Double Energy Module Configuration

**IFU Creation Form	
Artwork #: 501145836 Rev. A Component Drawing #: P000021P01	Project information: DC002871/CR20021
Product codes: ETHCM, ETHUSC, ETHCRT	

7 - Troubleshooting

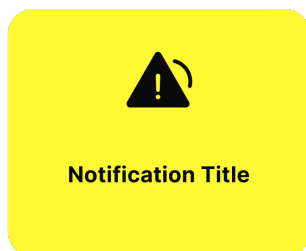
Alarm settings are not adjustable by the operator, nor can priority be reassigned. Alarm settings also do not adjust to operator inputs, nor do they change through power loss. The Power On Self Test (POST) verifies that the Total Energy System is operational. Since the alarms are integrated into the software algorithms responsible for running the appropriate instruments, the POST also verifies alarm operation. Therefore, a separate test for verifying the alarm output is not required. During the POST, an audio tone is emitted from the System so the user can verify that the audio output is operational. Visual output can also be verified through the start-up screens. Alarms and other events are logged in the module. The log is retained after power is removed and can be accessed through the System Settings screen.

Alarm Definitions

The following alarm priorities are used for the System. All alarms stop energy output on the port associated with the alarm, and higher priority alarms will take precedence over lower priority alarms in the event there are multiple triggered alarms. Multiple alarms can be displayed at one time on the User Screen unless all alarms are associated with the same port. If all alarms are associated with the same port, only one alarm will be displayed at a time based on alarm priority. If the alarm or alert is associated with a specific port, the port light will change color to match the notification level, and the notification will appear on the relevant port on the main screen. Additionally, if the alert or alarm is associated with a module, the notification will appear over the ports on the screen and the relevant module's lights will match the color of the notification level.

Low Priority Alarms

Requires surgical staff attention for continued, efficient procedural progress. A low priority issue will not generally progress to a hazardous condition even if not addressed promptly, but it must be addressed to continue the procedure. The User Screen shows a yellow pop-up message with a low priority alarm symbol. A two-tone audio alarm sound accompanies a low priority alarm.

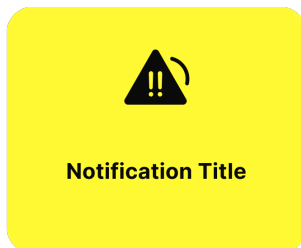


7.1 Low Priority Alarm

Medium Priority Alarms

Requires prompt surgical staff attention to reduce or mitigate a hazardous condition. Ignoring this alarm can result in a serious injury or death. The User Screen shows a flashing yellow pop-up message with a medium priority alarm symbol. A three-tone audio alarm sound accompanies a medium priority alarm. There are currently no medium priority alarm conditions associated with the operation of the Communications Module or User Screen.

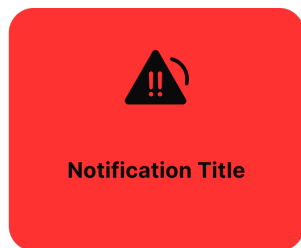
**IFU Creation Form	
Artwork #: 501145836 Rev. A Component Drawing #: P000021P01	Project information: DC002871/CR20021
Product codes: ETHCM, ETHUSC, ETHCRT	



7.2 Medium Priority Alarm

Contact Quality Monitoring (CQM) Alarm

Requires prompt surgical staff attention to reduce or mitigate a hazardous condition. Ignoring this alarm can result in a serious injury or death. The User Screen shows a flashing red pop-up message with a medium priority alarm symbol. A three-tone audio alarm sound accompanies a CQM alarm. There are currently no CQM Alarms associated with the operation of the Communications Module or User Screen as CQM alarms are only associated with energy delivery. For more information on CQM and CQM related alarms refer to the Energy Module Operator's Manual.



7.3 Medium Priority Alarm (CQM Alarm)

High Priority Alarms

There are currently no high priority alarm conditions associated with the operation of the Communications Module or User Screen.

Audio Sound Pressure Levels

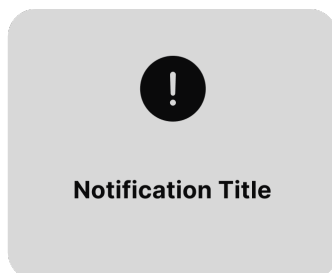
Low Priority Alarms: Within 60–65 dBA (not adjustable)

Medium Priority Alarms: Greater than or equal to 65 dBA (not adjustable)

Alert Notifications

Alerts are a type of information signal that notifies the user of conditions that relate to the patient, equipment, or workflow but are not an indicator of potential harm. The User Screen shows a gray pop-up message with the designated alert. Two quick audio tones accompany an alert. Energy delivery may continue depending on the nature of the alert.

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Product codes: ETHCM, ETHUSC, ETHCRT	



7.4 Alert

Troubleshooting Guidance

The System is designed to assist the user in identifying and correcting failures. When specific conditions are met a notification ID will be shown on the User Interface with the associated alert or alarm icon. Follow the guided, on-screen prompts to address the alarm or alert identified.

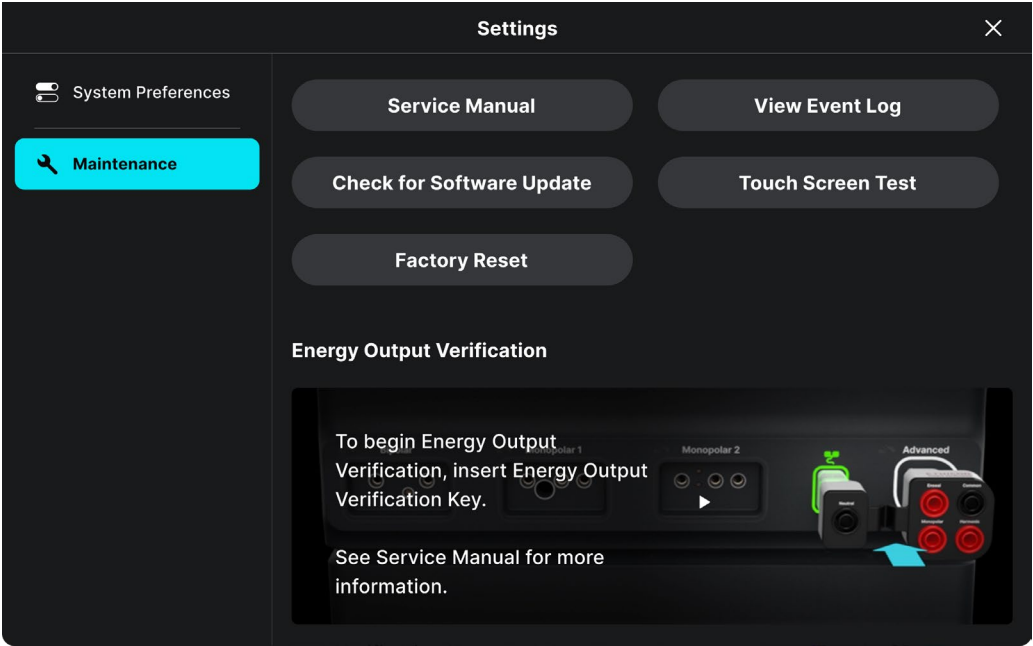
Note: Additional notifications other than the alerts and alarms listed for the Communications Module may be present. Refer to the User Manuals for the additional connected modules for a complete list of possible notifications.

If any of the notifications displayed are not resolved, contact the Ethicon Customer Support Center or your local representative for any customer or technical support. Call 1-877-ETHICON (1-877-384-4266) for support in the US only.

Event Log

Alarms, alerts, and other events are logged within the System. The log is retained after power is removed and is accessed under 'Maintenance' within the Settings feature on the User Screen. There is no reminder signal. The maximum capacity for the event log is 1.5 GB. Once the maximum capacity is reached, new events will override the oldest events stored on the System.

**IFU Creation Form	
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7.5 Settings Screen with View Event Log Icon

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Product codes: ETHCM, ETHUSC, ETHCRT	

Communications Module Alert Notifications

Notification ID	Notification Description	System Behavior	Required User Response
MODU-GEN001	Software Update Required to Use the Module	The System has detected one or more modules upon start-up with a module software version that does not match the currently installed system software version.	The newly added module(s) are not supported by the installed software version. Download and install latest software upgrade.
MODU-GEN004	Communication Module Error	The System has detected an error with the Communications Module connected.	This module may not be used. Contact your Service Department or Ethicon Representative for replacement.
HEAD-CON001	Software Update Error	The System could not complete the software update process.	Contact your Service Department or Ethicon Representative for further assistance.
HEAD-CON002	Data Upload Failure	The System could not complete upload of software update confirmation.	The Total Energy System was unable to complete the upgrade process. Reattempt software upgrade process or skip upload.
HEAD-TBL005	System Error	The System has detected a fault that requires further troubleshooting.	Reference Service Manual for trouble shooting steps. If this does not resolve the error, this module cannot be used and requires service. Contact your Service Department or Ethicon Representative.

**IFU Creation Form	
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Product codes: ETHCM, ETHUSC, ETHCRT	

Notification ID	Notification Description	System Behavior	Required User Response
HEAD-TBL006	Maintenance Required Soon - Clock Battery Low	Upon startup, the System has detected a low clock battery.	This module requires preventative maintenance. Contact your Service Department or Ethicon Representative.
HEAD-CFG002	Invalid Module(s) Detected	The System has detected an invalid configuration upon startup, due to an extra, invalid, or unidentified module.	A module cannot be identified or validated. Instructions on how to resolve system configuration issues can be found in the Service Manual. If issue persists, contact your Service Department or Ethicon Representative.
HEAD-CFG003	No Module(s) Detected	The System has detected an invalid configuration upon startup, due to no modules connected.	Ensure modules are properly connected. Instructions on how to resolve system configuration issues can be found in the Service Manual. If issue persists, contact your Service Department or Ethicon Representative.
HEAD-CFG007	Software/Hardware Conflict Detected	During Initial setup, the System has received a user input indicating there is an issue with the hardware configuration. The System is unusable until correctly configured.	Instructions on how to resolve system configuration issues can be found in the Service Manual. If issue persists, contact your Service Department or Ethicon Representative.
ACCSY-IO001-A	USB Port Error	The System has detected an error on one or more of the back panel USB ports.	Port is unusable. Try restarting the System. If issue persists, contact your Service Department or Ethicon Representative.

**IFU Creation Form	
Artwork #: 501145836 Rev. A Component Drawing #: P000021P01	Project information: DC002871/CR20021
Product codes: ETHCM, ETHUSC, ETHCRT	

Notification ID	Notification Description	System Behavior	Required User Response
ACCSY-IO001-B	Ethernet Port Error	The System has detected an error on the back panel Ethernet port.	Port is unusable. Try restarting the System. If issue persists, contact your Service Department or Ethicon Representative.
ACCSY-IO001-C	Digital Accessory Port Error	The System has detected an error on the back panel Digital Accessory Port.	Port is unusable. Try restarting the System. If issue persists, contact your Service Department or Ethicon Representative.

Communications Module Low Priority Alarm Notifications

Notification ID	Notification Description	System Behavior	Required User Response
HEAD-TBL001	System Restart Required	The System has detected an error that requires restarting the System.	A System Error has occurred. Please restart the Total Energy System. If issue persists, contact your Service Department or Ethicon Representative.
HEAD-TBL002	System Detected Module Error – System Unavailable for Use	The System has detected the presence of a faulty module.	Remove or replace modules and restart System. If the issue persists, contact your Service Department or Ethicon Representative.
HEAD-TBL003	System Power Loss	Power button illuminates red, and nothing is displayed on the User Screen.	Check power cord connections. If the issue persists, contact your Service Department or Ethicon Representative.
HEAD-TBL007	Clock Battery Maintenance Required	The System has detected the clock battery is critically low.	This module requires preventative maintenance and cannot be used until completed. Contact your Service Department or Ethicon Representative.
HEAD-TBL008	Communication Module Error	The System has detected an error in the Communications Module.	Try restarting the System. If issue persists, contact your Service Department or Ethicon Representative.

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Notification ID	Notification Description	System Behavior	Required User Response
SYST-LSE001	System Error	The System detects a fault and has stopped activation.	You may continue using the System by selecting 'Continue' on the screen. If issue persists, contact your Service Department or Ethicon Representative.
SYST-OVH001	Cooling Fan Error	The System has detected loss of operation of the cooling fan(s).	Try restarting the System. If issue persists, contact your Service Department or Ethicon Representative.
SYST-OVH002	Module Overheating	The System has detected one or more modules is overheating.	Check for obstructions to the airflow, including dust, drapes, or other objects. If temperature does not return to operational levels, shut down System and allow to cool. If issue persists, contact your Service Department or Ethicon Representative.
ACCSY-FSW001	Footswitch Port Error	The System has detected an error on one or more of the footswitch ports.	Footswitch Port is unusable. Try restarting the System or using a different Footswitch Port. If issue persists, contact your Service Department or Ethicon Representative.

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8 - Cleaning, Disinfection, Preventive Maintenance and Repair, and System Disposal

Cleaning and Disinfection Instructions

Before cleaning, thoroughly inspect the module(s) for any signs of damage, cracks, or improper mechanical function. Do not use the module(s) if there are signs of damage. Discard and replace module or send module to an authorized Ethicon service facility for repair, where appropriate, if damage or degradation is present.

- Operators in North America should refer to appropriate sections of AORN Standards & Recommended Practices for additional guidance on cleaning. All other localities should refer to appropriate guidelines: e.g., KRINKO-BfArM-Empfehlung zu Anforderungen an die Hygiene bei der Aufbereitung von Medizinprodukten in Germany.
- The operator must qualify cleaning effectiveness when deviating from the instructions in this manual.

Clean the Communications Module, User Screen, and Energy Cart following the hospital protocol and any other applicable local guidelines and regulations. Before cleaning, turn the module main power off and unplug the power cord from the grounded electrical outlet.

Cleaning agents that are indicated for both cleaning and disinfection are recommended for use on the System. CaviWipes disinfecting towelettes were utilized to support the cleaning and disinfection validation activities. Similar products may be used to clean and disinfect the System components.

Disinfectants that demonstrate effective kill against Mycobacterium, fungi, vegetative bacteria, and viruses should be used. Refer to hospital protocol and local guidelines and regulations for requirements of appropriate disinfectant label claims for use. It is important to understand the disinfectant label claims to ensure that contact times are appropriate to meet these requirements.

Any disinfection process including tools and solutions may influence the wear and tear of the device or equipment. In some instances, changing to another disinfectant may be required.

It is recommended that the Communications Module, User Screen, and Energy Cart be cleaned and disinfected between patient use to minimize risk to patients and health care workers.

Communications Module, User Screen, and Energy Cart

WARNING: Spilling or spraying fluids on or into the module, screen, or connectors or immersing the module may result in damage to the device and creates a risk of shock or fire.

Follow the cleaning and disinfection steps below.

1. Pre-clean all surfaces by thoroughly wiping down the System and accessories with unused wipe(s), e.g., CaviWipes disinfecting towelettes, following the manufacturer's instructions.

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2. Inspect the equipment to ensure that all soil, blood, or debris has been removed. If needed, repeat the cleaning steps and re-inspect.
3. Using new unused wipe(s), e.g., CaviWipes disinfecting towelettes, thoroughly wipe down the System and accessories following the manufacturer's instructions for surface contact time to ensure effective disinfection.
4. Follow manufacturer's instructions on required drying time to allow the System and accessory's surfaces to dry.

Other Instruments and Accessories

For other reusable accessories not listed in this manual, consult the appropriate instructions for use for guidance on disinfecting and sterilization, if required.

Maintenance and Repair

Software revision is displayed under System Information on the User Screen.

Periodic calibration is not required for the Communications Module or User Screen.

There are two fuses on the back of the Communications Module which may need to be replaced if the System doesn't power on or stops functioning, even though it is receiving power from a wall outlet. Refer to the Service Manual for information on obtaining and replacing the fuses.

The Communications Module contains a Lithium Coin Cell battery, which is used to power the internal clock. The battery life is approximately 10 years. An alert notification will be displayed if the coin cell battery is low and needs replaced (HEAD-TBL006). Contact your Ethicon Representative for battery replacement.

The Energy Cart has several available replacement parts. Refer to the Service Manual for the Energy Cart spare parts list and contact information for replacement. Once the Energy Cart will no longer support/transport the System or Energy Footswitches, the cart may be disposed of.

Electrical Safety Checks

The facility is responsible for ensuring that the unit has an electrical safety check performed by qualified service personnel at least once a year, as per the respective service manual.

WARNING: Do not operate the Communications Module with the cover removed. Removing bottom screws or opening of this device invalidates the warranty and could create hazardous conditions.

Disposing of Communications Module, User Screen, and Energy Cart (Environmental Protection)

The Communications Module, User Screen, and cart must not be disposed of at the end of life with other waste. To recycle waste equipment, obtain instructions from the Ethicon Customer Support Center. Call 1-877-ETHICON (1-877-384-4266) for support in the US or contact your local representative to discuss local waste

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disposal solutions and processes. The Communications Module and User Screen pose disposal risks similar to consumer electronics such as computers.

China RoHS Table of Toxic and Hazardous Substances and Elements

Component	Toxic and Hazardous Substances and Elements					
	Lead (Pb)	Mercury (Hg)	Cadmium (Cd)	Hexavalent Chromium (Cr(VI))	Polybrominated biphenyls (PBB)	Polybrominated diphenyl ethers (PBDE)
Washers and screws	O	O	O	O	O	O
Panels	O	O	O	O	O	O
Displays	O	O	O	O	O	O
Printed Circuit Boards	X	O	O	O	O	O
Wiring harnesses	X	O	O	O	O	O
Power Supply	O	O	O	O	O	O
Foot Assembly	X	O	O	O	O	O
Heat Sinks	O	O	O	O	O	O
Enclosure – Top	O	O	O	O	O	O
Enclosure - Bottom	O	O	O	O	O	O
Cable Ties	O	O	O	O	O	O
Tape	O	O	O	O	O	O
Flex Ribbons	O	O	O	O	O	O
Fuses	O	O	O	O	O	O
Gaskets	O	O	O	O	O	O
Fan	X	O	O	O	O	O
Power cord	X	O	O	O	O	O
Barbed Inserts	X	O	O	O	O	O
Note: O = omitted and X = substance present						

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9 - Conformance to Standards

The Total Energy System conforms to the following international standards:

EN (IEC) 60601-1 (with Canadian and US National Deviations)	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
EN (IEC) 60601-1-2	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
EN (IEC) 60601-2-2	Medical electrical equipment - Part 2-2: Particular requirements for the safety of high frequency surgical equipment
EN (IEC) 60601-1-8	Medical electrical equipment - Part 1-8: General Requirements for basic safety and essential performance - Collateral standard: General requirements, tests, and guidance for alarm systems in medical electrical equipment and medical electrical systems

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10 - System Specifications

Main Fuses	2 each: T 15 AH, 250 V used for 100 V – 127 V Application (Time-delay, Cartridge Style, High Breaking Capacity, 5x20 mm package size) 2 each: T 10 AH, 250 V used for 220 V – 240 V Application (Time-delay, Cartridge Style, High Breaking Capacity, 5x20 mm package size) Review fuse label on the back of the unit to confirm which fuse is installed.
Degree of Protection Against Electric Shock	No applied parts, see Energy Module Operator's Manual for applied parts
Class of Protection Against Electric Shock	Class I
Ingress Protection – Total Energy System	IP21
Main Input	Nominal Operating Voltage: 100 VAC – 240 VAC Nominal Operating Frequency: 50 Hz – 60 Hz Rated Input Power: 1200 VA
External Connections – USB	4 – USB 5Gbps Only USB Mass Storage Devices with DOS based filesystems (FAT, FAT16 or FAT32) are supported for read/write. Filesystems such as exFAT, NTFS, APFS, HFS+ are not supported. Not intended for cable connected USB, only fixed dongle type USB devices
External Connections – Ethernet	Connection Speed: 100/1000 Mbps Standards: IEEE 802.3u, IEEE 802.3ab

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External Connections – Energy Signal Port	2.5 mm mono jack
Ambient Operating Conditions	Temperature: 10°C – 40°C Humidity: 20% – 85% RH non-condensing Atmospheric Pressure: 700 hPa – 1060 hPa
Transport and Storage Conditions	Temperature: -25°C – +70°C Humidity: 10% – 95% RH non-condensing Atmospheric Pressure: 700 hPa – 1060 hPa Keep dry Keep away from heat
Weight	User Screen: 1.8 kg Communications Module: 5.7 kg Cart: 43.1 kg
Overall Dimensions	User Screen: 29.7 x 9.6 x 19.7 cm Communications Module: 38.1 x 42.6 x 9.8 cm Cart: 57.7 x 50.8 x 112.7 cm
Cart Weight Capacity	Total Cart Weight & Safe Working Load: 95 kg (208 lbs.) Cart Safe Working Load: 50.35 kg (111 lbs.) Maximum Shelf Capacity: 43.1 kg (95 lbs.)

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Power Cord	North American removable power cord set with the following characteristics: Plug Style: NEMA 5-15P (Hospital Grade, Clear) Receptacle: IEC 60320 C13 with straight non-angled cord entry Cord Length: 4.6 meters nominal Current Rating: 15 A Voltage Rating: 125 VAC minimum Wire Gauge: 14 AWG Wiring Code: North American Jacket Type: SJT/SJTW (UL) or SJT/SJTW (CSA) Jacket Color: Gray Agency Approvals Required: UL and CSA International removable power cord set with the following characteristics: Plug Style: as needed by particular country requirements Receptacle: IEC 60320 C13 with straight non-angled cord entry Cord Length: 2.44 – 4.57 meters nominal Power Cord Ratings: • 100 V – 127 V: 125 V minimum/15 A minimum • 220 V – 240 V: 250 V minimum/10 A minimum Minimum conductor cross-sectional area: 1.0 mm² copper Wiring: International Cordage Type: HAR Cordage Item to have certification by at least one of the following agencies: VDE, ASTA, SEMKO, KEMA, LCIE, DFT, IMQ, SEV
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Ethernet Cable	Plug Style: RJ45 Male (Both Sides) Cable Standard: Cat5e, Cat6, Cat6a, or Cat7 Cable Type: Shielded - F/UTP (Foil shield with Unshielded Twisted Pairs), S/UTP (braid Shielded with Unshielded Twisted Pairs), FTP (overall Foil shield with Twisted Pairs), STP (overall braid Shield with Twisted Pairs), S/STP (Shielded with Shielded Twisted Pairs), F/FTP (Foiled with Foil shielded Twisted Pairs), or S/FTP (Shielded with Foil shielded Twisted Pairs) Wire Gauge: 26 AWG Minimum Length: 15 feet Color: Black
IT Network Requirements	The Purpose of the Ethernet is for software upgrades, event log uploads, or provisioning. Software upgrades are downloaded by the user, such as facility service personnel, from DSP. These packages are encrypted and signed. Event log uploads must also be enacted by user, such as facility service personnel. If the IT Network were to fail during a software upgrade or event log upload, no hazardous situations would be presented. Network Characteristics: 802.3 1000BASE-T Required Configurations: DHCP, Static Configurations Technical Specifications: DSP - utilize TLS 1.2 During clinical modes, all Ethernet ports are disabled and there is no connectivity to the device.

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 E536052	Underwriters Laboratory classified mark (symbol) for Canadian and US standards. MEDICAL – APPLIED CURRENT/ENERGY EQUIPMENT AS TO ELECTRICAL SHOCK, FIRE AND MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH AAMI ES60601-1:2005/ (R)2012 and A1:2012/(R)2012 and A2:2021, CAN/CSA-C22.2 No. 60601-1:14 (Reaffirmed 2022), IEC 60601-2-2:2023
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Alarm Audio Frequencies

Alarm Type	Tone(s)	Duration	Volume
Alert	329 Hz $\pm$ 1%	One 100 msec tone, 50 msec of silence, one 90 msec tone followed by 1040 msec of decay	* $\geq$ 60 dBA
Low Priority Alarm	293 Hz $\pm$ 1% 329 Hz $\pm$ 1% 587 Hz $\pm$ 1% 660 Hz $\pm$ 1% 1175 Hz $\pm$ 1% 1318 Hz $\pm$ 1%	Two 400 msec tones with 98 msec in between	
Medium Priority Alarm & CQM Alarm	440 Hz $\pm$ 1% 587 Hz $\pm$ 1% 660 Hz $\pm$ 1% 880 Hz $\pm$ 1% 1175 Hz $\pm$ 1% 1318 Hz $\pm$ 1%	Three 200 msec tones with 98 msec in between	* $\geq$ 65 dBA

*The volume of the activation signals can be adjusted up and down. They have a minimum volume of 55 dBA measured from the rear of the System at a distance of 1 meter. The alarm and alert volume is $\geq$ 60 dBA for alerts and low priority alarms and $\geq$ 65 dBA for medium priority alarms at a distance of 1 meter.

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11 - Electromagnetic Compatibility (EMC)

The Total Energy System requires special precautions regarding electromagnetic compatibility (EMC) and must be installed and used in accordance with the EMC information provided in this guide. The Total Energy System is intended for use in the electromagnetic environments specified below.

Caution: Ensure that the Total Energy System is used only in these environments. Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operations. If such use is necessary, this equipment and the other equipment should be observed in the configuration in which it will be used to verify normal operation.

Cable Characteristics Utilized for EMC Compliance

The Total Energy System was performed with the following cabled accessories for demonstration of EMC compliance. Refer to the Energy Module Operator's Manual for the associated cables/accessories used for the Energy Module.

Model	Description	Port	Shield	Length	Tests
17970 8	Volex, AC Mains Cable/Power Cord, 14 Gauge, 15 A	Mains	No	20 ft (6.1 m)	Emissions Immunity
BM-6ASG015F	Bel, Ethernet Cable	Public Network Ethernet	Yes	15 ft (4.6 m)	Emissions Immunity
ETHEF2	Ethicon, Energy Double Footswitch	Footswitch	Yes	12 ft (3.7 m)	Emissions Immunity
2255JTES	MEGADYNE™ Energy Signal Cable	Energy Signal	No	10 ft (3.0 m)	Emissions Immunity

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Electromagnetic Emissions

The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required), this equipment may not offer adequate protection to radio frequency communication services. The user may need to take mitigation measures, such as relocating or re-orienting the equipment.

Emissions Test	Compliance	Guidance
CISPR 11 RF Emissions	Group 1	When not delivering RF Energy to the patient, the Total Energy System uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
		When delivering High Frequency (HF) RF Energy to the patient, temporary interference in nearby electronic equipment may occur. (Note 1)
CISPR 11 RF Emissions	Class A	The Total Energy System is suitable for use in a Professional Health Care facility environment and is not suitable for use in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
IEC 61000-3-2 Harmonic emissions	Class A	N/A
IEC 61000-3-3 Voltage fluctuations/flicker emissions	Complies	N/A

Note 1: Per IEC 60601-2-2, Clause 202: HF surgery is a very long-established modality with known interference inherent during activation. Since the clinical benefits of HF SURGICAL EQUIPMENT outweigh the RISKS of interference and since HF SURGICAL EQUIPMENT is normally operated for short periods only, this type of equipment is exempt from the EMISSIONS requirements of IEC 60601-1-2, 7.1.2 when the HF output is energized.

HF SURGICAL EQUIPMENT performs its CUTTING and COAGULATION functions through the use of radio frequency energy, and HF EMISSION frequently much above the CISPR 11 limits is present. The power levels and harmonic content of the output of the HF SURGICAL EQUIPMENT are necessary to enable the HF SURGICAL EQUIPMENT to carry out its clinical function effectively.

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Electromagnetic Immunity Guidance

For electromagnetic immunity, basic safety is:

- No energy output without activation switch closure
- Activation tones are coupled with energy output
- Energy output power in excess of 10% of the rated output power is within +/- 20% of nominal
- Energy output ceases when activation switches are opened

IEC Immunity Test	IEC 60601-1-2 Test Level	Compliance Level (Note 1)	Electromagnetic Environment-Guidance
61000-4-2 Electrostatic Discharge (ESD)	±8 kV Contact ±2,4,8,15 kV Air	A	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
61000-4-4 Electrical fast Transient/Burst	±2 kV, 100 kHz on Mains ±1 kV, 100 kHz on I/O	A	Mains power quality should be that of a typical hospital environment.
61000-4-5 Surge	±0.5,1 kV Line to Line ±0.5,1,2 kV Line to Earth	A	Mains power quality should be that of a typical hospital environment.
61000-4-8 Power Frequency Magnetic Fields	30 A/m	A	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical hospital environment.
61000-4-11 Voltage Dips and Interruptions	1) 0% U_T ; 0.5 cycle at 0, 45, 90, 135, 180, 225, 270, 315° 2) 0% U_T ; 1 cycle at 0° 3) 70% U_T ; 25/30 cycles at 0° 4) 0% U_T ; 250/300 cycles at 0°	1) B 2) B 3) C 4) C	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Total Energy System requires continued operation during power mains interruptions, it is recommended that the Total Energy System be powered from an uninterruptible power supply or a battery.

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IEC Immunity Test	IEC 60601-1-2 Test Level	Compliance Level (Note 1)	Electromagnetic Environment-Guidance
61000-4-3 Radiated RF	3 V/m, 80 MHz to 2.7 GHz 27 V/m, 385 MHz 28 V/m, 450 MHz 9 V/m, 710 MHz 9 V/m, 745 MHz 9 V/m, 780 MHz 28 V/m, 810 MHz 28 V/m, 870 MHz 28 V/m, 930 MHz 28 V/m, 1720 MHz 28 V/m, 1845 MHz 28 V/m, 1970 MHz 28 V/m, 2450 MHz 9 V/m, 5240 MHz 9 V/m, 5500 MHz 9 V/m, 5785 MHz	A	Portable RF communications equipment that are not part of the System (including peripherals such as antenna cables and external antennae) should be used not closer than 12 inches (30 cm) to any part of the System including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
61000-4-6 Conducted RF	3 Vrms, 150 kHz to 80 MHz 6 Vrms in ISM bands: - 6.765 MHz to 6.795 MHz - 13.553 MHz to 13.567 MHz - 26.957 MHz to 27.283 MHz - 40.66 MHz to 40.70 MHz	A	
61000-4-39 Proximity Magnetic Field	65 A/m, 134.2 kHz 7.5 A/m, 13.56 MHz	A	N/A

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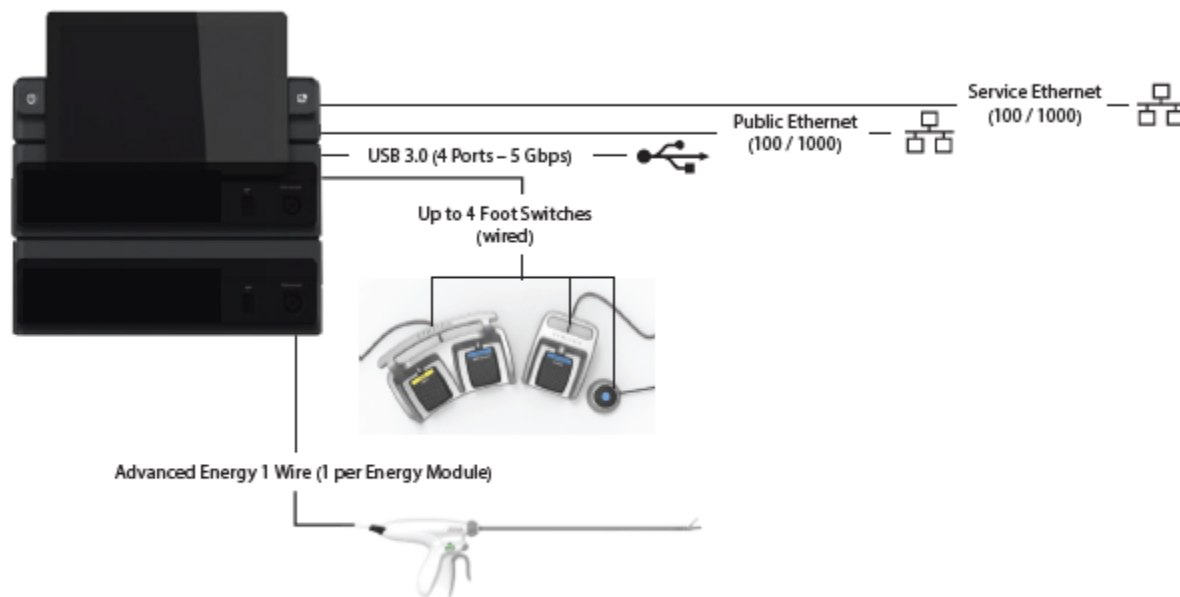
IEC Immunity Test	IEC 60601-1-2 Test Level	Compliance Level (Note 1)	Electromagnetic Environment-Guidance
Note 1: Compliance Levels as defined by IEC 60601-1-2 unless otherwise noted. Definition of compliance as follows: A) Performance Unaffected. B) Self-recovery occurs within 1 second, and operator may reactivate energy as required in response to 0% U_T for 0.5 cycle or 1 cycle Voltage Dips and Interruptions. C) Basic Safety is maintained. Functionality may become disabled, halted, or shutdown. Operator intervention may be required to power cycle and/or reconfigure System. Power cycling of System may consume up to 80 seconds.			

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Appendix A – Cybersecurity Guidance

Key Security Features

- Secure boot process
- Encrypted data at rest and in transit
- Hardware physical protections
- Digitally signed code
- Ongoing security threat monitoring
- Software upgrades
- Signed Certificates



Cybersecurity System Diagram

Cybersecurity System Diagram

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System Interfaces

Port	Direction	Function	Destination Endpoint
Advanced Energy	Bidirectional	Instrument Communication	ETHICON™ Total Energy System
Foot Switch	Input	Energy Activation	ETHICON™ Total Energy System
USB (4x)	Bidirectional	Software Upgrades Event Log Download User Profile Configuration	ETHICON™ Total Energy System
Service Ethernet	Bidirectional	Service Operations	Johnson & Johnson Customer Service
Public Ethernet	Bidirectional	Software Upgrades Event Log Download Johnson & Johnson Portal Communication Certificate Management Time Management	Johnson & Johnson Customer Portal Server Johnson & Johnson Certificate Authority Server Network Time Protocol Server (Selected by User)

Recommended Infrastructure Requirements

Control and monitor physical access to the ETHICON™ Total Energy System. Proper physical security is necessary to prevent tampering of the System. The network topology should be used to limit network access. This will ensure that interruptions to connectivity are minimized. Ensure regular anti-malware scanning is performed for the hospital system(s) on the network to which ETHICON™ Total Energy System is connected.

The ETHICON™ Total Energy System can operate as a stand-alone unit or connected to the internet through the Public 100/1000 Ethernet port. When connecting to the internet, the System uses TLS 1.3 when interfacing with the Johnson & Johnson online portal and certificate authority server. Unconnected systems are upgraded through USB communications utilizing encrypted upgrade files.

Software Bill of Material (SBOM)

The ETHICON™ Total Energy System SBOM may be requested by contacting customer service.

Software Update and Notification

The authorized user for the ETHICON™ Total Energy System will be notified when updated software is available.

Refer to the Service Manual for information on how to update the software.

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Security Event Notification

The ETHICON™ Total Energy System monitors system integrity to maintain system safety and effectiveness. The user will be notified, and the System log updated with any of the following system events.

Security Event	User Notification
Software and Hard Drive Authentication Failure	Low Alarm
Encryption Failure	Low Alarm
Decryption Failure	Low Alarm
Trust Store Verification Failure	Alert
Module Update Failure	Alert
Tamper Detection	Low Alarm
Real Time Clock Authentication Failure	Low Alarm
Real Time Clock Signal Loss	Low Alarm

Contact the Ethicon Customer Service Department or your local representative for technical support related to these security events.

Critical Functionality Protections

The ETHICON™ Total Energy System protects system integrity starting with a secure boot process. Data is encrypted both at rest and in transit. Hardware is selected to resist physical and side channel attacks. The System monitors for hardware and software tampering. Public network communications are suspended during clinical operation.

The ETHICON™ Energy firmware and software are monitored for vulnerabilities on an ongoing basis. Upgrade files are digitally signed to ensure authenticity and encrypted for transmission to the unit.

Backup and Restore

The ETHICON™ Total Energy System may be factory reset by an authenticated user. The System must be connected to the internet for authentication to be completed. Before initiating factory reset, user profiles should be exported to a USB drive or the Johnson & Johnson customer portal.

Refer to the Service Manual for information on how to complete a Factory Reset. Contact the Ethicon Customer Service Department or your local representative for technical support.

Device Configuration Recovery

User profiles may be imported after factory reset. Refer to the Energy Module Operator's Manual for information on how to import user profiles.

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Wireless Information

Federal Communications Commission:

This system supports an IEEE 802.11 a/b/g/n/ac WLAN interface.

- Specific Wi-Fi Standards supported
 - IEEE 802.11a, 802.11b, 802.11d, 802.11e, 802.11g, 802.11h, 802.11i, 802.11n, 802.11r, 802.11ac, 802.11w, 802.11k, 802.11v
- Supported Data Rates:
 - 802.11b (DSSS, CCK) 1, 2, 5.5, 11 Mbps
 - 802.11a/g (OFDM) 6, 9, 12, 18, 24, 36, 48, 54 Mbps
 - 802.11n (OFDM, HT20/HT40, MCS 0-15)
 - 802.11ac (OFDM, HT20, MCS0-8; OFDM HT40/HT80, MCS 0-9)

This equipment was tested and found to comply with the limits for a Class A digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

CAUTION: Any changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate this equipment.

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

Radiation Exposure Statement

This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment. This equipment should be installed and operated with a minimum distance of 20 centimeters between the radiator

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and your body. This transmitter must not be co-located or operated in conjunction with any other antenna or transmitter. Country Code selection feature to be disabled for products marketed to the US/CANADA.

Contains FCC ID: SQG-SU60SOMC

Listed under FCC ID: 2BDJP-ETHCM12

Industry Canada:

This device contains licence-exempt transmitter(s)/receiver(s) that comply with Innovation, Science and Economic Development Canada's licence-exempt RSS(s). Operation is subject to the following two conditions:

- This device may not cause interference; and
- This device must accept any interference, including interference that may cause undesired operation of the device

This equipment complies with Canada radiation exposure limits set forth for an uncontrolled environment. This equipment should be installed and operated with minimum distance 20 cm between the radiator and your body.

Contains IC ID: 3147A-SU60SOMC

Listed under IC ID: 28152-ETHCM12

Bluetooth

The system includes a Bluetooth 5.1 interface supporting data rates up to 3 Mbps

WARNING: RFID, WiFi, and Bluetooth function may be interfered with by other equipment even if that other equipment complies with CISPR emission requirements.

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Security:

WPA2/WPA3

FIPS 140-2 Validated

Security Configuration

The ETHICON™ Total Energy System security configuration is pre-configured and has no user adjustable features. Third party utilities cannot be installed and are not necessary to ensure system functionality. Public Ethernet communications are paused during clinical operation to minimize potential clinical disruptions. Service ethernet will only communicate with Johnson & Johnson authenticated services.

Event Log

Security events are recorded on the System event log and may be viewed through the Maintenance function. Events are retained until overwritten due to storage limitations or factory reset. The event log proprietary format is not intended for analysis by third party software. Contact the Ethicon Customer Service Department or your local representative for support related to the event log.

Cybersecurity Vulnerability or Incident Response

The ETHICON™ Total Energy System monitors the System for alteration. Any alteration to the software will prevent the System from operating. If you believe you have identified a potential security vulnerability, access productsecurity.jnj.com to review our disclosure and response processes.

System Decommissioning

To decommission the System, select the factory reset feature from within the maintenance function. Once factory reset is complete, remove the SD card from the system. The SD card may be sanitized through physical destruction or erasure. Refer to the Service Manual for information on how to complete a factory reset.

Contact the Ethicon Customer Service Department or your local representative for technical support.
1-877-ETHICON (1-877-384-4266) in US only
+1-513-337-8901 (English)

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Appendix B – Symbols

	Catalogue number
	Caution
	Date of manufacture
	Manufacturer/Date of Manufacture
	Authorized representative in the European Community/European Union
	Humidity limitation
	Temperature limit

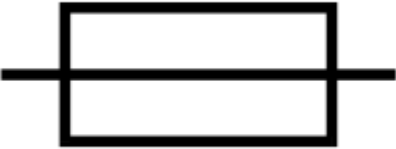
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	Keep away from heat
	Keep dry
	Non-sterile
	Caution: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.
	Serial number
	Batch code
	Unique Device Identifier

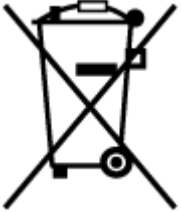
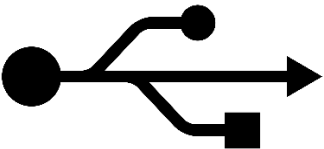
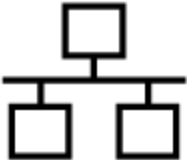
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	Packaging unit
	Refer to instruction manual/booklet (blue color represents a mandatory action)
 www.e-ifu.com EU: +800 8888 2020 EU: +32 2 4037222	Consult instructions for use or consult electronic instructions for use. EU: Call paper on demand help desk to get paper copies free of charge within 7 days.
	Medical Device
	Indicates that the Electrical and Electronic Product (EEP) contains toxic and hazardous substances or elements over the defined maximum concentration values. The names and content of the toxic and hazardous substances or elements shall be provided in the Chinese product instruction manual. The number "50" in the symbol refers to the environment-friendly use period; after their environment-friendly use period expires, they shall be put into the recycling system (People's Republic of China symbol for Restriction of Hazardous Substances (RoHS) in electrical and electronic products).

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	Fuse
	Equipotentiality
	Footswitch
	Non-ionizing electromagnetic radiation
	Mass; weight
IP21	Protection against solid ingress > 12mm gap for entry and Protection against vertically dripping water

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	Separate Collection
	Separate Collection
	NFC Reader – For use with compatible NFC-enabled products.
	USB Port
	Stand-by
	Ethernet port

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	Cutting Mode (GEM)
	Cutting Mode (Blend)
	Cutting Mode (Pure)
	Coagulation Mode (Coag 1)
	Coagulation Mode (Coag 2)
	Coagulation Mode (Soft Low)
	Coagulation Mode (Soft Medium)

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	Coagulation Mode (Soft High)
	Coagulation Mode (Spray)
	Bipolar Mode (Macro)
	Bipolar Mode (Micro)
	Maximum (Energy Button) for HARMONIC™ Devices
	Minimum (Energy Button) for HARMONIC™ Devices
	Advanced Hemostasis for HARMONIC™ Devices

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	Drag and drop
	Touch
	Low Priority Alarm
	Medium Priority Alarm

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	Alert
	Product Information
	Backward erase
	Return
	Change keyboard case

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	Selection; affirmative acknowledgement; success; ACK
	Language
	Hide keyboard
	Increase or Add
	Decrease or Minimize
	Exit/close
	Advanced Settings

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	High Volume
	Low Volume
	Settings
	System Preferences
	Maintenance
	Delete
	Edit

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	Rename
	Add/Manage Profiles
	Export
	Import or Download
	Search
	Favorited
	Not Favorited

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	Ready (finished); acknowledgement
	Shows the direction of an action and expands/contracts lists.
	Directional screen navigation
	Undo
	Save Profile
	Negative acknowledgement; failure
	Top Module

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	Bottom Module - double configuration
	Bottom Module
	Low Brightness
	High Brightness
	Date Picker
	Time
	Refresh

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	The Federal Communications Commission regulates interstate and international communications by radio, television, wire, satellite, and cable in all 50 states, the District of Columbia and U.S. territories.
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REF

ETHCM, ETHUSC, ETHCRT

EC REP

Johnson & Johnson Medical GmbH
Robert-Koch-Strasse 1
22851 Norderstedt
Germany



Ethicon Endo-Surgery, LLC
475 Calle C
Guaynabo, PR 00969 USA
1-877-ETHICON
+1-513-337-8901 (English)

CE 0123

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PRODUCT CODE	PART	ARTWORK DOCUMENT	TEMPLATE NUMBER	INK R-SPEC NUMBER	ETHICON™	CONFIDENTIAL : NOT TO BE REPRODUCED OR USED IN ANY WAY WITHOUT WRITTEN ETHICON
ETHCM, ETHUSC, ETHCRT	501145963	501145836 Rev. A	P000021P01 (T)	N/A		

Black