Johnson&Johnson MedTech

Energy



Surgical Energy, Simplified.

The DUALTO™ Energy System

Meet the next chapter of surgical energy delivery.
A new level of operating room efficiency for enhanced patient care.

The ETHICON™ Total Energy System is now referred to as the DUALTO™ Energy System, with no changes to its intended use, design, performance, or regulatory status under FDA 510(k) K243067.

Challenges in the OR

The impact of current generators on surgical workflow and patients.

Multiple energy generators and other capital systems take up valuable OR space, create inefficiencies during setup and use, and can impact cases due to complex troubleshooting, varying levels of staff experience, and device reconfiguration disruptions.

Space in the OR

- Current setups with multiple energy generators and other capital systems take up valuable OR space.

Setup Delays and Stress

- Setup of multiple systems creates pre-op inefficiencies and stress.
- Streamlined OR setup could help minimize stress levels for surgeons and their clinical teams in the OR.[3A]

Surgical Inefficiencies

- Using multiple energy generators during surgery can increase complexity and disruptions.
- Some surgical teams can spend up to 6 minutes per procedure trying to resolve generator issues.[1A]
- 82% of surgeons surveyed say generator troubleshooting sometimes or frequently impacts surgical flow.[2A]



Claims in this brochure were generated from a global usability study where surgeons (n=38) and nurses (n=39) completed simulated procedures in a porcine model using the DUALTO™ Energy System, where they could assess tissue effects, hemostasis, and workflow. They then rated statements about the generator's performance in comparison to what they are using today with Acceptable, Acceptable with Comments, or Not Acceptable. There will be a post-market clinical follow-up study after the product has received regulatory approval generating actual clinical performance data that will be used to update these claims.

1. In a pre-clinical summative usability study, with surgeons (n=33), that went through an end-to-end procedure and afterward responded to a series of statements regarding the DUALTO™ Energy System (7/33).
2. In a pre-clinical summative usability study, with surgeons (n=33), that went through an end-to-end procedure and afterward responded to a series of statements regarding the DUALTO™ Energy System (27/33).
3. In a pre-clinical summative usability study, with surgeons (n=33), that went through an end-to-end procedure and afterward responded to a series of statements regarding the DUALTO™ Energy System (32/33 agree).

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Introducing the DUALTO™ Energy System

Designed to deliver a new level of OR efficiency for enhanced patient care.

The DUALTO Energy System combines multiple energy modalities into a single system that is simple to use across procedures, configurable to different care settings, and is easily upgradable.[1B]

Unified Energy System

Multiple energy modalities in one, consolidated system – monopolar, bipolar, advanced bipolar, and ultrasonic.

Upgradable and Connected

Designed for cloud-based software updates and system diagnostics through built-in communication technologies.

Elevated User Experience

User-centric interface provides surgeons custom energy settings via surgeon profiles. Provides guided steps for generator setup and troubleshooting.



Standard Bipolar

Standard Monopolar

Advanced Energy Port powers HARMONIC™ and ENSEAL™ devices

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Consolidating Capital Equipment in the OR

Fewer generators required to support complex procedures vs. separate systems.

Up to 46%

less footprint vs. separate generators.[1C]

Common System Configurations

Two power cords for two separate outlets required for common system configurations.



GEN11 and Erbe VIO® 3



GEN11 and Valleylab™ FT10



GEN11 and MEGEN1

DUALTO™ Energy System

Single power cord for all energy modalities compared to multiple.



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1. In a R&D study measuring stacked volume of the DUALTO™ Energy System and current generator systems in the market. For any stacked generator measurements, the largest length and widths of one unit with the combined height of both units was measured. Measurements compare a Double DUALTO™ Energy System with two Energy Modules to four current systems stacked. A Single DUALTO™ Energy System with one energy module is up to 23% less footprint compared to two current systems stacked. Footprint defined as the volume of space, either potential floor or boom space, taken up by energy generators

Configurable to OR Needs

Easily add an additional Energy Module for simultaneous energy activation.

Communications Module

One Communications Module controls a single or double DUALTO™ Energy System.

The Communications Module has forward-looking technology installed, such as Wi-Fi, Bluetooth, and NFC, to enable future innovation.

Energy Module

Consolidation of energy modalities in an Energy Module reduces the OR space taken up by equipment.

Flexible architecture enables two Energy Modules to be powered by one Communications Module in a single system.



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Streamlining Setup

Single interface simplifies the user experience.

Step-by-step guidance enables setup and connection to multiple energy modalities.

Touchscreen energy setting adjustments and drag-and-drop footswitch assignment improves ease and speed of the procedure setup.





Personalized surgeon profiles for specific procedures and devices.

Each DUALTO™ Energy System can store up to 100 unique surgeon profiles that save energy settings by surgeon and procedure type. These profiles can be easily exported.





70% of surgeons think the use of surgeon profiles in DUALTO could reduce the risk of errors.[1A]

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1. In a pre-clinical summative usability study, with surgeons (n=33), that went through an end-to-end procedure and afterward responded to a series of statements regarding the DUALTO™ Energy System.

Maximizing Intra-op OR Efficiencies

76% of surgeons think DUALTO™ Energy System provides the most surgical flexibility of any energy system.[1A]

Simultaneous Energy Delivery

DUALTO is the only generator on the market that supports two surgeons activating energy simultaneously, supporting surgeons in complex procedures and improving OR efficiency.



Actual users delivering simultaneous energy on the DUALTO system in a pre-clinical lab.

Powerful Sealing

DUALTO uses Adaptive Tissue Technology to power HARMONIC™ and ENSEAL™ X1 devices. Adaptive Tissue Technology responds to changing tissue conditions, enabling more precise energy delivery and improved temperature management.[3D]

In addition to standard monopolar modes, DUALTO powers a proprietary Geometric Electron Modulation (GEM) monopolar mode that requires no power adjustments to maintain a scalpel-like cut through varying tissue types with minimal thermal damage.[4E]

1. In a pre-clinical summative usability study, with surgeons (n=33), that went through an end-to-end procedure and afterward responded to a series of statements regarding the DUALTO™Energy System.
2. In a pre-clinical summative usability study, with surgeons (n=29), that went through an end-to-end procedure and afterward responded to a series of statements regarding the DUALTO™ Energy System.
3. vs. HARMONIC ACE™ without Adaptive Tissue Technology.
4. Based on proprietary GEM Technology and pre-clinical porcine testing on abdominal wall dermis that measured thermal damage via histology ($p<0.05$). GEM Technology and test results are achieved when used on the MEGADYNE™ Mega Power generator in GEM Mode only.

Faster Intraoperative Troubleshooting

Lighted displays, auditory cues, and guided steps for troubleshooting enable clear feedback that can be seen from any position in the surgical field.

DUALTO detects and clearly communicates Patient Return Electrode Errors, HARMONIC™ Blade Errors, and ENSEAL™ Metal in Jaw Errors.





90%

of surgeons think DUALTO might reduce the medical staff stress level during surgery by improving diagnostics and equipment troubleshooting.[2A]

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Saving Post-op Troubleshooting Time

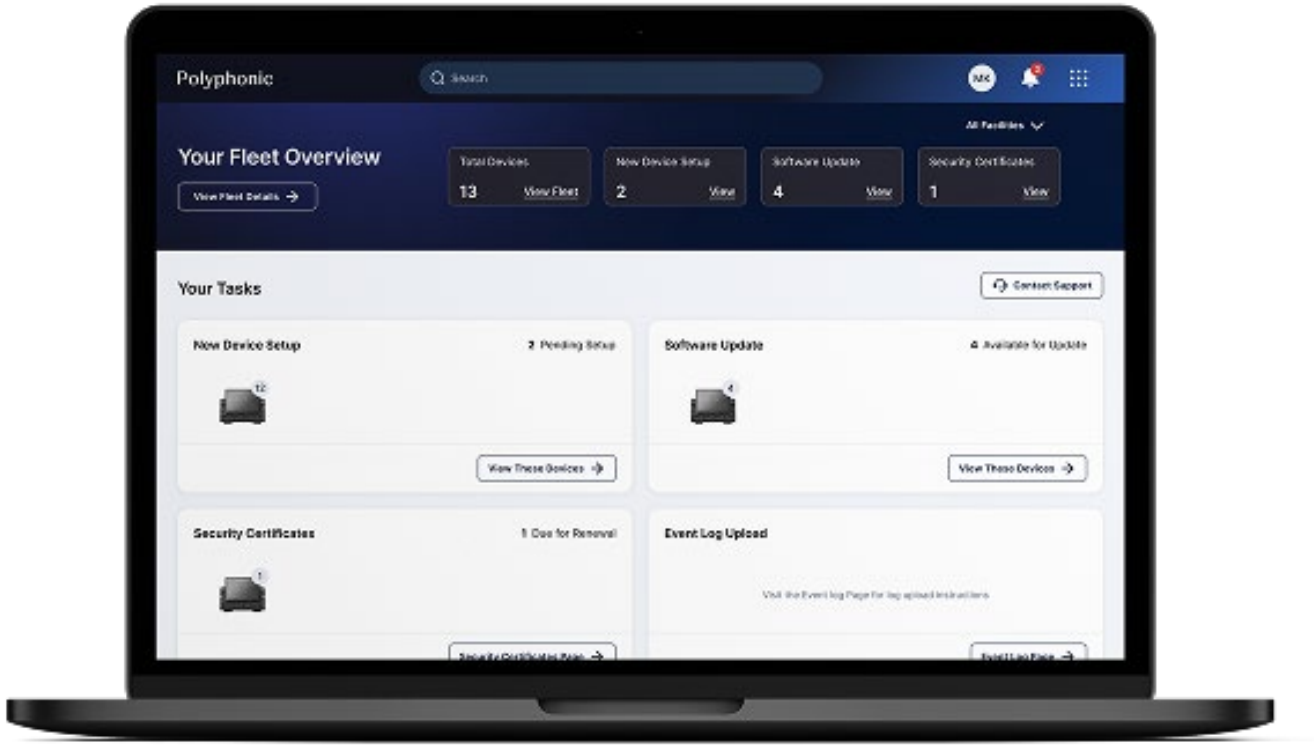
Seamless remote diagnostics and system updates can help the OR to continue running smoothly.

DUALTO™ Energy System performance and maintenance needs can be remotely monitored via Polyphonic™ Fleet, an online fleet management application powered by J&J MedTech. Polyphonic™ Fleet helps ensure DUALTO is running optimally without disrupting the OR schedule.

DUALTO can be easily connected to install software updates, upload event logs, and facilitate remote diagnostics from the biomedical or clinical engineer's office for faster post-op technology troubleshooting.

DUALTO is compliant with the latest FDA Cyber Security Guidance Document and all data at rest and in transit, although non-sensitive, is encrypted.

100% of biomedical or clinical engineer participants agreed that DUALTO could reduce the time required to perform annual maintenance by 25%.[1A]



Polyphonic™ Fleet

**Polyphonic™ Fleet is currently under development.

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1. In a summative usability study, with hospital Biomedical Engineers (n=15), that went through a simulated installation and annual preventative maintenance process, and afterward responded [1 SEP] to a series of statements regarding the DUALTO™ Energy System.

Ongoing Service and Maintenance

Peace of mind that equipment is performing at its best.

The DUALTO™ Energy System comes with a one-year warranty. Secure protection of DUALTO and save on future service needs by investing in Essential or Premier Support with the purchase of DUALTO. Flexible programs and coverage terms are available to maximize value and provide budget predictability.



Offering	Essential Support	Premier Support
24x7 Emergency Phone Support	●	●
Software Updates	●	●
Module Protection J&J MedTech ships a replacement Module to the customer. Customer then packages damaged module for return and keeps the provided replacement Module.	●	●
Installation Beyond assembly and setup support included with purchase, J&J MedTech conducts biomedical or clinical engineer training, inputs surgeon profiles, and provides provisioning and connectivity support on-site.	○	●
Annual Preventative Maintenance J&J MedTech conducts additional biomedical or clinical engineer training, supports output verification testing as needed, and manages HARMONIC™ handpiece checks.	○	●
Annual Biomed Training J&J MedTech trains on annual output verification, DUALTO Service Manual and Polyphonic™ Fleet updates.	○	●

● Included in the package

○ Discount from list price

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Ordering & Additional Information

Generator Elements

Product Code	Description	Product Image	Quantity	Compatible With
ETHCM	ETHICON™ Communications Module		1	The DUALTO™ Energy System with up to 2 Energy Modules
ETHUSC	ETHICON™ User Screen		1	
ETHEM	ETHICON™ Energy Module		1	All HARMONIC™, ENSEAL™ and MEGADYNE™ Instruments

Generator Elements

Product Code	Description	Product Image	Quantity	Compatible With
ESTES	ETHICON™ User Screen Single TES		1	All HARMONIC™, ENSEAL™ and MEGADYNE™ Instruments
ESTESP	ETHICON™ Single TES Package*		1	
EDTES	ETHICON™ Double TES		1	
EDTESP	ETHICON™ Double TES Package**		1	

*Single TES Package includes ESTES, ETHCRT and ETHEF2 **Double TES Package includes EDTES, ETHCRT and ETHEF2

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Accessories

Product Code	Description	Product Image	Quantity	Compatible With
ETHCRT	ETHICON™ Energy Cart		1	The DUALTO™ Energy System with up to 2 Energy Modules
ETHEF2	Energy Double Footswitch		1	The DUALTO™ Energy System
ETHEF1	Energy Single Footswitch		1	
ETHERF	Energy Round Footswitch		1	
ETHOVK	Energy Output Verification Key		1	
2255JTES	MEGADYNE™ Energy Signal Cable		1	Connects to MEGADYNE™ Smoke Evacuator, MESE1

For more information, contact your local J&J MedTech representative or visit **jnjmedtech.com**

References
A. Ethicon, Emergo Mantle Marketing Claims Report. 05/08/2024. Windchill Document #501949635
B. Ethicon, Emergo Mantle Marketing Claims Report. 05/08/2024. Windchill Document #501949635. Ethicon Communications Module, Ethicon User Screen, and Ethicon Energy Cart Operator's Manual
C. Ethicon, Mantle Space Claim Measurement Study. 10/17/2024. Windchill Document #502047373
D. Ethicon, HAR36 DV- ROIN 6175- Blade Heat. 10/30/2013. Windchill Document #PRC053965. Ethicon, HARMONIC ACE™ 5mm Diameter Shears + Adaptive Tissue Technology Instructions for Use
E. Ethicon, MEGADYNE™ ACE Blade Thermal Damage Claims. 10/31/2017. Windchill Document #PSP005780. Ethicon, MEGADYNE™ ACE Blade 700 Instructions for Use

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