Use Specification

**Approvals:**

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| --- | --- | --- | --- |
| **Function** | **Name** | **Signature** | **Date** |
| **NPD / Lifecycle Design Engineer** | Gracie Brooks | see e-Sig in EpiCenter | see e-Sig in EpiCenter |
| **NPD / Lifecycle Quality Engineer** | Scot Harris | see e-Sig in EpiCenter | see e-Sig in EpiCenter |
| **Industrial Design / Human Factors** | Racquel Redwood | see e-Sig in EpiCenter | see e-Sig in EpiCenter |

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| **Project Name** | Mega Power® Electrosurgical Generator |
| **Design Plan / Design Change Number** | ENG-IOM-010 |

**REVISION HISTORY**

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| --- | --- | --- |
| **Revision** | **Date** | **Summary of Change** |
| A | 31 July 2020 | Original Issue |

# Device/System Identification

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| **Applicable Product Code(s)** | 1000 |

# Part A: Identify Context of Use

| **Factors for Consideration** | | **Response / Comment** |
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| **Intended Use/Purpose** | | |
| 1. | What is the intended use of the device/system and how is the device/system to be used?  Identify any associated factors, including:   * Device/system’s role relative to diagnosis, prevention, monitoring, treatment, alleviation of disease, compensation for injury / handicap, or replacement / modification of anatomy * Indications for use * Whether the device/system sustains or supports life * Whether intervention is necessary in the case of failure of the device/system | The Ethicon Megadyne Electrosurgical Generator (ESU) is intended as a general-purpose electrosurgical generator designed to produce radio frequency (RF) current for cutting and coagulation to be delivered to target tissue through an accessory electrode during open and laparoscopic surgical procedures. |
| 2. | If the device/system is intended to contact the patient or other persons, describe the location of the intended contact or type of tissue applied to/interacted with and the nature of the intended contact (e.g. surface contact, invasive contact) and the period and frequency of contact for each. | N/A  The Ethicon Megadyne Electrosurgical Generator (ESU) does not contact the patient. The Nurse or Technician will contact the ESU controls, plug cords into the unit and move the unit from one location to another. This contact is strictly surface contact. |
| 3. | If the device/system is intended for single use, identify whether it is obvious that the device/system has been used. If the device has a signal that it has been used, identify that signal. | N/A  The device is intended for re-use. |
| 4. | If the device/system is intended to be reusable (i.e. routinely cleaned and disinfected)   * Identify whether device/system requires assembly/disassembly for cleaning, and if so are instructions required. | N/A  The Ethicon Megadyne Electrosurgical Generator (ESU) is intended for re-use. |
| **Intended Patient Populations** | | |
| 5. | Who are the intended patient populations?  Identify characteristics of each patient population. May include age, weight range, physical activity or condition, health, etc. | The Ethicon Megadyne ESU may be used for use on the general population (with multiple patients) with no patient age limit. |
| **Intended User Group Profiles** | | |
| 6. | Identify all users of the device/system and describe the profile for each user group (e.g. education, experience, procedure volume, etc.). For the profile, consider characteristics that would cause different behaviors or patterns of use among the user groups.  Consider whether the device/system will be used by:   * Persons with mental and/or physical limitations (e.g. handicapped persons, the elderly, or children). * Individuals with differing skill levels and educational backgrounds * People with different cultural backgrounds * People who use a variety of devices and systems (e.g. from different manufacturers) * Surgeons with varying surgical approaches and techniques (e.g. Bariatric vs. Colorectal)  |  |  |  | | --- | --- | --- | | **Groups** | **User of Device/**  **System?** | **User Group Profile**  **May be left blank if answer to “User of Device/System?” is no.** | | Surgeons | Yes  No | Open Surgery/Minimally invasive procedures should be performed only by persons having adequate training and familiarity with minimally invasive techniques. Consult medical literature relative to techniques, complications, and hazards prior to performance of any minimally invasive procedure.  Age ranges from medical school residents in their early twenties to retirement age.   * Gender is split depending upon specialty: typically, more heavily male in general, but the female population is rising. * Primary responsibility is to perform the surgical procedure and have a thorough working knowledge of all instruments / devices being used. | | Scrub technicians/nurses | Yes  No | * Primary responsibilities are to assist the surgeon by handing off / taking back surgical devices and having the proper devices / materials immediately available as needed. * The scrub nurse may be involved in troubleshooting of the device and reading the IFU. * Age ranges from entry level college students to retirement age. The current average age is in the 40’s; a reflection of the generally aging nurse population. * Gender may be male or female. Gender is significantly female. | | Circulating nurses | Yes  No | * Primary responsibilities include ensuring the availability of all instruments and equipment needed to perform the procedure. The circulating nurse is not scrubbed in and not part of the sterile staff. * The circulating nurse is often the one responsible for pulling a device for a procedure in case a surgeon calls out for a specific size/type device and may rely on package graphics to identify devices. * Same general age, gender, and education profile as scrub nurse. Gender is significantly female. * Nurses are typically college-educated. * Although having received intensive overall training in nursing school, the nurses typically require additional training (“in-service”) from the surgical equipment manufacturer for the proper use of technical equipment. * Circulating nurses tend to not have extensive knowledge of technology, and greatly appreciate equipment that is simple and intuitive to use. Their primary focus is on patient care. * There is relatively high turnover in the nursing staff, in terms of new nurses coming on board or nurses from other specialties “covering” for each other during certain times of the day. | | Nurse Practitioners (NP) | Yes  No | Primary responsibility is to ensure availability of instruments needed in surgical procedures and have a thorough working knowledge of all instruments / devices being used.  Age ranges from graduate school in their mid-twenties to retirement age.  Gender is split depending upon specialty: typically, more heavily male in general, but the female population is rising. | | Physician’s Assistants (PA) | Yes  No | Primary responsibility is to assist surgeon in surgical procedure and have a thorough working knowledge of all instruments / devices being used.  Minimally invasive procedures should be performed only by persons having adequate training and familiarity with minimally invasive techniques. Consult medical literature relative to techniques, complications, and hazards prior to performance of any minimally invasive procedure.  Age ranges from graduate school in their mid-twenties to retirement age.  Gender is split depending upon specialty: typically, more heavily male in general, but with the female population is rising. | | Central processing personnel | Yes  No | Primary responsibility is to collect the reusable devices from the operating room and have a thorough working knowledge of all instruments / devices being cleaned and sterilized in the central processing department.  Follow the cleaning and sterilization procedure from the IFU to clean/disinfect, dry and sterilize the devices.  Age ranges from high school graduates to retirement age.  Gender may be male or female, but more heavily female. | | Technicians  (e.g. Radiology, IVD Lab, dialysis, reprocessing) | Yes  No |  | | Therapists (physical, respiratory, etc.) | Yes  No |  | | Servicing personnel (e.g. biomedical technicians, etc.) | Yes  No |  | | Imaging personnel (e.g. for diagnostics, pre-operative templates, etc.) | Yes  No |  | | Pharmacists | Yes  No |  | | Emergency response personnel | Yes  No |  | | Lay people (e.g. patients, care givers) | Yes  No |  | | Other | Yes  No  n/a |  | | |
| **Use Environments** | | |
| 7. | Identify all use environments and describe the characteristics of each use environment that could affect use of the device. Important characteristics might include: lighting, noise level, distraction, work surface height, space limitations, procedure type, tissue type, access/visualization, etc.   |  |  |  | | --- | --- | --- | | **Environments** | **Device/**  **System Use Environment?** | **Use Environment Characteristics**  **May be left blank if answer to “Device/System Use Environment?” is no.** | | Operating room (OR) | Yes  No | * There is a distinct possibility of distractions, mainly from an audio perspective, from other instruments and pieces of equipment in the OR. There is noise from the various machines beeping and humming as well as the general noise from surgeons & nurses talking, sometimes music playing, instruments clanking, and various devices are used. While feedback from some other monitoring systems may employ an audible component, it will not be limited to just audio. * Typically, a dimly lit OR with task-specific lighting which can make it challenging to perform the operating procedures | | Catheterization lab | Yes  No |  | | Central processing | Yes  No | * There is a distinct possibility of distractions, mainly from an audio perspective, from other instruments and pieces of equipment in the Central Processing Unit. There is noise from the various machines beeping and humming as well as the general noise from other personnel talking, sometimes music playing, instruments clanking, and various devices are used. While feedback from some other monitoring systems may employ an audible component, it will not be limited to just audio. * Typically, a well-lit Central Processing Unit | | Patient room | Yes  No |  | | Doctor’s office | Yes  No |  | | Other procedure room | Yes  No |  | | Home | Yes  No |  | | Other: | Yes  No  n/a |  | | |

# Part B: Identify Operating Principle and User Interface Characteristics

| **Factors for Consideration** | | **Response / Comment** |
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| **Operating Principle** | | |
| 1. | How will information for safe use be provided (IFU, surgical technique guide, user manual, quick start up guide, quick reference guide, maintenance manual, etc.)?  Identify the following (if known):   * Whether information will be provided directly to the end user or if it will involve the participation of third parties such as installers, sales reps, care providers, health care professionals or pharmacists and whether this will have implications for training * Commissioning and handing over to the end user and whether it is likely/possible that installation can be carried out by people without the necessary skills (for capital equipment only) * Based on the expected life of the device/system, whether re-training or re-certification of operators or service personnel is required (for capital equipment only) | IFU: 3000158-01 (1000) provides instructions, warnings and precautions. An in-service training with an Ethicon Sales representative may occur and Ethicon.com includes information for safe use that is assessable by users.  This device is the capital equipment. The manual (3000158) is a guide for the proper use of the reusable Mega Power electrosurgical generator. The equipment described herein is for use by qualified medical personnel skilled in the particular techniques and procedures to be performed. Using the appropriate approved accessories, the qualified medical personnel identifies the part of the body and/ or tissue for cutting and/or coagulation during the procedure. |
| 2. | Describe any potential problems associated with patient compliance. | N/A |
| 3. | If the device/system is intended for use in conjunction with medicines or other medical technologies, list the medicines/technologies that are necessary to use the specific device/system (such as imaging systems). | N/A  The Ethicon Megadyne Electrosurgical Generator (ESU) will be used with accessories manufactured by Megadyne and other companies. The accessories include electrosurgical pencils, laparoscopic electrodes with foot control cables, bipolar forceps, and return electrodes. The design of these accessories is relatively standard throughout the industry.  The Ethicon Megadyne Electrosurgical Generator (ESU) will also interact with two different foot control switches. A single pedal footswitch activates the Bipolar circuit and a dual pedal footswitch activates either cut or coagulation functions of the monopolar circuit. Megadyne supplies these feet control switches. |
| 4. | If applicable, list the consumables, connecting parts, or accessories associated with the use of the device/system. Examples of consumables, connecting parts, or accessories include bone biopsy needle, trocars, batteries, other implant systems or surgical devices/instruments which are to be used with the device/system, etc. | N/A  There are accessories required to use the Ethicon Megadyne Electrosurgical Generator (ESU). The active electrode for Monopolar cutting or coagulation is one of two types. There is the electrosurgery pencil and the foot control cord. The electrosurgery pencil is controlled by buttons on the pencil. The foot control cord (with electrode attached) is controlled by a  footswitch.  There are foot switches that are used with the foot-controlled electrodes for Monopolar and Bipolar. The Monopolar footswitch has two pedals, one for Cut and one for Coag. The Bipolar footswitch has one pedal. These footswitches plug into the back panel of the ESU.  A return electrode is required for use with Monopolar electrosurgery. These are either disposable or reusable types. They also come in two styles, single plate and  dual plate. The single plate does not allow for any return electrode monitoring other than a cable fault detector. The dual plate style allows for return electrode monitoring circuitry in the ESU to monitor for safe contact of the return electrode to the patient. There are variations of the disposable return electrode that |
| 5. | If maintenance and/or calibration are necessary, identify whether:   * Maintenance or calibration are to be carried out by the operator/user or by a specialist * Special substances or equipment are necessary for proper maintenance or calibration | N/A  It is recommended that maintenance calibration testing be performed at annual intervals by personal that have training in electronics such as Biomeds in hospitals. Specific calibration testing is outlined in the Mega Power Service Manual. In addition to calibration testing, routinely inspect the power cord, footswitch cables, and connectors for any signs of damage. Replace damaged cords and/or connectors immediately. |
| 6. | If the device/system contains software, identify whether software is intended to be installed, verified, modified, or exchanged by the operator or user or by a specialist. | N/A  Software is incorporated in the microprocessor controlled Mega Power® Generator, including constant controlled technology circuitry. This feature monitors tissue impedance and automatically adjust power output to reduce tissue damage and drag for a smooth, clean, accurate cutting effect at the lowest possible settings. The software is not designed or intended for user interaction. |
| 7. | If use or installation of the device/system requires special training, describe the training and whether the training is required for sale of the device.  For example, special training for health care professionals may go beyond general medical expertise learned in their course of training that will otherwise affect/impact the outcome of the procedure. Such training may be required prior to the purchase/receipt of the device/system. | N/A  It is recommended that safety checks, preventive maintenance, and calibration testing be performed at annual intervals by personnel that have training in electronics such as Biomeds in hospitals.  the IFU explains the proper installation and use of the device. |
| **User Interface** | | |
| 8. | If the device/system has a control interface (e.g. handles, grip points, foot pedals, knobs, dials, graphical user interface, menus, etc.), briefly describe the control interface.  Factors to consider when designing the device/system control interface include, but are not limited to visibility, modes of feedback, direction of activation or change, whether the controls are continuous or discrete, spacing, grouping, mapping, and the reversibility of settings or actions. | N/A  IFU: 3000158-01 (1000) contains the illustrations and nomenclatures for all user interface controls.  The controls are for power output and mode. The power output indicators are  large numeric displays and the mode indicators are lights on the button for each  individual mode.  The followings are the controls, indicators, and receptacles on the front panel of the generator:  **Power**: The power on/off switch is located in the top left-hand corner of the unit. The unit is turned “ON” when the ‘|’ is depressed and the green light switch is illuminated. The generator is turned “OFF” when the” O” is depressed and the green light is extinguished.  **Recall**: The RECALL button is provided as a convenience to users and recalls the last mode and the last power setting used after the system is turned on, and the recall button is pushed. During use, toggling between modes will maintain the last power setting used.  **Cut:** The cut controls are color coded yellow. The large numerical display indicates the power setting. The arrow ‘up’ button will increase power settings in one watt increments up to 40W and in increments of 5W thereafter to a maximum of 300W (depending on the Mode). The arrow ‘down’ button will decrease power settings in increments of five watts from 300W to 40W and in one watt increments thereafter.  **Coag**: The coag controls are color coded blue. The large numerical display indicates the power setting. The arrow ‘up’ button will increase power settings in increments of one watt up to 40W and in 5W increments thereafter to a maximum of 120W. The arrow ‘down’ button will decrease power settings in increments of 5W from 120W to 40W and in one watt increments thereafter.  **Bipolar:** The BIPOLAR controls are color coded green. The large numerical display  indicates the power setting. The arrow ‘up’ button will increase power settings in  increments of one watt up to 80W. The arrow ‘down’ button will decrease power settings in increments of one watt. |
| 9. | If the device/system displays information (e.g. using instrument markings, perceptual cues and feedback, graphical user interface, etc.), identify any known factors affecting use including visibility in various environments, orientation, the visual capabilities of the user, populations and perspectives, clarity of the presented information, units, color coding, and the accessibility of critical information. | N/A  The device displays the power setting and the mode of output. |
| 10. | If the device/system is intended to be mobile or portable (e.g. cases, trays, packaging, capital equipment, etc.), identify how it is transported. Also identify any necessary features (e.g. grips, handles, wheels, brakes, mechanical stability, and durability) for mobility and portability. | N/A |

**TEMPLATE FRM003984 REVISION HISTORY**

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| **REV** | A | **Summary** |
| **ECN** | ECN021673 | Original Issue |