SUMMARY OF SAFETY AND EFFECTIVENESS DATA (SSED)

I. GENERAL INFORMATION

Device Generic Name:	PadPro Multifunction Electrodes and PadPro MFE Adapters
Device Trade Name:	ConMed PadPro Multifunction Electrodes, ConMed PadPro Multifunction Electrode Adapters
Device Product code:	MKJ
Applicant's Name and Address:	ConMed Corporation 525 French Road Utica, NY, USA 13502
Date(s) of Panel Recommendation:	No Panel required
Premarket Approval Application (PMA) Number:	P200004
Date of FDA Notice of Approval:	9/26/2021

The PadPro Multifunction Electrodes (MFEs) and Multifunction Electrode Adapters (MFE Adapters) have been commercially available since initial clearance under respective 510(k) submissions as summarized in the Marketing History Section. This pre-market application has been submitted in response to the Final Order issued January 29, 2015, in the Federal Register Volume 80 Number 19, Docket No. FDA-2013-N-0234 and republished February 3, 2015, in the Federal Register Volume 80 Number 22, Docket No. FDA-2013-N-0234. The Final Order requires premarket approval of marketed pre-amendment Class III Automated External Defibrillators (AED), product code MKJ. As accessories to AEDs, PMA approval is required for PadPro MFEs and MFE Adapters.

A combination of postmarket experience data, relevant literature, and preclinical bench testing has been reviewed to demonstrate a reasonable assurance of safety and effectiveness for the PadPro MFEs and MFE Adapters.

II. INDICATIONS FOR USE

Adult / Child Models, 2001 (Radiotransparent) and 2516 (Radiotranslucent)
The ConMed PadPro radiotransparent and radiotranslucent external multifunction electrodes (MFEs) are indicated for use by trained medical professionals in medical facilities or medical transport environments to deliver energy for defibrillation, cardioversion, external pacing, and ECG monitoring applications. The MFE is a non-sterile, disposable device for single patient use only. The electrodes provide the conductive interface between the defibrillator and/or the external transcutaneous (noninvasive) cardiac pacemaker and the patient's skin. This device is intended for use on defibrillators whose output is classified as low power (up to 360 joule maximum).

AED Use:

- When used in AED mode i.e. for victims of cardiac arrest where there is apparent lack of circulation as indicated by unconsciousness, absence of breathing, and absence of

pulse, the electrode is intended for use on patients weighing 25kg (55 lbs.) or more. PadPro MFEs are not intended to be used for public access pediatric AED defibrillation purposes.

Manual Use:

- When used in manual mode, i.e. under direction of a qualified health care professional, the electrode is intended for use on adult / child patients weighing 10kg (22 lbs.) or more.

Adult / Child Model 2502 (Sterile):

The ConMed PadPro radiotransparent external multifunction electrodes (MFEs) are indicated for use by trained medical professionals in medical facilities or medical transport environments to deliver energy for defibrillation, cardioversion, external pacing, and ECG monitoring applications. The MFE is a sterile, disposable device for single patient use only. The electrodes provide the conductive interface between the defibrillator and/or the external transcutaneous (noninvasive) cardiac pacemaker and the patient's skin. This device is intended for use on defibrillators whose output is classified as low power (up to 360 joule maximum).

AED Use:

- When used in AED mode i.e. for victims of cardiac arrest where there is apparent lack of circulation as indicated by unconsciousness, absence of breathing, and absence of pulse, the electrode is intended for use on patients weighing 25kg (55 lbs.) or more. PadPro MFEs are not intended to be used for public access pediatric AED defibrillation purposes.

Manual Use:

- When used in manual mode, i.e. under direction of a qualified health care professional, the electrode is intended for use on adult / child patients weighing 10kg (22 lbs.) or more.

Infant Model 2603 and Mini-Infant Model 2602:

The ConMed PadPro radiotranslucent external multifunction electrodes (MFEs) are indicated for use by trained medical professionals in medical facilities to deliver energy for defibrillation, cardioversion, external pacing, and ECG monitoring applications. The MFE is a non-sterile, disposable device for single patient use only. The electrodes provide the conductive interface between the defibrillator and/or the external transcutaneous (noninvasive) cardiac pacemaker and the patient's skin.

Not for use in AED mode.

Manual Use:

- When used in manual mode, i.e. under direction of a qualified health care professional, the electrode is intended for use on infant patients (3-10kg) and mini-infant patients (<3kg). Follow American Heart Association (AHA) guidelines for administration of energy levels, which recommends a first dose of 2J/kg, and subsequent doses of 4J/kg. During Refractory ventricular fibrillation, do not exceed a maximum energy level of 10J/kg.

PadPro MFE Adapters

The ConMed PadPro adapters are indicated for use by trained medical professionals in medical facilities or medical transport environments to adapt connection systems associated with a specific defibrillator/therapy cable to a different style connection system. The PadPro

MFE adapters are intended for delivery of energy for defibrillation, cardioversion, external pacing, and ECG monitoring applications. The PadPro MFE adapter is a non-sterile, reusable device, providing conductive interface between the defibrillator and/or therapy cable and MFE electrode. This device is intended for use on defibrillators whose output is classified as low power (up to 360 joule maximum).

III. CONTRAINDICATIONS

For information on contraindications, refer to the labeling of the compatible defibrillator.

IV. WARNINGS AND PRECAUTIONS

The warnings and precautions can be found in the PadPro MFE and PadPro MFE Adapter labeling.

V. DEVICE DESCRIPTION

PadPro Multifunction Electrodes (PadPro MFEs) are intended as accessories to manual defibrillators and AED devices for defibrillation, cardioversion, external pacing, and ECG monitoring applications in adult and pediatric patients. PadPro Multifunction Electrode Adapters (PadPro MFE Adapters) are accessories to the MFEs and provide optional adaptive connection for institutions where different defibrillator device brands or models are in use. **Figure 1** provides a general depiction of the PadPro MFE and PadPro MFE Adapter.

PadPro Adult / Child MFE Pad	PadPro MFE Adapter
	

Figure 1: PadPro MFE and MFE Adapter

Table 1 lists the models of ConMed PadPro Multifunction Electrodes and Multifunction Electrode Adapters included in this PMA application.

Table 1: Multifunction Electrodes and Multifunction Electrode Adapters with the scope of P200004

Trade or Proprietary or Model Name	Model (Catalog) Number	Type
PadPro Multifunction Electrode: Adult/Child ≥ 10 kg, Radiotransparent Electrode, Anderson/Universal Connector	2001	Adult/Child, Radiotransparent Electrode
PadPro Multifunction Electrode: Adult/Child ≥ 10 kg, Radiotransparent Electrode, Carbon Leadwires, Anderson/Universal Connector	2001-C	
PadPro Multifunction Electrode: Adult/Child ≥ 10 kg, Radiotransparent Electrode, Large Posterior Pad, Anderson/Universal Connector	2001-EPS	
PadPro Multifunction Electrode: Adult/Child ≥ 10 kg, Radiotransparent Electrode, Pre-Connect, Anderson/Universal Connector	2001-PC	
PadPro Multifunction Electrode: Adult/Child ≥ 10 kg, Radiotransparent Electrode, Physio-Control QUIK-COMBO Connector	2001M	
PadPro Multifunction Electrode: Adult/Child ≥ 10 kg, Radiotransparent Electrode, Carbon Leadwires, Physio-Control QUIK-COMBO Connector	2001M-C	
PadPro Multifunction Electrode: Adult/Child ≥ 10 kg, Radiotransparent Electrode, Pre-Connect, Physio-Control QUIKCOMBO Connector	2001M-PC	
PadPro Multifunction Electrode: Adult/Child ≥ 10 kg, Radiotransparent Electrode, ZOLL Connector	2001Z	
PadPro Multifunction Electrode: Adult/Child ≥ 10 kg, Radiotransparent Electrode, Carbon Leadwires, ZOLL Connector	2001Z-C	
PadPro Multifunction Electrode: Adult/Child ≥ 10 kg, Radiotransparent Electrode, Pre-Connect, ZOLL Connector	2001Z-PC	
PadPro Multifunction Electrode: Adult/Child ≥ 10 kg, Radiotransparent Electrode, Split Leadwires, Universal/Anderson Connector, Sterile	2502	Adult/Child, Radiotransparent Electrode, Sterile

Trade or Proprietary or Model Name	Model (Catalog) Number	Type
PadPro Multifunction Electrode: Adult/Child ≥ 10 kg, Radiotransparent Electrode, Physio-Control QUIK-COMBO Connector, Sterile	2502M	
PadPro Multifunction Electrode: Adult/Child ≥ 10 kg, Radiotransparent Electrode, ZOLL Connector, Sterile	2502Z	
PadPro Multifunction Electrode: Adult/Child ≥ 10 kg, Radiotranslucent Electrode, Anderson/Universal Connector	2516	Adult/Child, Radiotranslucent Electrode
PadPro Multifunction Electrode: Adult/Child ≥ 10 kg, Radiotranslucent Electrode, Pre-Connect, Anderson/Universal Connector	2516-PC	
PadPro Multifunction Electrode: Adult/Child ≥ 10 kg, Radiotranslucent Electrode, Physio-Control QUIK-COMBO Connector	2516M	
PadPro Multifunction Electrode: Adult/Child ≥ 10 kg, Radiotranslucent Electrode, Pre-Connect, Physio-Control QUIKCOMBO Connector	2516M-PC	
PadPro Multifunction Electrode: Adult/Child ≥ 10 kg, Radiotranslucent Electrode, ZOLL Connector	2516Z	
PadPro Multifunction Electrode: Adult/Child ≥ 10 kg, Radiotranslucent Electrode, Pre-Connect, ZOLL Connector	2516Z-PC	
PadPro Multifunction Electrode: Infant < 10 kg, Radiotranslucent Electrode, Anderson/Universal Connector	2603	Infant, Radiotranslucent Electrode
PadPro Multifunction Electrode: Infant < 10 kg, Radiotranslucent Electrode, Pre-Connect, Anderson/Universal Connector	2603-PC	
PadPro Multifunction Electrode: Infant < 10 kg, Radiotranslucent Electrode, Physio-Control QUIK-COMBO Connector	2603M	
PadPro Multifunction Electrode: Infant < 10 kg, Radiotranslucent Electrode, ZOLL Connector	2603Z	

Trade or Proprietary or Model Name	Model (Catalog) Number	Type
PadPro Multifunction Electrode: Mini Infant < 3 kg, Radiotranslucent Electrode, Anderson/Universal Connector	2602	Mini Infant, Radiotranslucent Electrode
PadPro Multifunction Electrode: Mini Infant < 3 kg, Radiotranslucent Electrode, Physio-Control QUIK-COMBO Connector	2602M	
PadPro Multifunction Electrode: Mini Infant < 3 kg, Radiotranslucent Electrode, ZOLL Connector	2602Z	
PadPro Multi-Function Electrode Adapter (Zoll Male, Physio-Control Female)	ZMMF	MFE Adapter
PadPro Multi-Function Electrode Adapter (Zoll Male, Universal/Anderson Female)	ZMUF	
PadPro Multi-Function Electrode Adapter (Physio-Control Male, Zoll Female)	MMZF	
PadPro Multi-Function Electrode Adapter (Physio-Control Male, Universal/Anderson Female)	MMUF	

Each PadPro MFE device is comprised of a connection to a defibrillator, a cord set (two wires connecting to each of two pads) that conduct the energy from the OEM defibrillator therapy cable, and adhesive pads that deliver the therapeutic energy to the patient. PadPro MFE adapters utilize a male connector that mates to an OEM defibrillator therapy cable connection, joined to a female connector that adapts the MFE pad connection from another OEM MFE connection type. In this manner, a single facility can standardize the connector types of the MFE pads to one specific type of MFE pad connection independent of defibrillator OEM manufacturer brand.

PadPro MFEs are single-use devices used as a means of delivering therapeutic defibrillation energy from Manual Defibrillators and AED devices to the patient, as well as to propagate pertinent ECG signal monitoring back to the device. For therapeutic (manual) administration, a physician directs the type and magnitude of energy to be delivered to the patient as appropriate for the procedure being performed. MFE pads are placed on the person's exposed chest, and the external shock delivered can restore the heart's electrical system to a normal rhythm.

PadPro MFE adapters are re-usable, non-sterile devices selected for compatibility with the institution's typical OEM defibrillator use. PadPro MFE Adapters are connected to the OEM therapy cable and typically remain attached to facilitate multiple uses.

Refer to the PadPro MFE and MFE Adapter Instructions for Use for complete device information and use instructions.

VI. ALTERNATIVE PRACTICES AND PROCEDURES

Alternative products are available for the purpose of defibrillation, synchronized cardioversion, pacing, or ECG monitoring:

- Defibrillation and synchronized cardioversion can be performed using paddles or approved self-adhesive electrodes provided by the original equipment manufacturer (OEM).

- Pacing can be performed using paddles or approved self-adhesive electrodes provided by the original equipment manufacturer (OEM).

- ECG monitoring can be performed using approved self-adhesive electrodes provided by the original equipment manufacturer (OEM). ECG monitoring can also be performed using ECG-specific electrodes.

VII. MARKETING HISTORY

The ConMed PadPro MFE device and accessories have been marketed in the United States since original clearance of the devices in 2001. PadPro MFE MFEs and MFE Adapters and were originally cleared through the premarket notification process as provided in the following table.

Table 2. 510(k) Clearance History for the ConMed PadPro MFE Device

510(k) Number	Clearance Date	Product Name	Product Description
K002280	2/5/2001	Padpro Model 2602	Pediatric Electrode
K003548	9/4/2001	Padpro System Defibrillator Electrode Adapters	Defibrillator system adapters
K014209	1/18/2002	Padpro, Model 2001,2001-S, 2001-C, 2001-EPS	2001 - Standard connector 2001-S Split Connector 2001-C Radiotransparent Leadwire 2001-EPS Larger Posterior Pad
K020288	2/27/2002	Padpro, Model 2603	Pediatric Multifunction Electrodes
K020203	5/8/2002	Padpro, Model 2516	Radiotranslucent multifunction electrodes
K020743	5/28/2002	Padpro, Model 2502	Sterile multifunction electrodes

PadPro legacy MFEs and MFE Adapters are commercially available globally (including within the US and 18 countries OUS). PadPro Adapters are sold only in the United States. PadPro MFEs have been sold in eighteen countries: within the US, EU, Canada, Asia Pacific, Australia, Latin America and the Middle East.

These devices have not been withdrawn from marketing for any reason relating to its safety or effectiveness.

VIII. POTENTIAL ADVERSE EFFECTS OF THE DEVICE ON HEALTH

Below is a list of the potential adverse effects (e.g., complications) associated with the use of multifunction electrodes and adapters.

- No delivery of energy
- Intermittent delivery of energy
- Incompatibility of MFEs or MFE Adapters with OEM Devices
- Skin burns around MFE placement area
- Skin disruption (minor rash) around MFE placement area

IX. SUMMARY OF PRECLINICAL STUDIES

A. Bench Testing

Table 3. Summary of Bench Testing

Test	Purpose	Acceptance Criteria	Results
Device Performance	Electrical Safety and Performance per ANSI/AAMI ES60601-1:2005/(R)2012 and A1:2012	Per established standard requirements and validated ConMed test methods	Pass
Electromagnetic Compatibility	Test for electromagnetic disturbance impact in environments of use per IEC 60601-1-12:2014 and ANSI/AAMI/IEC 60601-1-2:2014	Per established standard requirements and validated ConMed test methods	Pass
System Compatibility	Demonstrate acceptable performance with each PMA-approved compatible OEM defibrillator / AED device. Ensure that the the interface between the OEM system and MFE accessory results in acceptable performance.	PadPro MFEs must generate no warning messages or delays in functionality per the IFU defibrillators as specified in device labeling after three (3) years of accelerated aging	Pass
Oscilloscope Wave Form Comparison	Verify acceptable performance through side-by-side comparison of the defibrillation waveforms delivered by ConMed PadPro MFEs and PMA-approved (defibrillation device) with currently marketed OEM defibrillation pads	MFE pad output must produce results that are similar as OEM manufacturer MFEs when delivering a defibrillation waveform.	Pass

Test	Purpose	Acceptance Criteria	Results
Adapter Reliability End of Life	Verify that Multi-function Electrode (MFE) Adapters meet the reliability requirements for a reusable device over the claimed lifetime per requirements in IEC 60601-1.	When standardized testing is performed, acceptance criteria as defined within the standard is applied. MFE adapter must conform to applicable functional and safety levels as additionally defined within design input requirements.	Pass
Packaging and Shelf Life	Demonstrate ability of the packaging to protect devices from shipping over the lifetime of the device	Must meet all applicable packaging integrity and Performance and System Compatibility acceptance criteria	Pass
Biocompatibility	To determine the potential for an unacceptable adverse biological response resulting from contact of the component materials of the device with the body by evaluating cytotoxicity, sensitization and irritation studies	Per ISO 10993-1, ISO 10993-5 and ISO 10993-10.	Pass
Sterilization (2502 Series Only)	To determine the minimum gamma radiation dose that will achieve a 10^{-6} sterility assurance level for Adult PadPro MFE pads and validate sterilization processes per ISO 11607-1 and ISO 11607-2 guidelines.	The minimum gamma radiation dose that will achieve a 10^{-6} sterility assurance level for Adult PadPro MFE pads must be achieved and maintained.	Pass
Human Factors / Usability	Validate, through a simulated-use summative usability test conducted in accordance with IEC 62366 that the use of the PadPro MFEs, MFE accessories and associated Instructions for Use and packaging results in use-safety, clarity and effectiveness of device labeling.	N/A per ISO 62366, no acceptance criteria are provided.	N/A Any remediation activities identified were implemented and validated.
Design Validation Study	Validate that use of the PadPro MFEs and MFE Adapters results in use-safety, clarity and effectiveness of device labeling.	Minimum ratings and responses are defined within ConMed testing protocols.	Pass

Test	Purpose	Acceptance Criteria	Results
MFE Pad Wear Analysis	Validate that the patient adhesion of the PadPro MFE Infant, series 2603, and MFE Mini-Infant, series 2602 meets the end user needs through a retrospective analysis of post-market experience.	Meet user design input requirement for MFE adherence	Pass

Pre-clinical testing was conducted per standardized requirements when possible and incorporated current medical guidelines[1]. Testing included Device Performance (including Electrical Safety Testing), Electromagnetic Compatibility (EMC), System Compatibility Testing (with Oscilloscope Wave Form Comparison), and Adapter Reliability End of Life testing. Device packaging was evaluated to demonstrate that the package design will retain integrity of the sealed barrier or the sterile barrier (depending on product configuration) over the lifetime of the device.

B. Performance Testing

Table 4. Summary of Performance Testing

Test Name	Test Objective	Test Method Summary	Results
Legibility of marks	For the markings required by 7.2, 7.3, 7.4, 7.5 and 7.6 of IEC 60601-1, the markings are clearly legible from the intended position of the operator.	Tested per ANSI/AAMI 60601-1, Clause 7.1.2 & IEC 60601-1-12, Clause 6.1 Legibility conducted from intended operator position at 10 to 10,000 lx.	Pass
Durability of Marks	Simulate typical use over the course of the product life cycle, to ensure adequate reliability of the device performance at the end of life (200 defibrillations or 2 year service life). For the markings required by 7.2, 7.3, 7.4, 7.5 and 7.6 of IEC 60601-1, the markings shall be sufficiently durable and clearly legible during the expected service life of the MFE Adapter.	Tested per ANSI/AAMI 60601-1, Clause 7.1.3	Pass
Pre-Pacing DC Offset Voltage (DCO)	To confirm that that pad to pad offset potential is not excessive to interfere with monitoring capabilities.	IEC 60601-2-4:2010 +AMD1:2018, §201.108.1.6 A pair of electrodes connected gel-to-gel shall, after 1 min. stabilization period, exhibit an offset voltage no greater than 100mV. Data to be taken at 5°C conditions and 35°C conditions.	Pass

Test Name	Test Objective	Test Method Summary	Results
Pre-pacing AC Large Signal Impedance	Post defibrillation, to ensure MFE pad can still function, specifically providing adequate transmission of ECG signal (low impedance).	IEC 60601-2-4:2010 +AMD1:2018, §201.108.1.2 The impedance of an electrode pair connected gel-to-gel, in series with a 50 W load and measured at the maximum rated energy of the DEFIBRILLATOR shall not exceed 5 Ω. Data to be taken at 5°C conditions and 35°C conditions.	Pass
Post-Pacing AC Large Signal Impedance	Post defibrillation, to ensure MFE pad can still function, specifically providing adequate transmission of ECG signal (low impedance).	IEC 60601-2-4:2010 +AMD1:2018, §201.108.1.2 The impedance of an electrode pair connected gel-to-gel, in series with a 50 W load and measured at the maximum rated energy of the DEFIBRILLATOR shall not exceed 5 Ω.	Pass
Pre-pacing Defibrillation Overload Recovery (DEFR) @ 4 seconds	To ensure adequate dissipation of potential after three defibrillation shocks at max energy.	IEC 60601-2-4:2010 +AMD1:2018, §201.108.1.4 The potential of a pair of gel-to-gel electrodes in series with a 50 W resistor and subjected to three shocks at 360 J or maximum energy at 1 min intervals shall not exceed 500 mV at 4 s after the last shock delivery. Data to be taken at 5°C conditions and 35°C conditions.	Pass
Post-Pacing Defibrillation Overload Recovery (DEFR) @ 4 seconds	To ensure adequate dissipation of potential after three defibrillation shocks at max energy.	IEC 60601-2-4:2010 +AMD1:2018, §201.108.1.4 The potential of a pair of gel-to-gel electrodes in series with a 50 W resistor and subjected to three shocks at 360 J or maximum energy at 1 min intervals shall not exceed 1000 mV at 4 s after the last shock delivery	Pass

Test Name	Test Objective	Test Method Summary	Results
Pre-pacing Defibrillation Overload Recovery (DEFR) @ 60 seconds	To ensure adequate dissipation of potential after three defibrillation shocks at max energy.	IEC 60601-2-4:2010 +AMD1:2018, §201.108.1.4 The potential of a pair of gel-to-gel electrodes in series with a 50 W resistor and subjected to three shocks at 360 J or maximum energy at 1 min intervals shall not exceed 400 mV at 60 s after the last shock delivery Data to be taken at 5°C conditions and 35°C conditions.	Pass
Post-Pacing Defibrillation Overload Recovery (DEFR) @ 60 seconds	To ensure adequate dissipation of potential after three defibrillation shocks at max energy.	IEC 60601-2-4:2010 +AMD1:2018, §201.108.1.4 The potential of a pair of gel-to-gel electrodes in series with a 50 W resistor and subjected to three shocks at 360 J or maximum energy at 1 min intervals shall not exceed 750 mV at 60 s after the last shock delivery	Pass
Pre-Pacing AC small signal impedance, 10Hz	To ensure adequate transmission of ECG signal (low impedance) at lower bandwidth range.	IEC 60601-2-4:2010 +AMD1:2018, §201.108.1.1 The 10 Hz impedance for any of at least 12 electrode pairs connected gel-to-gel, at a level of impressed current not exceeding 100 microamperes (mA) peak-to-peak, shall not exceed 3 KΩ. Data to be taken at 5°C conditions and 35°C conditions.	Pass
Post-Pacing AC small signal impedance, 10Hz	To ensure adequate transmission of ECG signal (low impedance) at lower bandwidth range.	IEC 60601-2-4:2010 +AMD1:2018, §201.108.1.1 The 10 Hz impedance for any of at least 12 electrode pairs connected gel-to-gel, at a level of impressed current not exceeding 100 microamperes (mA) peak-to-peak, shall not exceed 3 KΩ.	Pass

Test Name	Test Objective	Test Method Summary	Results
Pre-pacing AC small signal impedance, 30kHz	To ensure adequate transmission of signal (low impedance) at upper bandwidth range, typically used for leads off detection.	IEC 60601-2-4:2010 +AMD1:2018, §201.108.1.1 The 30 kHz impedance for any of at least 12 electrode pairs connected gel-to-gel, at a level of impressed current not exceeding 100 microamperes (mA) peak-to-peak, shall not exceed 10Ω. Data to be taken at 5°C conditions and 35°C conditions.	Pass
Post-Pacing AC small signal impedance, 30kHz	To ensure adequate transmission of signal (low impedance) at upper bandwidth range, typically used for leads off detection.	IEC 60601-2-4:2010 +AMD1:2018, §201.108.1.1 The 30 kHz impedance for any of at least 12 electrode pairs connected gel-to-gel, at a level of impressed current not exceeding 100 microamperes (mA) peak-to-peak, shall not exceed 10Ω.	Pass
Universal function electrodes	Following an hour of pacing, electrodes shall meet the requirements of each specification: 201.108.1.1 – 201.108.1.4; or disclosure of performance capabilities shall be included in the instructions for use.	IEC 60601-2-4:2010 +AMD1:2018, §201.108.1.10 Electrodes are subjected to 60min of pacing at the maximum current output and maximum rated pacing rate through a pair of gel-to-gel electrodes in series with a 50Ω resistor.	Pass
Cord Anchorage	MFE to cord set connection shall have adequate strain relief as to not produce an electrical hazard if used as a means to remove the MFE pad from the patient.	IEC 60601-2-4:2010 +AMD1:2018, Clause 201.15.4.101, test 2	Pass
Active Electrode Area	Ensure that active electrode area complies with minimum requirements as addressed within the standard	Dye of hydrogel and measurement of surface area with vision system IEC 60601-2-4:2010 +AMD1:2018, clause 201.108.1.7	Pass

Test Name	Test Objective	Test Method Summary	Results
Mechanical Strength for handheld equipment – Drop Test	Accidental drop of unopened pouch or MFE adapter shall not impact compliance with functional tests, as defined per IEC 60601-1, Cl 15.3.4.1.	Drop in three different orientations from 1m height onto 50mm thick hardwood surface IEC 60601-1, Cl 15.3.4.1 IEC 60601-1-12, Cl 10.1.3 c)	Pass
Dielectric Strength and Insulation Resistance	MFE pad, cord set, connectors, and adapters shall not present an operator or patient hazard due to electrical shock hazards for surfaces not intended to supply energy, as defined per the requirements of Dielectric Strength and Insulation Resistance, IEC 60601-2-4, Clause 201.8.8.3.	IEC 60601-2-4: 2010 +AMD1:2018, Clause 201.8.8.3 – MFEs: A. between defibrillation circuit and cable B. between defibrillation circuit and foam pad C. between defibrillation circuit and connector MFE Adapters: A. between defibrillation circuit and molded housing	Pass
Push Test for Handheld Equipment	Pad insulation materials must be able to withstand 250 N ± 10 N (56.2lbf) over palm surface of hand (adult mean surface area 75.756cm2) without deterioration of insulation or electrical performance.	IEC 60601-1, clause 15.3.2, with 250 N ± 10 N (56.2lbf) force over 75.75cm^2 surface area	Pass

Test Name	Test Objective	Test Method Summary	Results
EMC Testing	Demonstrate that the PadPro MFE (with PadPro MFE adapters) does not emit an unacceptable amount of electromagnetic interference (radiated and conducted emissions) and that the PadPro device continues to function as intended in the presence of several electromagnetic phenomena. Radiated emissions pre-scans Radiated emissions (Class B) Electro-Static Discharge Immunity Radiated, Radio-Frequency, Electromagnetic field Immunity Immunity to Proximity Fields From FR Wireless Communications Equipment Conducted, Radio-Frequency, Electromagnetic Immunity Test Power Frequency Magnetic Field Immunity Test Clause 5 of IEC 60601-1-2 Review	ANSI AAMI IEC 60601-1-2:2014	Pass

Test Name	Test Objective	Test Method Summary	Results
System Compatibility	Demonstrate the ability of the PadPro MFE pads to function equivalently to OEM MFE pads when used with OEM defibrillators. System Software Compatibility Excessive Temperatures Visual Inspection for Sparks Patient Leakage Cord set length	Following procedures as identified within the OEM defibrillator IFU, defibrillator software shall start up as intended and performs defibrillation and other functions when connected to PadPro MFE without error or delay in therapy. Discharge of defibrillator at max. energy 15 times at a rate for three per minute into 50Ω load shall not generate temperature rise of greater than 6°C, otherwise temperature shall be disclosed in the instructions for use. IEC 60601-2-4:2010 +AMD1:2018, §201.11.1.3 Observation for presence for light / spark during defibrillation IEC 60601-2-4:2010 +AMD1:2018, §201.8.7.4.7 Measurement of overall cordset length (per IEC 60601-2-4:2010 +AMD1:2018, clause 201.108.1.11) with calibrated tape measure. The MFE was secured and measurements recorded for both Cord Set Length and Cord Set Separation.	Pass

Adapter Reliability

PadPro MFE adapters are reusable devices that have a rated end of life of 200 defibrillations within a 2 year service life. Post reliability conditioning electrical tests included AC Small Signal Impedance at 10Hz and 30kHz, Defibrillation Recovery at 4s and 60s, and AC Large Signal Impedance per IEC 60601-2-4 electrical tests. Additionally, a pin to pin DC resistance measurement was conducted for each MFE adapter.

Oscilloscope Waveform Testing

Design verification testing comparing the oscilloscope waveform of the PadPro MFEs and MFE Adapters as part of the host device defibrillation system and the original defibrillator systems (e.g. Zoll and Physio-Control defibrillator and their pad electrodes) demonstrated that the therapeutic defibrillation waveform transmitted from the defibrillation unit to the patient, via the PadPro MFEs and MFE adapters with no significant difference to the defibrillation waveform characteristics as produced by the defibrillator. This testing showed that the MFEs

and MFE adapters performed the same as the MFEs manufactured by defibrillator manufacturers when used on these manufacturers' defibrillators.

Scientifically representative samples of each PadPro MFE and MFE adapter was utilized in testing. 2602 Mini-infant series and 2603 Infant series were selected to represent pediatric electrodes. 2001-EPS was selected to represent adult electrodes as it has the largest pad electrode conductive surface area owing to its large posterior pad. MFE adapters were also included in each test configuration in order to demonstrate the safety and effectiveness of the entire PadPro defibrillation system (MFE pad + MFE adapter).

The following defibrillation waveform characteristics generated utilizing ConMed PadPro MFE and MFE adapters as part of the host OEM defibrillation system were analyzed and satisfied the acceptance criteria of ±15% when compared to those waveform characteristics generated utilizing the original host OEM defibrillation system (OEM defibrillator and their pad electrodes).

- Peak current of leading edge of first and second phases
- Peak voltage of leading edge of first and second phases
- First and second phase durations
- First and second phase tilts
- Selected energy and delivered energy

Table 5. Waveform Testing

OEM Defibrillator	**PadPro MFE + MFE Adapter Combination**	**OEM MFE**	**Acceptance Criteria**	**Pass/Fail**
ZOLL R Series	2602 + MFE Adapter	ZOLL Pedi-Padz® Pediatric Multi-function Electrodes	Each of the following defibrillation waveform characteristics generated utilizing ConMed Pediatric PadPro MFE and MFE adapters as part of the ZOLL R Series defibrillation system shall be within 15% when compared to those utilizing the original ZOLL R Series defibrillation system (ZOLL R Series defibrillator and ZOLL pediatric electrodes): • Peak current of leading edge of first and second phases • Peak voltage of leading edge of first and second phases • First and second phase durations • First and second phase tilts • Selected energy and delivered energy Defibrillation energies tested: 2J, 5J, 10J, 30J, 50J, 75J, 100J Simulated thoracic impedance tested: 25Ω, 50Ω, 75Ω, 100Ω, 125Ω, 150Ω, 200Ω	Pass
	2603 + MFE Adapter			

OEM Defibrillator	PadPro MFE + MFE Adapter Combination	OEM MFE	Acceptance Criteria	Pass/Fail
	2001-EPS + MFE Adapter	ZOLL Stat-Padz® Adult Multi-function Electrodes	Each of the following defibrillation waveform characteristics generated utilizing ConMed Adult PadPro MFE and MFE adapters as part of the ZOLL R Series defibrillation system shall be within 15% when compared to those utilizing the original ZOLL R Series defibrillation system (ZOLL R Series defibrillator and ZOLL adult electrodes): • Peak current of leading edge of first and second phases • Peak voltage of leading edge of first and second phases • First and second phase durations • First and second phase tilts • Selected energy and delivered energy Defibrillation energies tested: 2J, 5J, 10J, 30J, 50J, 75J, 100J, 150J, 200J Simulated thoracic impedance tested: 25Ω, 50Ω, 75Ω, 100Ω, 125Ω, 150Ω, 200Ω	Pass
ZOLL X Series	2602 + MFE Adapter	ZOLL Pedi-Padz® Pediatric Multi-function Electrodes	Each of the following defibrillation waveform characteristics generated utilizing ConMed Pediatric PadPro MFE and MFE adapters as part of the ZOLL X Series defibrillation system shall be within 15% when compared to those utilizing the original ZOLL X Series defibrillation system (ZOLL X Series defibrillator and ZOLL pediatric electrodes): • Peak current of leading edge of first and second phases • Peak voltage of leading edge of first and second phases • First and second phase durations • First and second phase tilts • Selected energy and delivered energy Defibrillation energies tested: 2J, 5J, 10J, 30J, 50J, 75J, 100J Simulated thoracic impedance tested: 25Ω, 50Ω, 75Ω, 100Ω, 125Ω, 150Ω, 200Ω	Pass
	2603 + MFE Adapter			

OEM Defibrillator	PadPro MFE + MFE Adapter Combination	OEM MFE	Acceptance Criteria	Pass/Fail
	2001-EPS + MFE Adapter	ZOLL Stat-Padz® Adult Multi-function Electrodes	Each of the following defibrillation waveform characteristics generated utilizing ConMed Adult PadPro MFE and MFE adapters as part of the ZOLL X Series defibrillation system shall be within 15% when compared to those utilizing the original ZOLL X Series defibrillation system (ZOLL X Series defibrillator and ZOLL adult electrodes): • Peak current of leading edge of first and second phases • Peak voltage of leading edge of first and second phases • First and second phase durations • First and second phase tilts • Selected energy and delivered energy Defibrillation energies tested: 2J, 5J, 10J, 30J, 50J, 75J, 100J, 150J, 200J Simulated thoracic impedance tested: 25Ω, 50Ω, 75Ω, 100Ω, 125Ω, 150Ω, 200Ω	Pass
Physio-Control LIFEPAK 15	2602Z + MFE Adapter	Physio-Control QUIK-COMBO® Pediatric Multi-function Electrodes	Each of the following defibrillation waveform characteristics generated utilizing ConMed Pediatric PadPro MFE and MFE adapters as part of the Physio-Control LIFEPAK 15 defibrillation system shall be within 15% when compared to those utilizing the original Physio-Control LIFEPAK 15 defibrillation system (Physio-Control LIFEPAK 15 Series defibrillator and Physio-Control pediatric electrodes): • Peak current of leading edge of first and second phases • Peak voltage of leading edge of first and second phases • First and second phase durations • First and second phase tilts • Selected energy and delivered energy Defibrillation energies tested: 2J, 5J, 10J, 30J, 50J, 70J, 100J Simulated thoracic impedance tested: 25Ω, 50Ω, 75Ω, 100Ω, 125Ω, 150Ω, 200Ω	Pass
	2603Z + MFE Adapter			

OEM Defibrillator	PadPro MFE + MFE Adapter Combination	OEM MFE	Acceptance Criteria	Pass/Fail
	2001-EPS + MFE Adapter	Physio-Control QUIK-COMBO® Adult Multi-function Electrodes	Each of the following defibrillation waveform characteristics generated utilizing ConMed Adult PadPro MFE and MFE adapters as part of the Physio-Control LIFEPAK 15 defibrillation system shall be within 15% when compared to those utilizing the original Physio-Control LIFEPAK 15 defibrillation system (Physio-Control LIFEPAK 15 defibrillator and Physio-Control adult electrodes): • Peak current of leading edge of first and second phases • Peak voltage of leading edge of first and second phases • First and second phase durations • First and second phase tilts • Selected energy and delivered energy Defibrillation energies tested: 2J, 5J, 10J, 30J, 50J, 70J, 100J, 150J, 200J, 300J. 360J Simulated thoracic impedance tested: 25Ω, 50Ω, 75Ω, 100Ω, 125Ω, 150Ω, 200Ω	Pass
Physio-Control LIFEPAK 20e	2602Z + MFE Adapter 2603Z + MFE Adapter	Physio-Control QUIK-COMBO® Pediatric Multi-function Electrodes	Each of the following defibrillation waveform characteristics generated utilizing ConMed Pediatric PadPro MFE and MFE adapters as part of the Physio-Control LIFEPAK 20e defibrillation system shall be within 15% when compared to those utilizing the original Physio-Control LIFEPAK 20e defibrillation system (Physio-Control LIFEPAK 20e Series defibrillator and Physio-Control pediatric electrodes): • Peak current of leading edge of first and second phases • Peak voltage of leading edge of first and second phases • First and second phase durations • First and second phase tilts • Selected energy and delivered energy Defibrillation energies tested: 2J, 5J, 10J, 30J, 50J, 70J, 100J Simulated thoracic impedance tested: 25Ω, 50Ω, 75Ω, 100Ω, 125Ω, 150Ω, 200Ω	Pass

OEM Defibrillator	PadPro MFE + MFE Adapter Combination	OEM MFE	Acceptance Criteria	Pass/Fail
	2001-EPS + MFE Adapter	Physio-Control QUIK-COMBO® Adult Multi-function Electrodes	Each of the following defibrillation waveform characteristics generated utilizing ConMed Adult PadPro MFE and MFE adapters as part of the Physio-Control LIFEPAK 20e defibrillation system shall be within 15% when compared to those utilizing the original Physio-Control LIFEPAK 20e defibrillation system (Physio-Control LIFEPAK 20e defibrillator and Physio-Control adult electrodes): • Peak current of leading edge of first and second phases • Peak voltage of leading edge of first and second phases • First and second phase durations • First and second phase tilts • Selected energy and delivered energy Defibrillation energies tested: 2J, 5J, 10J, 30J, 50J, 70J, 100J, 150J, 200J, 300J. 360J Simulated thoracic impedance tested: 25Ω, 50Ω, 75Ω, 100Ω, 125Ω, 150Ω, 200Ω	Pass

Biocompatibility Testing

The biocompatibility assessment for the PadPro MFEs is based on the matrix for body contact and contact duration included in AAMI/ISO 10993-1:2009/(R) 2013, Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process (FDA recognition number: 2-156), and per recommendations contained in Use of International Standard ISO 10993-1, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process, Guidance for Industry and Food and Drug Administration Staff, Issued June 16, 2016. The PadPro MFEs demonstrated acceptable biocompatibility at the recommended biological endpoints.

Sterilization

A subset of the PadPro MFE portfolio (2502 Series) is offered as sterile product via Gamma Irradiation. Sterilization validation has been conducted per recommendations in AAMI ANSI ISO 11137-1:2006/(R)2010, Sterilization of health care products – Radiation – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices. Results of the sterilization process validation and monitoring demonstrate the ability of the product packaging to maintain a 10-6 sterility assurance level over the lifetime of the device.

Packaging and Shelf life

Shelf Life (Stability) testing is conducted to demonstrate that the PadPro MFE packaging and product design meets all applicable performance requirements impacted by aging. PadPro MFE devices will be distributed with a shelf life of three (3) years. Shelf life for PadPro devices was demonstrated by simulating variables that can potentially impact device performance

over time, and then testing the sterile barrier package integrity (for the 2502 sterile devices) and MFE functional testing for all devices.

Functional Testing after aging conditioning demonstrated the ability of device packaging to protect the PadPro packaging and packaging barriers, for both moisture and sterility, as any impact to the package would cause dried hydrogel and would be clearly evident in performance testing results. Passing results for performance testing establishes that the requirements for device performance after the claimed shelf life of 3 years have been met. Device functional testing was comprised of Performance and System Compatibility testing as described above.

B. Animal Studies

No animal studies were conducted to support this PMA.

C. Additional Studies

Human factors

A summative Human Factors / Usability test was conducted to assess the user interface and comprehension, and use-related hazard mitigations. Results provided minor recommendations and ultimately confirmed that the PadPro MFE pads, MFE adapters, IFUs, and packaging meet users' needs, and that the user interface supports safe and effective use. Additional Validation studies were conducted to demonstrate that minor design changes made to address HFE test results continue to meet end user needs by addressing use activities that are not related to critical tasks comprising the Human Factors Study.

The test was conducted using a simulated-use approach as the PadPro system complexity and the nature of user interactions allow for a thorough evaluation of the MFE pads, MFE adapters, and associated documentation under simulated conditions.

To create a worst case scenario, none of the participants received training before participating in his / her respective test session. Each test session lasted approximately 90 minutes and included a single participant. During the test session, each participant performed various tasks (discrete use steps or expected actions), including all critical tasks, within four representative, naturalistic use scenarios (activities used to evaluate critical tasks related to users' interactions with the PadPro MFE pads and MFE adapters). Participants also performed seven knowledge tasks to evaluate critical tasks that cannot be evaluated during the hands-on use scenarios.

During each evaluation activity (i.e., use scenario and knowledge task), test personnel documented all failures, use errors, close calls, difficulties, and instances of test administrator assistance. Failures and use errors, as well as instances of test administrator assistance, close calls, difficulties, and participants' subjective feedback regarding the root cause(s) of key events were the focus of the study's documentation.

There are no predetermined acceptance criteria for this type of usability evaluation. Upon receipt of the test report including test data and aggregated results, a multi-functional group at ConMed reviewed any use errors or problems that occurred during the test to determine the root cause of any such problems or use errors. The root causes were considered in relation to associated risks to ascertain any potential for resulting harm and to determine the priority for implementing any additional risk management measures and subsequent retesting.

As a result of this study, ConMed determined that a subset of the results would require action based upon observed test results and root cause analysis. Remediation activities were identified, implemented, and validated. Considering results of this study conducted in a worst case simulated-use summative usability environment, combined with extensive real-

world clinical use as reflected in post-market use data, ConMed concludes that the PadPro system, accessories, and associated IFU and packaging results in use-safety, clarity and effectiveness of device labeling.

Cleaning / Disinfection / Sterilization for all Reusable Components

All PadPro MFEs are clearly labeled with “Single Use”, and “Do Not Resterilize” instructions. No cleaning validation is applicable or required.

The following cleaning Information is provided in the IFU for the PadPro MFE Adapters:

- PadPro MFE Adapters may be cleaned by wiping clean with disinfectant wipe or cloth soaked in isopropyl alcohol.
- Clean PadPro MFE Adapter after each use as instructed in “Cleaning Instructions” section of this Instructions for Use.
- Warning: - Clean PadPro MFE Adapter after each use as instructed in “Cleaning Instructions” section of this Instructions for Use.

Per CDC Guidelines, PadPro MFE Adapters are considered to be devices that are not critical in a health care environment for disinfection purposes[2]. As devices that come into contact with intact skin and not mucous membranes, CDC provides that “most noncritical reusable items may be decontaminated where they are used and do not need to be transported to a central processing area. Virtually no risk has been documented for transmission of infectious agents to patients through noncritical items when they are used as noncritical items and do not contact non-intact skin and/or mucous membranes”.

Results demonstrate that the PadPro MFEs and MFE Adapters meet all pre-defined specifications and perform as intended, demonstrating a reasonable assurance of PadPro MFE and MFE Adapter safety and effectiveness.

X. SUMMARY OF PRIMARY CLINICAL STUDY(IES)

There were no clinical studies required per the Final Order for MFE accessories. PadPro MFEs and MFE Adapters have been in clinical use for over seventeen years.

A. Published Clinical Data

The final order, “Effective Date of Requirement for Premarket Approval for Automated External Defibrillator Systems”, published on January 29, 2015 states that clinical study information can be leveraged for AEDs from both published studies and clinical data previously submitted to the FDA. ConMed provided a comparison of oscilloscope captures of the defibrillation waveform of the PadPro MFEs and MFE Adapters as part of the host device defibrillation system and the original defibrillator systems (e.g. Zoll and Physio-Control defibrillator and their pad electrodes). The following defibrillation waveform parameters utilizing ConMed PadPro MFE and MFE adapters as part of the host OEM defibrillation system were compared to those waveform parameters utilizing the original host OEM defibrillation system (OEM defibrillator and their pad electrodes):

- Peak current of leading edge of first and second phases

- Peak voltage of leading edge of first and second phases
- First and second phase durations
- First and second phase tilts
- Selected energy and delivered energy

The data provided by ConMed demonstrates that the waveforms from the previous ConMed defibrillator accessories and the original defibrillator systems (e.g. Zoll and Physio-Control defibrillator and their pad electrodes) are almost identical. There are very small differences in the parameter measurements, as expected, and within the error margin accepted for these parameters (15%). Therefore, the following published clinical data can be leveraged to support the adult and pediatric PadPro Multifunction Electrodes and Adapters.

For the PadPro Multifunction Electrodes claiming compatibility with the Physio-Control defibrillators, the following studies are being leveraged based on Physio-Control SSED for P1600266[10]:

A comparison of biphasic and monophasic shocks for external defibrillation:

S.L. Higgins et al[4] reported on a prospective, double-blind, randomized multicenter clinical trial to evaluate the Physio-Control biphasic waveform for external defibrillators. The study compared the efficacies of first shock of 200-J monophasic, 200-J biphasic and 130-J biphasic waveforms administered to terminate VF (ventricular fibrillation). Secondary outcomes studied were a 1) a comparison of hemodynamic recoveries and distributions of post-shock rhythms observed after successful shocks of these three waveforms; and 2) to observe the first-shock efficacies of the three shock types for termination of ventricular tachycardia (VT). The study device was a Physio-Control LIFEPAK 7 defibrillator modified to deliver the same BTE as the LIFEPAK 500. Study groups were organized as follows: 200-J Monophasic (n=68, 54M/14F, 69 yrs. ±12 yrs); 200-J Biphasic (n=39, 31M/8F, 66 yrs. ±13 yrs) and 130-J Biphasic (n=47, 39M/8F, 67 yrs. ±12 yrs). Ventricular fibrillation (VF) was induced in 115 patients during evaluation of implantable cardioverter defibrillator function and 39 patients during electrophysiologic evaluation of ventricular arrhythmias. After 19±10 seconds of VF, a randomized transthoracic shock was administered. The first shock VF termination rates of the three groups (200J BTE, 130J BTE, and 200J MDS) were then statistically compared. First shock VF termination rates were 90% (61/68) for the 200J Monophasic Group, 100% (39/39) for the 200J Biphasic Group, and 83% (39/47) for 130J Biphasic Group. The authors concluded that the 200J biphasic shocks were superior in first-shock efficacy to both 200J MDS shocks and 130J BTE shocks in patients with short-duration electrically induced VF. There were no significant differences in hemodynamic parameters between the three (3) groups after successful shocks. The authors stated this study demonstrated that 200J biphasic shocks were more effective than monophasic and the 130J BTE shocks and may allow earlier termination of VF in cardiac arrest patients. The authors concluded that 200 J biphasic shocks may have the potential to improve outcome in resuscitation of patients with cardiac arrest.

A Prospective, Randomized and Blinded Comparison Of First Shock Success Of Monophasic And Biphasic Waveforms In Out-Of-Hospital Cardiac Arrest:

A.P. van Alem et al[5] conducted a multicenter prospective randomized, double-blind comparison clinical study of the prehospital care within the city Amsterdam, Netherlands, from January 2000 to June 2002 to compare the success of biphasic truncated exponential (BTE) and monophasic damped sine (MDS) shocks for

defibrillation in OHCA. It included all patients suffering witnessed and un-witnessed cardiac arrest and VF as initial recorded rhythm, who received the first shock from an AED by non-medical first responders. Patients below the age of 18 and patients with traumatic cardiac arrest were excluded. The first responders were equipped with LIFEPAK 500 two-button MDS and BTE AED's; these AEDs were set at random for either MDS or BTE prior to distribution to the first responders. The study patients in VF received BTE or MDS first shocks of 200J; the ECG was recorded for subsequent analysis continuously. The primary endpoint for the success of the first shock was the removal of VF and required a return of an organized rhythm for at least two QRS complexes, with an interval of <5s, within 1 min after the first shock. The secondary endpoint was termination of VF at 5s. VF was the initial recorded rhythm in 120 patients in OHCA; 51 patients received BTE shocks and 69 received MDS shocks. The authors reported that success rate of 200J first shocks was significantly higher for BTE, showing 69% of the BTE patient group (35 patients from 51) experiencing successful VF termination and return of organized rhythm for at least two QRS complexes; this was compared to the MDS Group which showed 45% of the MDS patient group (31 patients from 69) experiencing successful VF termination and return of organized rhythm. They found that there was no difference between the BTE and MDS groups with respect to the secondary endpoint - termination of VF at 5s - and with respect to survival to hospital discharge. The authors concluded that this blinded and randomized study in out-of-hospital cardiac arrest demonstrated that the BTE waveform with impedance compensation is superior to the MDS waveform in its ability to defibrillate and yield return of an organized rhythm. They recommended further study but believed that BTE-waveform AEDs provide significantly higher rates of successful defibrillation with return of an organized rhythm in OHCA, than do the MDS waveform AEDs.

For the PadPro Multifunction Electrodes claiming compatibility with the ZOLL Medical defibrillators, the following studies are being leveraged based on ZOLL SSED for P1600226.[12]:

Performance Of A Rectilinear Biphasic Waveform In Defibrillation Of Presenting And Recurrent Ventricular Fibrillation: A Prospective Multicenter Study:

E.E. Hess et al[6] described a multicenter prospective clinical study of the prehospital care at 9 EMS sites in Minnesota and Wisconsin from September 2008 to March 2010 on out-of-hospital cardiac arrest patents with ventricular fibrillation (VF). The purpose of this study was to test the hypothesis that shock success differs with initial and recurrent episodes of VF. Ninety- four patients presenting with VF were included in the study group;(n=94, 74M/20F, 65.9 yrs. Mean Age ±12.9 yrs.) These patients presented with VF as the initial rhythm and were defibrillated by paramedics using a rectilinear biphasic waveform. The Zoll M-Series defibrillators were used by all paramedics. The study protocol used a fixed energy 120J sequence for the first three shocks for persistent or recurrent VF. If the VF/VT (ventricular tachycardia) persisted or recurred after the 3rd shock, 150J was authorized and a 4th shock administered. If VFVT persisted and/or recurred, a 5th shock of 200J would be administered; subsequent shocks could be delivered as needed at 200J. The primary outcome was termination of VF within 5 seconds of shock delivery. Secondary outcomes included restoration of spontaneous circulation (ROSC), survival to hospital discharge, and neurologically intact survival. The authors reported that initial shocks terminated VF in 87.8% of the cases and in 97.8% within three shocks. The authors observed no significant difference in the frequency of shock success between initial versus recurrent VF. VF recurred in the majority of patients and did not adversely affect shock success, restoration of spontaneous circulation (ROSC) or patient

neurologically intact survival. No significant difference in ROSC or neurologically intact survival to hospital discharge was observed between those with and without VF recurrence. The authors concluded that they showed a high rate of success for both initial and recurrent episodes of VF using a rectilinear biphasic waveform in defibrillation.

B. Pediatric Extrapolation

In this premarket application, existing clinical data was leveraged to support the reasonable assurance of safety and effectiveness of the proposed device in pediatric patients.

Literature searches were conducted to identify published clinical studies and reviews relevant to the ConMed PadPro Multifunction Electrodes and Accessories during defibrillation, cardioversion, pacing, and ECG monitoring applications. Three reviewed articles were found which specifically described field experience and clinical use of PadPro Pediatric Multifunction Electrodes and equivalent pediatric multifunction electrodes to a pediatric patient population and discussed the potential benefits and complications to the use of MFE's on this population:

Defibrillation And Cardioversion In Children:

E.C. Suddaby et al[7] conducted a review of the indications for cardioversion and/or defibrillation in children by evaluation of normal conduction, common arrhythmias, and hemodynamic assessment in children requiring this treatment approach. Arrhythmias which require defibrillation and cardioversion occur less often in children than adults. Cardioversion uses a timed or synchronized shock. In contrast defibrillation requires an electric current that cannot be synchronized. Potential complications for both procedures are burns, arrhythmias and conduction disturbances. The author concluded that the use of MFE's over gelled paddles could help control arcing during the procedures and avoid burns to the patient because of their flexibility and more consistent adhesion to the patient's skin surface. The use of the MFEs with their integrated gel pads also prevented gel from conducting current to other areas of the skin than the area immediately under MFE contact for pediatric patients. Finally, placement of the self-adhesive MFE electrodes is easier and more stable than with hand-held paddles for pediatric patients. During use, the rigid paddles could be moved, inadvertently lifted or tilted during administration of the current. The flexible MFE's adhere to and conform to the patient's body and the adhesive gel significantly reduces the chance of electrode movement during use. Also, pediatric MFE's are sized to the smaller body mass of pediatric patients. The author concluded that MFE's could potentially lessen the occurrence of burns and provide a more consistent conduction of the therapeutic current. The author specifically discussed the ConMed R2 MFE's in her discussion of self-adhesive, pre-gelled multifunction electrodes.

Improper Defibrillator Pad Usage By Emergency Medical Care Providers For Children: An Opportunity For Re-education:

K.N. Fraser et al[9] reported on an observational educational interventional study conducted between October 2010 to March 2011 to measure the baseline fund of knowledge of various emergency providers regarding choice and proper placement of defibrillator pads in children. The purpose of this was to improve the survival rate of pediatric patients who have a cardiac arrest in a "shockable rhythm." The study group included pediatric residents, emergency medicine residents, pediatric ED nurses, emergency medicine attendings (ES), pre-hospital personnel (EMT) and

adult ED nurses. The study included a training program, which was followed up at 6-months to test for training/knowledge retention. The authors concluded that pediatric emergency providers have a poor understanding of pad choice and placement. After the interventional education, these healthcare workers retained that knowledge for at least 6 months. Since incorrect pad placement can increase transthoracic impedance and incorrect pad size choice could lead to inadequate defibrillation, these are critical factors for patient survival rates. This article is included in this review because it indicates the importance of practitioner training and knowledge on the correct use of the PadPro Multifunction Electrodes for pediatric patients.

For the PadPro Multifunction Electrodes claiming compatibility with the Physio-Control defibrillators, the following studies are being leveraged based on Physio-Control SSED for P160026[10]:

Attenuated adult biphasic shocks compared with weight-based monophasic shocks in a swine model of prolonged pediatric ventricular fibrillation:

R.A. Berg et al[11] reported on a single center clinical swine model study of 48 piglets. The safety and effectiveness of attenuated adult biphasic dosage and the standard weight based monophasic dose (2-4 J/Kg) was compared using the resuscitation of the piglets from 7 minutes of untreated ventricular fibrillation. The piglets' size was representative of the weights of human newborn, 3-years old and 8-years old children. The primary endpoints measured were 24h survival, with a good neurological outcome and post-resuscitation cardiac function. The attenuated adult biphasic dosage resulted in higher 24h survival rate with good neurological outcome and less myocardial dysfunction 4 h post-resuscitation in animal model This indicates that the attenuated adult biphasic dosage is as safe and effective as the standard weight based monophasic dose for use with children.

For the PadPro Multifunction Electrodes claiming compatibility with the ZOLL Medical defibrillators, the following studies are being leveraged based on ZOLL SSED for P160022[12]:

Comparison of a novel rectilinear biphasic waveform with a damped sine wave monophasic waveform for transthoracic ventricular defibrillation. ZOLL:

Mittal et al[12] reported on a randomized multicenter prospective clinical study of patients undergoing ventricular defibrillation, during electrophysiological studies, implantable cardioverter defibrillator (ICD) implants, and tests, to compare the defibrillation efficacy of ZOLL's rectilinear biphasic waveform was compared to a monophasic damped sine waveform. The primary goal of this study was to compare the first shock efficacy of the 120J rectilinear biphasic waveform with a 200J monophasic waveform. The secondary goal was to compare all shock (three consecutive 120, 150, 170J) efficacy of the rectilinear biphasic waveform with that of a monophasic waveform (three consecutive 200, 300, 360J). A significance level of p=0.05 or less was considered statistically significant using Fischer Exact test. Also, differences between the two waveforms were considered statistically significant when the 90% confidence interval between the two waveforms was greater than 0%. 184 Patients were randomly divided into two groups to receive either a monophasic 200 J damped sine wave or a biphasic 120 J rectilinear shock. The first shock, first induction efficacy of biphasic shocks at 120J was 99% versus 93% for monophasic shocks at 200J (p=0.0517, 90% confidence interval of the difference of -1.01% to 15.3%). Successful defibrillation with rectilinear biphasic shocks was achieved with 58% less delivered current than with monophasic shocks (14±1 vs. 33±7 A, p=0.0001). The authors concluded that 120 J biphasic shocks had a greater efficacy than 200 J damped sine wave monophasic shocks for transthoracic ventricular

defibrillation, particularly for patients with high transthoracic impedance (greater than 90 ohms). They also noted that ventricular defibrillation was achieved with less delivered current for patients who received the biphasic 120 J rectilinear shock. The data demonstrated the equivalent efficacy of low energy rectilinear biphasic shocks compared to standard high energy monophasic shocks in patients with high transthoracic impedance. Finally, there were no unsafe outcomes or adverse events due to the use of the rectilinear biphasic waveform.

The ZOLL SSED for P1600226.[12] also included summaries of two pre-clinical animal studies which ZOLL submitted in their submission for PMA P160022:

The first study compared the response to a Rectilinear Biphasic Waveform to a standard monophasic damped sine wave (DSW) in piglets. Piglet size ranged from 4 kg to 16 kg, representing pediatric patients less than 8 years of age. The purpose of this study was to demonstrate the safety and effectiveness of the Rectilinear Biphasic Waveform when used to treat pediatric VF patients. The defibrillation dose/response curves observed using the Rectilinear Biphasic Waveform and the standard monophasic DSW defibrillator to treat short duration (~30 seconds) ventricular fibrillation were compared. The study demonstrated that the biphasic waveform defibrillates pediatric pigs as safely and effective as a standard monophasic DSW defibrillator but with lower energy (on a Joules/kg basis) than the monophasic DSW defibrillators. The study also compared measures of cardiac function before and after both DSW and Rectilinear Biphasic Waveform defibrillation shocks over a range of relevant energies. Results demonstrated that the biphasic defibrillation produced equivalent or milder disturbances of cardiac function when compared to traditional DSW defibrillation at the same energies.

ZOLL completed another pre-clinical animal study that compared the ZOLL rectilinear biphasic (RLB) waveform to a biphasic truncated exponential (BTE) waveform. The study used a piglet animal model (n=21), to determine the dose response curves for the RLB and BTE defibrillation waveforms. The study was a prospective, randomized, and of controlled design. The piglet weight ranged from 4 to 24 kg representing pediatric patients. Patients less than 1 year old (infant subgroup) were represented by piglets weighing from 4 to 8 kg. Patients between the ages of 2 and 8 years old (young children subgroup) were represented by piglets weighing from 16 to 24 kg. The ZOLL RLB waveform demonstrated a statistically better capability to defibrillate an animal pediatric model with less energy required for a BTE waveform (D50 energy: RLB 25.6 ± 15.7 J, BTE 28.6 ±17.0 J, $P \leq 0.0232$; D90 energy: RLB 32.6 ± 19.1 J, BTE 37.8 ± 23.2 J, $P \leq 0.0228$). Additionally, the RLB waveform demonstrated a safe dosing level of 4 J/Kg to achieve a 100% probability of defibrillation success. The 4 J/Kg dosing level was consistent for both the infant subgroup and the young child subgroup.

C. Financial Disclosure

The Financial Disclosure by Clinical Investigators regulation (21 CFR 54) requires applicants who submit a marketing application to include certain information concerning the compensation to, and financial interests and arrangement of, any clinical investigator conducting clinical studies covered by the regulation. There was no pivotal clinical study. None of the clinical investigators in the leveraged studies had disclosable financial interests/arrangements as defined in sections 54.2(a), (b), (c), and (f).

XI. SUMMARY OF SUPPLEMENTAL CLINICAL INFORMATION

N/A

XII. PANEL MEETING RECOMMENDATION AND FDA'S POST-PANEL ACTION

In accordance with the provisions of section 515(c)(3) of the act as amended by the Safe Medical Devices Act of 1990, this PMA was not referred to the Cardiovascular Review Panel an FDA advisory committee, for review and recommendation because the information in the PMA substantially duplicates information previously reviewed by this panel.

XIII. CONCLUSIONS DRAWN FROM PRECLINICAL AND CLINICAL STUDIES

A. Effectiveness Conclusions

As no clinical study was required for these devices, effectiveness determination is based on the similarity of the defibrillation waveform delivered by the ConMed defibrillator accessories and the original defibrillator systems (e.g. Zoll and Physio-Control defibrillator and their pad electrodes). Pre-clinical testing has demonstrated that PadPro MFEs and MFE adapters meet all pre-defined acceptance criteria for continued effectiveness and are compatible with OEM devices.

ConMed conducted an analysis of all post-market surveillance for all currently marketed PadPro MFEs and MFE Adapters from 1/1/2014 – 11/30/2019. Of approximately 5,000,000 devices sold, a total of 115 complaints have been received, supporting the preclinical findings with post-market data set from the clinical environment which indicate continued acceptable device effectiveness.

B. Safety Conclusions

Data provided through extensive non-clinical testing leveraged clinical studies and post-market real world clinical use data support a conclusion of device safety, providing reasonable assurance of safety and effectiveness of this device when used in accordance with indications of use. ConMed conducted an analysis of all post-market surveillance for all currently marketed PadPro MFEs and MFE Adapters from 1/1/2014 – 11/30/2019. Of approximately 5,000,000 devices sold, a total of 115 complaints have been received and 27 MDRs have been filed: no patient deaths have been confirmed to be attributed to PadPro devices. As the proposed MFE and MFE Adapter device designs are substantively identical to currently marketed devices this real-world clinical experience provides a substantial record of safe and effective clinical use of PadPro MFEs and MFE Adapters.

Third party manufacturers of MFEs and MFE adapters provide compatible devices for OEM defibrillators. In combination with risk-mitigations inherent in typical MFE use, ConMed has developed strategies for mitigation of any impact should OEM devices undergo modification.

C. Benefit-Risk Conclusions

The probable benefits of the device are based on published literature and data provided through extensive non-clinical testing and confirmatory post-market real world clinical use over 17 years to support PMA approval as described above. OEM defibrillators provide a large benefit experienced by a large proportion of patients. Effective transmission of the OEM-generated energy to and from the patient by PadPro MFEs and MFE Adapters

constitutes the clinical benefit of restoration of cardiac function (life versus death) and continuation of life (supportive treatment).

Timely defibrillation is the single most important factor in saving either adult or pediatric patients from SCA due to ventricular tachyarrhythmias. The earlier defibrillation therapy can be provided, the higher the likelihood of survival. In adults, there is an approximately 7% to 10% decline in survival for every minute a shock is delayed after collapse.

The duration of benefit cannot be accurately estimated as the restoration of cardiac function is impacted by the patient's health and degree of underlying disease state. However, in typical use the duration of effect is primarily immediate. Ultimate duration of benefit is highly dependent on subsequent treatment of the underlying disease.

1. Patient Perspective
   This submission either did not include specific information on patient perspectives or the information did not serve as part of the basis of the decision to approve or deny the PMA for this device.

In conclusion, given the outcomes of restoration of life or continuation of life, the data support that for defibrillation, cardioversion, external pacing, and ECG monitoring applications the probable benefits outweigh the probable risks.

D. Overall Conclusions

The data in this application support the reasonable assurance of safety and effectiveness of this device when used in accordance with the indications for use.

XIV. CDRH DECISION

CDRH issued an approval order on 9/26/2021.

The applicant's manufacturing facilities have been inspected and found to be in compliance with the device Quality System (QS) regulation (21 CFR 820).

XV. APPROVAL SPECIFICATIONS

Directions for use: See device labeling.

Hazards to Health from Use of the Device: See Indications, Contraindications, Warnings, Precautions, and Adverse Events in the device labeling.

Post-approval Requirements and Restrictions: See approval order.

XVI. REFERENCES

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