



CONMED Corporation
525 French Rd
Utica NY, 13502

URGENT NOTICE

December 15, 2021

To Our Valued CONMED PADPRO® Customers,

CONMED appreciates your loyalty as a customer. This notification outlines several points that are pertinent to our ability to provide you with ongoing supply of our PADPRO® products considering the new FDA requirements for manufacturers of automated external defibrillators (AEDs) and devices with an integrated AED mode, along with their necessary accessories.

As noted on the U.S. Food & Drug Administration website, the FDA published a final order in February 2015 requiring pre-market approval (PMA) applications for new and existing AEDs and necessary AED accessories. The FDA intends to enforce compliance with the PMA submission requirement on **February 3, 2022**. For additional details pertaining to the FDA's PMA requirement for AED accessories, please visit:

<https://www.fda.gov/medical-devices/cardiovascular-devices/automated-external-defibrillators-aeds>

CONMED PADPRO® electrodes and accessories that have FDA approval:

CONMED is pleased to announce that specific products within the CONMED PADPRO portfolio have received PMA approval from the FDA. These SKUs are noted in **Table 1**. You can continue to purchase these products with no change in part numbers or current pricing. As part of the premarket approval process, CONMED obtained approval to extend the length of the pre-attached leadwires from 48" to 60" (on all adult/child and Infant size electrodes). CONMED is working diligently to implement the 60" leadwires on all affected SKUs. **However, to ensure there is no disruption in supply to your facility during this transition, we recommend you purchase ample stock from CONMED or your Distributor prior to January 1st.**

To support the "standardization solution" that compliments the use of the PADPRO electrodes, CONMED obtained premarket approval for a portfolio of four new adapters (that are intended for use with specific FDA approved AEDs). These new adapters are designed to be more intuitive and convenient to use. Please see details in **Table 2**.

CONMED PADPRO® electrodes and accessories that do not have FDA approval:

Because certain AEDs had not received premarket approval prior to the CONMED submission to the FDA, the CONMED PADPRO electrodes and accessories noted in **Table 3** are not currently PMA approved and thus, will no longer be available for purchase from CONMED or your U.S. Distributor partner after February 3, 2022. **For these items, we suggest you purchase PADPRO electrodes & accessories prior to January 1st to support the use of your devices until they are replaced with an FDA approved AED.** From the FDA website listed above, there is a link to the FDA letter dated September 26, 2019. As stated in the letter, AEDs are important devices for emergency situations. Hence, the FDA recommends that you keep your AED available for use until you obtain an FDA-approved AED. Please note CONMED has PADPRO compatible products for both Stryker/Physio Control and ZOLL Defibrillators. Our team will be happy to help you transition to PADPRO products that will support your new PMA approved AEDs.

We apologize for any inconvenience this may cause and we thank you for your continued support of CONMED PADPRO electrodes and accessories. Please be sure to share this information with all departments and healthcare professionals within your institution, who use CONMED PADPRO electrodes and/or accessories with their defibrillation/AED equipment. Please share with those who service the defibrillators/AEDs, too (i.e., Clinical Engineering/Biomedical Engineering).

If you have any questions or concerns, please contact your local CONMED AET Territory Manager or CONMED Customer Experience at 1-866-426-6633.

Sincerely,

Jennifer A. Silverman
Vice President of Marketing
CONMED Advanced Endoscopic Technologies

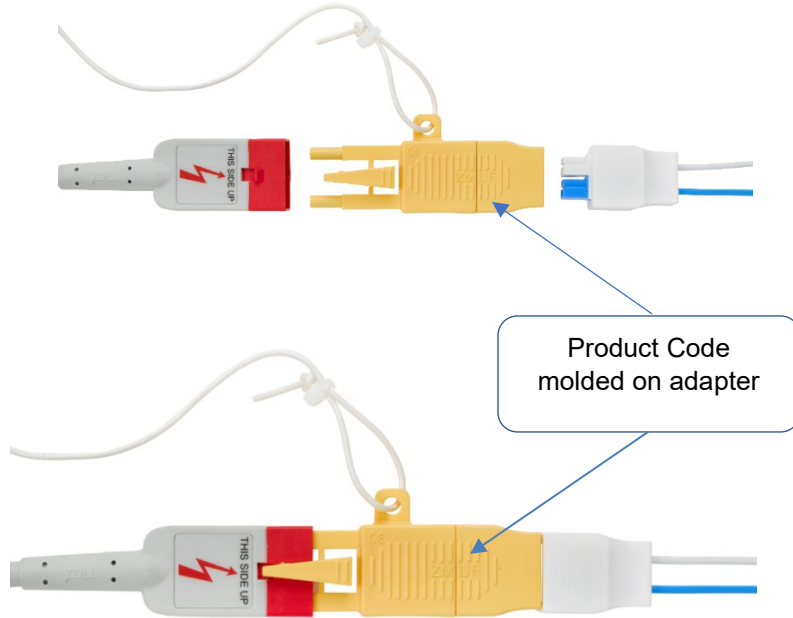
Table 1 – CONMED PADPRO® electrodes that have FDA approval:

Catalog Number	Connector Style	PADPRO Description
2516	Universal/Anderson	ADULT/CHILD, Radiolucent
2516-PC	Universal/Anderson	ADULT/CHILD, Radiolucent, Pre-connect
2001	Universal/Anderson	ADULT/CHILD, Radiotransparent
2001-C	Universal/Anderson	ADULT/CHILD, Radiotransparent, Carbon Leads
2001-EPS	Universal/Anderson	ADULT/CHILD, Radiotransparent, Large Pad
2001-PC	Universal/Anderson	ADULT/CHILD, Radiotransparent, Pre-connect
2502	Universal/Anderson	ADULT/CHILD, Radiotransparent, Sterile
2603	Universal/Anderson	INFANT, Radiolucent
2603-PC	Universal/Anderson	INFANT, Radiolucent, Pre-connect
2602	Universal/Anderson	MINI INFANT, Radiolucent
2516M	Stryker/Physio-Control	ADULT/CHILD, Radiolucent
2516M-PC	Stryker/Physio-Control	ADULT/CHILD, Radiolucent, Pre-connect
2001M	Stryker/Physio-Control	ADULT/CHILD, Radiotransparent
2001M-C	Stryker/Physio-Control	ADULT/CHILD, Radiotransparent, Carbon Leads
2001M-PC	Stryker/Physio-Control	ADULT/CHILD, Radiotransparent, Pre-connect
2502M	Stryker/Physio-Control	ADULT/CHILD, Radiotransparent, Sterile
2603M	Stryker/Physio-Control	INFANT, Radiolucent
2602M	Stryker/Physio-Control	MINI INFANT, Radiolucent
2516Z	ZOLL	ADULT/CHILD, Radiolucent
2516Z-PC	ZOLL	ADULT/CHILD, Radiolucent, Pre-connect
2001Z	ZOLL	ADULT/CHILD, Radiotransparent
2001Z-C	ZOLL	ADULT/CHILD, Radiotransparent, Carbon Leads
2001Z-PC	ZOLL	ADULT/CHILD, Radiotransparent, Pre-connect
2502Z	ZOLL	ADULT/CHILD, Radiotransparent, Sterile
2603Z	ZOLL	INFANT, Radiolucent
2602Z	ZOLL	MINI INFANT, Radiolucent

Table 2 - CONMED PADPRO® Adapters that have FDA approval:

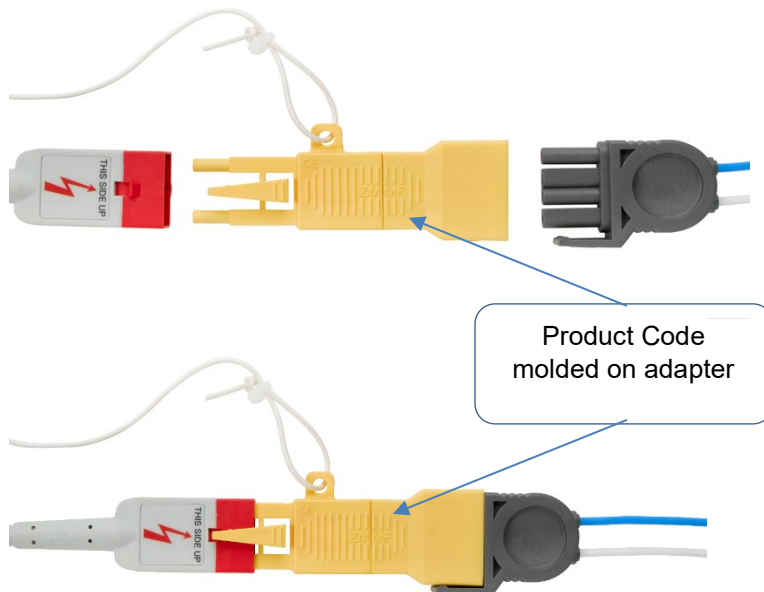
For accounts with certain ZOLL defibrillators, there are two “standardization” options available:

1. To standardize to PADPRO electrodes with the Universal/Anderson connector, use adapter **ZMUF** (which represents “ZOLL Male connector” with “Universal Female connector”).



ZMUF replaces the existing PADPRO adapter with part # **ZOLL**.

2. To standardize to PADPRO electrodes with the Stryker/Medtronic/Physio-Control connector, use adapter **ZMMF** (which represents “ZOLL Male connector” with “Medtronic Female connector”).

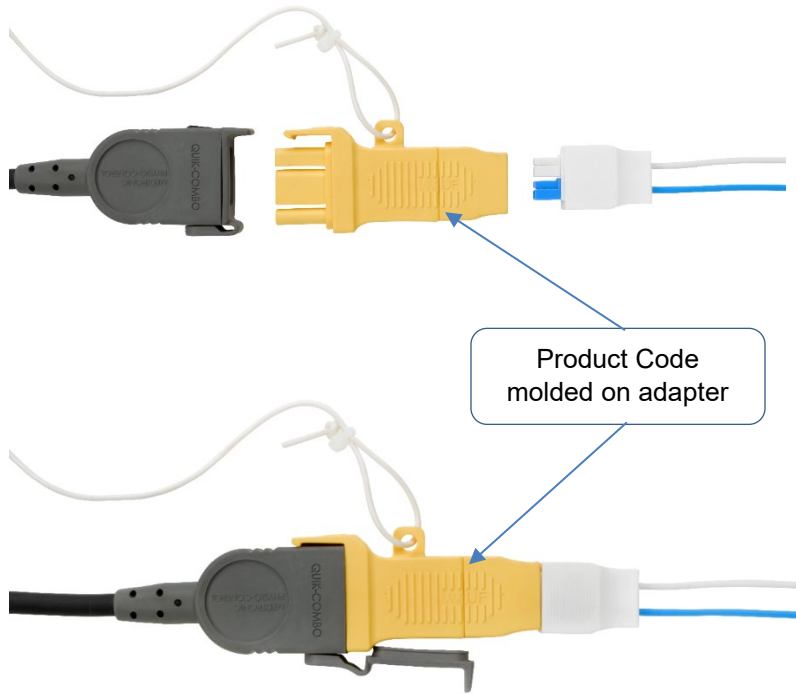


ZMMF provides a standardization solution that previously required two PADPRO adapters in series (**ZOLL** with **QUICK PIG**).

Table 2 - CONMED PADPRO® Adapters that have FDA approval (continued):

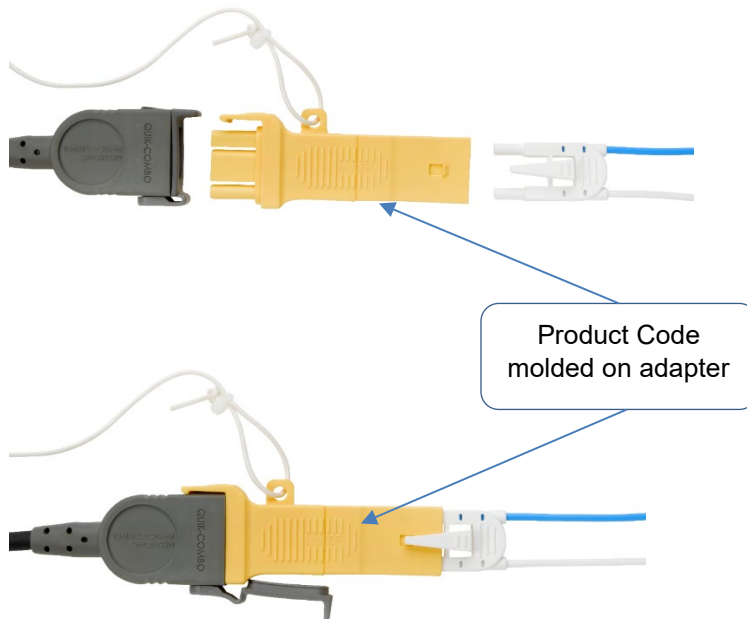
For accounts with certain Stryker/Medtronic/Physio-Control defibrillators, there are two “standardization” options available:

- 3. To standardize to PADPRO electrodes with the Universal/Anderson connector, use adapter **MMUF** (which represents “Medtronic Male connector” with “Universal Female connector”).



MMUF replaces the existing PADPRO adapter with part # **QUICK**.

- 4. To standardize to PADPRO electrodes with the ZOLL connector, use adapter **MMZF** (which represents “Medtronic Male connector” with “ZOLL Female connector”).



MMZF provides a standardization solution that previously required two PADPRO adapters in series (**QUICK** with **ZOLL PIG**).

Table 3 – CONMED PADPRO® electrodes and accessories that will not have FDA approval after February 3, 2022:

Catalog Number	Connector Style	PADPRO Product Line
2516P	Philips Barrel	ADULT/CHILD, Radiolucent
2516P-PC	Philips Barrel	ADULT/CHILD, Radiolucent, Pre-connect
2001P	Philips Barrel	ADULT/CHILD, Radiotransparent
2001P-C	Philips Barrel	ADULT/CHILD, Radiotransparent, Carbon Leads
2001P-PC	Philips Barrel	ADULT/CHILD, Radiotransparent, Pre-connect
2502P	Philips Barrel	ADULT/CHILD, Radiotransparent, Sterile
2603P	Philips Barrel	INFANT, Radiolucent
2602P	Philips Barrel	MINI INFANT, Radiolucent
2516H	Philips Plug	ADULT/CHILD, Radiolucent
2516H-PC	Philips Plug	ADULT/CHILD, Radiolucent, Pre-connect
2001H	Philips Plug	ADULT/CHILD, Radiotransparent
2001H-C	Philips Plug	ADULT/CHILD, Radiotransparent, Carbon Leads
2001H-PC	Philips Plug	ADULT/CHILD, Radiotransparent, Pre-connect
2603H	Philips Plug	INFANT, Radiolucent
2602H	Philips Plug	MINI INFANT, Radiolucent
2516R	R2 Connector	ADULT/CHILD, Radiolucent
2001R	R2 Connector	ADULT/CHILD, Radiotransparent
2603R	R2 Connector	INFANT, Radiolucent
HP	Accessory	PP: ADAPTER; PHILIPS BARREL-STYL
HP PIG	Accessory	PP: PIGTAIL; PHILIPS BARREL-STYL
HP SHORT	Accessory	PP: SHORTING BLOCK, BARREL
HP4R	Accessory	PP: ADAPTER; FR2/HEARTSTREAM
HS-XL	Accessory	PP: ADAPTER; HEARTSTREAM W/PIG
HS-XL PIG	Accessory	PP: PIGTAIL; PHILIPS PLUG
LP-10	Accessory	PP: CABLE; PHYSIO LP-10
LP-12	Accessory	PP: CABLE; PHYSIO LP-12 OR LP-20
LP-500	Accessory	PP: ADAPTER; PHYSIO LP-500 W/PIG
LP9-8	Accessory	PP: CABLE; PHYSIO LP-9
M3507A	Accessory	PP: CABLE; PHILIPS W/BARREL-STYL
M3508A	Accessory	PP: CABLE; PHILIPS W/PLUG-STYLE
QUICK	Accessory	PP: ADAPTER, PHYSIO QUIK-COMBO
QUICK PIG	Accessory	PP: PIGTAIL; PHYSIO QUIK-COMBO
R2	Accessory	PP: ADAPTER; R2/KIMBERLY CLARK
ZOLL	Accessory	PP: ADAPTER; ZOLL MEDICAL
ZOLL PIG	Accessory	PP: PIGTAIL; ZOLL MEDICAL
1105	Accessory	PP: CABLE; PHYSIO PACING
HP4R	Accessory	PP: ADAPTER; FR2/HEARTSTREAM
1200	Accessory	PP: CABLE; ZOLL 1200
1400	Accessory	PP: CABLE; ZOLL 1400
EXT10	Accessory	PP: CABLE; 10 FT EXTENSION
DT 2200	Accessory	Defibrillator Tester (50-ohm Load)