

Product Bulletin

Product Bulletin: 2020-014



International Release of Software Rev. 6.03.006 for ZOLL AED 3 Product Family

Overview

An overview of the key changes included with Software Release 6 (6.03.006) for the ZOLL AED 3[®] device is provided below. Detailed information on any of the new product features can be found in the latest Operator's and Administrator's Guides, which are available in the manuals section of <u>www.zoll.com</u>

Regulatory Restrictions

Due to local regulatory requirements, the following countries will receive devices with previous, approved software versions until local regulatory approval is received:

Country	Language Code	Software Revision	
US	-01	SW Release 1: 01.03.203 - ZOLL AED 3 BLS	
		SW Release 1: 01.03.602 - ZOLL AED 3 and ZOLL AED 3 Automatic	
Canada	-06 and -26	SW Release 5: 05.03.010	
Singapore	-59	SW Release 2: 02.03.016	

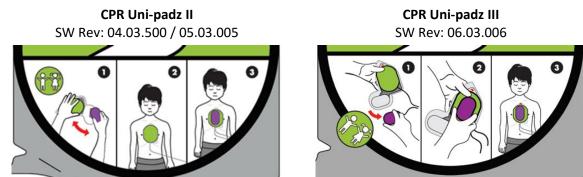
The following countries have regulatory applications in local review:

Country	Language Code	Software Revision		
China	-15	Pending Approval - SW Release 4: 04.03.500		
Korea	-14	Pending Approval - SW Release 5: 05.03.010		
Thailand	-33	PAD Devices Only Pending Approval - SW Release 6: 6.03.006 - ZOLL AED 3 BLS is <i>approved</i> .		
Taiwan	-54	PAD Devices Only Pending Approval - SW Release 6: 6.03.006 - ZOLL AED 3 BLS is <i>approved</i> .		
Singapore	-59	Pending Approval - SW Release 6: 6.03.006		
Thailand	-81	PAD Devices Only Pending Approval - SW Release 6: 6.03.006 - ZOLL AED 3 BLS is <i>approved</i> .		

Updated CPR Uni-padz[®] Placement Illustrations for Child/Pediatric Use

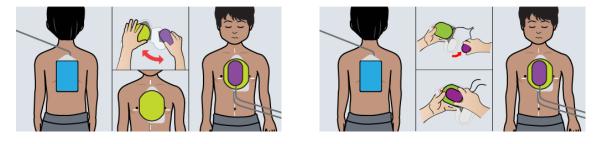
With software Release 6, ZOLL is updating the illustration used for the placement and location of the CPR Unipadz electrodes on pediatric/child patients.

Updated CPR Uni-padz Illustrations:



Updated ZOLL AED 3 Pediatric Mode UI Images

ZOLL AED 3 Device SW Rev: 04.03.500 / 05.03.005 **ZOLL AED 3 Device** SW Rev: 06.03.006



Updated Prompt Flow for Child/Pediatric Use

Several changes were made to the ZOLL AED 3 device prompts including the addition of four new prompts when in pediatric mode. These new prompts focus on the placement of the CPR Uni-padz on a child/pediatric patient.

The changes include:

- The removal of the initial announcement of "ADULT PATIENT SELECTED" prompt . The ZOLL AED 3 device will now only announce "IF PATIENT IS A CHILD, PRESS CHILD BUTTON"
- The addition of new prompts during the attach electrodes sequence (for pediatric patients only):
 - "ATTACH BLUE PAD TO CHILDS BACK"
 - "TEAR PURPLE SENSOR AWAY FROM GREEN PAD"
 - "PLACE PURPLE SENSOR ON GREEN PAD"
 - o "ATTACH GREEN PAD TO CENTER OF CHILD'S CHEST"

Updated Part Numbers for CPR Uni-padz

With this change ZOLL is releasing an updated version of the CPR Uni-padz electrodes. The new part numbers are listed below. All ZOLL AED 3 devices shipped with Software Release 6 will include the new version of CPR Uni-padz. ZOLL will continue to offer all three versions of CPR Uni-padz, refer to the latest International AED price book for pricing. All CPR Uni-padz III part numbers are below:

	CPR Uni-padz I	CPR Uni-padz II	CPR Uni-padz III
CPR Uni-padz (Clinical Electrodes)	8900-000260	8900-000270	8900-000280
CPR Uni-padz Training Kit	8900-000264	8900-000274	8900-000284
CPR Uni-padz Training Pads (Qty. 8)	8900-000265	8900-000275	8900-000285

Customers with existing CPR Uni-padz Demo/Training pads do not need to purchase new kits, they simply can purchase updated training pad gels that use the updated placement recommendations.

Self-test Push to USB

USB Self Test Push Enabled:

- The user can now configure their ZOLL AED 3 to automatically export the device self-test file (DSF) to a pre-installed USB drive following the completion of a periodic self-test. This feature allows users to collect the results of ZOLL AED 3 device self-test without using WiFi transmission.
- When this option is set to On, the device sends the self test data file automatically to the pre-installed USB drive. This option is located within the Advanced Configuration Menu, in the Device Configuration section.
- The number of DSF's stored on the USB drive is dependent on the size of the drive, files will not be overwritten.

ZOLL AED 3 Release 6 – Language Releases/Updates

New Language Releases. The table below outlines the newly released languages for the ZOLL AED 3 device, with associated language codes. All three versions of the ZOLL AED 3 device (Semi-automatic, Fully Automatic, and BLS) are released in each language.

New Language / Code	Primary Language	Additional Language	Additional Language
Hindi (-44)	Hindi	English	-
Lithuanian (-48)	Lithuanian	-	-
Croatian (-52)	Croatian	-	-
Slovenian (-53)	Slovenian	-	-
Turkish (-55)	Turkish	-	-
Vietnamese (-70)	Vietnamese	English	Chinese Mandarin
Bulgarian (-72)	Bulgarian	-	-
Tagalog (-74) - (Philippines)	Tagalog	English	-
Thai (-81)	Thai	English	Japanese

Please contact Global Product Management (<u>gpm@zoll.com</u>) or ZOLL Regulatory Affairs (<u>IReg@zoll.com</u>) for information on the release of these languages should you have any questions

Device System Hardware Requirements

This software release is compatible with ALL ZOLL AED 3 devices manufactured to date.

Production Release

ZOLL Operations will phase in the updates as follows:

• ALL applicable ZOLL AED 3 devices shipped from ZOLL Chelmsford after 08 July 2020 will include SW Release 6.

Software Upgrade Process

There are two options to obtain the Release 6 software upgrade files:

- 1) FREE Electronic Delivery. Email ZOLL Technical Service to request an electronic delivery of the software file (download from secure file server)
- 2) Purchase a Programmed USB Stick. You can purchase a USB stick with the Software Release 6 file preloaded (\$25 USD) from ZOLL Technical Service

IMPORTANT Changes to the Software Upgrade Process

 When updating the software on your ZOLL AED 3 device, the USB stick now MUST include individual languages files. If the USB stick does NOT include these files, the image shown below will appear and you will not be able to update the AED's software. Please contact ZOLL Technical Service should this appear, to obtain the associated language files. Adding additional languages or changing the default language files is not possible, only the pre-installed language files will be updated.



- Following the completion of the software update the device will display an "UPGRADE COMPLETE" message.
- Should the software upgrade fail for any reason the following image will be displayed. Please contact ZOLL Technical Service for support.



Please contact Technical Support for compatibility details and installation instructions.

Contact your local ZOLL Service Center or Authorized Distribution Partner

ZOLL Customer Outside the US

If you need further assistance, please email ZOLL Chelmsford Service



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Thank you,



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