

## Overview

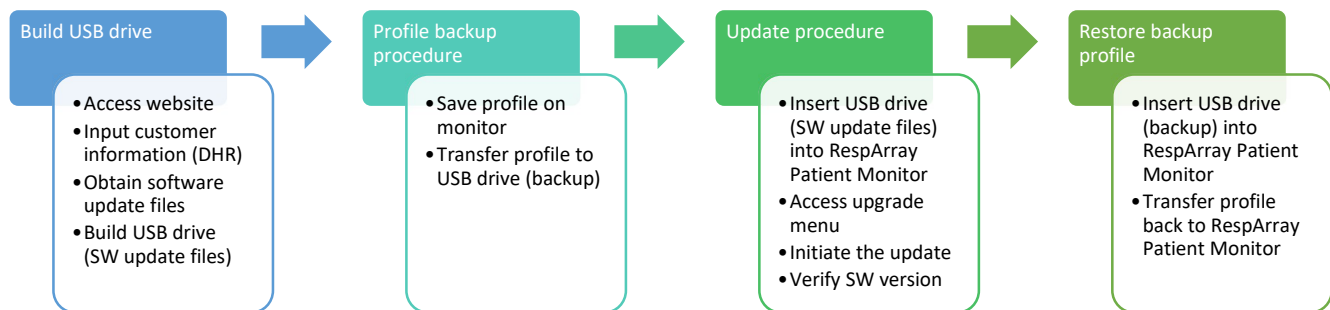
<b>Purpose</b>	<ul style="list-style-type: none"><li>▪ The purpose of this TSB is to provide guidance to Medtronic service personnel and customers regarding the RespArray Patient Monitor v01.03.01.02 software update via USB drive. This is an update of the existing v01.03.00.00 software revision that focuses on the following major updates: enablement of “Measure Mode” to be set as default and remain default, the optimization of the alarm reset function, and the addition of other enhancements. This is an optional update for customers.</li></ul>
<b>Scope</b>	<ul style="list-style-type: none"><li>▪ This document applies to Medtronic PM OU service personnel and customers who operate and support the RespArray Patient Monitor. Additionally, this document provides service guidance for conducting v01.03.01.02 software updates at the regional service centers or on the field. Any other service provided to the RespArray Patient Monitor is out-of-scope of this TSB.</li><li>▪ This TSB is not intended to replace local service instructions or the RespArray Patient Monitor service manual.</li><li>▪ This TSB shall be used to supplement the local service instructions and the RespArray Patient Monitor service manual.</li></ul>
<b>Roles</b>	<ul style="list-style-type: none"><li>▪ <b>Medtronic Patient Monitoring (PM) Global Technical Service:</b> Manage the v01.03.01.02 software update field strategy and process for Service.</li><li>▪ <b>Medtronic Service Personnel:</b> Conduct the v01.03.01.02 software update with guidance from PM Global Technical Service.</li><li>▪ <b>Customer:</b> Conduct the v01.03.01.02 software update with guidance from PM Global Technical Service.</li><li>▪ <b>Medtronic Global Product Management:</b> Provide input for customer-facing affairs associated with the v01.03.01.02 software update.</li><li>▪ <b>Medtronic Regulatory Affairs:</b> Provide guidance on regulatory clearance including priority and dates for different regions for the v01.03.01.02 software update as the former is a requirement prior the installation of such update. Regions must seek approval prior to proceed with the installation.</li><li>▪ <b>Medtronic U.S. Technical Support:</b> Provide troubleshooting support to service personnel/customer regarding the v01.03.01.02 software update as needed. Manage the documentation provided by service personnel/customer as evidence of completing the v01.03.01.02 software update.</li></ul>

## Terms and Definitions

<b>Term</b>	<b>Definition</b>
CDP	Change Development Process
DHR	Device History Record - Device history records are a compilation of records containing the production history of a finished device.
etCO2	End-tidal carbon dioxide
IFU	Instructions for Use
GUI	Graphical User Interface
NIBP	Non-Invasive Blood Pressure
PC	Personal computer
PM	Patient Monitoring
PM OU	Patient Monitoring Operating Unit
PR	Pulse Rate
SN	Serial Number
SW or S/W	Software
TSB	Technical Service Bulletin
U.S.	United States
USB	Universal Serial Bus

## Process Overview

The development of this document is in support of [R1] Change Development Process (CDP) CDP-0038764, RespArray: CO2 timer issue fix + 5 CFN creation. In summary, all the service activities involved in the v01.03.01.02 software update are initiated based on input from the project team managing the CDP. PM Global Technical Service must convert those inputs into actionable items and execute them under a service strategy. Subsequent activities are executed by regional service personnel/customer in conjunction with the U.S. Technical Support team. The following diagram provides a general overview of the v01.03.01.02 software update process.



- This is an optional update to the RespArray Patient Monitor that focuses on the following major updates: enablement of “Measure Mode” for the CO2 module to be set as default and remain default, the optimization of the alarm reset function, and the addition of other enhancements.
- Regulatory clearance is required for regions to receive the v01.03.01.02 software update. Service personnel/customers located in regions that have received clearance for the v01.03.01.02 software update may proceed with the installation.
- There are no pre-requisites for the installation of the v01.03.01.02 software.
- The RespArray Patient Monitor devices may be updated as they are sent in for periodic maintenance or repair to the regional service centers or when the field service personnel/sales representatives coordinate visits to the medical facilities.
- Service personnel/customers may obtain training, troubleshooting and other relevant guidance from PM Global Technical Service and the U.S. Technical Support team.
- Sales representatives can act as an extension of service personnel and work directly with their biomedical customers to schedule visits for software update work.
- Service personnel/customers responsible for executing the v01.03.01.02 software update will be given access to the update files through a website. The update files can be stored in a USB drive which can be leveraged to deliver the update files to the RespArray Patient Monitor.

## Overview of improvements

The RespArray Patient Monitor v01.03.01.02 software update carries over previous software update improvements and adds the enhancement of the CO2 module and “Alarm Authority” functionalities, and improves wireless setting management post-software upgrade.

v01.03.01.02 software update benefits:

- Enables the CO2 module for “Measure Mode” to be defaulted on and to remain as default.
- Add Wi-Fi background scanning switch and background scanning channel copied to the factory maintain menu.
- Replace “Alarm Authority” with “Alarm Reset” switch:
  - When the alarm reset switch is on, the user can use the reset function.
  - When the alarm reset switch is off, the alarm reset function is grayed out and not active. When the user presses the alarm reset switch, a message that the alarm reset function is disabled appears on the screen.
- Wi-Fi settings are inherited post-upgrade with the exception of Connection Method which will be set to wired by default. User can set Connection Method to “WLAN” after the software upgrade is completed and wireless connection will be automatically reestablished per the pre-upgrade settings.
- Add Portuguese IFU to GUI.

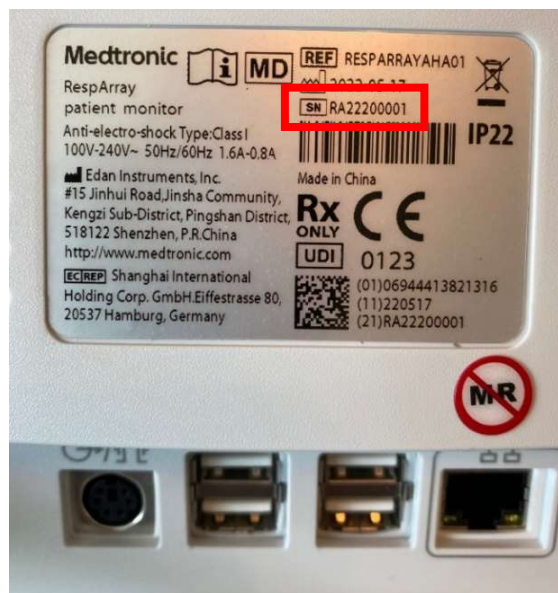
## Process Detail

### 1. Build USB drive

Process Step	Requirement
<b>Step 1 – Gather needed tools</b>	<ul style="list-style-type: none"> <li>▪ RespArray Patient Monitor with power cord</li> <li>▪ USB drive (to manage User Profile and deliver SW upgrade files) per the following requirements:                             <ul style="list-style-type: none"> <li>– Format using FAT32</li> <li>– Recommended storage capacity &lt;32GB (minimum of 512 mb)</li> </ul> </li> <li>▪ Software update files v01.03.01.02 (“target” folder)</li> <li>▪ PC</li> <li>▪ Factory password reset key (contact U.S. Technical Support team)</li> <li>▪ User password</li> </ul>
<b>Step 2 – Download the update files</b>	<ul style="list-style-type: none"> <li>▪ Access the following website to gain access to the software update files:                             <ul style="list-style-type: none"> <li>– &lt;<a href="https://www.medtronic.com/covidien/en-us/support/software/patient-monitoring-products/resparray-software.html">https://www.medtronic.com/covidien/en-us/support/software/patient-monitoring-products/resparray-software.html</a>&gt;</li> </ul> </li> <li>▪ Service personnel/customers must provide contact information and serial number(s) of the devices being updated before access to the v01.03.01.02 software files is granted. Serial numbers for <b>ALL DEVICES</b> must be provided as the software update must be documented in the DHR. The serial number is found in the back of the device on the product label (refer section 1.1).</li> </ul>
<b>Step 3 – Build the USB drive</b>	<ul style="list-style-type: none"> <li>▪ Refer to section 1.2 for additional information on how to build the USB drive.</li> </ul>

#### 1.1 Locating the serial number of the RespArray Patient Monitor

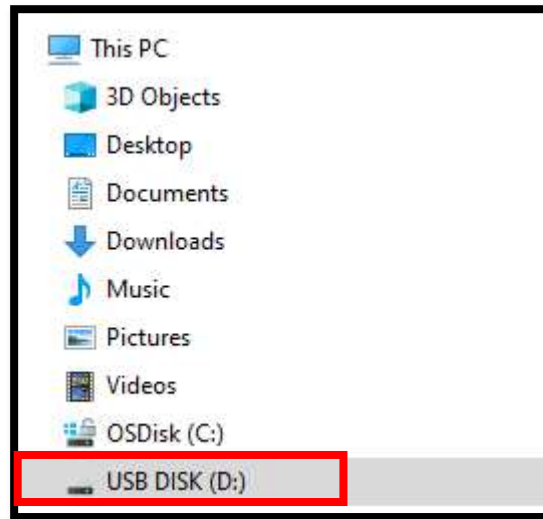
The image below illustrates an example of a product label where the serial number (SN) can be found.



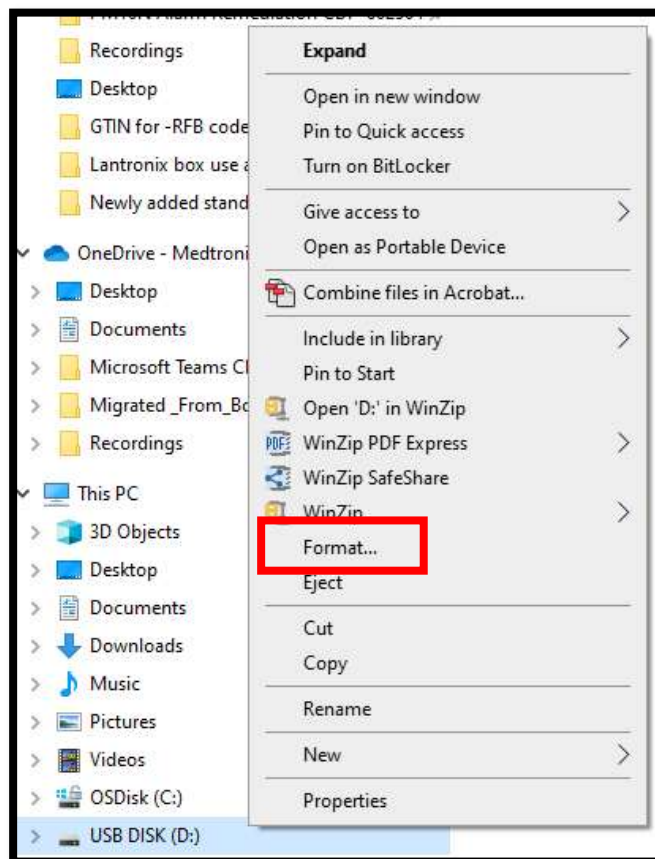
## 1.2 Building the USB drive

### 1.2.1 Format the USB drive

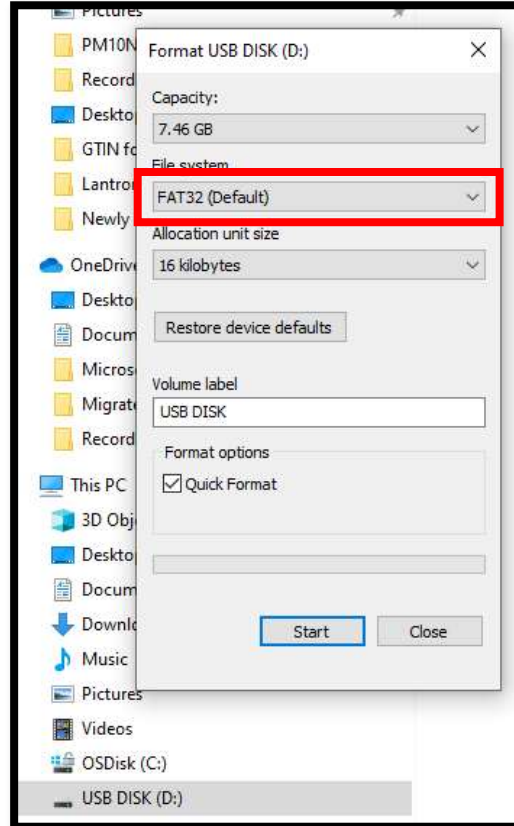
Insert USB flash drive into PC and locate the flash drive in the Windows File Explorer



Right-click on the USB drive and select "Format..."



Ensure the correct option is selected for File system before proceeding, FAT32. Select “Start” to begin formatting the flash drive.



Once the formatting process is completed. Save the RespArray Patient Monitor v01.03.01.02 software update files folder titled “target” into the USB drive. Ensure the folder is not saved into a specific folder in the USB flash drive but in the root directory. Avoid utilizing a folder with the .zip extension. The content of your USB drive should match the following:

Name	Date modified	Type	Size
target	2/15/2023 14:37	File folder	

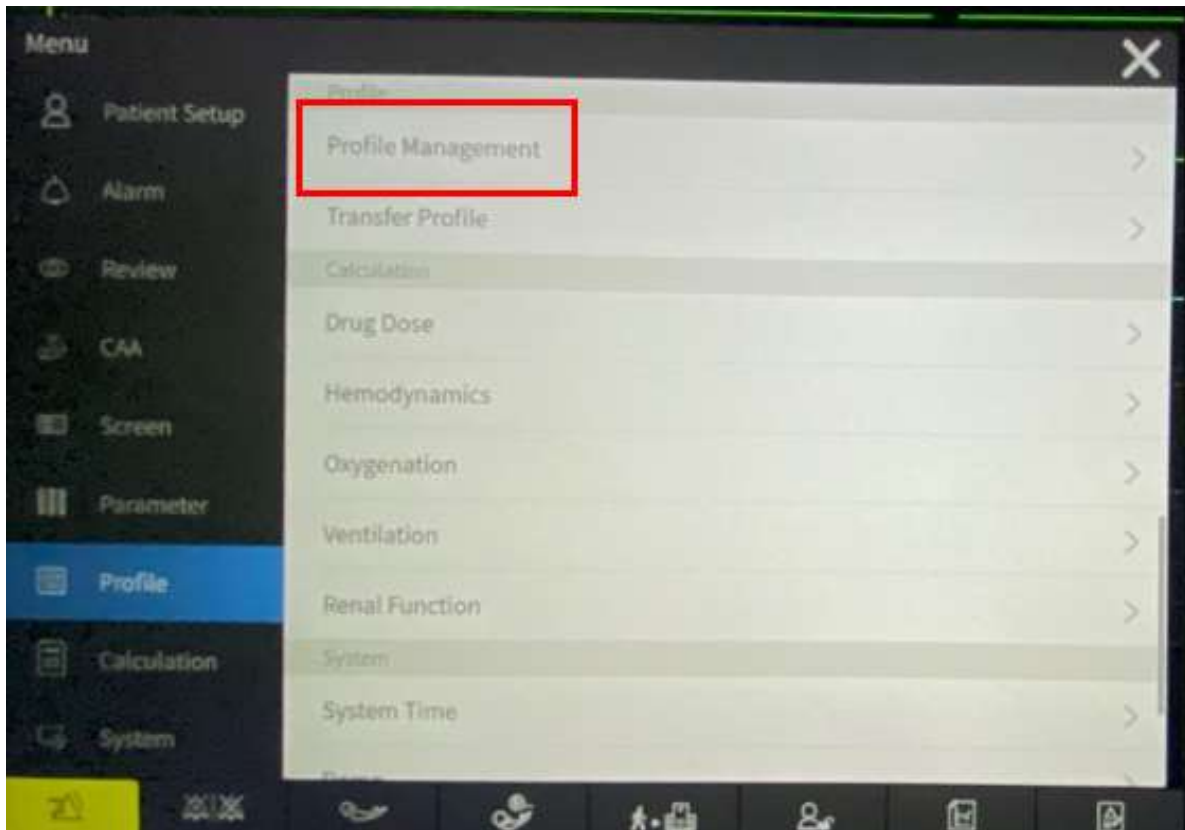
## 2. Profile backup procedure

Process Step	Requirement
<b>Step 4 – Save profile on monitor</b>	<ul style="list-style-type: none"> <li>▪ Access <b>Menu &gt;&gt; Profile &gt;&gt; Profile Management</b> on the monitor’s menu. Select which Default or User Profile will be saved. Select <b>Save and Apply</b>.</li> <li>▪ Input user password to proceed with saving and applying the profile.</li> <li>▪ Specify Profile Name, select <b>Confirm</b>.</li> <li>▪ Refer to section 2.1 for illustrations of the menu structure.</li> </ul>

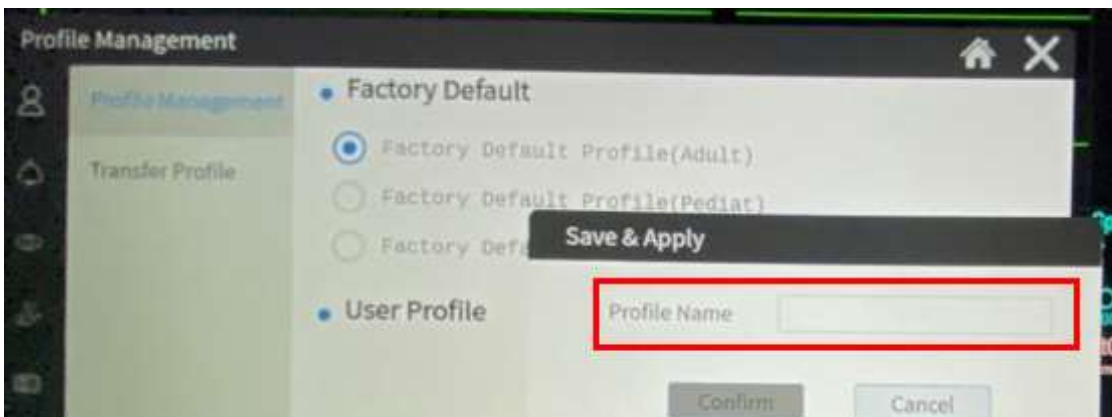
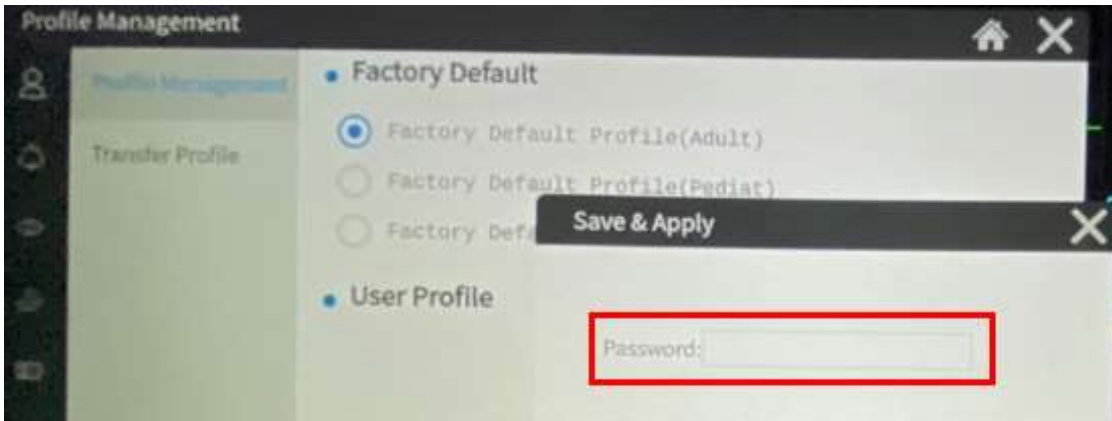
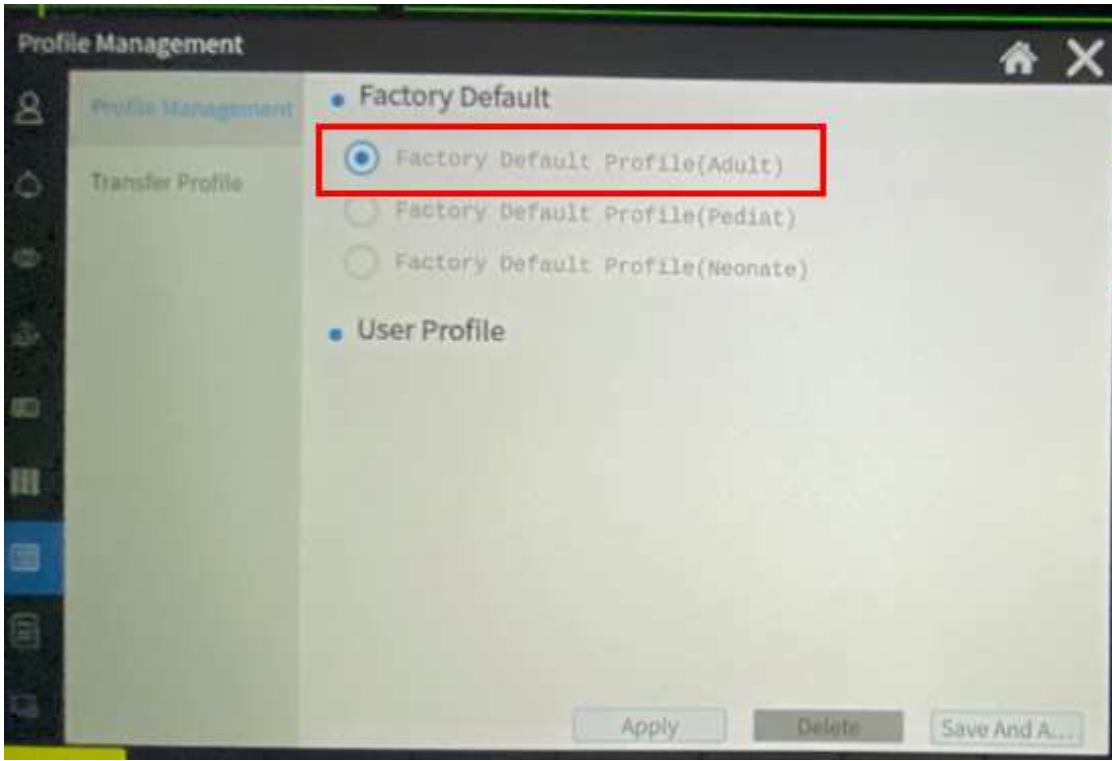
Process Step	Requirement
<b>Step 5 – Transfer profile to USB drive</b>	<ul style="list-style-type: none"><li>▪ Plug in USB drive into USB port located on the back of the monitor.</li><li>▪ Access <b>Menu &gt;&gt; Profile &gt;&gt; Transfer Profile</b> on the monitor’s menu. Enter user password to proceed.</li><li>▪ Select <b>USB Drive</b> option from the top right corner for External Profile. Select <b>Export</b> then choose which Internal Profile will be exported to the USB drive. Move the selected Internal Profile to the USB drive by selecting the &gt;&gt; arrows. Select <b>Confirm</b> and enter user password to complete the action.</li><li>▪ Refer to section 2.2 for illustrations of the menu structure.</li></ul>

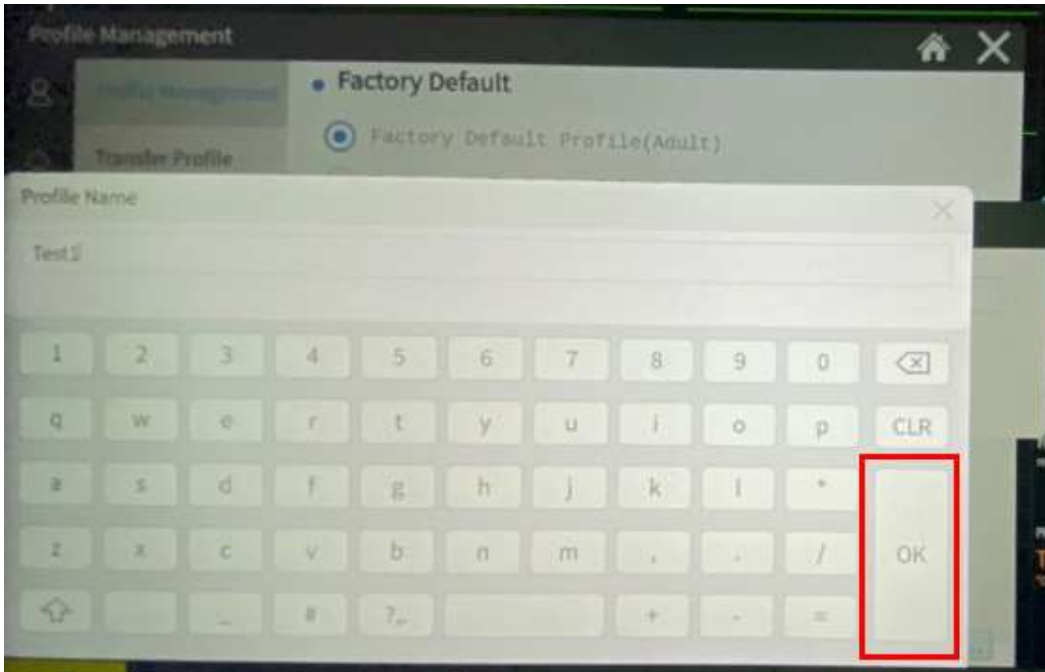
### 2.1 Step 4 visual aids – Saving user profile

The images below help explain the steps followed to save a user profile prior to importing the profile to the USB drive. A profile name must be established.









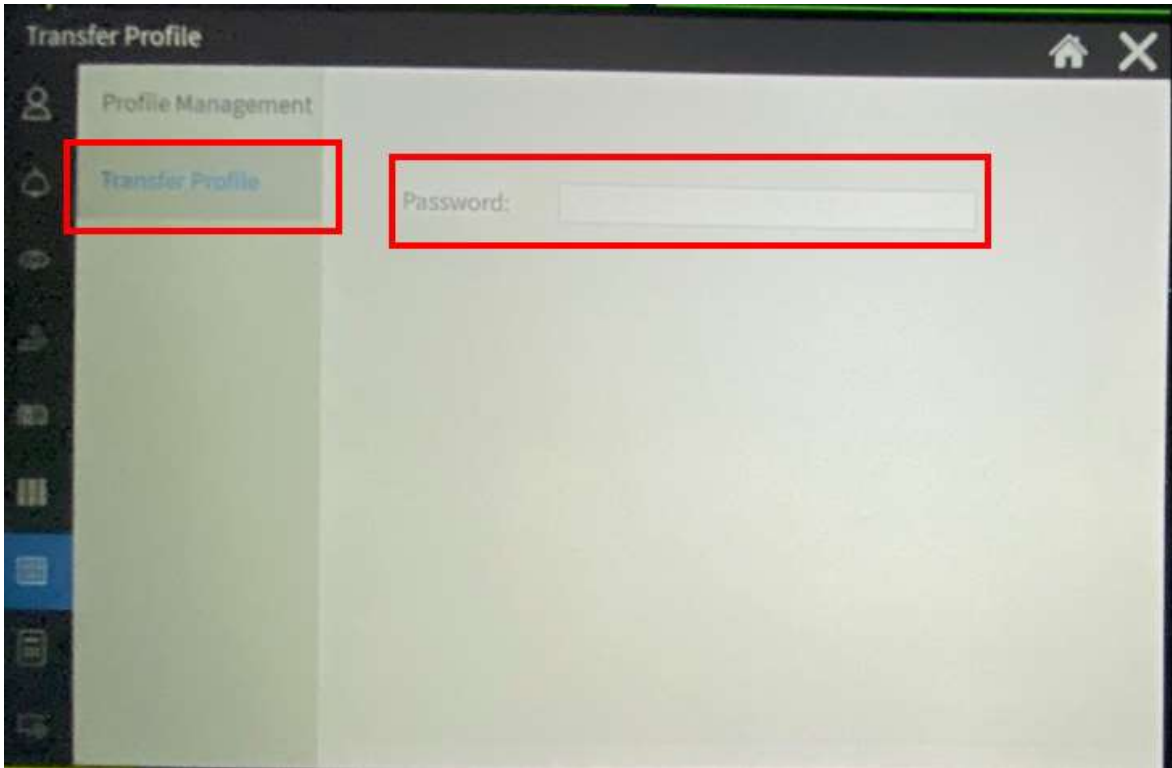
5.

## 2.2 Step 5 visual aids – Exporting profile to USB drive

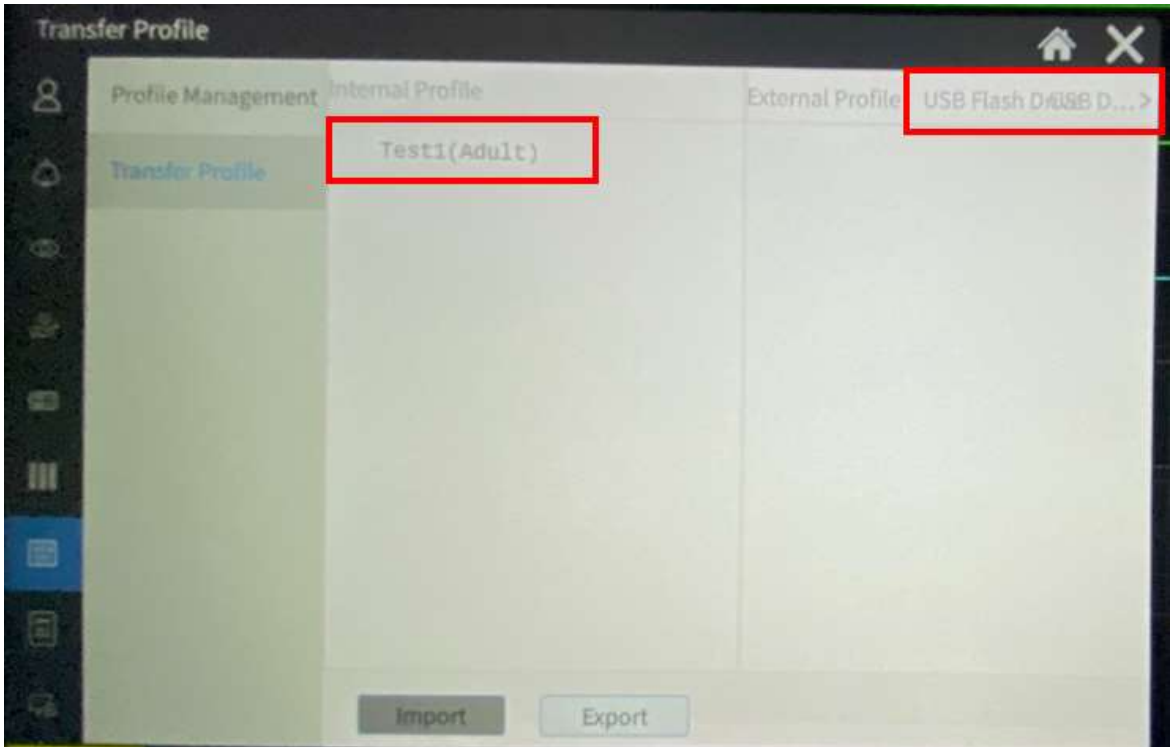
The images below help explain the steps followed to export a user profile to the USB drive prior to conducting the installation of the software update files.



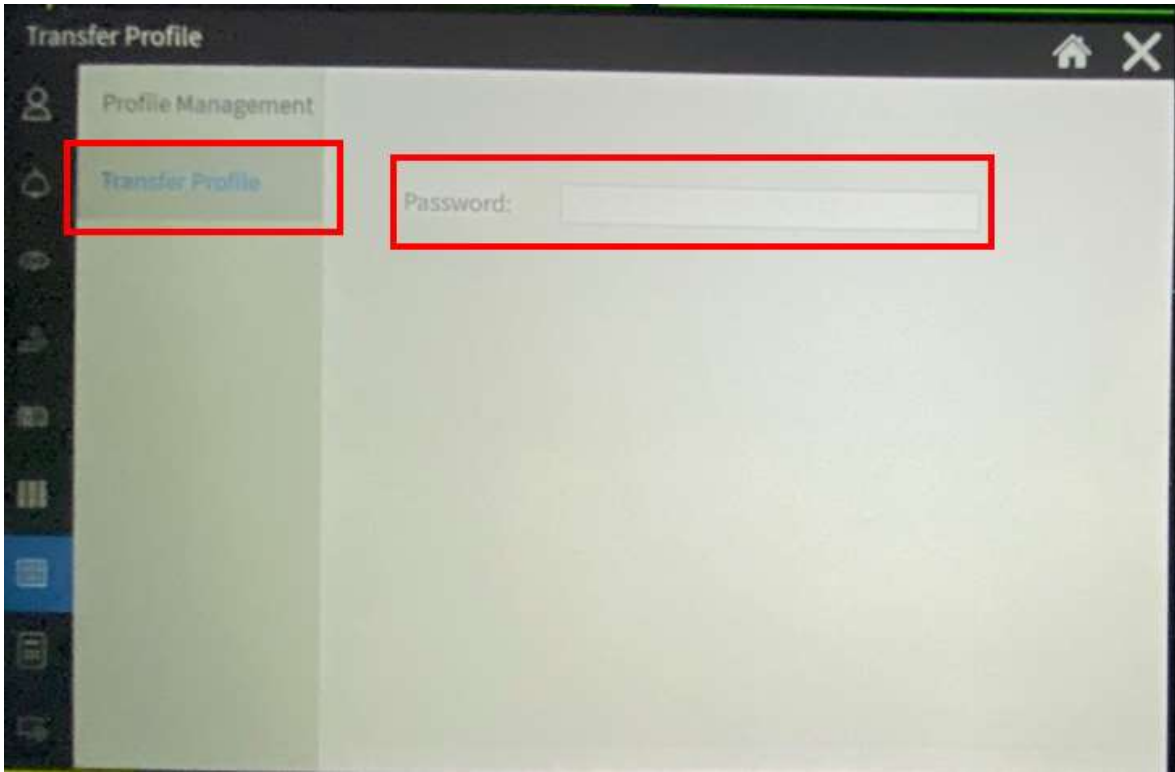
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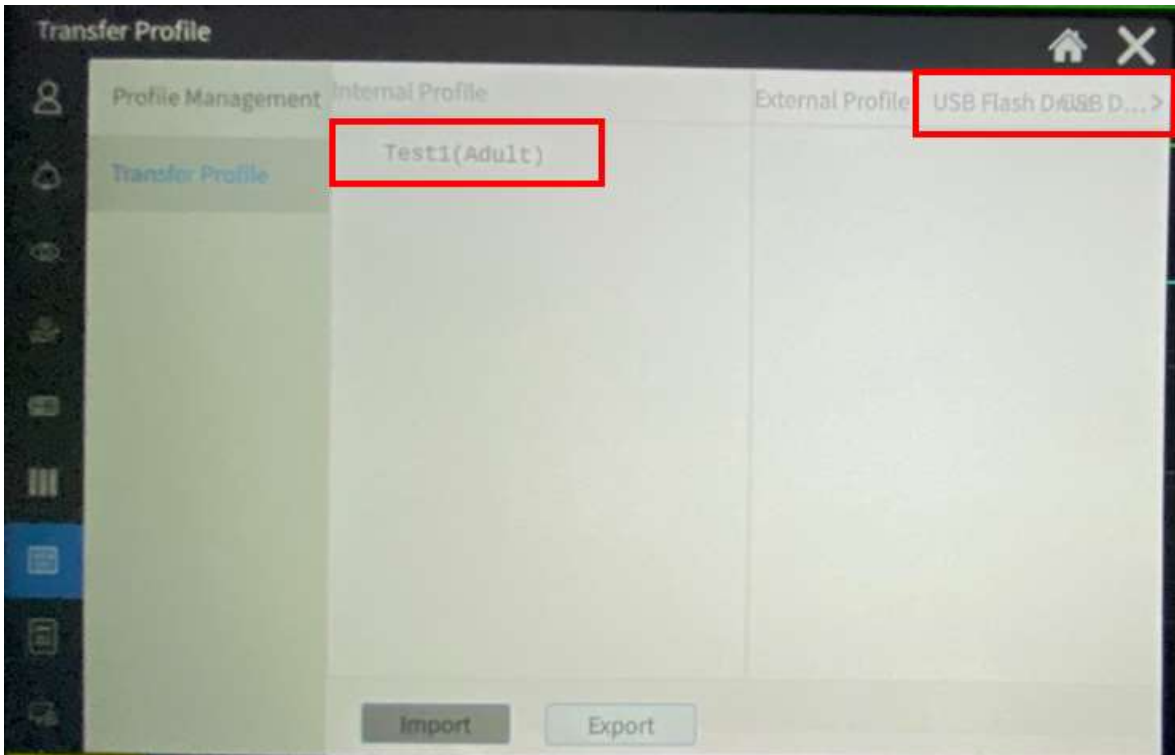
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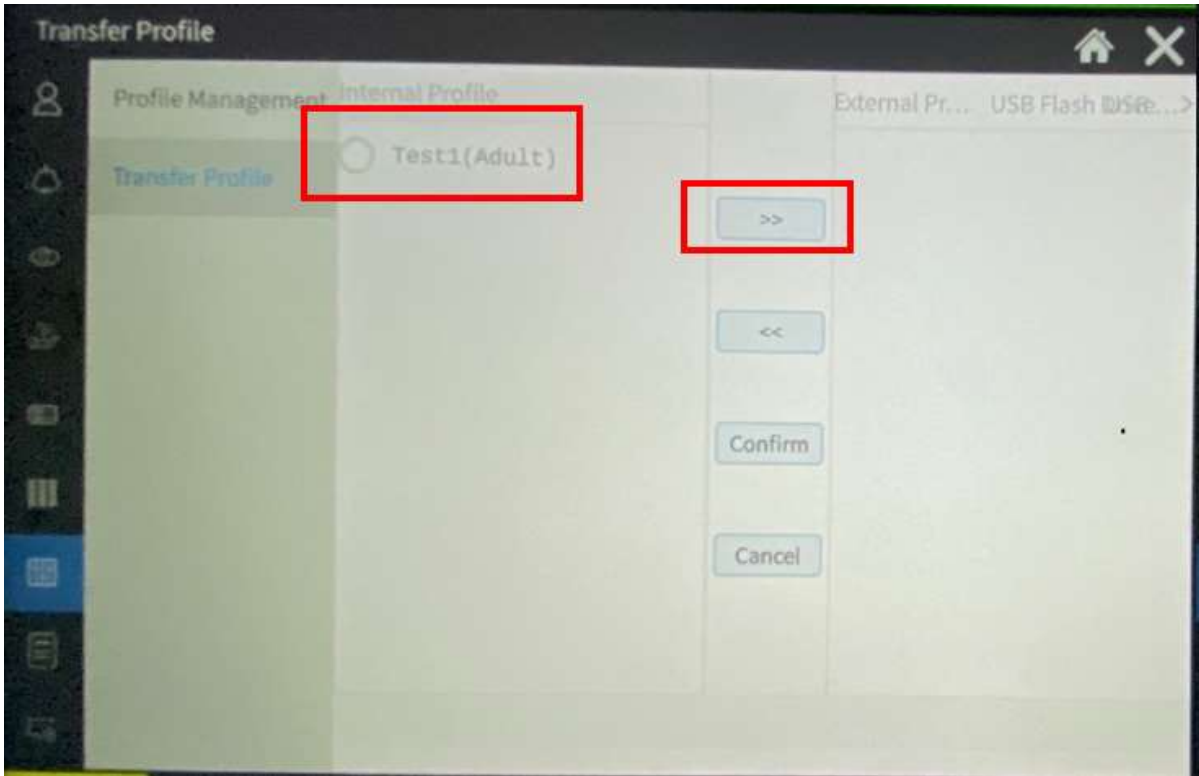
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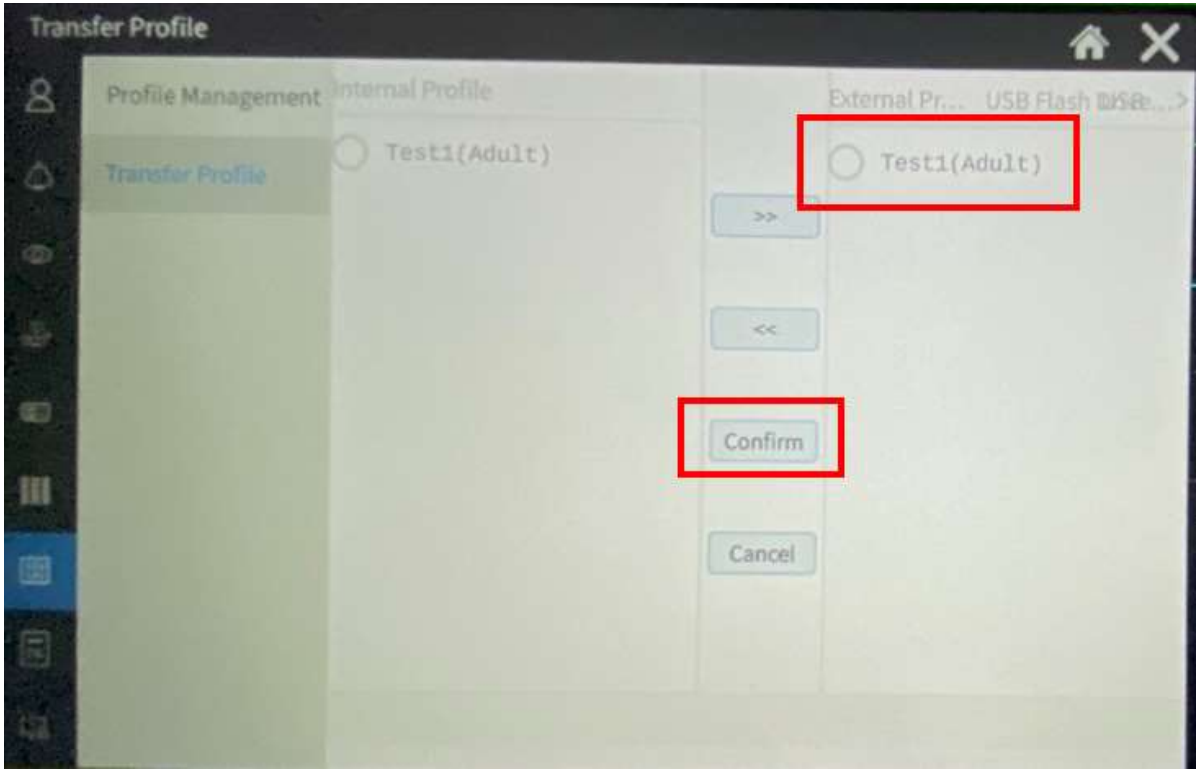
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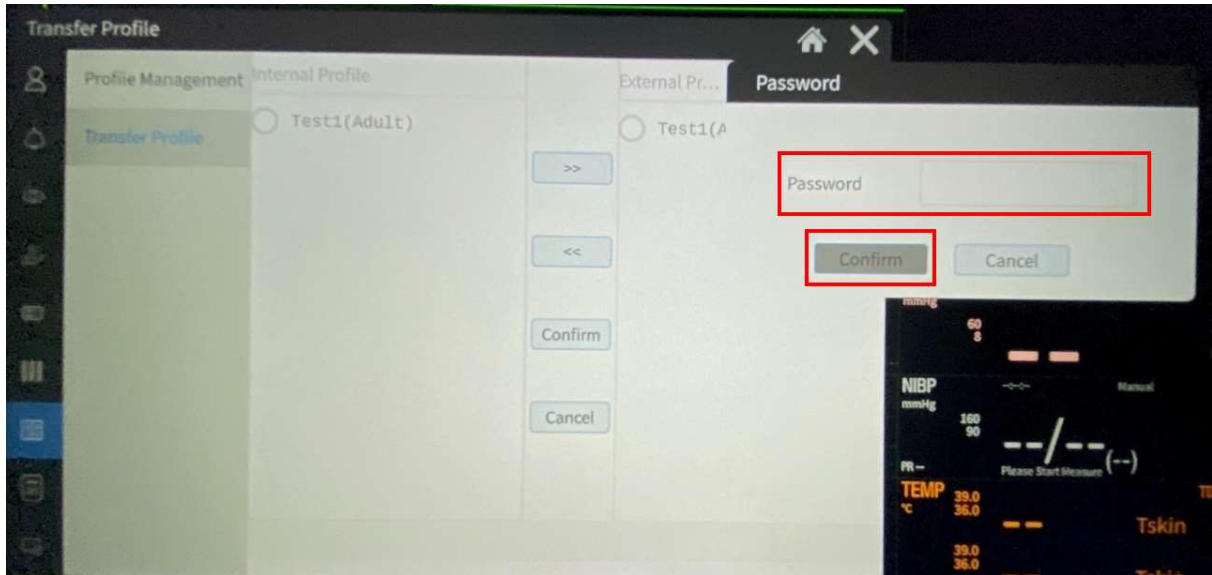
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6.



7.



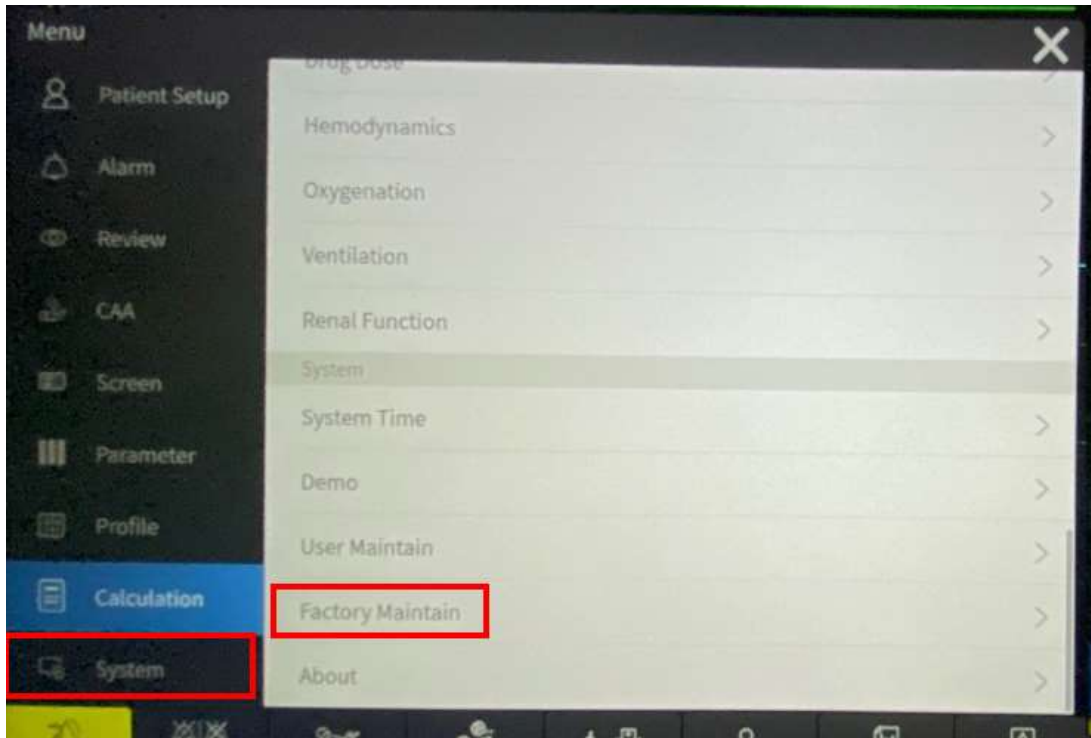
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### 3. Update procedure

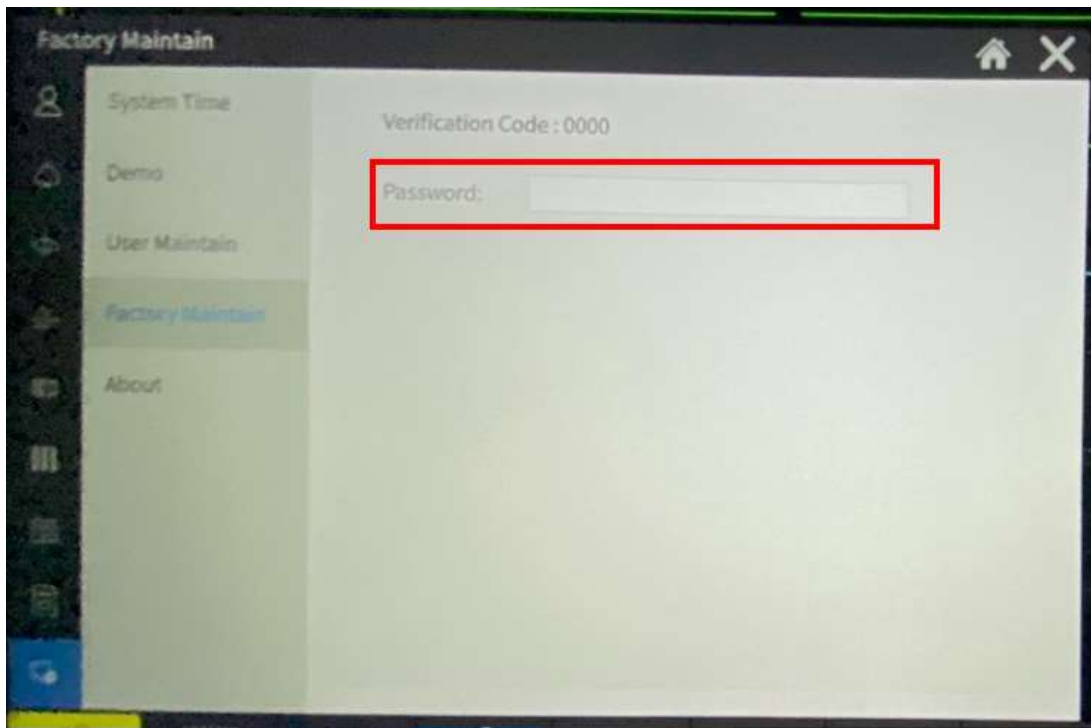
Process Step	Requirement
<b>Step 6 – Connect USB drive into monitor</b>	<p><b>Note: Ensure the monitor is connected to a power outlet prior to initiating the update process.</b></p> <ul style="list-style-type: none"> <li>Plug in USB drive containing the upgrade files into USB port located on the back of the monitor.</li> </ul>
<b>Step 7 – Access upgrade menu</b>	<ul style="list-style-type: none"> <li>Access <b>Menu &gt;&gt; System &gt;&gt; Factory Maintain</b> on the monitor’s menu. If verification code is 0000, input 998 as the password. Otherwise, reference [R2] for further instructions on how to obtain a Dynamic Password.</li> <li>Once password is entered, access <b>Upgrade Management</b>.</li> <li>Refer to section 3.1 for illustrations of the menu structure.</li> </ul>
<b>Step 8 – Initiate the upgrade</b>	<ul style="list-style-type: none"> <li>In <b>Upgrade Management</b>, select <b>USB Drive</b> from the top right corner as the Method. Select <b>Start</b> to initiate the software update process.</li> <li>The monitor will begin validating the update files from the USB drive.</li> <li>After the monitor concludes verification of the update files, a pop-up window confirming the detection of the target image will appear, select <b>Confirm</b> to proceed with the software update process.</li> <li>The monitor will initiate the update process and will restart the operating system to the System Recovery mode. Upon completion of the update, the monitor will prompt the user to <b>restart</b> the machine to continue.</li> <li>Refer to section 3.1 for illustrations of the menu structure.</li> </ul>

### 3.1 Step 7 and Step 8 visual aids – Exporting profile to USB drive

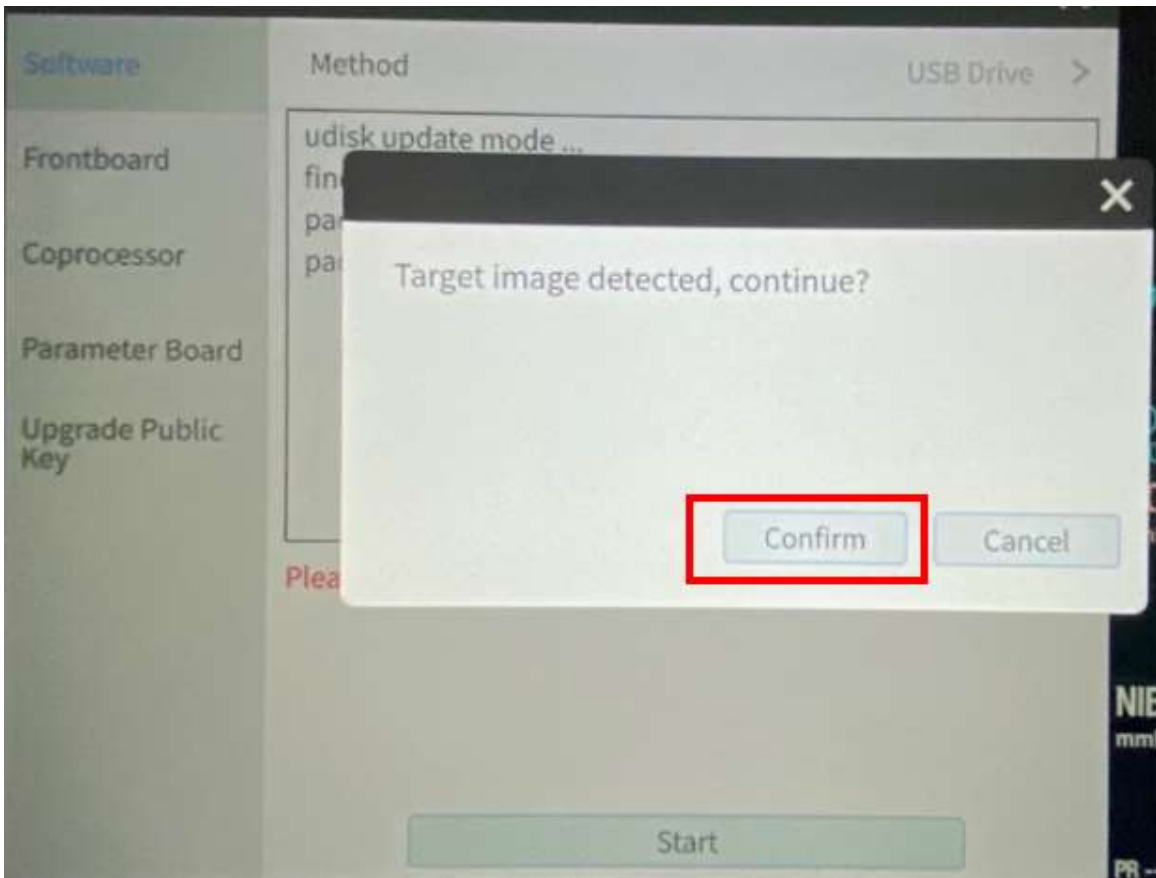
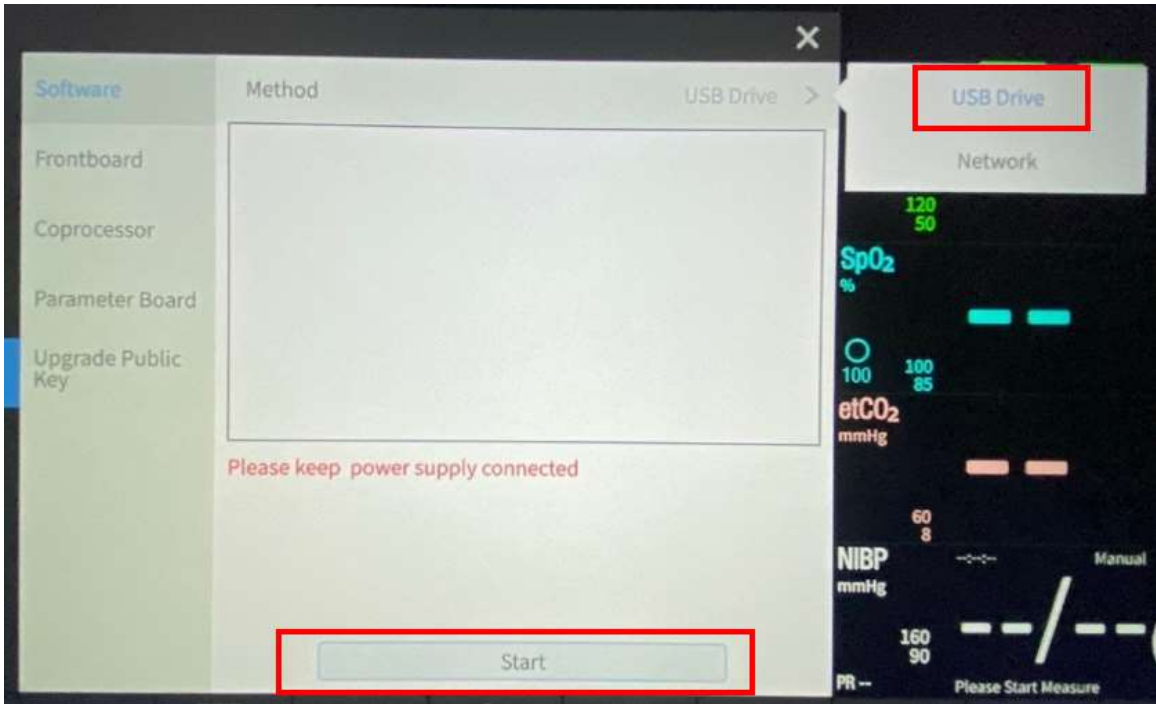
The images below help explain the steps followed to access the **Upgrade Management** menu to execute the software update process.



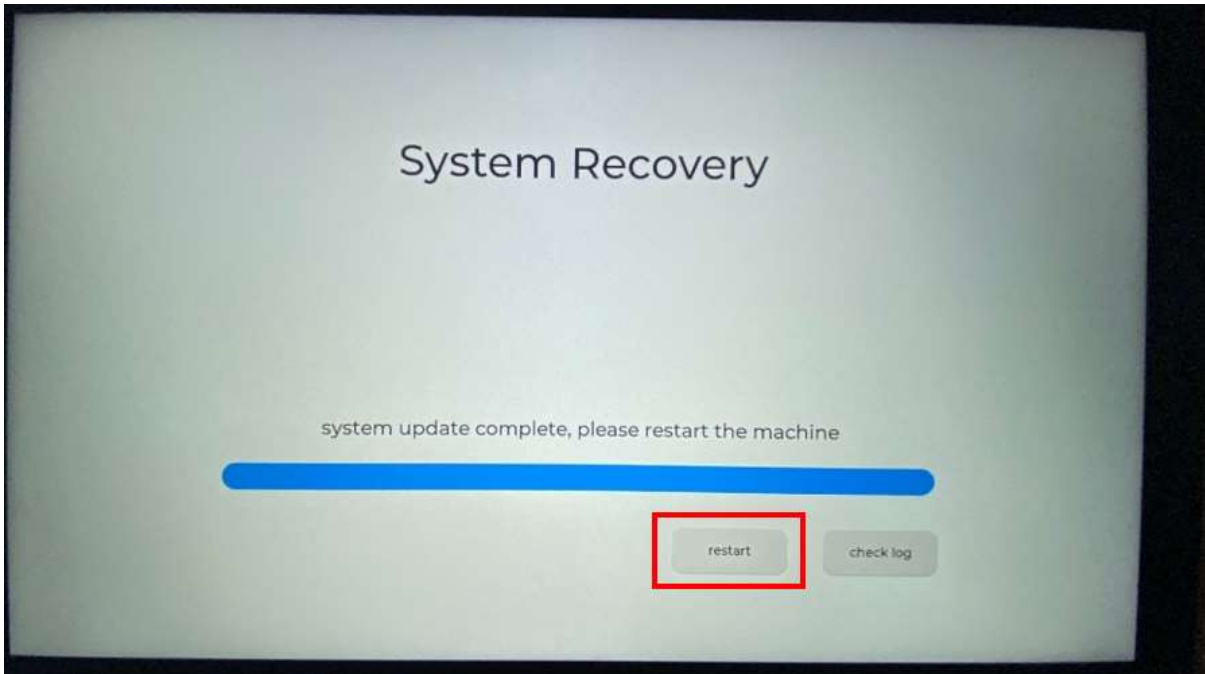
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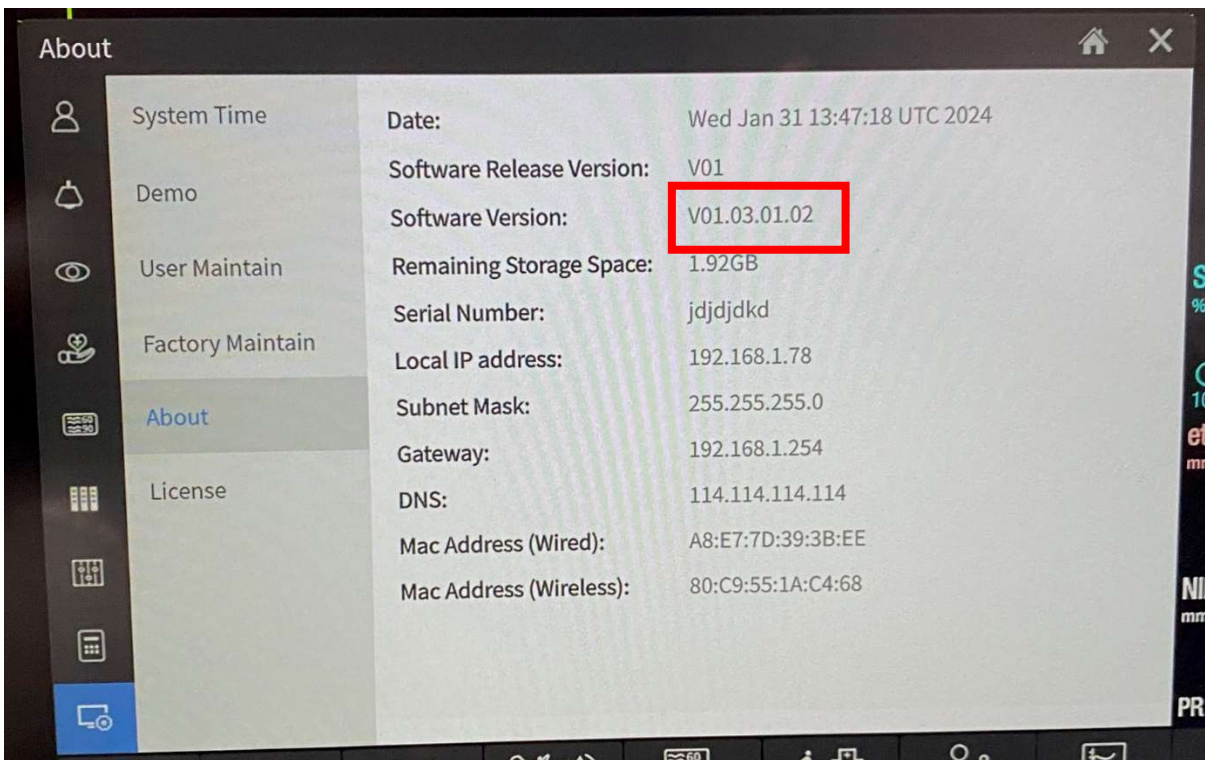
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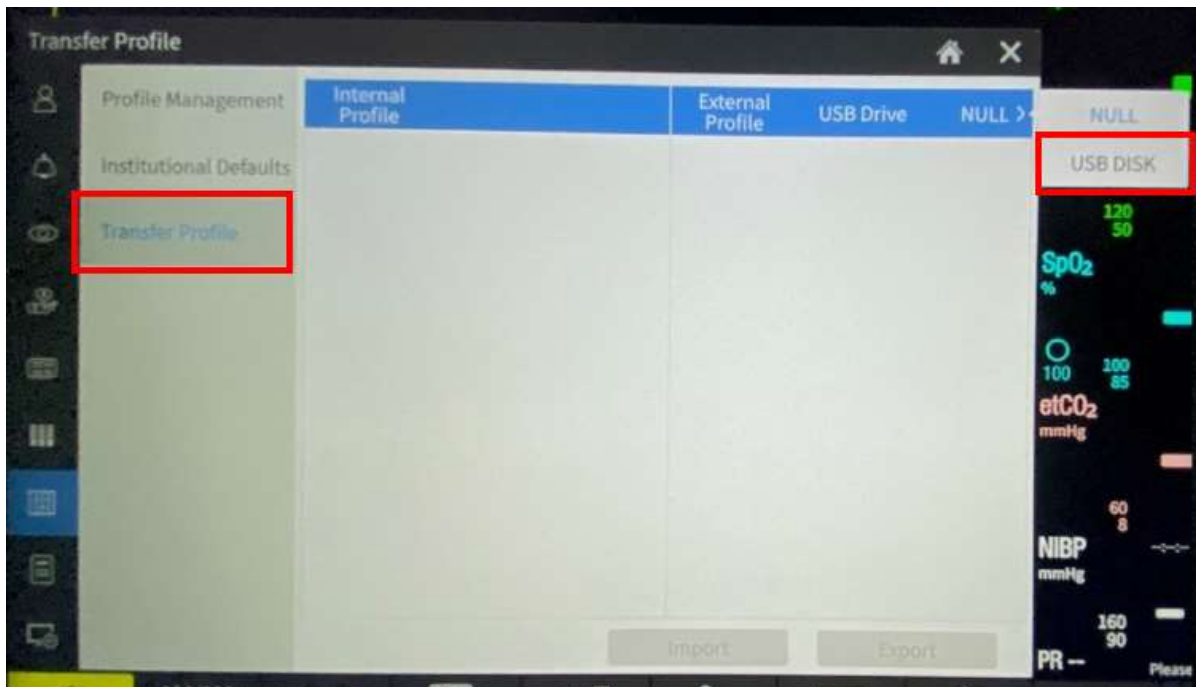
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## 4. Restore backup profile

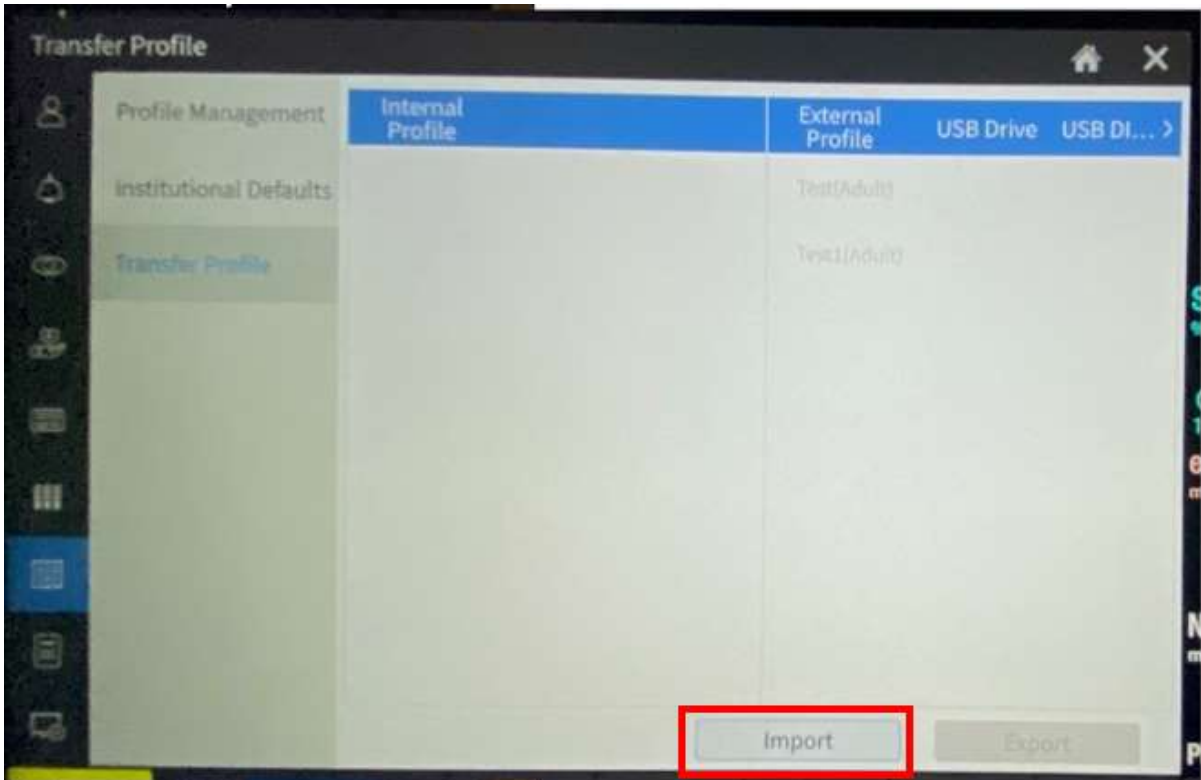
Process Step	Requirement
<b>Step 9 – Transfer backup profile from USB drive to monitor</b>	<ul style="list-style-type: none"> <li>Plug in USB drive containing the profile information into USB port located on the back of the monitor.</li> <li>Access <b>Menu &gt;&gt; Profile &gt;&gt; Transfer Profile</b> on the monitor’s menu. Enter user password to proceed.</li> <li>Select <b>USB drive</b> option from the top right corner for External Profile. Select <b>Import</b> then choose which External Profile will be imported to the monitor. Move the selected External Profile to the monitor by selecting the &lt;&lt; arrows. Select <b>Confirm</b> and enter user password to complete the action.</li> </ul>

### 4.1 Step 9 visual aids – Exporting profile to USB drive

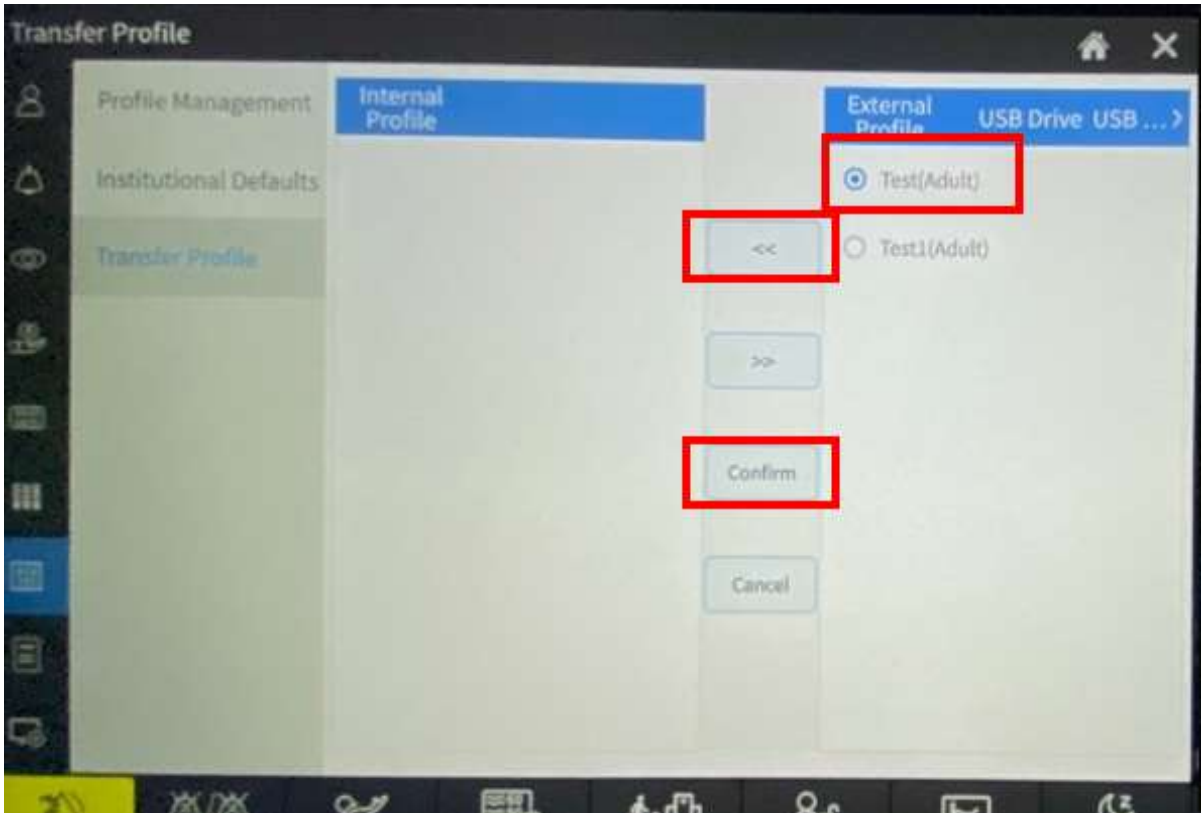
Follow the steps in section 2.2 to access the Transfer Profile menu.



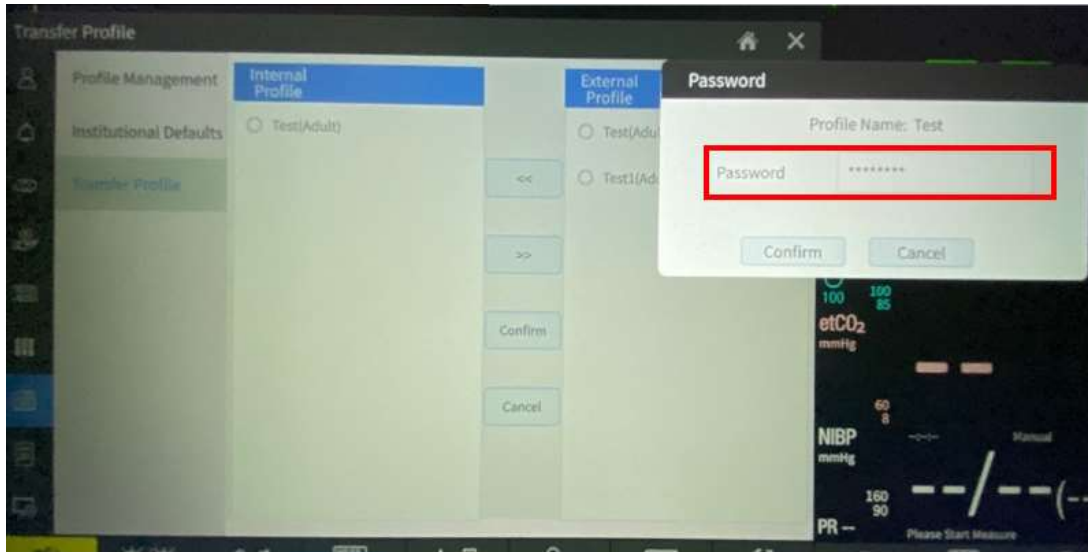
1.



2.



3.



4.

## Technical Support

For additional questions on this process, contact the U.S. Technical Support team through the following means:

- [rs.hqtsweb@medtronic.com](mailto:rs.hqtsweb@medtronic.com)
- 1-800-255-6774 Option 1, Option 2 for RespArray Patient Monitor technical support.

## References

Reference	Number	Title
[R1]	CDP-0038764	RespArray: CO2 timer issue fix + 5 CFN creation
[R2]	DC00144964	Technical Service Bulletin (TSB) RespArray Patient Monitor Password Reset Instructions

## Quality Records

Service personnel/customers performing the v01.03.01.02 software update on the RespArray Patient Monitor must provide input on name of user performing the update, customer name, facility, and number of devices being updated when requesting the update files through the following website:

<<https://www.medtronic.com/covidien/en-us/support/software/patient-monitoring-products/resparray-software.html>>

Requesting the update files will generate a report with all pertinent information as evidence of performance. These records will be maintained in a database managed by the U.S. Technical Support team and stored in the DHR of the device.

Quality Record	Required Approvals
Software update form	None