Technical Service Bulletin (TSB) RespArray Patient Monitor Password Reset Instructions		Work Instruction	
DC00144964	Revision B	Page 1 of 12	Medtronic

Overview

Purpose	 The purpose of this TSB is to provide guidance to Medtronic service personnel and customers on managing the RespArray Patient Monitor system passwords.
Scope	 This document applies to Medtronic PM OU service personnel and customers who support and operate the RespArray Patient Monitor. Additionally, this document provides service guidance for conducting password management actions at the regional service centers or on the field. Any other service provided to the RespArray Patient Monitor is out-of-scope for this document. This TSB is not intended to replace local service instructions or the RespArray Patient Monitor service manual. This TSB shall be used to supplement the local service instructions and the RespArray Patient Monitor service manual.
Roles	 Medtronic Patient Monitoring (PM) Global Technical Service: Provide guidance on management of passwords and reset procedures. Medtronic Service Personnel: Manage passwords and reset procedures with guidance from PM Global Technical Service. Customer: Manage passwords and reset procedures with guidance from U.S. Technical Support. Medtronic Global Product Management: Provide input for customer-facing affairs associated with the password management processes. Medtronic U.S. Technical Support: Provide troubleshooting support to service personnel/customer regarding the password management processes.

Technical Service Bulletin (TSB) RespArray Patient Monitor
Password Reset InstructionsWork
Instruction

DC00144964

Revision B

Page 2 of 12

Terms and Definitions

Term	Definition
Auto-acquisition Interval	Monitor setting used to generate a new Verification Code on an established time interval
CDP	Change Development Process
Manual Update	User can select this option to manually generate a new Verification Code
PC	Personal computer
PM	Patient Monitoring
PM OU	Patient Monitoring Operating Unit
S/W	Software
TSB	Technical Service Bulletin
UacKeyTool	Software application used to generate a Dynamic Password based on a specific Verification Code
U.S.	United States
USB	Universal Serial Bus
Verification Code	User can use this verification code to obtain the Dynamic Password through the UacKeytool application

Technical Service Bulletin (TSB) RespArray Patient Monitor Password Reset Instructions		Work Instruction		
	DC00144964	Revision B	Page 3 of 12	Medtronic

Process Overview

The development of this document is in support of [R1] Change Development Process (CDP) CDP-0033856, RespArray Monitor S/W 1.12. In summary, all the service activities involved in the v1.12 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 Medtronic regional service personnel/customer in conjunction with the U.S. Technical Support team. The following diagram provides a general overview of all passwords that manage the RespArray Patient Monitor.

RespArray Patient Monitor Passwords			
User Password	Factory Maintain Password	Dynamic Password	Demo Password

- 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 may support the customer with password-related inquiries or support.
- Service personnel/customers will be provided access to any applications needed to support the management of passwords.
- Refer to [R2] for instructions on how to conduct a software update on the RespArray Patient Monitor.

Password Structure Guidance

Type of Password	Default Password	Customized Password Requirements
Start-up Password	ABC	8-64 digits, choose from letter (upper or lower case), number, or special character
User Password	Customized	8-64 digits, choose from letter (upper or lower case), number, or special character
Factory Password	998 (if verification code is 0000) Use tool (if verification code is not 0000)	Number + letter if by tool
Demo Password	demo3045 or customized	8-64 digits, choose from letter (upper or lower case), number, or special character

Revision B

DC00144964

Page 4 of 12

Process Detail

1. User Password

Process Step	Requirement
Password setup at system start-up	 User must set a new customized password upon initial start-up of the RespArray Patient Monitor (refer to Section 4.1.3 Login Management of the RespArray Patient Monitor operator's manual). The new password must contain 8 – 64 characters. The new password must contain at least one letter type (upper or lower case), number, or special character.
Modify existing user password	 If user desires to modify an existing password, the Modify User Password menu can be accessed.
Menu navigation to Modify User Password	 Menu >> System >> Factory Maintain If the Factory Maintain password is unknown, refer to the Dynamic Password process. Once Factory Maintain password is entered, access Password Management >> Modify User Password User to set new customized password and select Confirm. The user will be prompted to confirm the password change and the monitor will restart as part of the process. Refer to section 1.1 for illustrations of the menu structure.

1.1 Menu path to access Modify User Password

The images below illustrate the path to access the Modify User Password command.



Revision B

DC00144964

Work Instruction Medtronic

Page 5 of 12

Factory Maintain × 8 System Time Verification Code: 590402db 0 Password: 4 0 User Maintain Sp(2 Factory Maintain About License 詽 MI 50 PR **300** 3 凶/凶 92 2 ★ 山 ۲ -21 Audio Pause NIBP Screen Setup Admission Discharge Alarm Reset Review Standby **Factory Maintain** × **Module Select** Auto-acquisition Interval Verification Code **Factory Setup** Manual Update Parameter Maintain Modify User Password 6 Log Management Reset User Password Upgrade Management Reset Demo Password Password Management 5 Bluetooth About LED Test 2. C 92 〆/〆 ★•□ Ł ·2 larm Rese Audio Pause NIBP Screen Setup Admission Discharge Review Standby

Revision B

Page 6 of 12

Factory Maintain	Modify Demo Password X
Module Select	Modify Demo Password
Factory Setup	New Password:
Parameter Maintain	Confirm New Password:
Log Management	%
Upgrade Management	Confirm 8
Password Management	
Bluetooth	
About	
LED Test	P
Alarm Reset	Image: NIBPImage: Screen SetupImage: AdmissionImage: Screen SetupImage: Screen Setup<
Factory Maintain	×
Module Select	Auto-acquisition Interval never >
Factory Setup	Verification Code Warning
Parameter Maintain	Initialize the user password and shut down the
Log Management	monitor?
Upgrade Management	
Password Management	Confirm 9
Bluetooth	
About	NIB
LED Test	PR
が Alarm Reset Audio Pause	Constraint Constraint Constraint Constraint NIBP Screen Setup Admission Discharge Review Standby

DC00144964

Medtronic Controlled Information

DC00144964

Page 7 of 12

2. Factory Maintain Password

Process Step	Requirement	
Factory Maintain Password	 Default Factory Maintain Password is 998 when verification code is 0000. If verification code is not 0000, it means the user has selected the Manual Update menu option (see the Dynamic Password section). 	
Menu navigation to Factory Maintain	 Menu >> System >> Factory Maintain Refer to section 2.2 for illustrations of the menu structure. 	

2.1 Menu path to access Factory Maintain Password

The images below illustrate the path to access the Modify User Password command.



3. Dynamic Password

Update procedure	Requirement
Dynamic Password	 This process is followed when the Verification Code is not 0000 which means the user has selected the Manual Update menu option.
	 Execute the UacKeyTool application on PC to generate a Dynamic Password.
	 The Verification Code from the Factory Maintain screen is used as input to
	this process (see 3.1).
	The Dynamic Password obtained from using the UacKeyTool will not change
	if the Verification Code does not change.
	 The Verification Code can be changed by the user either by:
	 Selecting Manual Update or
	 Setting up an Auto-acquisition Interval

Work Instruction

Page 8 of 12

Update procedure	Requirement
Manual Update	 Note: This process is irreversible once user selects this option, even after software updates. The user will NEED to utilize the UacKeyTool application to obtain a Dynamic Password when accessing the Factory Maintain menu option. Adds an additional layer of security to password management. Once this option is selected, the password will be variable, and user will need to obtain a Dynamic Password as a result. See section 3.2 for an illustration of the menu options.
Auto-acquisition Interval	 This option will allow the user to automatically change the Verification Code given a specific time interval. User can select Never, 3 days, 30 days, or 180 days. Once the Verification Code changes, the UacKeyTool will be needed to generate a new Dynamic Password See section 3.2 for an illustration of the menu options.
UacKeyTool application (Medtronic service personnel only)	 The executable file can be found in the Attachments section of DC00144964 in CAP Agile. Download the application to your PC and execute it. Input the Verification Code from the Factory Maintain screen (section 3.1) to generate a Dynamic Password. Refer to section 3.3 for an illustration of the UacKeyTool application.

3.1 Verification Code

Use the Verification Code shown on your monitor's screen as input to the UacKeyTool to generate a **Dynamic Password**. The Verification Code below is shown as reference only and should not be used.

Facto	ory Maintain						Â	×	
8	System Time								
٥	Demo	Ver	ification Code	: 590402db					
0	User Maintain	Pas	sword:						SpO
2	Factory Maintain								96
	About								O 100 etC
	License								mmH
									MIB mml
G									PR
Alarm R	eset Audio Pause	NIBP	Screen Setup	於・ 凸 Admission	2 Discharge	Review	Stand	lby	

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Medtronic Controlled Information



3.2 Auto-acquisition Interval and Manual Update

Factory Maintain		×
Module Select	Auto-acquisition Interval never	>
Factory Setup	Verification Code 590402db	1
Parameter Maintain	Manual Update	
Log Management	Modify User Password	
Upgrade Management	Reset User Password Reset Demo Password	
Password Management		
Bluetooth		
About		
LED Test		
が Alarm Reset Audio Pause	Image: NiBP Screen Setup Admission Discharge Review State	ndby

3.3 UacKeyTool – Generate Dynamic Password

🖂 UacKeyTool	×	
Please enter your 8 Verification Code to generate Dynamic Password		
	Use Verificatio	
Verification Code	Code from Factory	
Dynamic Password	Maintain Scree	n
·		
Generate	Cancel	

Revision B



Page 10 of 12

DC00144964

4.

Demo Password

Process Step	Requirement
Default Demo Password	 Demo Password is demo3045 by default. Plug in USB drive containing the profile information into USB port located on the back of the monitor. Access Menu >> Profile >> Transfer Profile on the monitor's menu. Enter user password to proceed. Select USB drive option from the top right corner for External Profile. Select Import then choose which External Profile will be imported to the monitor. Move the selected External Profile to the monitor by selecting the << arrows. Select Confirm and enter user password to complete the action.
Customizing Demo Password	 User can customize the Demo Password. The new password must contain 8 – 64 characters. The new password must contain at least one letter type (upper or lower case), number, or special character.
Menu navigation to Modify Demo Password	 Menu >> System >> Demo >> Modify Demo Password User to set new customized password and select Confirm. Refer to section 4.1 for illustrations of the menu structure.

4.1 Menu navigation to Modify Demo Password

The images below illustrate the path to access the Modify Demo Password command.



Technical Service Bulletin (TSB) RespArray Patient Monitor
Password Reset InstructionsWork
Instruction

DC001	44964	Revision B	Page 11 of 12	Medtronic
Demo				ÂΧ
8	System Time	Demo Mode		>
۵	Demo	Modify Demo Password		>
0	User 4			
BBB	Factory Maintain			
88 88 88	About			
	License			
G				
Demo	D N	Iodify Demo Password		×
8	System Time	Modify	Demo Password	
۵	Demo	Old Password:		
0	User Maintain	New Password:		5
8	Factory Maintain	Confirm New Password:		•
	About			
	License		Confirm	6
L.☉				

DC00144964

Revision B

Page 12 of 12

Guide for retention of settings/data/passwords

The table below provides an overview of what settings/data remain on the RespArray Patient Monitor prior to conducting a software update.

Setting/Data	Remains post-update	Available to export for backup	Backup method
Patient Data	Х	√	USB Drive
Alarm Settings	х	V	USB Drive
Waveform Setup	х	V	USB Drive
Network Setup (Bluetooth, Wi-Fi)	х	х	N/A
User Password	V	N/A	N/A

Technical Support

Customers must reach out to the U.S. Technical Support team for assistance with the Dynamic Password process and use of the UacKeyTool. For additional questions on any of the password management processes, contact the U.S. Technical Support team through the following means:

- <u>rs.hqtsweb@medtronic.com</u>
- 1-800-255-6774 Option 1, Option 2 for Patient Monitoring technical support for the RespArray

References

Reference	Number	Title
[R1]	CDP-0033856	RespArray Monitor S/W 1.12
[R2]	DC00144953	Technical Service Bulletin (TSB) RespArray Patient Monitor v1.12 SW Release and Update Instructions

Quality Records

Quality Record	Required Approvals
N/A	None

Reason for Revision

- 1. Initial release of work instruction.
- 2. Removal of CONFIDENTIAL wording throughout document.