

Urgent: Field Safety Notice FA-2021-12-001-MKE-004

Subject: Single Sign-On (SSO) Password Vulnerability

Commercial name of the affected product:	Details on affected devices: Software versions impacted
Q-Stress® System	Q-Stress – 6.x.x (all versions from 6.0.0 to 6.3.1)
XScribe™ System	XScribe – 5.xx to 6.xx (all versions from 5.01 to 6.3.1)
HScribe™ System	HScribe – 5.xx and 6.x.x (all versions from 5.01 to 6.4.0)
Vision Express ™ System	Vision Express – 6.x.x (all versions from 6.1.0 to 6.4.0)
Diagnostic Cardiology Suite™(DCS)	DCS – 2.x.x (version 2.1.0)
Connex®Cardio ECG	Connex Cardio – 1.x.x (version 1.0.0 to 1.1.1)
RScribe™ System	RScribe – 5.xx, 6.xx and 7.x.x (all versions from 5.01 to 7.0.0)

FCA-identifier: FA-2021-12-001-MKE-004

Type of action: Field Safety Notice

Date:

To: Chief Executive; Facility Risk Manager; Facility Administrator; Facility Engineer; Vigilance Manager; Biomedical Engineering; Medical Device Liaison Officer; Information Security Director

Description of the problem:

Hillrom has become aware of a software vulnerability for the above devices, which allows the entry of any username, that is provisioned in the application, without supplying a password. Entry of such username will grant access, with the same privileges of the username, to the software application within the medical device. This vulnerability occurs only when the device is activated with the Single Sign-On (SSO) feature in either stand alone, or client/server configurations.

Potential Risk

According to the security risk assessments conducted for the products, the reported vulnerability is categorized as uncontrolled, resulting in unacceptable residual risk, with an unlikely probability of critical injury due to delay of critical care or incorrect treatment.

Actions to be taken by user:

Please disable the SSO feature in the respective modality manager configuration settings. Please refer to the **Appendix A** below for instructions on how to disable SSO.

Actions to be taken by the distributor:

Please share this notification with your end users. Contact <u>HillromMKE004OUS@Sedgwick.com</u> to receive an editable copy of this notification. Please include your contact details on the editable copy to allow your customers contact you directly.



Welch Allyn, Inc. 4341 StateStreet

Baxter

Welch Allyn, Inc. 4341 StateStreet Road Skaneateles Falls, NY 13153 USA Urgent: Field Safety Notice FA-20

FA-2021-12-001-MKE-004

Contact reference person:

If you have any questions regarding this notification, please contact Hillrom Technical Support, using email or number below.

Market / Region /	Phone Number	Technical Support Email
Country		
Austria	43 1 79567186	emea.support@hillrom.com
Germany	+49 (0) 69 509 851 32 option 2	emea.support@hillrom.com
Switzerland	41 44 6545315	emea.support@hillrom.com
UK	+44 (0) 207 365 6780 option 2	emea.support@hillrom.com
Netherlands	+31 (0) 20 206 13 60 option 2	emea.support@hillrom.com
Spain	+34 (0) 91 749 93 57 option 2	emea.support@hillrom.com
Italy	+39 02 696 824 25 option 2	emea.support@hillrom.com
France	+33 (0)1 57 32 49 94 option 2	emea.support@hillrom.com
Sweden	+46 (0) 85 853 65 51 option 3	emea.support@hillrom.com
Ireland	+353 (0) 46 90 67 790 option 2	emea.support@hillrom.com
Eastern Europe	+353 (0) 46 90 67 790 option 2	emea.support@hillrom.com
Middle East & Africa	+353 (0) 46 90 67 790 option 2	emea.support@hillrom.com
India Subcontinent	+353 (0) 46 90 67 790 option 2	emea.support@hillrom.com
For all other countries	+353 (0) 46 90 67 790 option 2	emea.support@hillrom.com
South Africa	27 800 998 290	emea.support@hillrom.com

Transmission of this Field Safety Notice:

Please ensure this notice is circulated to all appropriate personnel. This may include, but is not limited to:

A&E departments	In-house maintenance staff
Adult intensive care units	 IV nurse specialists
All wards & Clinics	Medical directors
Biomedical engineering staff	 Nursing executive directors
Clinical governance leads	 Oncology units
Day case theatres	 Pediatric intensive care units
EBME departments	Risk managers
 Equipment stores & Libraries 	 Supplies managers
 Health and safety managers 	Theatres

Hillrom considers patient safety and customer satisfaction our top priorities. We appreciate your time and attention in reading and disseminating this important product notification.

Yours sincerely,



Y 13153 USA Urgent: Field Safety Notice FA-2021-12-001-MKE-004

Appendix A – Instructions for Disabling Single Sign-On(SSO)

Products affected

- Q-Stress 6.x.x (all versions from 6.0.0 to 6.3.0) and XScribe 5.xx to 6.x.x (all versions from 5.01 to 6.3.0)
- HScribe 5.xx and 6.x.x (all versions from 5.01 to 6.4.0) and Vision Express 6.x.x (all versions from 6.1.0 to 6.4.0)
- RScribe 5.xx, 6.x.x, and 7.x.x (all versions from 5.01 to 7.0.0)

Notes

- This instruction is applicable for systems currently configured with the logon authentication method set to *Active Directory* and with *Single Sign On* (SSO) turned on.
- This process will briefly interrupt service. Perform these steps at an appropriate time.
- After turning off SSO, users will then need to enter their account name and password when logging into the system.

Steps to turn off SSO

- 1. Log into Windows as an administrator.
- 2. In the Start menu go to *Mortara Modality Manager* and then select *Modality Manager Configuration Tool.*
- 3. When prompted that services will be stopped, click OK.
- 4. The *Modality Manager Configuration Utility* window will be displayed.

Localization	
English ~	System user interface language
in ~ lb ~	Default height and weight units
Server Address	
localhost	Computer name or IP address of Modality Manager server
LOG port	Modality Manager centralized event log service port. Keep default unless not available
API port 7502 OK	Working port of the Modality Manager service. Keep default unless not available
Logon Mode Active Directory V	Choose the logon authentication method - local: Modally Manager will maintain its own list of user/password pairs - Active Directory: Modally Manager will get the list of users from the Windows domain
Remote slot settings SDM Remote slot path	Remote Slot directory missing in configuration file.

- 5. Make sure *Single Sign On* is off.
- 6. Click **Save** then **Exit**.



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Appendix A – Instructions for Disabling Single Sign-On(SSO)

Products affected

• DCS 2.x.x (version 2.1.0) and Connex Cardio 1.x.x (version 1.0.0 to 1.1.1)

Notes

- This instruction is applicable for systems currently configured with the logon authentication method set to *Active Directory* and with *Single Sign On* (SSO) turned on.
- This process will briefly interrupt service. Perform these steps at an appropriate time.
- After turning off SSO, users will then need to enter their account name and password when logging into the system.

Steps to turn off SSO

- 7. Log into Windows as an administrator.
- 8. In the Start menu go to *Hillrom* and then select *Connex Cardio Configuration Tool*.
- 9. When prompted that services will be stopped, click OK.
- 10. The Modality Manager Configuration Utility window will be displayed.

English System user interface language in ib Default height and weight units Server Address locarboat Computer name or IP address of Modality Manager server LOG port 7500 OK API port 7502 OK Working port of the Modality Manager service. Keep default unless not available
Server Address Computer name or IP address of Modalky Manager server LOG port T500 OK Modalky Manager centralized event log service port. Keep default unless not available API port Working port of the Modalky Manager service.
ocahost Computer name or IP address of Modality Manager server LOG port Nodality Manager centralized event log service port. Keep default unless not available API port Working port of the Modality Manager service.
Coahost Modality Manager service LOG port T500 OK Modality Manager centralized event log service port. Keep default unless not available API port Working port of the Modality Manager service.
API port Working port of the Modality Manager service.
Working port of the Modality Manager service.
7502 OK Keep default unless not available
Spirometry Calibration port
7503 OK Spirometry Calibration tool service port. Keep default unless not available
Logon Mode Choose the logon authentication method
Active Directory Active Directory Clobe the logar aumentation memory Clobe the logar aumentation memory Clobe the logar aumentation is own list of user/password pairs - Active Directory: Modaity Manager will get the list of users from the Windows domain
Remote slot settings SDM
Remote slot path

- 11. Make sure Single Sign On is off.
- 12. Click Save then Exit.



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Response Form

Subject: Single Sign-On (SSO) Password Vulnerability (FA-2021-12-001-MKE-004)

It is important that you return this form/receipt as acknowledgement of your receipt and provide us with the necessary information.

Please complete the following with the correct information and **return this Response Form** within 2 weeks.

Hillrom account number (if known):		_
Name of the facility:		
Address of the facility:		
City: Zip: Country:		_
Facility Contact Person Name: (print)		_
Signature:	Date://	
Title:	Phone:	
Email		

Check actions taken: (Please do not leave any questions without an answer)

We have reviewed and understand the attached Field Safety Notice. □ Yes □ No

Results from the inspection of our product inventory show: □ We do not have any potentially affected products. □ We have affected products. Quantity

We confirm we have disabled the SSO feature in the impacted units in our possession. \square Yes \square No

For Distributors only: We confirm we have shared this notification with our end users: □ Yes □ No

Comments

Response form shall be returned to HillromMKE004OUS@Sedqwick.com within 2 weeks.