Welch Allyn, Inc. 4341 State Street Road Skaneateles Falls, NY 13153 USA	**URGENT: Field Safety Notice**	2021-07-001-MKE-005

Date:

Commercial name of affected product:
ELI280, MLBUR280 and BUR280 Electrocardiographs

Subject:
ELI280 resting electrocardiograph - Patient mismatch/Software Upgrade

Affected Devices: All ELI, Burdick and McKesson brand 280 Electrocardiographs software (v.2.1.0 and above) manufactured from: 01-July-2016 thru 01-Jul-2021 with serial numbers: 116280503226 thru 121250000503. A list of the affected part numbers is provided in Table 1.

Type of action: **Software Upgrade**

FSCA-identifier: 2021-07-001-MKE-005

To: Chief Executive; Facility Administrator; Facility Engineer; Vigilance Manager; Biomedical Engineering; Medical Device Liaison Officer; Distributor

Description of the problem:
Following the receipt of a complaint from an end user, Welch Allyn has identified that a software fault exists on the ELI 280 software which may lead to one of the following transmission errors:

1) A specific sequence of operator inputs can lead to the transmission of a different ECG record than the record intended to be transmitted into an Electronic Medical Record(EMR) system.
2) A specific sequence of operator inputs could cause patient exam demographics to be incorrectly attached to the waveform of another patient and be printed or transmitted into an EMR system.

Potential Risk:
Under specific operator workflows (1 & 2 below), the software fault potentially results in a delay in critical care.

Hillrom can confirm there have been no reports of any harm during the estimated 202 million patient experiences, however Hillrom is conducting this Field Safety Corrective Action to correct the software and therefore prevent the above potential scenarios from occurring.

Workflow 1

The following workflow can result in the transmission of a different ECG record than the record intended to transmit. The record transmitted contains accurate clinical information, however it is not the record intended to be sent.

1. An ECG is acquired for Patient A and stored to the cardiograph.
2. An ECG is acquired for Patient B and stored to the cardiograph.
3. The ECG record associated with Patient A is retrieved from memory and any Patient Demographic information is edited.
4. After editing, the "Resting ECG" screen is presented as shown below. Figure 1
5. Pressing the TRANSMIT button from this screen (following any Patient Demographic edit) will transmit an ECG record other than for patient A. (see figure 2, which shows the Resting ECG screen).

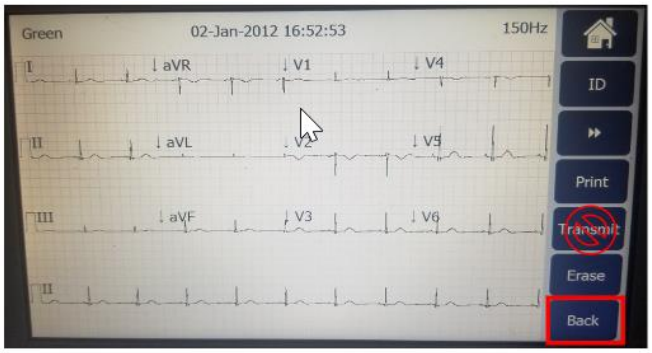

Figure.1

Temporary mitigation for Workflow 1:

If an ECG record is retrieved from the patient directory for a Patient Demographic edit to be performed, once the information has been edited and the screen above (Fig 1) is presented, do not press the transmit button. Instead, press the BACK button which will SAVE the changes to memory and present the user with the following screen, where the SYNC button can be used to transmit the desired record to the configured destination.

Figure.2

Workflow 2:

The following workflow has been identified as resulting in the transmission of a "hybrid record" that contains the patient demographic information for patient A and the ECG morphology and measurement data for patient B.

1. An ECG is acquired for Patient A and stored to the cardiograph.
2. An ECG is acquired for Patient B and stored to the cardiograph.
3. The ECG record associated with Patient A is retrieved from memory and ID information is edited.
4. After editing, the "Resting ECG" screen is presented as shown in Figure 3.
5. The user decides to make another ID Edit without leaving the "Resting ECG" screen and presses the "ID" button - Figure 3.

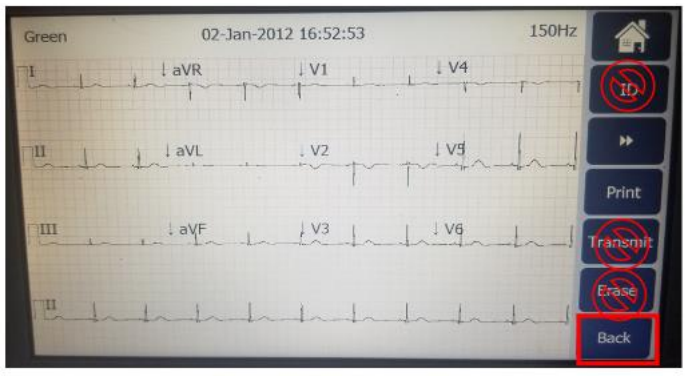

Figure.3

6. After the second edit is performed, the "Resting ECG" screen is once again presented as shown above.
7. Pressing the TRANSMIT button from this screen (following two ID edits in a row as defined above) will transmit an ECG record with the patient demographics

from Patient A and the ECG record for Patient B, this "hybrid" record is then stored in the cardiograph as second record with patient A demographics, and Patient B will no longer be listed in the directory.

8. Pressing the ERASE button from this screen will erase an undesired record. If the edits are performed on the last ECG record acquired, this situation does not occur.

Temporary mitigation for Workflow 2:

If an ECG record is retrieved from the patient directory for an ID Edit to be performed, once the information has been edited and the screen (Figure 4) is presented, do not press the Transmit, Erase, or the ID button. Instead, press the BACK button which will SAVE the changes to memory and present the user with the DIRECTORY screen (Figure 5). Subsequent ID Edits should also be performed using this workflow to prevent this issue from occurring. To then transmit the record to the configured location, press the SYNC button.

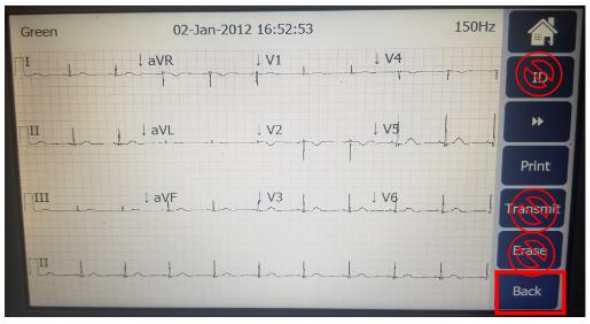

Figure.4

Figure.5

Actions to be taken by User:

Please identify if you have any affected devices , and send an email to HillromMKE005OUS@stericycle.com requesting the Software upgrade link. Hillrom will arrange to send a download link with details on how to install the software. After the Software has been installed on all affected product, complete the attached response form and return to HillromMKE005OUS@stericycle.com.

Until the devices are corrected through a software upgrade, please utilize mitigation for Workflow 1 and mitigation for Workflow 2 as described above to prevent the potential occurrence of the identified software fault

Actions to be taken by the distributor:

Contact HillromMKE005OUS@stericycle.com to receive an electronic copy of this notification and further instructions for notifying and upgrading devices sold to your accounts.

Actions being taken by Hillrom:

Hillrom has completed a software update to correct this potential issue. Once you have identified units affected by this Field Safety Corrective Action and you have responded back to Hillrom via email, you will be provided a link to download the software update.

Contact Reference Person:

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

Market / Region / Country	Phone Number	Technical Support Email
Austria	43 1 79567186	eme.techsupport@hillrom.com
Germany	49 6950 985 132	eme.techsupport@hillrom.com
Switzerland	41 44 6545315	eme.techsupport@hillrom.com
UK	44 207 365 6780	eme.techsupport@hillrom.com
Netherlands	31 20 206 13 60	eme.techsupport@hillrom.com
Spain	34 91 749 9357	eme.techsupport@hillrom.com
Italy	39 0512987811	eme.techsupport@hillrom.com
France	33 157 32 49 94	eme.techsupport@hillrom.com
Sweden	46 85 85 36 551	eme.techsupport@hillrom.com
Ireland	353 46 9067790	eme.techsupport@hillrom.com
Eastern Europe	353 46 9067790	eme.techsupport@hillrom.com
Middle East & Africa	353 46 9067790	eme.techsupport@hillrom.com
India Subcontinent	353 46 9067790	eme.techsupport@hillrom.com
For all other countries	353 46 9067790	eme.techsupport@hillrom.com
South Africa	27 800 998 290	eme.techsupport@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

Please ensure a copy of the FSN is passed on to any organisations to which the devices have been transferred.

The Competent (Regulatory) Authority of your country has been informed about this communication.

Sincerely,

Mark Elliott
Director, Quality Assurance

Table 1: Affected Product

Model number	Model number	Model number	Model number
ELI280-DDB-ADAAX	ELI280-BDB-ACAAX	ELI280-CAA-AAFAD	ELI280-BDB-BDFAX
ELI280-BCB-AAAAX	ELI280-DDB-ACAAX	ELI280-DBA-BAFAX	ELI280-DCB-AAAAX
ELI280-DBA-AAFBD	ELI280-AAA-AAEBX	ELI280-BBA-ADFBD	ELI280-DDB-ACFAX
MLBUR280-81X	ELI280-CAA-ACEBX	ELI280-AAA-AAHBX	ELI280-DDB-BDFAX
ELI280-CAA-AAFBT	ELI280-DCD-ADFAD	ELI280-DDB-AACBX	ELI280-JXX-BDFAX
ELI280-CAA-ADCBX	ELI280-BCB-AACBD	ELI280-LDX-ADFBX	ELI280-LDX-ADCBX
ELI280-BDD-ADFAD	ELI280-BDB-AAFBD	ELI280-BDB-ACCAD	ELI280-BDB-ADFAD
ELI280-LDX-ADFBD	ELI280-DDB-AAFBD	ELI280-DCB-ACFAD	ELI280-AAA-BAFAF
MLBUR280-W1X	ELI280-DCB-AAABX	ELI280-AAA-ACAAX	ELI280-ADA-ABFBX
ELI280-BCB-AAFBD	ELI280-BCB-AAFBX	ELI280-CEA-ADFBX	ELI280-CDA-ADABX
ELI280-BDB-AAABX	ELI280-DDB-ACFBD	ELI280-DDB-BCFAX	ELI280-ADA-ADCAX
ELI280-BDB-AACBX	ELI280-BCB-ACAAX	BUR280-81X	ELI280-DCB-AAFBG
ELI280-BDB-AAFBT	ELI280-DCB-AAFAD	ELI280-CAA-ADFBX	ELI280-BDB-AAFBG
ELI280-BDB-AAFBX	ELI280-DCA-ACAAX	ELI280-CAB-ACFBX	ELI280-ADA-ACFAX
ELI280-CAA-AAFAT	ELI280-CAA-ACFBD	ELI280-CDA-ADCBX	ELI280-AAA-ADCBX
ELI280-CAA-AAFBD	ELI280-DCB-BAFBT	ELI280-BBA-AAAAX	ELI280-BBA-AAFAD
ELI280-DBA-AAFAD	ELI280-DCB-AAFBT	ELI280-DBA-ADFAX	ELI280-BBA-AAFBD
MLBUR280-C1X	ELI280-BBA-ADFAX	ELI280-DDD-ADFAD	ELI280-DBA-AAFAX
MLBUR280-W1D	ELI280-BCB-AACBX	ELI280-DCB-AACBD	ELI280-LDX-ADFBG
ELI280-DCB-AACBX	ELI280-DBA-ADFBD	ELI280-DDB-AAFBG	ELI280-DBA-AAABD
ELI280-DCB-AAFBX	ELI280-AAA-AAFBT	MLBUR280-C1D	ELI280-AAB-ADAAX
ELI280-DDB-AAFBT	ELI280-CAA-AACBX	ELI280-CEB-ACFBX	ELI280-CAA-ABFAX
ELI280-DDB-AAFBX	ELI280-DBA-AAAAX	ELI280-BCB-AAFBG	ELI280-BFA-ADCBX
ELI280-LDX-ADABX	MLBUR280-81D	ELI280-BBA-ADFAD	ELI280-CAA-ADHAX
ELI280-CEB-ACFBD	ELI280-AAB-ADCAD	ELI280-BDB-AACBD	ELI280-LDX-ADCBD
ELI280-AAB-ACCBX	ELI280-AAA-ABFBX	ELI280-DAB-ADCAD	ELI280-AFB-ABCBX
ELI280-DCB-AACAX	ELI280-DEB-ACFBD	ELI280-ADA-ACAAX	ELI280-AAB-ADFAD
ELI280-DCB-AAFBD	ELI280-CAA-AAAAX	ELI280-BDB-ACCAX	ELI280-CAA-AAFBX
ELI280-DDB-AAABX	ELI280-DCB-ACAAX	ELI280-CAA-ADFBD	ELI280-CBB-ACCBX
ELI280-DDB-AACBD	ELI280-DDB-ACCAX	ELI280-A	ELI280-DFA-ADCBX
ELI280-BCA-AAAAX	ELI280-DDB-AAAAX	ELI280-E	ELI280-C
ELI280-AAA-AAFBD	ELI280-DFC-ADFAD	BUR280-C1X	ELI280-D
ELI280-BAA-ACCBD	ELI280-AAA-AAAAX	BUR280-W1X	ELI280-B
ELI280-BCB-AAABX	ELI280-BCB-AACAX	BUR280-W1D	ELI280-F
ELI280-BCB-AAFAD	ELI280-BCB-BAFAX	BUR280-81D	

Welch Allyn, Inc. 4341 State Street Road Skaneateles Falls, NY 13153 USA	**URGENT: Field Safety Notice**	2021-07-001-MKE-005

Response Form / Receipt

SUBJECT: ELI280 resting electrocardiograph - Patient mismatch/Software Upgrade

(2021-07-001-MKE-005)

It is important that you return this form/receipt to confirm you have upgraded all impacted devices in your possession.

Please complete the following with the correct information and **return this Response Form** within one month of receiving the software upgrade link.

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:

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

We confirm we have upgraded all impacted units in our possession.
□ Yes □ No

Response form shall be returned to HillromMKE005OUS@stericycle.com within one month of receiving the software upgrade link.