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Entity:	Welch Allyn - Milwaukee
Description:	**ELI280 Product Family** **Scenario 1) Wrong Demographics Associated with Waveform:** An ECG record retrieved from the directory that has been double edited after test is associated with an incorrect ECG record. **Scenario 2) Wrong ECG Transmitted or Deleted:** After an ECG record that undergoes a single edit and remains displayed, an unintended ECG in the directory is transmitted or deleted instead of the ECG intended.

Section A: Background and Description

1. Reason for Assessment: (Completed by QA/RA Rep)	Check the box that best describes the reason for this assessment. ☐ Defect ☐ Malfunction ☐ Off-Label Use ☐ Complaint Trending ☒ Other (describe): **Engineering Confirmation of a customer complaint regarding a software issue**	
2. Intended Usage and Relevant Performance Claims: (Completed by QA/RA Rep)	Intended Usage:	Location: (i.e.: 510K, Marketing or User's Manual.
	The ELI 280 is intended to be a high-performance, 12-lead, multifunctional electrocardiograph. As a resting electrocardiograph, ELI 280 simultaneously acquires data from 12 leads. Once the data is acquired, it can be reviewed and/or stored, and/or printed. It is a device primarily intended for use in hospitals but may be used in medical clinics and offices of any size. The device can also be configured with expanded memory, bidirectional connectivity, and DICOM® protocol support, and operates on battery or line power. **Specific Indications for use:**	Eli280 User Manual: 9515-181-50-ENG REV N Revision date: 2021-03 9515-181-53-ENG REV G Revision date: 2021-03

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	• Device is indicated for use to acquire, analyze, display, and print electrocardiograms. •Device is indicated for use to provide interpretation of the data for consideration by a physician. •Device is indicated for use in a clinical setting, by a physician or by trained personnel who are acting on the orders of a licensed physician. It is not intended as a sole means of diagnosis. •The interpretations of ECG offered by the device are only significant when used in conjunction with a physician over-read as well as consideration of all other relevant patient data. •Device is indicated for use on adult and pediatric populations. •The device is not intended to be used as a vital signs physiological monitor.	
3. Medical Device Classification (Completed by QA/RA Rep)	Is the device considered a Medical Device in any of the countries into which it was shipped?	
	☐ No ☒ Yes (Please complete the data below for each region.)	
	United States: Classification Number: **21 CFR 870.2340** Listing Number: **D339461** Pre-Market Approval #: **K122073**	
	Canada: Class: **2** License Number: **89610**	
	Europe: MDD Class: **IIa**	
	International / Rest of World: ☐ No ☒ Yes ☐ N/A	
	Is the device specifically identified on any Notified Body Quality System EC Certificates / Certificate of Registration?	

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<table>
<tr><td>4. Notified Body EC Certificate(s)
(Completed by RA/QA Rep)</td><td>☐ No
☒ Yes (If yes, list the certificate(s) in which the product is identified below. Add more lines as necessary.)
<table>
<tr><th>Certificate</th><th>Product Family</th><th>Model</th><th>Product Name</th><th>Classification</th></tr>
<tr><td>38602</td><td>Electrocardiograph</td><td>ELI280 - XXX-XXXXX

X=A TO Z</td><td>ELI 280</td><td>Class IIa</td></tr>
<tr><td colspan="5">Refer to Appendix 1 for full list</td></tr>
</table></td></tr>
<tr><td>5. Description of the Issue including Root Cause (if known) (Completed by Field Action Team)</td><td>Engineering investigation of anomaly #B104604 and B104605 confirmed that, an ELI280 Operator, through a sequence of operator inputs, could transmit incorrect patient ECG waveform exam information to an EMR system. Additionally, 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 to an EMR system. Both issues have the same potential root cause in the ELI280 Electrocardiograph Software version 2.1.0 through 2.3.0 but are caused by different operator sequence workflows. (NCE002629) was opened on 30Jun2021 and the investigation is on-going to confirm root cause.</td></tr>
<tr><td>6. Responsible Quality and Regulatory Location/ Personnel: (Completed by QA/RA Rep)</td><td>Mark (First Name) | Elliott (Last Name) | QA Director, Milwaukee (Title & Location)</td></tr>
</table>

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Section B: Affected Product

1. Common or Usual Name:
(Completed by Marketing / Service / QA/RA Representative)

List the common name and Model (Item Number in JDE) of product as known by the customer.
Add more lines if necessary.

Product Name:	ELI280 MLBUR280 BUR280	Model: (Base Item Number)	ELI280- XXX-XXXXX MLBUR280-XXX BUR280-XXX X=A TO Z

ELI280-DDB-ADAAX
ELI280-BCB-AAAAX
ELI280-DBA-AAFBD
MLBUR280-81X
ELI280-CAA-AAFBT
ELI280-CAA-ADCBX
ELI280-BDD-ADFAD
ELI280-LDX-ADFBD
MLBUR280-W1X
ELI280-BCB-AAFBD
ELI280-BDB-AAABX
ELI280-BDB-AACBX
ELI280-BDB-AAFBT
ELI280-BDB-AAFBX
ELI280-CAA-AAFAT
ELI280-CAA-AAFBD
ELI280-DBA-AAFAD
MLBUR280-C1X
MLBUR280-W1D
ELI280-DCB-AACBX
ELI280-DCB-AAFBX
ELI280-DDB-AAFBT
ELI280-DDB-AAFBX
ELI280-LDX-ADABX
ELI280-CEB-ACFBD
ELI280-AAB-ACCBX
ELI280-DCB-AACAX
ELI280-DCB-AAFBD
ELI280-DDB-AAABX
ELI280-DDB-AACBD
ELI280-BCA-AAAAX
ELI280-AAA-AAFBD
ELI280-BAA-ACCBD
ELI280-BCB-AAABX
ELI280-BCB-AAFAD
ELI280-CAA-AAFAD
ELI280-DBA-BAFAX
ELI280-BBA-ADFBD
ELI280-AAA-AAHBX
ELI280-DDB-AACBX
ELI280-LDX-ADFBX
ELI280-BDB-ACCAD
ELI280-DCB-ACFAD
ELI280-AAA-ACAAX
ELI280-CEA-ADFBX
ELI280-DDB-BCFAX
BUR280-81X
ELI280-CAA-ADFBX
ELI280-CAB-ACFBX
ELI280-BDB-ACAAX
ELI280-DDB-ACAAX
ELI280-AAA-AAEBX
ELI280-CAA-ACEBX
ELI280-DCD-ADFAD
ELI280-BCB-AACBD
ELI280-BDB-AAFBD
ELI280-DDB-AAFBD
ELI280-DCB-AAABX
ELI280-BCB-AAFBX
ELI280-DDB-ACFBD
ELI280-BCB-ACAAX
ELI280-DCB-AAFAD
ELI280-DCA-ACAAX
ELI280-CAA-ACFBD
ELI280-DCB-BAFBT
ELI280-DCB-AAFBT
ELI280-BBA-ADFAX
ELI280-BCB-AACBX
ELI280-DBA-ADFBD
ELI280-AAA-AAFBT
ELI280-CAA-AACBX
ELI280-DBA-AAAAX
MLBUR280-81D
ELI280-AAB-ADCAD
ELI280-AAA-ABFBX
ELI280-DEB-ACFBD
ELI280-CAA-AAAAX
ELI280-DCB-ACAAX
ELI280-DDB-ACCAX
ELI280-DDB-AAAAX
ELI280-DFC-ADFAD
ELI280-AAA-AAAAX
ELI280-BCB-AACAX
ELI280-BCB-BAFAX
ELI280-BDB-BDFAX
ELI280-DCB-AAAAX
ELI280-DDB-ACFAX
ELI280-DDB-BDFAX
ELI280-JXX-BDFAX
ELI280-LDX-ADCBX
ELI280-BDB-ADFAD
ELI280-AAA-BAFAF
ELI280-ADA-ABFBX
ELI280-CDA-ADABX
ELI280-ADA-ADCAX
ELI280-DCB-AAFBG
ELI280-BDB-AAFBG
ELI280-ADA-ACFAX

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	ELI280-CDA-ADCBX ELI280-BBA-AAAAX ELI280-DBA-ADFAX ELI280-DDD-ADFAD ELI280-DCB-AACBD ELI280-DDB-AAFBG MLBUR280-C1D ELI280-CEB-ACFBX ELI280-BCB-AAFBG ELI280-BBA-ADFAD ELI280-BDB-AACBD ELI280-DAB-ADCAD ELI280-ADA-ACAAX ELI280-BDB-ACCAX ELI280-CAA-ADFBD ELI280-A ELI280-E BUR280-C1X BUR280-W1X BUR280-W1D BUR280-81D ELI280-AAA-ADCBX ELI280-BBA-AAFAD ELI280-BBA-AAFBD ELI280-DBA-AAFAX ELI280-LDX-ADFBG ELI280-DBA-AAABD ELI280-AAB-ADAAX ELI280-CAA-ABFAX ELI280-BFA-ADCBX ELI280-CAA-ADHAX ELI280-LDX-ADCBD ELI280-AFB-ABCBX ELI280-AAB-ADFAD ELI280-CAA-AAFBX ELI280-CBB-ACCBX ELI280-DFA-ADCBX ELI280-C ELI280-D ELI280-B ELI280F
2. Serial Number or Lot Numbers and Date range of affected product: (Completed by Field Action Team; refer to MOR00601 Impacted Unit List Generation, which describes the process for generating a list of all impacted units for field actions or product recalls)	**116280503226 thru 121250000503** Serial numbers take the following form: 1XXCWZZZZZZZ Where "XX is the year of manufacture (ex. "XX" = 20XX), "CW" is the Calendar week of manufacture (ex CW=01 – First week In January), "ZZZZZZZ" is a rolling 7 digit counter number. Product affected was produced between July 1, 2016 through July1, 2021.
3. Total Estimated Quantity in Distribution / Extent of Impact: (Completed by Field Action Team)	14,807 units Shipped
4. Geographical Distribution Data: (Completed by Service)	

Country	Device(s)	Country	Device(s)
Afghanistan	1	LEBANON	16
Angola	3	LITHUANIA	13
ARGENTINA	10	Malaysia	8
AUSTRALIA	696	Mexico	30
Austria	8	Monaco	6
BAHRAIN	35	MOROCCO	26
BANGLADESH	16	Netherlands	368
BELGIUM	56	NEW ZEALAND	57

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	Bermuda	2	Northern Mariana Islands	8
	BRAZIL	173	NORWAY	118
	Bulgaria	1	OMAN	22
	CANADA	43	PAKISTAN	6
	CHILE	26	Panama	10
	China	50	PERU	25
	Colombia	3	Philippines	1
	Costa Rica	34	POLAND	154
	Croatia	5	PORTUGAL	26
	Cyprus	2	PUERTO RICO	6
	CZECH REPUBLIC	1	QATAR	66
	Czechia	16	ROMANIA	14
	DENMARK	1	SAUDI ARABIA	73
	Dominican Republic	2	SINGAPORE	8
	Ecuador	2	Slovakia	14
	Finland	39	SLOVENIA	5
	FRANCE	168	South Africa	1
	GERMANY	490	SPAIN	61
	GUATEMALA	10	SRI LANKA	9
	Hong Kong	1	SWEDEN	1
	HUNGARY	6	SWITZERLAND	13
	INDIA	7	Taiwan (Province of China)	2
	INDONESIA	33	THAILAND	87
	IRAN	5	THE NETHERLANDS	469
	Ireland	199	Trinidad and Tobago	12
	ISRAEL	188	TURKEY	146
	ITALY	827	U.ARAB EMIRATES	74
	Japan	1	United Arab Emirates	51
	JORDAN	8	United Kingdom	1375
	Kuwait	5	United States of America	8163
	LATVIA	30		

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Section C: Field Post Market Data

1. Number of Device Vigilance Reports Filed (Completed by QA/RA; contact the MDR Coordinator / International QA/RA Representative for support)	Review and identify any MDR(s), MDPR(s) or Vigilance reports associated with this action. Either add the references to this section or add as an attachment. Identify the associated number. Currently, there is 1 MDR **2183461-2021-00007**

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Section D: Hazard Details

1. Hazard Description: (Completed by Field Action Team)	1. Mismatched demographic/physiological data. 2. Delay in transmitting exam data or deletion of exam data

2. Foreseeable Sequence of Events:	**Scenario 1**
	Wrong Demographics Associated with Waveform
	1. ECG Operator acquires ECG for Patient A (Result=Normal) and Patient B (Result=STEMI)
	2. ECG Operator *may* print Patient A or B's ECG for interpretation and treatment guidance
	3. ECG Operator selects Patient A ECG from the directory
	4. ECG Operator performs edit to the demographic data without leaving the resting ECG screen
	5. ECG Operator edits Patient A's exam demographic data a *second time*
	6. On saving the exam the second time, Patient A's demographics are inserted onto Patient B's ECG waveform.
	7. Patient A now has 2 ECGs in directory; one correct=normal, and one incorrect=STEMI from Patient B
	8. ECG Operator transmits the ECGs to the patient's electronic medical records
	(serial comparison, follow up, history of treatment decisions, ongoing treatment guidance, or for initial review of ECG)
	9. Patient B's ECG is no longer discoverable under patient identifiers
	    1. Clinician does not recognize missing ECG
	        1. Patient B experiences delay in critical care for STEMI which may result in further deterioration of clinical condition
	    2. Clinician recognizes Patient B ECG is missing and repeats ECG exam
	        1. Patient B in ED/Inpatient setting: patient under ongoing surveillance and clinical assessment while awaiting repeat ECG; Repeat ECG again reveals STEMI. Patient experiences delay in critical care for STEMI which may result in further deterioration of clinical condition
	        2. Patient B in Outpatient setting: Patient experiences delay in critical care for STEMI

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	which may result in further deterioration of clinical condition 10. Clinician reviews Patient A's ECG which reveals STEMI from Patient B 1. Patient A in ED setting: 1. Clinical and vital sign assessment performed 2. Adjunct therapy initiated (aspirin, nitroglycerin, O2, Morphine if discomfort, labs ordered, continuous cardiac monitoring) 3. Reperfusion therapy risk assessment performed for rapid intervention 4. Fibrinolysis initiated or patient undergoes percutaneous coronary intervention (PCI) 5. Patient receives unnecessary invasive treatment and experiences complications 2. Patient A in Outpatient setting: 1. Clinician assesses patient or contacts at home and advises they call 911 or present to the ED for evaluation 2. Patient presents to ED and ECG is repeated which is normal 3. Observation, lab work, x-ray, medications and/or serial ECGs performed 4. Pt. experiences unnecessary non-invasive treatment **<u>Scenario 2 Wrong ECG Transmitted or Deleted</u>** 1. ECG Operator acquires ECG for Patient A (Result=STEMI) and Patient B (Result=Normal) 2. ECG Operator selects ECG A from directory, edits to demographics are completed and saved without leaving the resting ECG screen 3. ECG Operator presses **transmit** button 4. System incorrectly transmits Patient B normal ECG to the EKG management system with correct demographics and waveform; Patient A STEMI ECG does not transmit into EKG management system as intended 5. Clinician does not recognize Patient A missing ECG a. Patient A in ED or Outpatient setting: Patient experiences delay in critical care for STEMI which

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	may result in further deterioration of clinical condition 6. Clinician identifies Patient A ECG is missing and requests it to be retransmitted or orders new ECG a. Patient A in ED setting: patient under ongoing surveillance and clinical assessment while awaiting transmission. Patient experiences delay in critical care for STEMI which may result in further deterioration of clinical condition b. Patient A in Outpatient setting: Patient experiences delay in critical care for STEMI which may result in further deterioration of clinical condition 7. Patient B normal ECG remains in directory based on auto-delete rule of ECG Operator; no harm **OR** 8. ECG Operator presses **delete** button 9. Patient B ECG is unintentionally deleted from system instead of intended Patient A ECG 10. Clinician identifies Patient B ECG is missing and requests a repeat ECG a. ECG normal, patient experiences inconvenience 11. If patient B ECG=STEMI and deleted: a. Potential delay in critical care for STEMI which may result in further deterioration of clinical condition
1. Hazardous Situation:	1. Since the exam with the incorrect data would not necessarily be obvious to the viewer this fault represents risk DHF-RAC-154388-00 Rev 11 ID #19.3 - Incorrect interpretation of resting ECG resulting from mismatch of patient demographic data with physiological data. This could result in MOR00074 Rev C, HS-016 – "delay of critical care OR incorrect treatment" a Critical severity risk. 2. Since an exam not arriving in the EMR as desired would be obvious to the caregiver and would require the exam to be resent from the cardiograph this could, in an acute care setting, temporarily delay critical care. This could result in MOR00074 Rev C, HS-016 – "delay of critical care" a Critical severity risk.

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2. Review of Risk Documents: (Completed by Field Action Team)	☒ Risk Assessment: DHF-RAC-154388-00 Rev 11 Do any of the above checked documents need to be updated based on this assessment ☐ No ☒ Yes? 1. DHF-RAC-154388-00 Rev 12, ID #19.3 post-mitigation P_1 value to be updated from "Improbable" to "Remote." Pre- and Post-mitigation P_2 value to be updated from "Very Unlikely" to "Likely." No change to residual risk (4E-Medium). 2. DHF-RAC-154388-00 Rev 12, add new risk for clinician believing an intended exam has been sent when it has in fact not been sent to the EMR.
3. Population At Risk if Exposed to the Condition: (Completed by Field Action Team)	☒ Patient ☐ Caregiver ☐ Maintenance personnel ☐ Housekeeping ☐ Visitor ☐ Other:
4. Harm / Health Consequences (consider prior occurrences of issue in this and/or other products): (Completed by Field Action Team)	This could result in delay of critical care OR incorrect treatment leading to inadequate perfusion of a critical organ.

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Section E: Risk Index Calculation
Table 1

PROBABILITY INPUTS (Completed by Service / RA/QA Representative)	
DEVICE (Capital) DAYS (Record the total number of days all capital devices have been in the field below.)	Describe the method as to how the data was determined:
12,161,331	This number is derived by summing total days the 14,807 affected products introduced with the release of 2.1.0 software (July 2016), assuming full 5-year design life, and have been in service at or around the manufacture date.
DEVICE (Rental) DAYS (Record the total number of days all rental devices have been in the field.)	Describe the method as to how the data was determined.
0	This device is not rented.
COMPLAINTS (Record the total number of complaints from Hazard Conditions From Malfunctions or Use Errors.)	List below or add an attachment that identifies the complaints by document number and the source of the complaint information.
2	2 – No Injuries C-1454082 C-1442342

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PATIENT EXPERIENCES (P.E.) (Record the total number of Patient Days, 1 Patient Day is Equivalent to 1 Patient Experience.)	Patient experiences were determined using observed usage rates for given customer profiles (Sm./Med. Primary Care, Large Primary Care, and Acute Care) and the Device Days for all fielded ELI 280 products within their 5-year design life starting with the release of 2.1.0 software on July 2016.
201,844,776	**Utilization Rate:** **Patient Experiences:**

Cust.	IB %	Exams/Day	Days/Week	Weeks	Utilization Rate/yr	Utilization Rate/Day
Sm/Med Pri	70%	14	5	52	2,548	7.0
Lg. Pri.	15%	20	5	52	780	2.1
Acute	15%	50	7	52	2,730	7.5
					Total Utilization Rate:	**16.6**

$$Utilization\,Rate * Capitol\,Device\,Days = Patient\,Experiences$$

$$16.6\,\frac{Patient\,Experiences}{Day} * 12{,}161{,}331\,Days = Patient\,Experiences$$

$$\mathbf{201,878,095}\ \boldsymbol{Patient\,Experiences}$$

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Table 2

HARM ANALYSIS DATA COLLECTION			
See below for instruction on how to complete this table			**Justification for Expected Injuries per Predicted Product Lifetime of the Device** *(The basis for Predicted Product Lifetime determination is to be added below. If the basis for assessment does not Include published data, document the research efforts)*
NEGLIGIBLE Temporary discomfort or inconvenience	N/A	☐ Allegations Received ☒ Expected over the Lifetime* *Justification Required	Per the risk assessment and reevaluation of the issue during the FAA/HHE, the foreseeable sequence of events will not result in this level of harm. Therefore, this potential for harm is not applicable and is indicated as "N/A".
MINOR INJURIES (Record the total number of Minor Injuries Alleged or expected over the Predicted Product Lifetime P.E.)	N/A	☐ Allegations Received ☒ Expected over the Lifetime* *Justification Required	Per the risk assessment and reevaluation of the issue during the FAA/HHE, the foreseeable sequence of events will not result in this level of harm. Therefore, this potential for harm is not applicable and is indicated as "N/A".
MODERATE INJURIES (Record the total number of Moderate Injuries Alleged or expected over the Predicted Product Lifetime P.E.)	N/A	☐ Allegations Received ☒ Expected over the Lifetime* *Justification Required	Per the risk assessment and reevaluation of the issue during the FAA/HHE, the foreseeable sequence of events will not result in this level of harm. Therefore, this potential for harm is not applicable and is indicated as "N/A".
CRITICAL INJURIES (Record the total number of Critical Injuries Alleged or expected over the Predicted Product Lifetime P.E.)	1-60	☐ Allegations Received ☒ Expected over the Lifetime* *Justification Required	According to post-market data, there have been two complaints however there are **0 allegations of injury**. A fault tree was developed to assess possible scenarios that would create this fault. Based on post-market data and customer use data it is anticipated this situation *could occur* at a rate of 0.055% and would Likely lead to harm should it occur. ***(See Fault Tree Red-Scenario #1 & Purple-Scenario #2 Outputs)***

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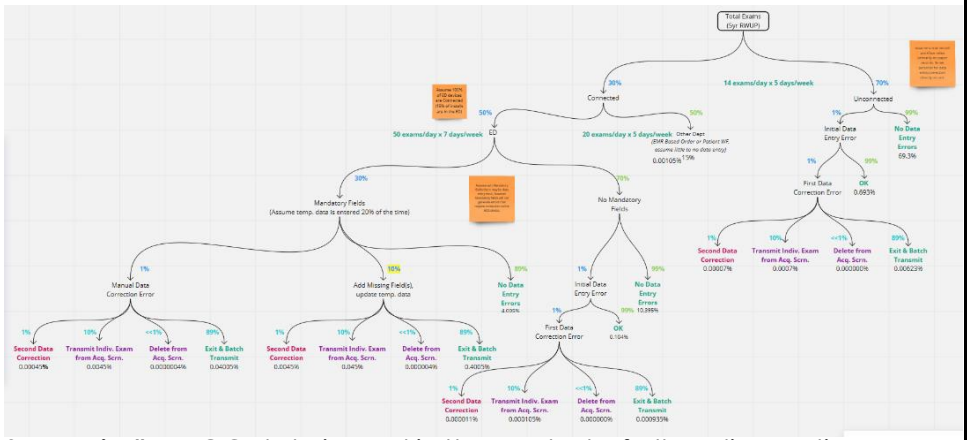

Scenario #1 - ECG data is used in the context of other diagnostic parameters including patient history, physical exam, and other tests. Furthermore, the caregiver would be familiar with their patient and identify data mismatch preventing potential mistreatment or delay in care. However, there is still a possibility the mismatch is not apparent to a caregiver who is unfamiliar with the patient. This caregiver could prescribe incorrect treatment which could result in this harm. The caregiver may act on the presented ECG and patient clinical symptoms, especially in an acute care setting, without guidance of additional lab work and diagnostic exams to provide emergent reperfusion intervention to improve patient outcome.

Scenario #2 - It is possible that exam data loss or not sending the intended ECG to the EMR would only be able to be seen when trying to access the data from the directory/storage or EMR. Depending on the data that was deleted or not sent from the cardiograph another measurement period may be required resulting in a delay in care or

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			diagnosis. It would however be obvious to the caregiver that the data was lost and retransmission or a second ECG acquisition would be required. **Summary -** Fault tree analysis confirms this issue could potentially occur, theoretically at a rate as high as 0.055%. However there have also been no reported allegations of any harm during the estimated 202M patient experiences. Therefore, based on the probability of occurrence, the probability the clinician may/may not recognize mismatched data, and available post market complaint data it is believed harm is **Unlikely** ($1/454{,}400{,}000 < P_U < 1/7{,}570{,}000$) and harm could therefore potentially occur between 1-60 times over the design life of the installed base.
CATASTROPHIC INJURIES (Record the total number of Catastrophic Injuries Alleged or expected over the Predicted Product Lifetime P.E.)	N/A	☐ Allegations Received ☒ Expected over the Lifetime* *Justification Required	Per the risk assessment and reevaluation of the issue during the FAA/HHE, the foreseeable sequence of events will not result in this level of harm. Therefore, this potential for harm is not applicable and is indicated as "N/A".

- See the Harm Severity Classification (Table 3) for the injury type descriptions.
- To determine the predicted Product Lifetime P.E. use the denominator from calculation (P_{IU}) found in Table 4
- If you have no complaints of a severity of harm and your risk assessment and/or the clinical opinion is that one or more of the severities is outside of the foreseeable sequence of events for the harm, then replace the "x" with "N/A" and add justification in the column to the far right of that injury type to support that determination.
- If complaint data is available and you have over the predicted lifetime patient experiences, the total of each type of harm is to be identified in the table above. Replace the "x" with the number of injuries identified from the complaint data and check the "Allegations Received" check box, no justification is required.
- If the Patient Experience is less than the predicted lifetime patient experiences, and an injury has occurred, then extrapolate the potential for injuries to occur over the life of the product up to the Predicted Lifetime Patient Experiences if the product were to be left in the field without mitigation. Check the "Allegations Received" check box and add how you determined the potential for injury in the column to the far right for each injury type affected.
- If no complaint data is available, and there is published data or the Field Action Team suspects that the injury will occur more frequently than once in the predicted lifetime of the product, enter the number of injuries expected over the expected lifetime to the table above. "Expected over the Lifetime" is to be checked and the basis for this determination is to be added into the Justification column to the far right for each injury type affected.

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Table 3
The following will be used to classify the severity of potential harm:
(Note: This table originates in the Risk Management, MOR00002, and is reproduced here for convenience)

Severity of Harm	Criteria Description of potential consequences of hazards.
Negligible Harm	The hazard could result in a temporary discomfort or inconvenience to a person.
Minor Harm	The hazard could result in a reversible non-serious injury to a person where the injury doesn't require professional medical intervention (e.g., laceration, bruise or contusion).
Serious Harm	The hazard could result in a reversible injury to a person where the injury requires professional medical intervention (e.g., laceration requiring stitches).
Critical Harm	The hazard could result in a serious illness or serious injury to a person that results in permanent impairment of a body function or permanent damage to a body structure, or a condition necessitating medical or surgical intervention to prevent permanent impairment of a body function or permanent damage to a body structure.
Catastrophic Harm	The hazard would result in an illness or injury that results in a person's death.

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Table 4

The following table will be used to rate the likelihood resulting from the hazardous situation:

(Note that this table originates in the Risk Management MOR00002 and is reproduced here for convenience)

Likelihood Classification		
Likelihood	**Definition**	**Objective Range***
Improbable	Harm is extremely unlikely, and it is estimated that the harm will never occur during the life of a product.	$X < P_{IU}$
Unlikely	Harm is very unlikely but possible to occur during the life of a product.	$P_{IU} \leq X < P_{UR}$
Remote	Harm is not anticipated but may occur during the life of the product.	$P_{UR} \leq X < P_{RO}$
Occasional	Harm is likely to occur sometime during the life of the product.	$P_{RO} \leq X < P_{OF}$
Frequent	Harm is likely to occur multiple times during the life of a product.	$P_{OF} \leq X$

* The Likelihood Classification Objective Ranges values are to be derived using the instruction given in Appendix B & C of QS00119. Identify below the outcome from the calculations: Example P_{IU} from MOR00002 equals 1/250,000,000

P_{IU} =	1/454,400,000
P_{UR} =	1/7,570,000
P_{RO} =	1/1,750,000
P_{OF} =	1/250,000

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Table 5

PROBABILITY OUTPUTS (Completed by Field Action Team)		
	Enter data from Table 2 / data from Table 1	**Enter Likelihood based on Table 4 using the objective range**
HAZARD PROBABILITY (Calculate: Complaints / P.E.)	2 Complaints/201,878,095 PE **1/100,939,047 Complaints/PE**	**P_1=Unlikely**
NEGLIGIBLE PROBABILITY (Calculate: Temporary Discomfort / P.E.)	n/a	n/a
MINOR INJURY PROBABILITY (Calculate: Minor Injuries / P.E.)	n/a	n/a
MODERATE INJURY PROBABILITY (Calculate: Moderate Injuries / P.E.)	n/a	n/a
CRITICAL INJURY PROBABILITY (Calculate: Critical Injuries / P.E.)	0 Complaints/201,878,095 PE	Although there have been **0 allegations of injury** analysis shows this scenario *may* still occur and can potentially result in harm. Therefore, **P_{Harm}=Unlikely**
CATASTROPHIC INJURY PROBABILITY (Calculate: Catastrophic Injuries / P.E.)	n/a	n/a

Table 6 Risk Index Summary (Completed by QA/RA Representatives)

The following table provides the decision rules for assigning risk acceptability: (Note that this table originates in the Risk Management, MOR00002, and is reproduced here for convenience.)

Severity of Harm							
	Catastrophic	5	n/a	n/a	n/a	n/a	n/a
	Critical	4	n/a	n/a	n/a	☒	n/a
	Moderate	3	n/a	n/a	n/a	n/a	n/a
	Minor	2	n/a	n/a	n/a	n/a	n/a
	Negligible	1	n/a	n/a	n/a	n/a	n/a
			A Frequent	**B** Occasional	**C** Remote	**D** Unlikely	**E** Improbable

Notes:

1. The FDA and EU require reporting for a correction or removal that is initiated to mitigate the possibility of death, serious injury or serious deterioration to the state of health posed by the device.
2. Health Canada requires the same reporting as note 1, plus reporting if the device is failing to meet stated performance claims.
3. The sections highlighted in RED above meet the criteria for reporting to the FDA, Health Canada and EU Competent Authorities as applicable.
4. The section highlighted in BLUE above may require reporting in Canada. It is up to the CFAC to determine if regulatory reporting is required and, if so, this is to be documented in section H.
5. Table 6 does not determine if a field corrective action is required; it is only an indication of the probability of the hazard and harms.

Field Action Assessment Checklist/Health Hazard Evaluation

Section F: Summary and Recommendations

1. Summary: (Completed by Field Action Team)	The initial customer complaint (C-1454082) states: periodically studies being sent from an ELI280 Electrocardiograph machine to an EMR system have the wrong waveform with the wrong patient demographics. Engineering investigation of anomaly #B104604 and #B104605 confirmed that, an ELI280 Operator, through a sequence of operator inputs, could transmit incorrect patient ECG waveform exam information to a EMR system. Additionally, 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 to an EMR system. Both issues have the same potential root cause in the ELI280 Electrocardiograph Software version 2.1.0 through 2.3.0 but are caused by different operator sequence workflows. (NCE002629) was opened on 30Jun2021 and the investigation is on-going to confirm root cause. **Scenario 1) Wrong Demographics Associated with Waveform** If a user selects ECG A from the directory, double edits demographic information, and then without leaving the Resting ECG screen, edits the ID again, ECG A's demographics will be inserted into the stored ECG B record. The cause is the same as above. After the first edit, the directory is left in a corrupted state. The directory entry is pointing to the wrong stored ECG record. The second edit then causes ECG A's demographics to be written to ECG B. At this point, the cardiograph contains 2 stored records for patient A. The original Patient A ECG and the ECG with demographics from patient A and patient B's waveform.

Field Action Assessment Checklist/Health Hazard Evaluation

	Scenario 2) Wrong ECG transmitted or Deleted If a user selects an ECG from the directory, single edits the demographic information, and then without leaving the Resting ECG screen presses the Transmit button, an ECG different from the one being displayed will be transmitted. The cause of this error is that after the ECG edit, the directory is left in a corrupted state. The directory refers to the internal software mechanism used to keep track of and allow the user to interface with the ECG records stored on the cardiograph. The function Update_ECG_Record() is called when the user edits the ECG. This function updates the demographic section of the ECG record with the new changes. Within Update_ECG_Record(), the function DirListRec_Delete() is called to remove the old entry (the entry prior to editing) from the directory structure, so that the new edited entry can be added. The function DirListRec_Add() is later called to add the newly edited entry. The problem occurs due to an error in the function DirListRec_Delete(). When DirListRec_Delete() is called, the wrong directory entry is removed. The result is that when DirListRec_Add() is called the new directory entry (the edited ECG) is added but is pointing to a different stored ECG. When the Transmit button is pressed, the wrong ECG is transmitted. At this point, no stored records have been affected by the error. If the user exits the directory and then re-enters the directory, the directory is correctly rebuilt. Nonconformance: NCE002629 was opened on 30Jun2021 Product Hold: MISC-QS-0085 was completed on 02July2021
2. Recommended Correction or Removal: (Completed by Field Action Team)	The Milwaukee Site is recommending that corrective action be taken in the field. There are 14,807 units on the market with 2 open allegations.

Section G: Prepared and Reviewed By

Field Action Assessment Checklist/Health Hazard Evaluation

Section H: Field Action Committee

(Completed by Head of QA/RA (or designee) with input from Corporate Field Action Committee)

1. Date of CFAC meeting:	
2. Recommended Action:	☐ Approved as Recommended by the Field Action Team ☐ Approved as Recommended, No Action Required
3. Field Action Plan Required:	☐ Yes ☐ No, Agreement by the CFAC that no action need be taken.
4. Assignment of Modification Number:	MOD#
5. Assignment of World Field Action Coordinator (WFAC):	☐ No ☐ Yes (If Yes, record name, title, and location) _____ (Name) Title _____ Location
6. Target Date to Review Field Action Plan:	Date: _____
7. Regulatory Agency Notification:	☐ Not Required ☐ Food and Drug Administration (USA) ☐ Health Canada (Canada) ☐ International RA/QA will be contacted to determine if Regulatory reporting is required outside USA and Canada. The results will be defined in the Field Action Plan. ☐ Other (Define):
8. CAPA	☐ CAPA Not Required: (No Field Corrective Action) ☐ CAPA Number Previously Assigned: _____ ☐ CAPA determination and status is to be defined in the Field Action Plan Section 2.

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Section I: Corporate Field Action Committee Approval

My approval indicates acceptance of the document content and that it applies to the entities identified.

	Printed Name	Signature	Date
Chairperson RA/QA			
Legal			
Finance			
Marketing			
Service			

Appendix#1

Product	Region	Country	Primary Regulator	License / Registration Number
ELI 280	APAC	American Samoa (US)	US FDA	K122073
ELI 280	LA	American Virgin Islands (US)	US FDA	K122073
ELI 280	EUROPE	Andorra (EU)	Notified Body	EC Certificate No.35913 rev. 2
ELI 280	LA	Anguilla (UK)	Notified Body	EC Certificate No.35913 rev. 2
ELI 280	LA	Argentina	Argentina - ANMAT	PM 2509-6
ELI 280	LA	Aruba (NL)	Notified Body	EC Certificate No.35913 rev. 2
ELI 280	APAC	Australia	Australia TGA	ARTG 324622
ELI 280	EUROPE	Austria (EU)	Notified Body	EC Certificate No.35913 rev. 2
ELI 280	MEATI	Bahrain	National Health Regulatory Authority (NHRA)	
ELI 280	EUROPE	Belgium (EU)	Notified Body	EC Certificate No.35913 rev. 2
ELI 280	LA	Bermuda (UK)	Notified Body	EC Certificate No.35913 rev. 2
ELI 280	APAC	Bouvet Island (NO)	Notified Body	EC Certificate No.35913 rev. 2
ELI 280	APAC	British Indian Ocean Territory (UK)	Notified Body	EC Certificate No.35913 rev. 2
ELI 280	LA	British Virgin Islands (UK)	Notified Body	EC Certificate No.35913 rev. 2
ELI 280	CANADA	Canada	Health Canada	89610
ELI 280	LA	Cayman Islands (UK)	Notified Body	EC Certificate No.35913 rev. 2
ELI 280	APAC	China	CFDA	GXZJ 20182070318
ELI 280	APAC	Christmas Island (AU)	Australia TGA	ARTG 324622
ELI 280	LA	Colombia	Colombia - INVIMA	INVIMA 2019DM-0019210
ELI 280	APAC	Cook Islands (NZ)	MEDSAFE	191017-WAND-6TFE3E
ELI 280	APAC	Coscos Islands (AU)	Australia TGA	ARTG 324622
ELI 280	EUROPE	Croatia (EU)	Notified Body	EC Certificate No.35913 rev. 2
ELI 280	EUROPE	Cyprus (EU)	Notified Body	EC Certificate No.35913 rev. 2
ELI 280	EUROPE	Czech Republic (EU)	Notified Body	EC Certificate No.35913 rev. 2
ELI 280	EUROPE	Denmark (EU)	Notified Body	EC Certificate No.35913 rev. 2
ELI 280	LA	Dutch Antilles (NL)	Notified Body	EC Certificate No.35913 rev. 2
ELI 280	LA	Falkland Islands (UK)	Notified Body	EC Certificate No.35913 rev. 2
ELI 280	EUROPE	Faroe Islands (Denmark)	Notified Body	EC Certificate No.35913 rev. 2
ELI 280	EUROPE	Finland (EU)	Notified Body	EC Certificate No.35913 rev. 2
ELI 280	EUROPE	France (EU)	Notified Body	EC Certificate No.35913 rev. 2
ELI 280	LA	French Guayana (FR)	Notified Body	EC Certificate No.35913 rev. 2

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Product	Region	Country	Primary Regulator	License / Registration Number
ELI 280	APAC	French Polynesia (FR)	Notified Body	EC Certificate No.35913 rev. 2
ELI 280	APAC	French Southern Territories (FR)	Notified Body	EC Certificate No.35913 rev. 2
ELI 280	EUROPE	Georgia	Notified Body	EC Certificate No.35913 rev. 2
ELI 280	EUROPE	Germany (EU)	Notified Body	EC Certificate No.35913 rev. 2
ELI 280	EUROPE	Gibraltar (EU)	Notified Body	EC Certificate No.35913 rev. 2
ELI 280	EUROPE	Greece (EU)	Notified Body	EC Certificate No.35913 rev. 2
ELI 280	EUROPE	Greenland (Denmark)	Notified Body	EC Certificate No.35913 rev. 2
ELI 280	LA	Guadeloupe (FR)	Notified Body	EC Certificate No.35913 rev. 2
ELI 280	APAC	Guam (US)	US FDA	K122073
ELI 280	APAC	Heard and McDonald Islands (AU)	Australia TGA	ARTG 324622
ELI 280	EUROPE	Hungary (EU)	Notified Body	EC Certificate No.35913 rev. 2
ELI 280	EUROPE	Iceland (EFTA)	Notified Body	EC Certificate No.35913 rev. 2
ELI 280	APAC	Indonesia	Ministry of Health Republic of Indonesia	20502021873
ELI 280	EUROPE	Ireland (EU)	Notified Body	EC Certificate No.35913 rev. 2
ELI 280	EUROPE	Israel	MoH	670794
ELI 280	EUROPE	Italy (EU)	Notified Body	EC Certificate No.35913 rev. 2
ELI 280	EUROPE	Latvia (EU)	Notified Body	EC Certificate No.35913 rev. 2
ELI 280	EUROPE	Liechtenstein (EFTA)	Notified Body	EC Certificate No.35913 rev. 2
ELI 280	EUROPE	Lithuania (EU)	Notified Body	EC Certificate No.35913 rev. 2
ELI 280	EUROPE	Luxembourg (EU)	Notified Body	EC Certificate No.35913 rev. 2
ELI 280	APAC	Malaysia	Malaysia MDA	GB7422420-42749
ELI 280	EUROPE	Malta (EU)	Notified Body	EC Certificate No.35913 rev. 2
ELI 280	APAC	Marshall Islands (US)	US FDA	K122073
ELI 280	LA	Martinique (FR)	Notified Body	EC Certificate No.35913 rev. 2
ELI 280	EUROPE	Mayotte (FR)	Notified Body	EC Certificate No.35913 rev. 2
ELI 280	LA	Mexico	COFEPRIS	2170E2018 SSA
ELI 280	APAC	Micronesia (US)	US FDA	K122073
ELI 280	US	Minor Outlying Islands (US)	US FDA	K122073
ELI 280	EUROPE	Monaco (EU)	Notified Body	EC Certificate No.35913 rev. 2
ELI 280	LA	Montserrat (UK)	Notified Body	EC Certificate No.35913 rev. 2
ELI 280	MEATI	Morocco	Ministry of Health	8473-2020-DMP
ELI 280	EUROPE	Netherlands (EU)	Notified Body	EC Certificate No.35913 rev. 2
ELI 280	APAC	New Caledonia (FR)	Notified Body	EC Certificate No.35913 rev. 2

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Product	Region	Country	Primary Regulator	License / Registration Number
ELI 280	APAC	New Zealand	MEDSAFE	191017-WAND-6TFE3E
ELI 280	APAC	Norfolk Islands (AU)	Australia TGA	ARTG 324622
ELI 280	APAC	North Mariana Island (US)	US FDA	K122073
ELI 280	EUROPE	Norway (EFTA)	Notified Body	EC Certificate No.35913 rev. 2
ELI 280	APAC	Palau (US)	US FDA	K122073
ELI 280	APAC	Philippines	Center for Device Regulation, Radiation Health and Research (CDRRHR)	
ELI 280	APAC	Pitcairn Islands (UK)	Notified Body	EC Certificate No.35913 rev. 2
ELI 280	EUROPE	Poland (EU)	Notified Body	EC Certificate No.35913 rev. 2
ELI 280	US	Puerto Rico (US)	US FDA	K122073
ELI 280	EUROPE	Reunion (FR)	Notified Body	EC Certificate No.35913 rev. 2
ELI 280	EUROPE	San Marino (EU)	Notified Body	EC Certificate No.35913 rev. 2
ELI 280	MEATI	Saudi Arabia	Saudi Arabia MoH	GHTF-2020-0437
ELI 280	APAC	Singapore	Singapore Health Science Authority (HAS)	DE0504056
ELI 280	MEATI	South Africa	Department of Health Directorate Radiation Control	626/28139
ELI 280	LA	South Sandwich Islands (UK)	Notified Body	EC Certificate No.35913 rev. 2
ELI 280	EUROPE	Spain (EU)	Notified Body	EC Certificate No.35913 rev. 2
ELI 280	APAC	St. Helena (UK)	Notified Body	EC Certificate No.35913 rev. 2
ELI 280	EUROPE	St. Pierre and Miquelon (FR)	Notified Body	EC Certificate No.35913 rev. 2
ELI 280	EUROPE	Svalbard (NO)	Notified Body	EC Certificate No.35913 rev. 2
ELI 280	EUROPE	Sweden (EU)	Notified Body	EC Certificate No.35913 rev. 2
ELI 280	EUROPE	Switzerland (EFTA)	Notified Body	EC Certificate No.35913 rev. 2
ELI 280	APAC	Thailand	Thailand FDA	USA 6401067
ELI 280	APAC	Tokelau Islands (NZ)	MEDSAFE	191017-WAND-6TFE3E
ELI 280	MEATI	Turkey	Turkey Ministry of Health	M523ELI2808F
ELI 280	LA	Turks and Caicos Islands (UK)	Notified Body	EC Certificate No.35913 rev. 2
ELI 280	MEATI	United Arab Emirates (UAE)	Ministry of Health & Prevention	
ELI 280	EUROPE	United Kingdom (EU)	Notified Body	EC Certificate No.35913 rev. 2
ELI 280	US	United States	US FDA	K122073
ELI 280	EUROPE	Vatican City (EU)	Notified Body	EC Certificate No.35913 rev. 2
ELI 280	APAC	Wallis and Futuna (FR)	Notified Body	EC Certificate No.35913 rev. 2