
# How to Manage Medical Device Incidents

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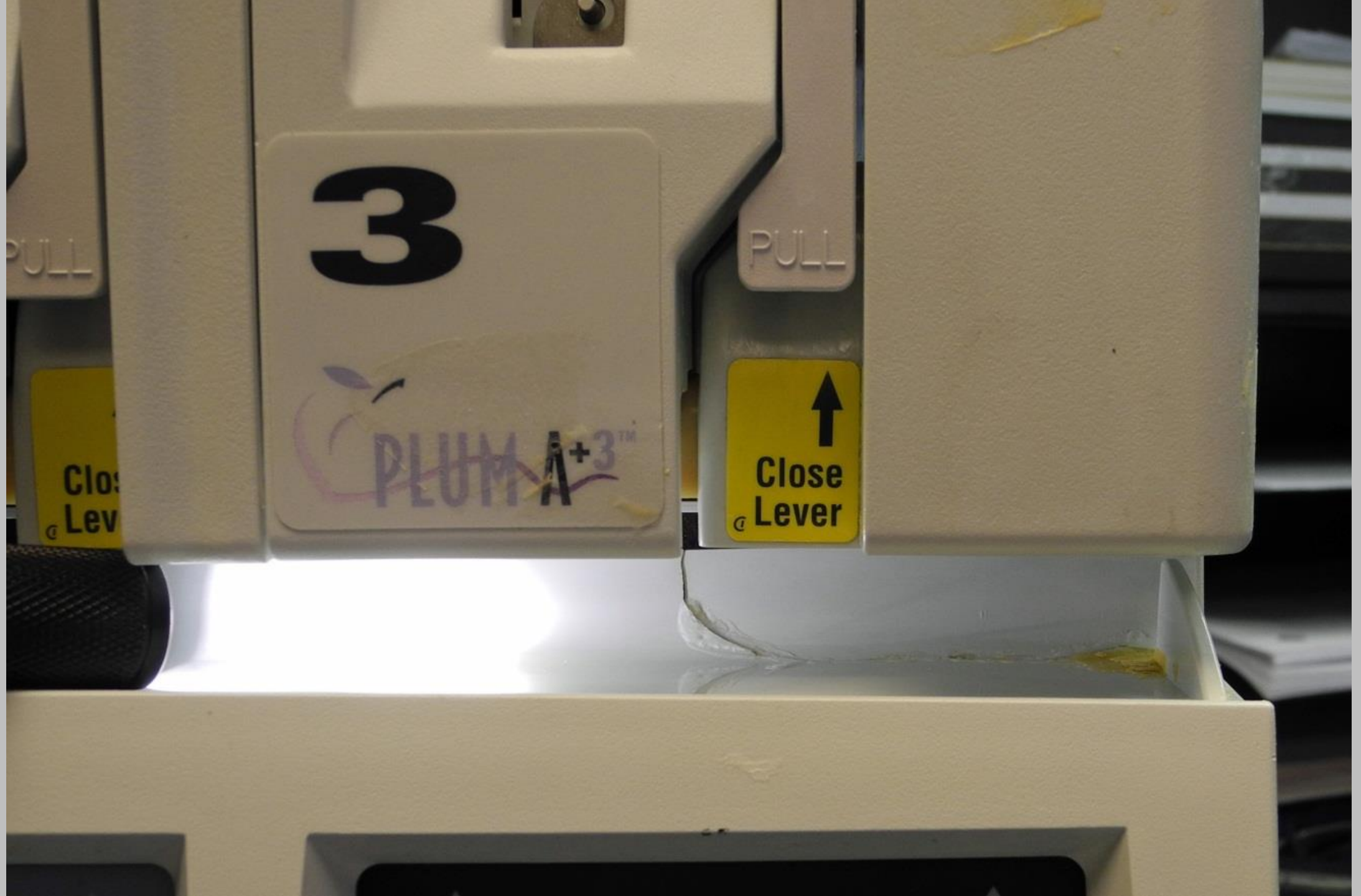
# Medical Device Incident

A patient care provider
has a clinical objective
that requires a medical device
but is unable to achieve the objective
and harm occurs.

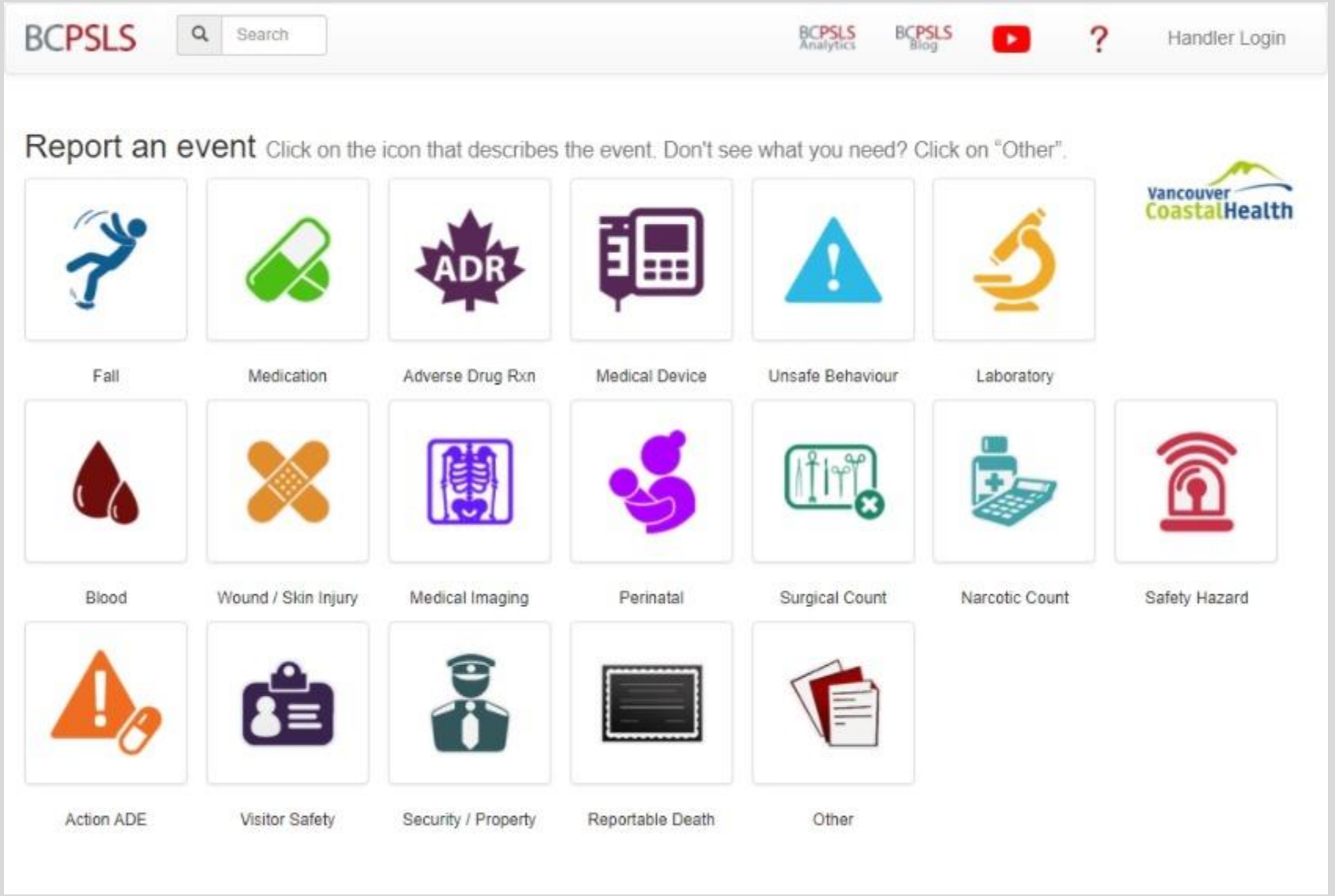
1. Take care of the patient


1
2
3
Close Lever
Close Lever
Close Lever
ABBOTT
channel #1 running inaccurately? can this be fixed out
START
STOP
ON/OFF
SILENCE
SELECT
NEC
MultiSync LCD2090UXi


3
PULL
PULL
PLUM A+3™
Close
Lever


CR19
C17
C87
VR1
DF08
4A06
U14
+
CE FUSES AS MARKED

# 2. Report internally


BCPSLS
Search
BCPSLS Analytics
BCPSLS Blog
Handler Login
Report an event Click on the icon that describes the event. Don't see what you need? Click on "Other".
Vancouver Coastal Health
ADR
Fall
Medication
Adverse Drug Rxn
Medical Device
Unsafe Behaviour
Laboratory
Blood
Wound / Skin Injury
Medical Imaging
Perinatal
Surgical Count
Narcotic Count
Safety Hazard
Action ADE
Visitor Safety
Security / Property
Reportable Death
Other

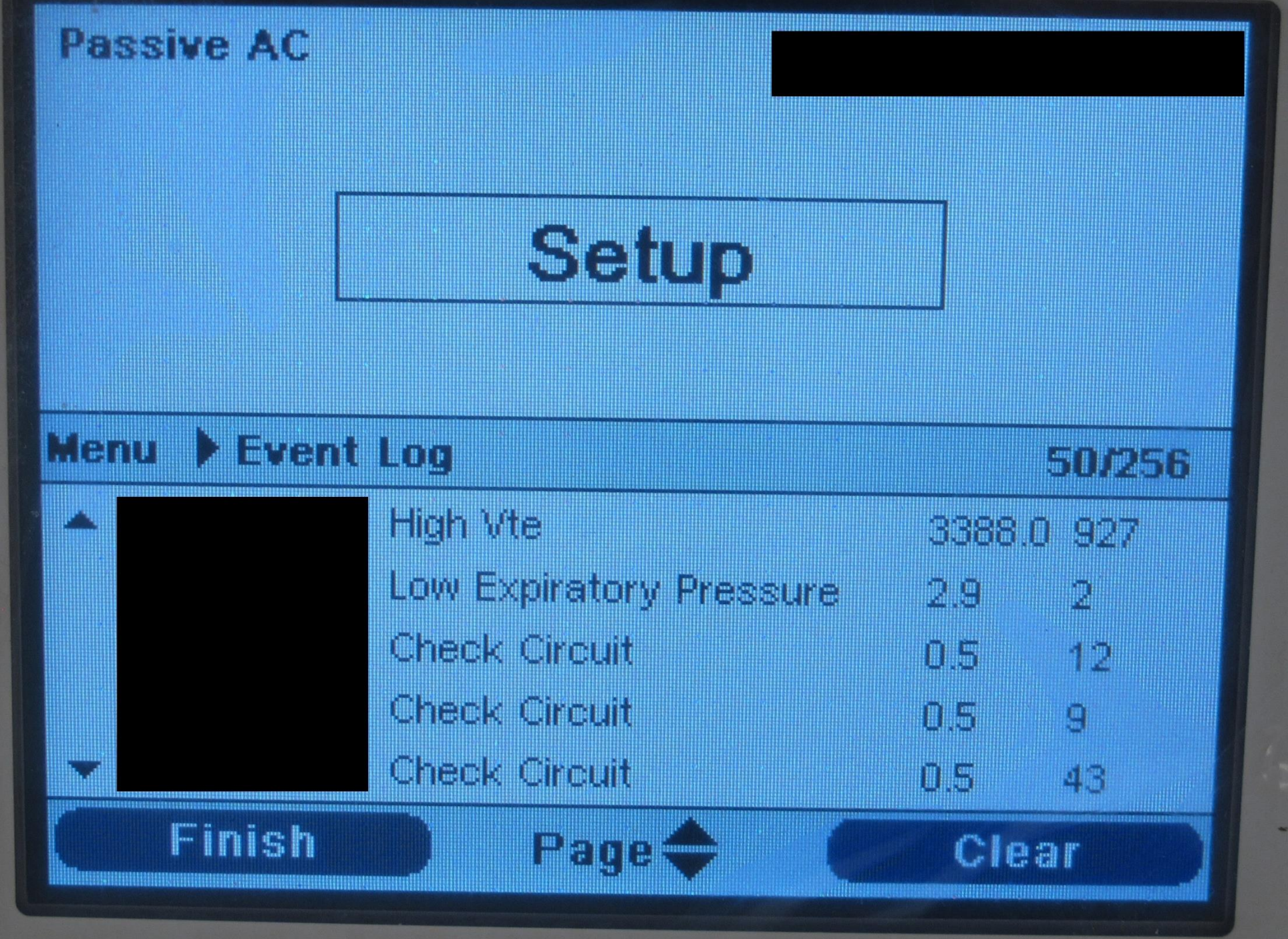
# 3. Sequester the device

- Out of service and locked up
- Preserve disposables and packaging
- Preserve the settings
- Plug in the device

# 4. Preserve patient data

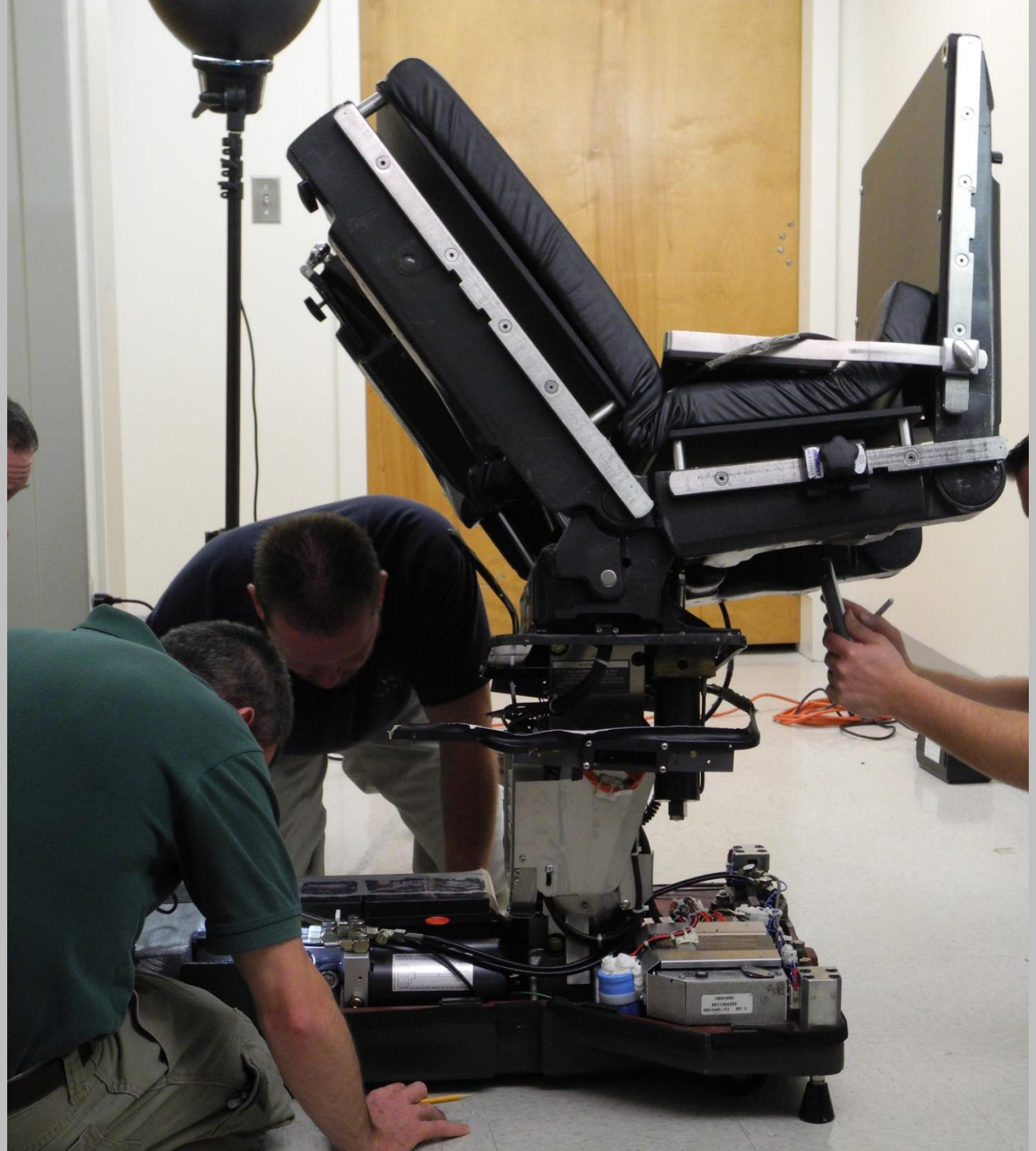
- Paper records: hand-written notes, printouts, etc.
- Electronic Medical Record (EMR) systems
- Medical device event and alarm logs


Primary: AVAPS
24/14/2007 04:54 PM
cm H2O
0 5 10 15 20 25 30
Pressure
7.9 cm H2O
RR
14 BPM
Vtz
2 ml
Leak
10 l/min
RR 8.0 BPM
I:E Ratio 1:1.6
Peak Flow 3.0 l/min
PIP 5.5 cm H2O
MinVent 0.0 l/min
Access
Card
Detach
Int
Menu▲


Passive AC
[redacted]
Setup
Menu
Event Log
50/256
[redacted]
High Vte 3388.0 927
Low Expiratory Pressure 2.9 2
Check Circuit 0.5 12
Check Circuit 0.5 9
Check Circuit 0.5 43
Finish
Page
Clear

# 5. Investigate the incident


STERIS
Amsco 3085 SP



# 6. Report externally

U.S. Food and Drug Administration (FDA)

- Safe Medical Devices Act (SMDA)
- Medical Device Reporting (MDR) System

# MAUDE - Manufacturer and User Facility Device Experience

FDA Home › Medical Devices › Databases

The MAUDE database houses medical device reports submitted to the FDA by mandatory reporters [1] (manufacturers, importers and device user facilities) and voluntary reporters such as health care professionals, patients and consumers.

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Product Problem

Product Class

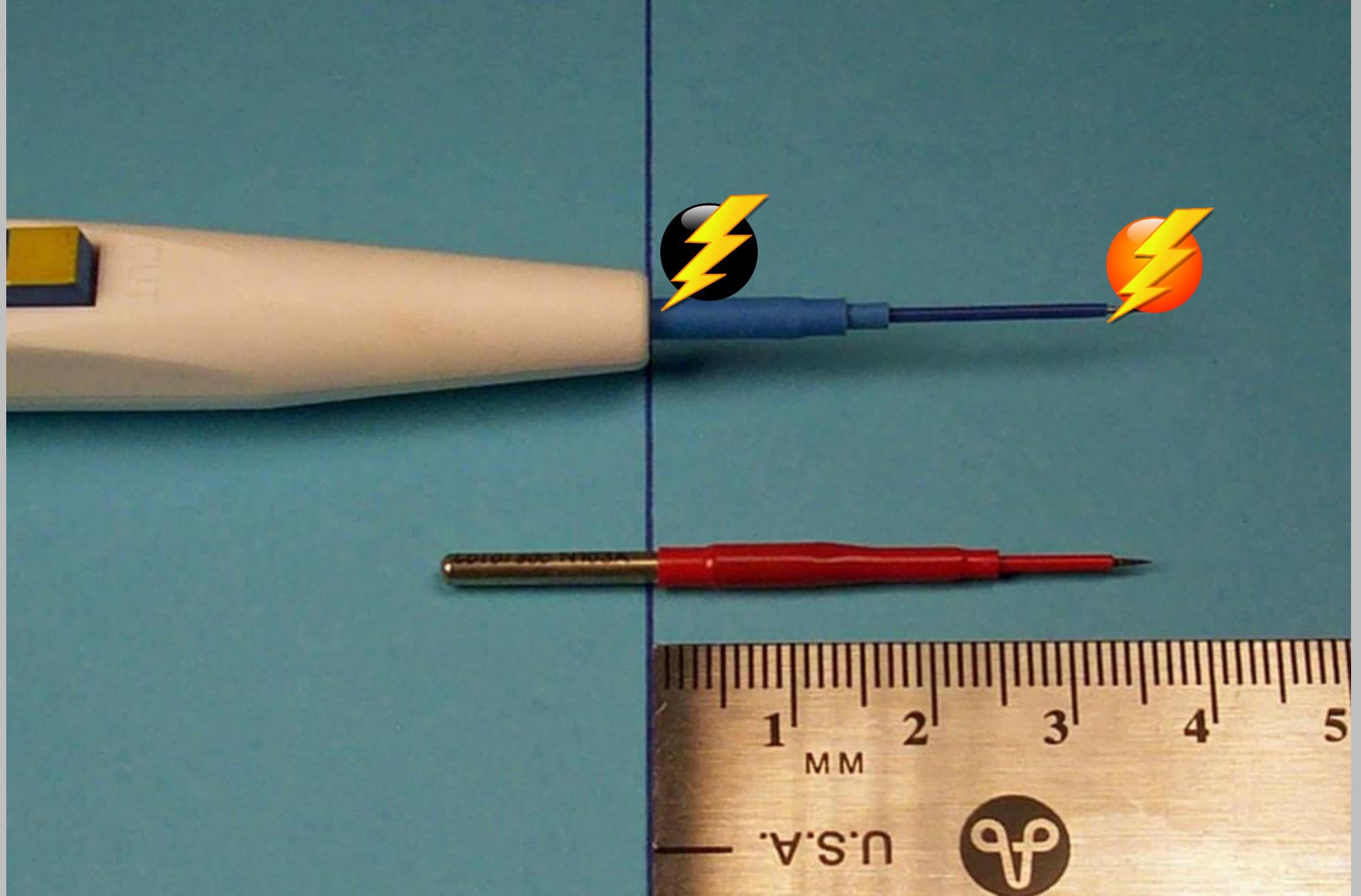
Event Type | Manufacturer

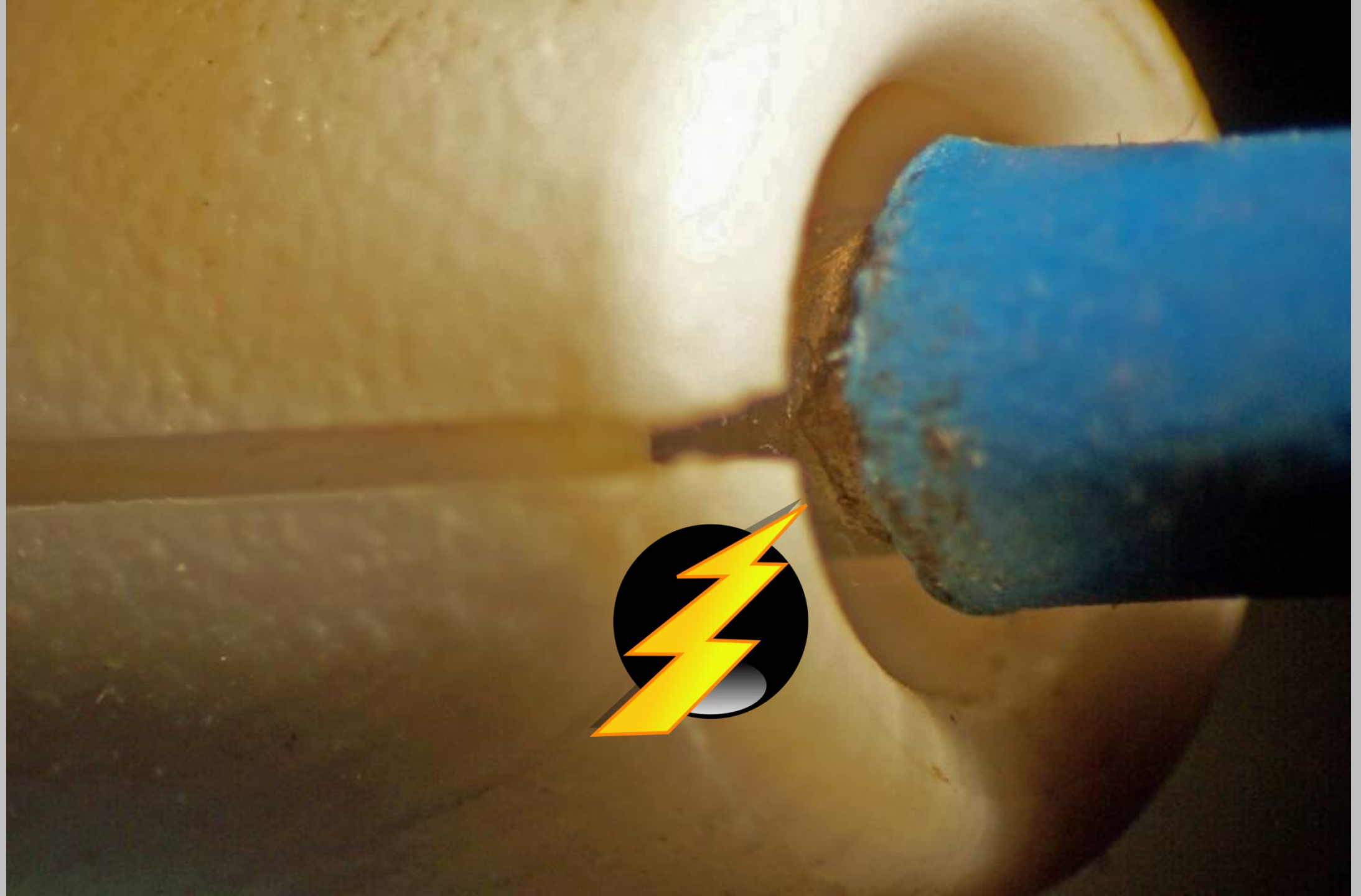
Model Number | Report Number

Brand Name | Product Code

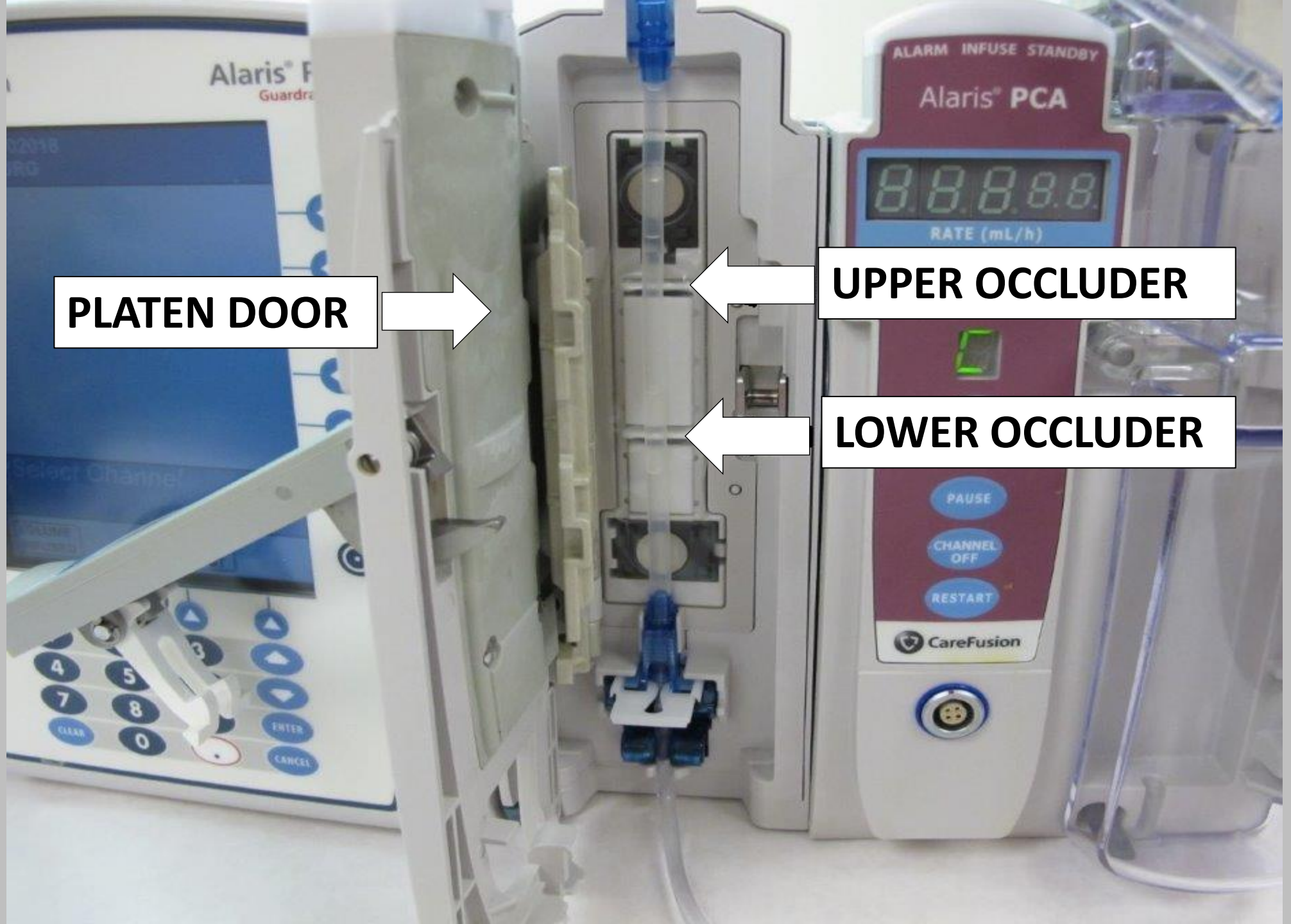
Date Report Received by FDA *(mm/dd/yyyy)* 02/01/2019 to 02/28/2019

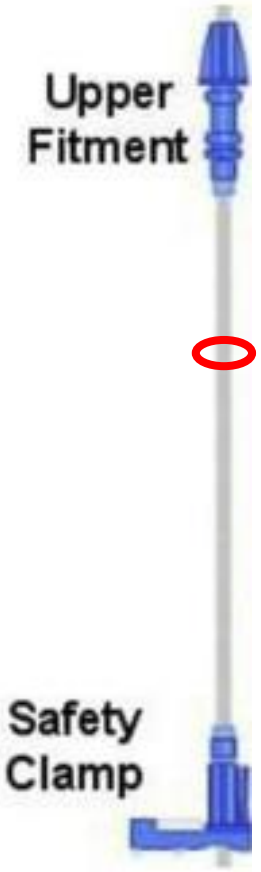
Go to Simple Search | 10 Records per Report Page | Clear Form | Search

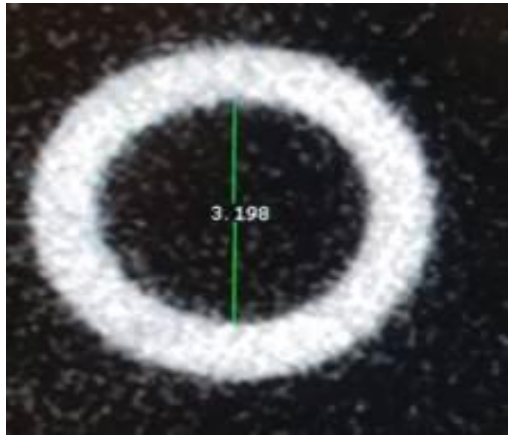

1
2
3
4
5
MM
U.S.A.



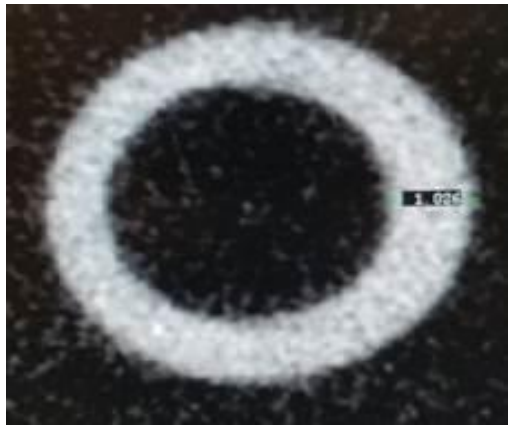
# 7. Avoid recurrences


PLATEN DOOR
UPPER OCCLUDER
LOWER OCCLUDER
ALARM INFUSE STANDBY
Alaris® PCA
RATE (mL/h)
PAUSE
CHANNEL OFF
RESTART
CareFusion




Exemplar Tubing: wall thickness is uniform (Good)



Incident Tubing: wall thickness is non-uniform (Bad)

1. Take care of the patient
2. Report internally
3. Sequester the device
4. Preserve patient data
5. Investigate the incident
6. Report externally
7. Avoid recurrences

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# Thank you!

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