ACCE
AMERICAN COLLEGE OF CLINICAL ENGINEERING

2023-2024 Educational Webinar Series

Incidents Investigation Best Practices

December 14, 2023

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ACCE gratefully acknowledges the sponsorship of the 2023-2024 Educational Webinar series by

About the Moderator

Juuso Leinonen, BEng
Director of Medical Device Cybersecurity and Integration
Crothall Healthcare

Juuso Leinonen is currently the Director of Medical Device Cybersecurity and Integration at Crothall Healthcare where he leads a team of Cybersecurity and Integration Specialists.

Previously, Juuso served at the Device Evaluation group at ECRI where he led various medical technology projects from comparative medical device evaluations to complex medical device accident investigations. Juuso's research efforts led to over 100 ECRI publications, including some global medical device recalls.

In 2022, Juuso received the ACCE-HIMSS Excellence in Clinical Engineering and IT Synergies Award for his work in tackling challenges of managing medical device cybersecurity. Juuso has presented about the challenges of managing medical device cybersecurity at several international, national and local conferences, including at HIMSS and AAMI.

Juuso currently serves as the co-chair of ACCE Education Committee

Logistics

- All attendees have their microphones muted during the presentation.
- Questions to the panelists must be submitted via the "Q&A" feature in Zoom at any time. They will be addressed at the Q&A portion.
- If there is any urgent issue, please use the "chat" feature to communicate with the host/moderator.
- Please remember to complete the webinar evaluation after attending. A link will be provided at the end.

About the Speaker

Matt Baretich is President of Baretich Engineering, Inc. (Fort Collins CO) and Clinical Engineering Consultant for Lower Mainland Biomedical Engineering (Vancouver BC).

He has been active in medical device-related incident investigation for more than 25 years. He is a Certified Clinical Engineer (CCE), Certified Professional in Patient Safety (CPPS), and a Certified Professional in Healthcare Risk Management (CPHRM).

Matthew F. Baretich, P.Eng., Ph.D.

Baretich Engineering

LOWER MAINLAND
BIOMEDICAL ENGINEERING

Session Description

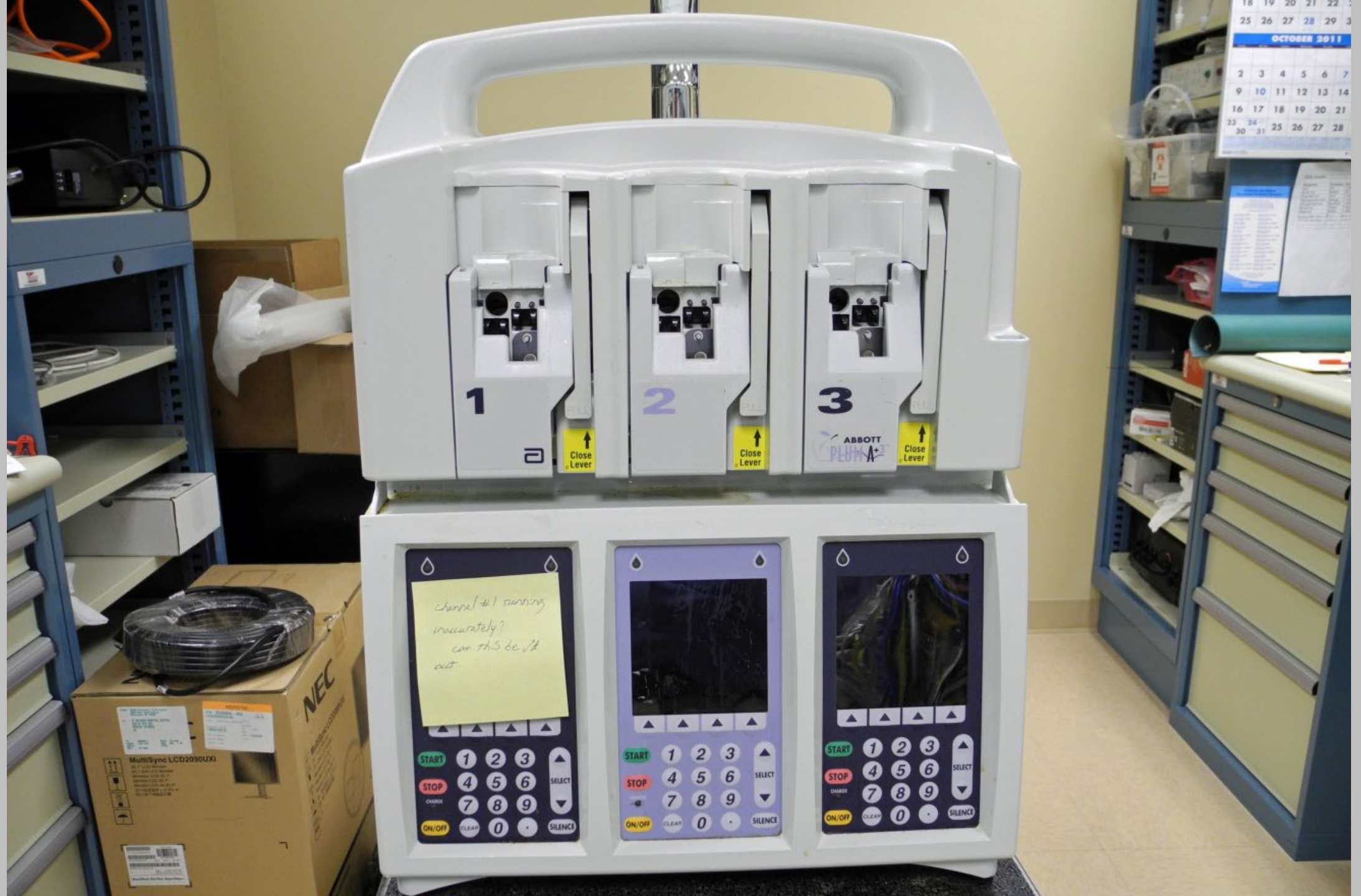
- Medical device-related incidents are inevitable.
- HTM professionals need to understand how to investigate adverse incidents and how participate effectively in the organization's response.
- The objective of incident management is organizational learning for improved patient safety.

Medical Device-Related 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
2. Report internally
3. Sequester the device
4. Preserve patient data
5. Investigate the incident
6. Report externally
7. Avoid recurrences

1. Take care of the patient


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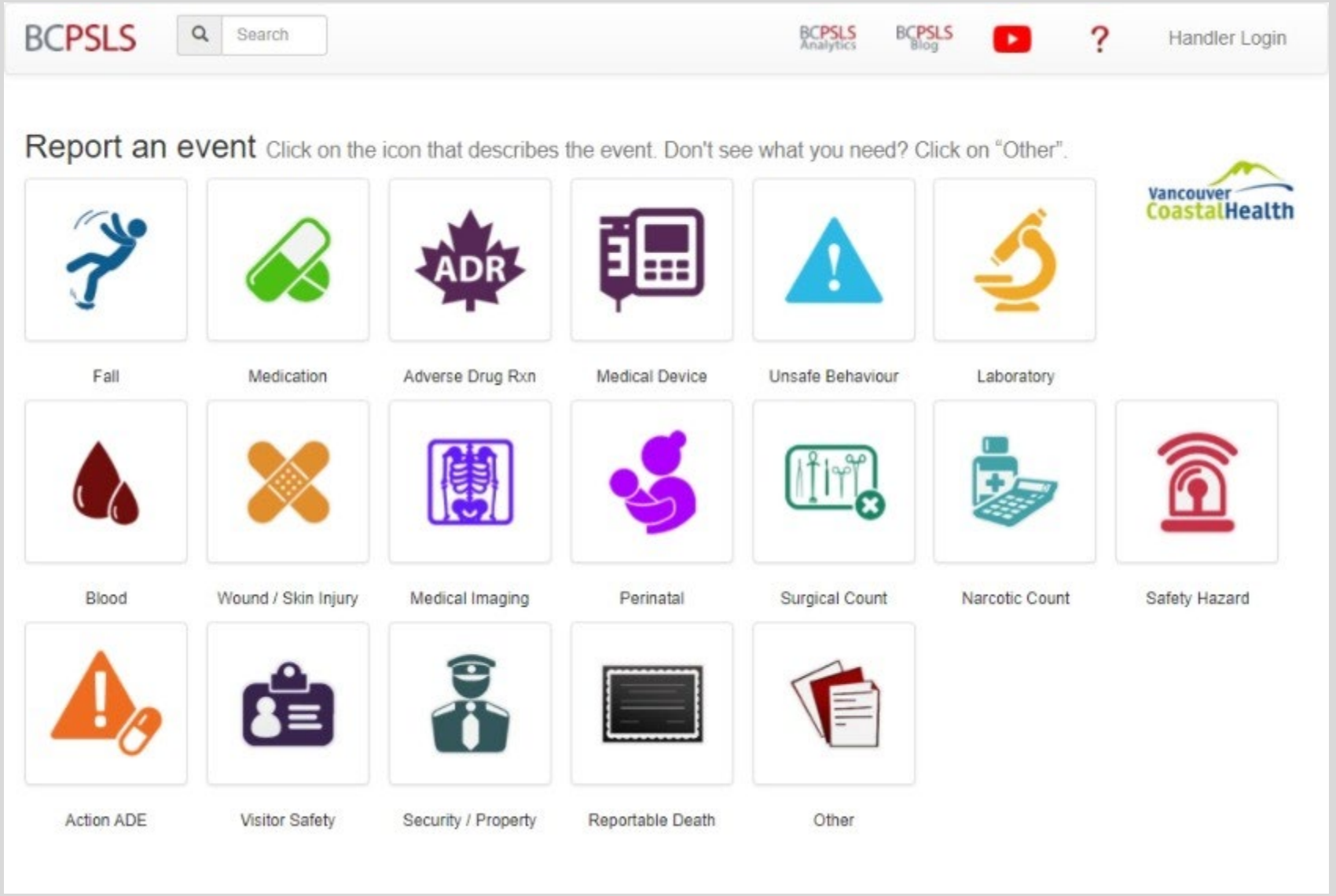
3
Close Lever
Close Lever
Close Lever
ABBOTT
channel #1 running inaccurately? can this be d/t out
START
STOP
ON/OFF
SELECT
SILENCE
NEC
MultiSync LCD2090UXi


3
PULL
PULL
PLUM A+3™
Close Lever


CR19
C17
C87
VR1
DF08
4A02
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

Datix

Provincial Medical Device Incident (MDI) Report Form

Use this form to report a **medical device incident (MDI)**.

The definition of **medical device** is very broad and includes invasive, non-invasive, active and other devices, covering electronic and non-electronic equipment, implants, products, supplies and general items used in all aspects of patient care.

ALL suspected medical device incidents should be reported, regardless of severity. **Serious MDIs** that lead to death or serious deterioration in health of a patient, user, or other person OR could do so if they were to recur must be reported in accordance with the *Protecting Canadians from Unsafe Drugs Act* (Vanessa's Law). After appropriate investigation by your health authority, reports of confirmed MDIs will be submitted by BCPSLS to Health Canada. For more information about Health Canada's Medical Devices Sentinel Network, click here.

If you require assistance, please contact the PSLS Coordinator at your health authority.

BCPSLS

A MDI is an incident related to the failure of a medical device, deterioration in its effectiveness or inadequacy in its labeling or directions that results in, or could result in, harm to a patient.

Should a MDI **ARISE**:
A Assess and protect the patient
R Report to your supervisor as appropriate
I Isolate the device (see below)
S Speak to the appropriate device experts (e.g. Biomedical Engineering) as appropriate
E Enter a PSLS report

Isolate the device to assist with follow-up investigation:
- Leave accessories and any disposable products (e.g. IV sets, bags, wires, pads) AS IS on the device, and save any packaging
- DO NOT turn off the device unless absolutely necessary
- If you move the device, ensure it is plugged into a power supply
- Protect the device from further damage and label it to ensure it is not put back in service
- If your health authority policy allows, supporting photos and videos of the device can be helpful

* Type of MDI	Patient Safety Event

LOCATION

* Health Authority	Vancouver Coastal Health Authority
* Service area	
* Facility	
* Type of location	
* Specific location	
* Was there a second location, organization or program involved?	○ Yes ◉ No

DISCOVERY DATE & TIME

* Date (dd/MM/yyyy)	16/11/2021
* Time period	

MDI DATE & TIME

* Date (dd/MM/yyyy)	16/11/2021
* Do you know the exact time the MDI happened?	○ Yes ○ No

DESCRIPTION

* Describe the medical device incident

Include as much detail as possible to assist with follow-up.

DO NOT INCLUDE NAMES OR OTHER PERSONAL IDENTIFIERS

MEDICAL DEVICE DETAILS
Complete all relevant fields

* Type of device	
* Category of device	
* Name or description of device Provide the name of the device from the product label or a description	

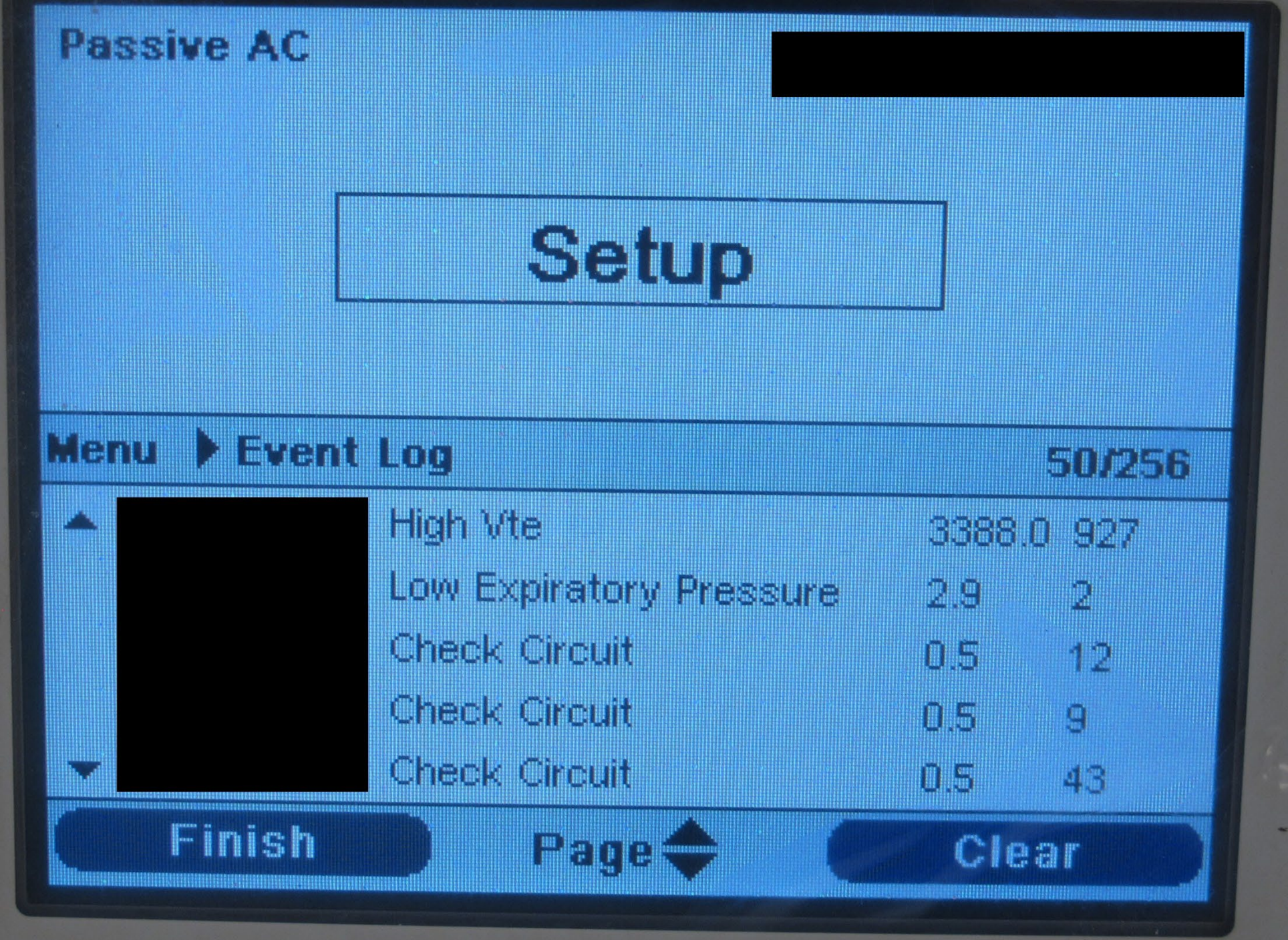
3. Sequester the device

- 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
RR
Vtz
Leak
7.9 cm H2O
14 BPM
2 ml
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▲

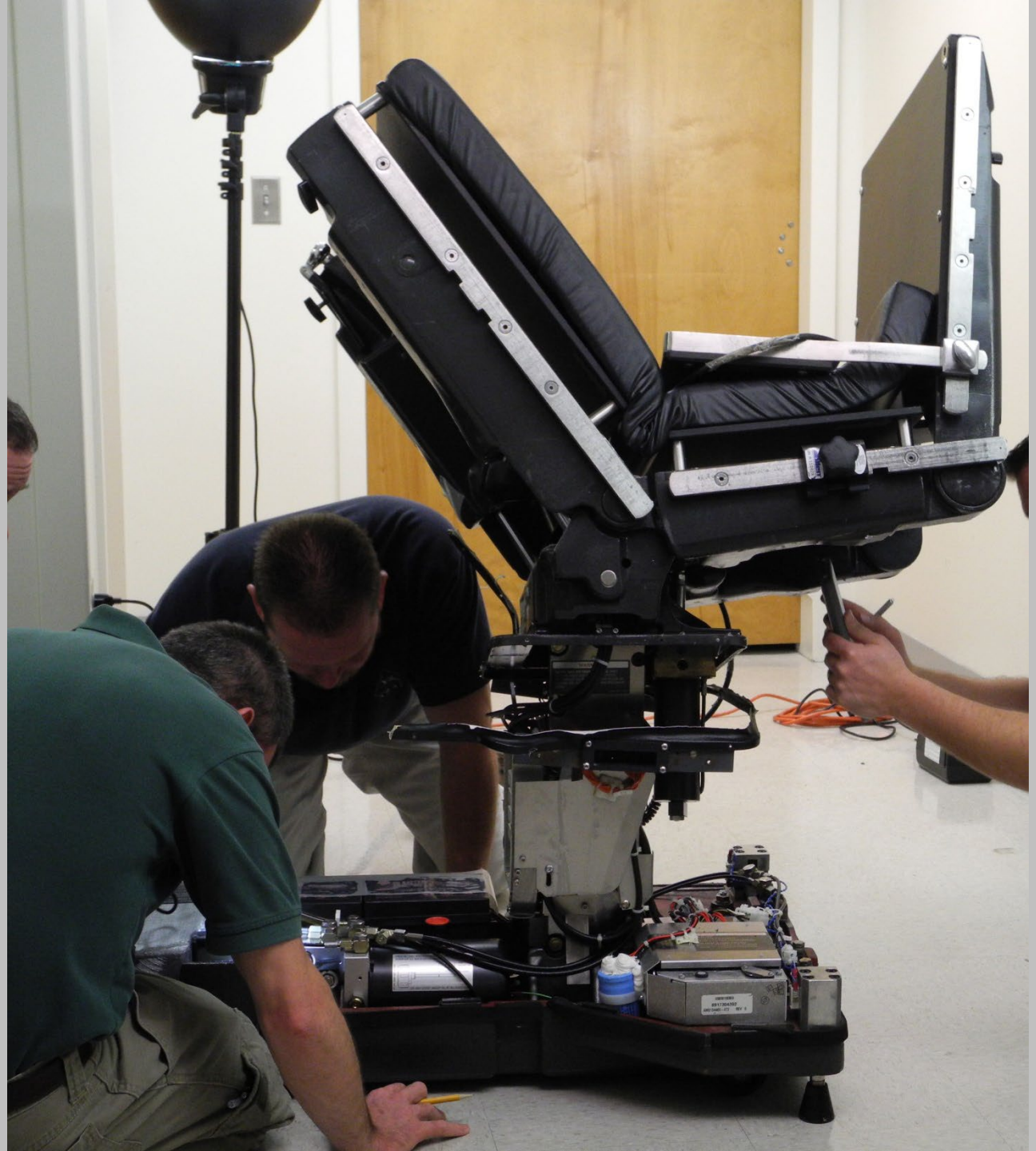

Passive AC
[redacted]
Setup
Menu
Event Log
50/256
[redacted]
High Vte 3388.0 927
Low Expiratory Pressure 2.9 2
Check Circuit 0.5 12
Check Circuit 0.5 9
Check Circuit 0.5 43
Finish
Page
Clear

5. Investigate the incident


STERIS
Amsco 3085 SP


REND.
HEIGHT
SIDE
AUXILIARY


P10



6. Report externally

Health Canada

- Protecting Canadians from Unsafe Drugs Act
- Vanessa’s Law

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.

Learn More Disclaimer

Search Database

Help Download Files

Product Problem

Product Class

Event Type Manufacturer

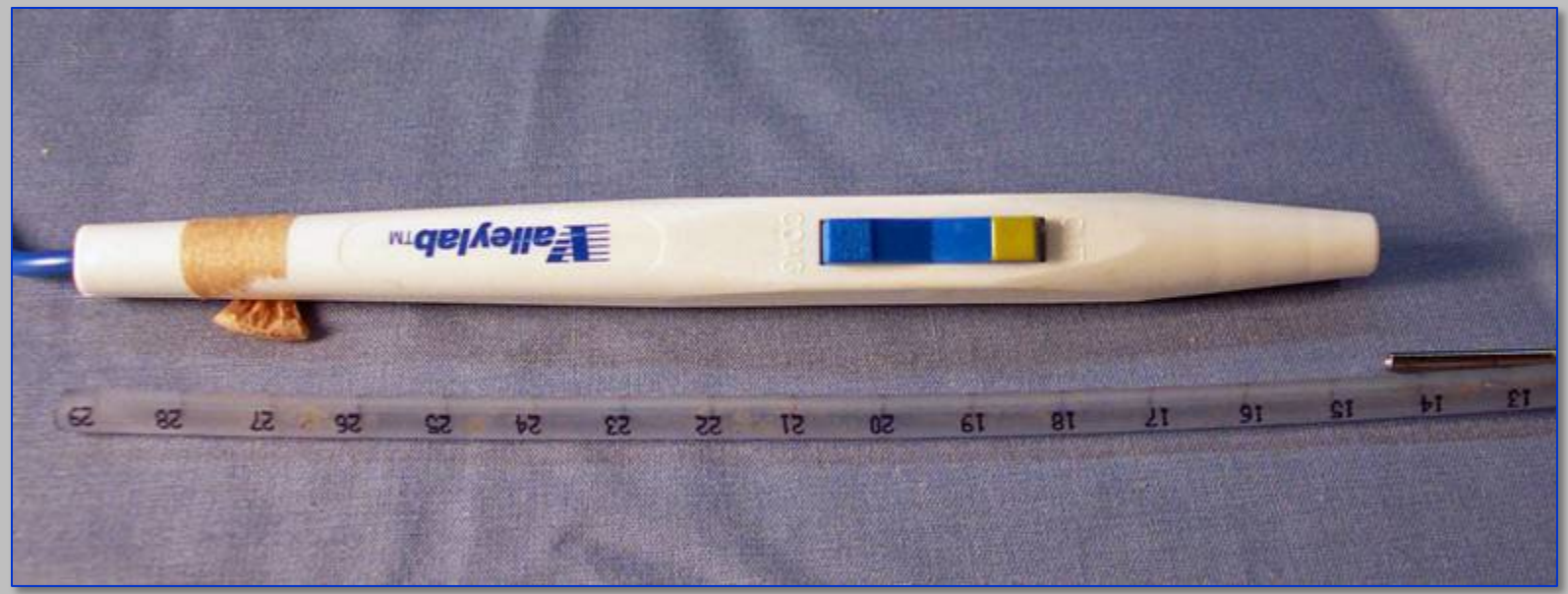
Model Number Report Number

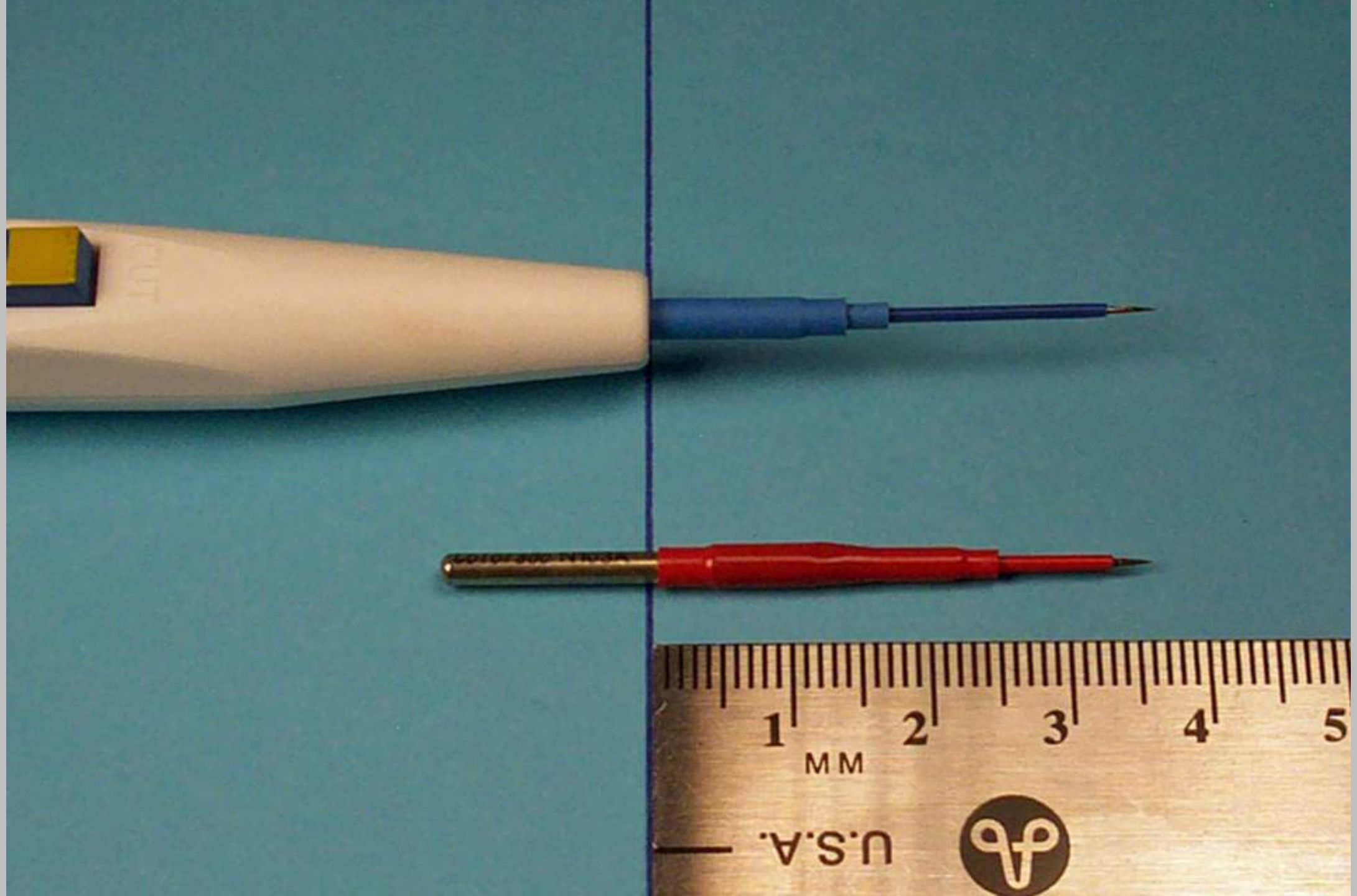
Brand Name Product Code

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


Valleylab
Force 2
Electrosurgical Generator
45
300
WATTS
120
WATTS
MBP POWER
CUT POWER
COAG POWER
FOOTSWITCH
SELECTOR
Valleylab
MICROBIPOLAR
DO NOT USE
Equipment Repair


ValleylabTM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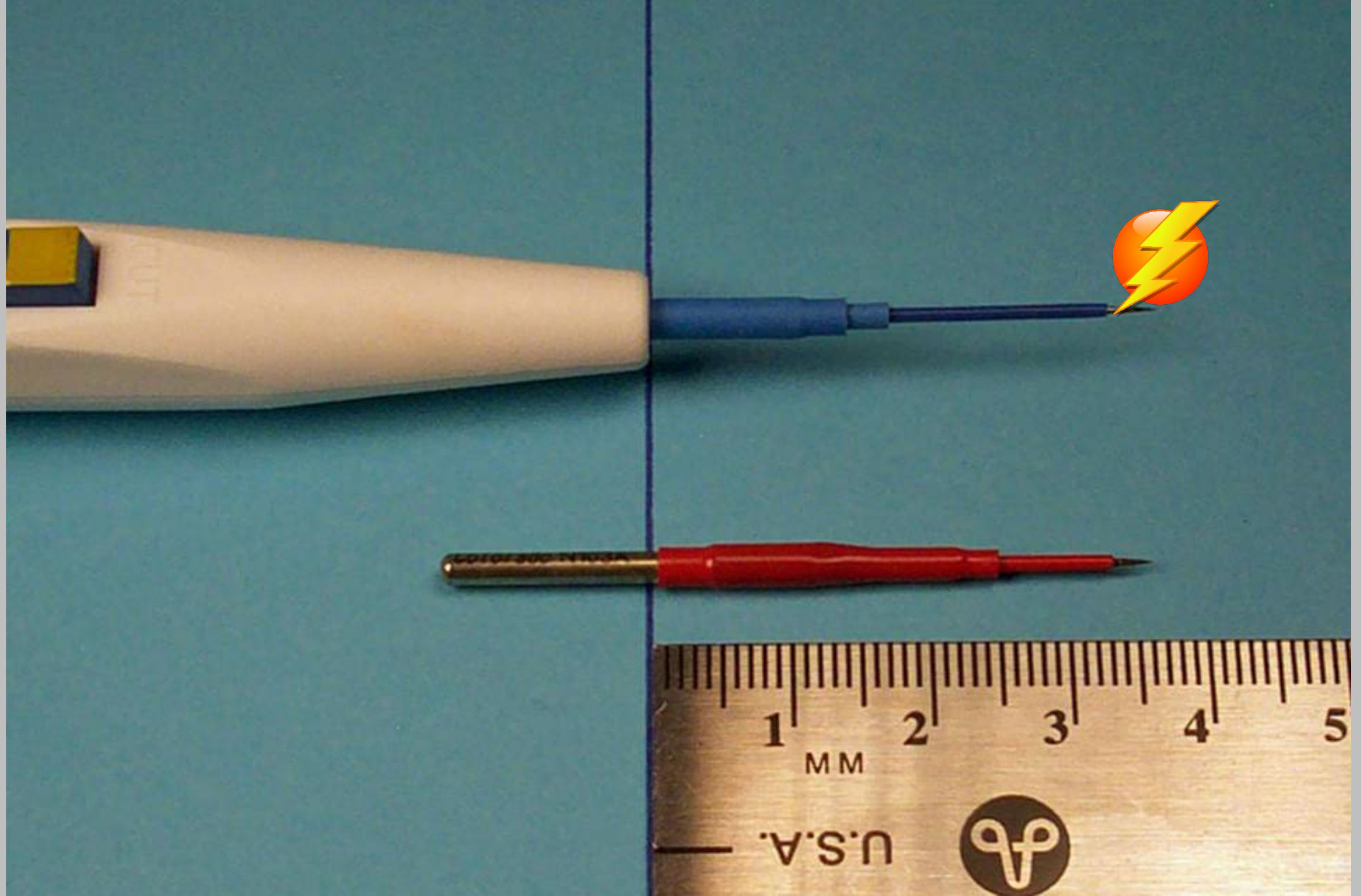
MM
U.S.A.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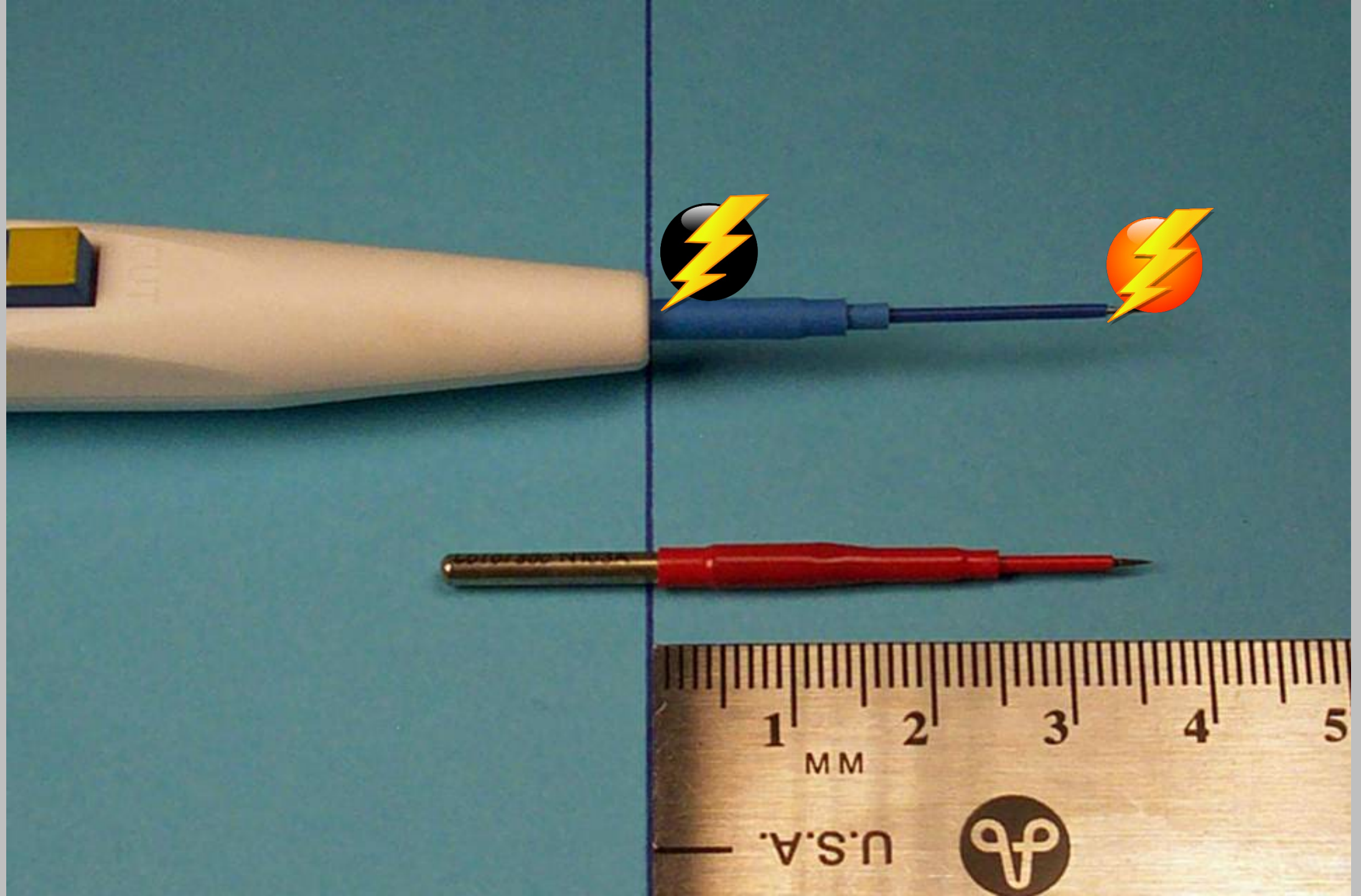
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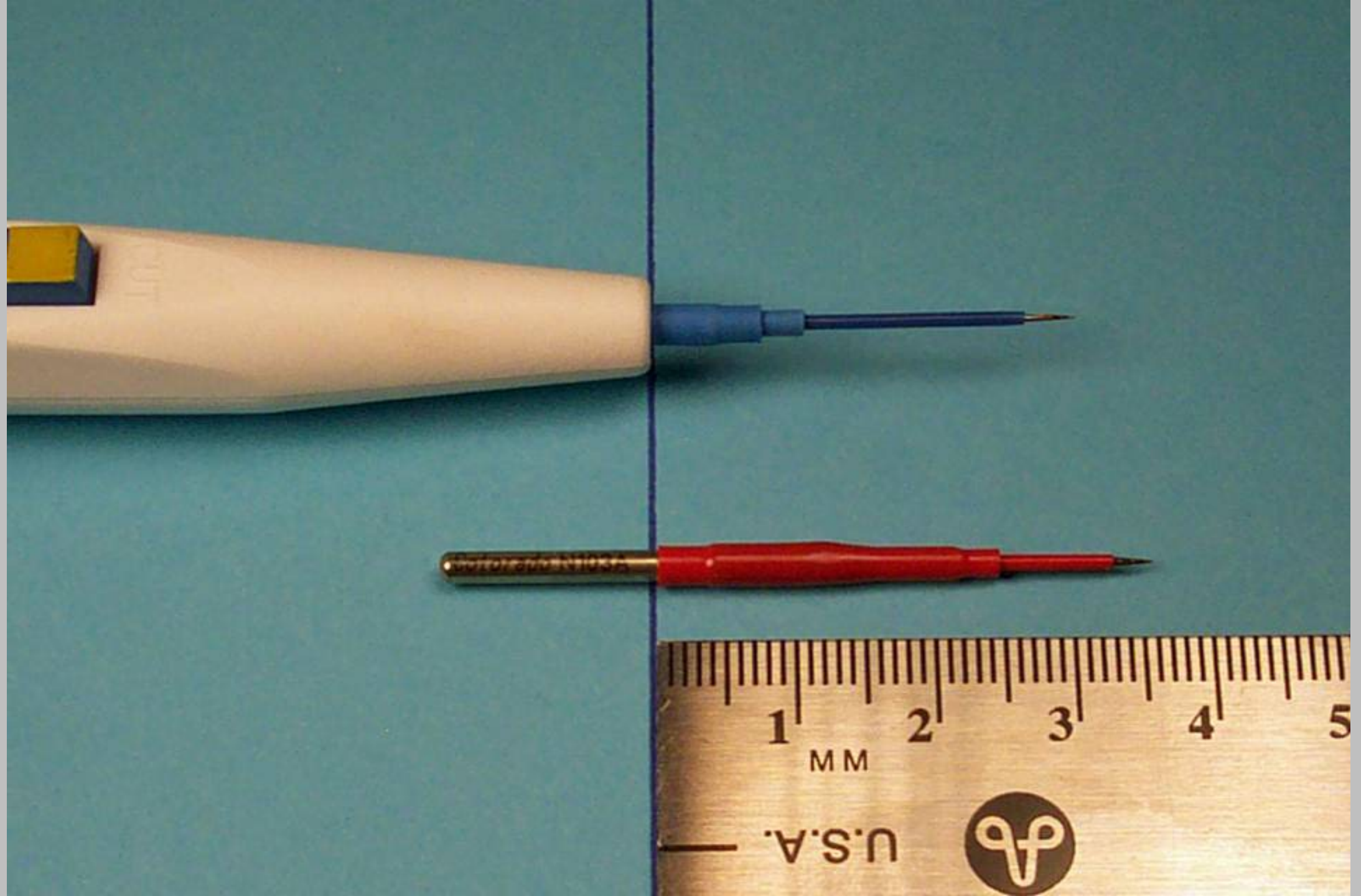
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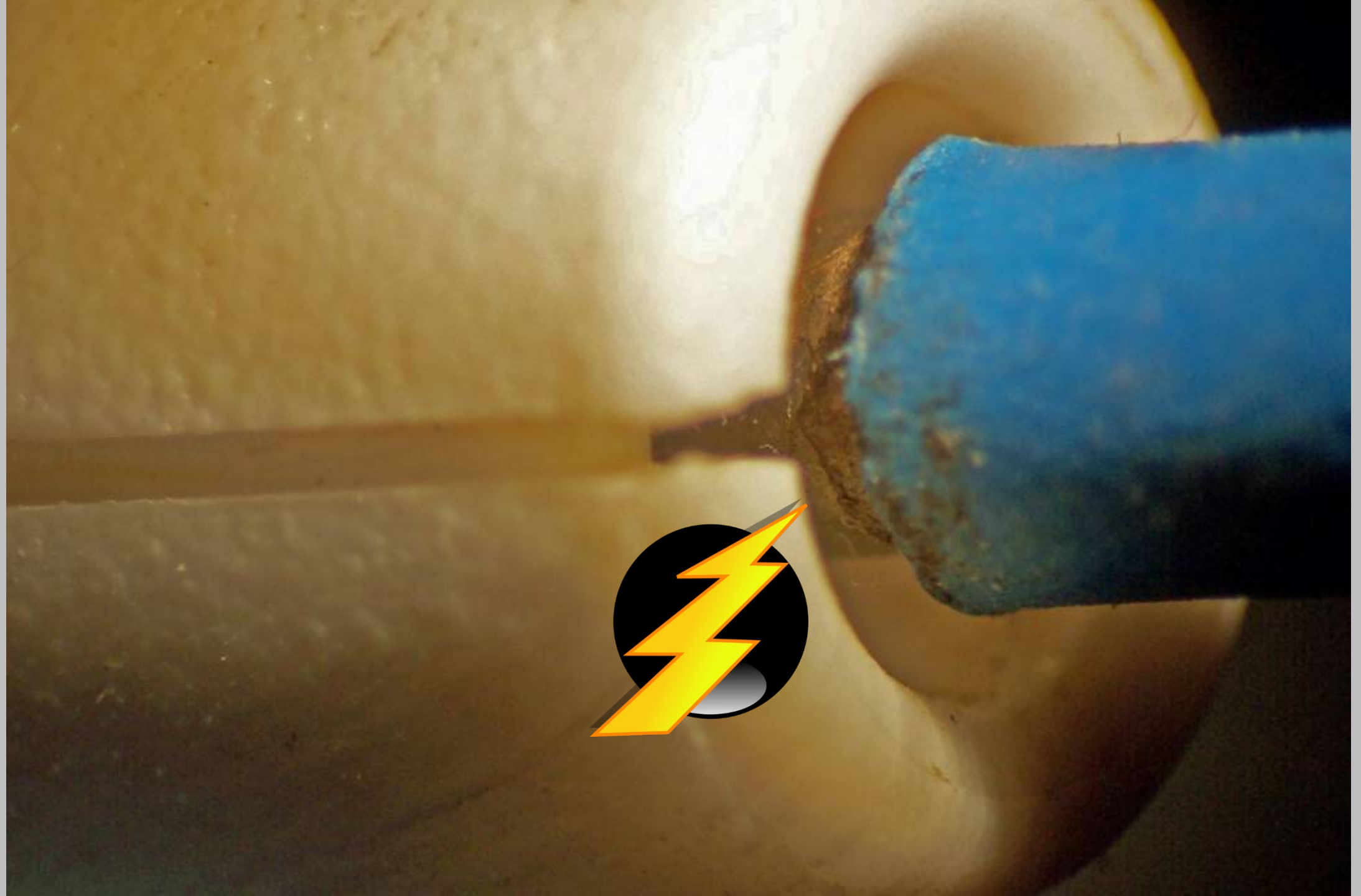
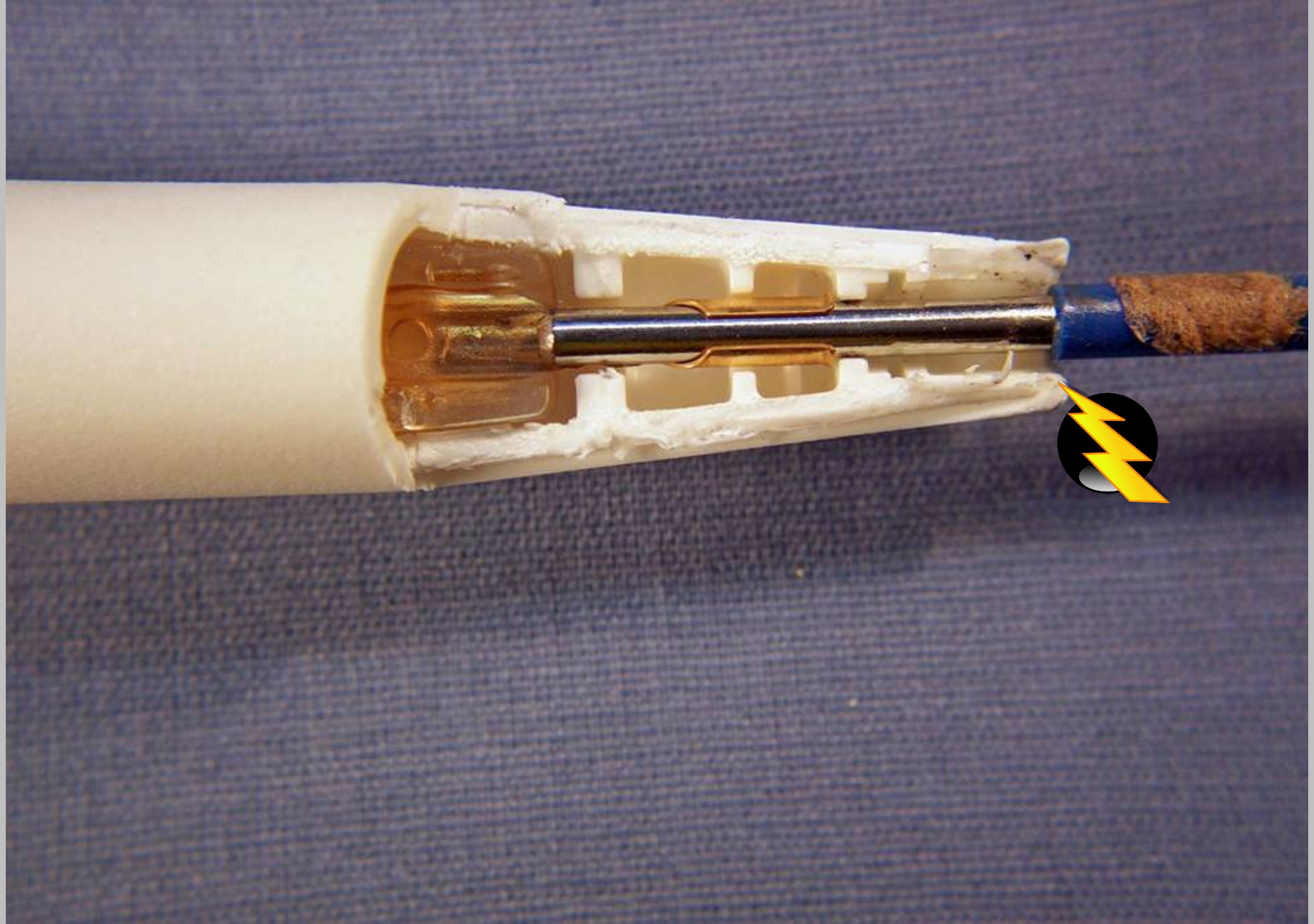
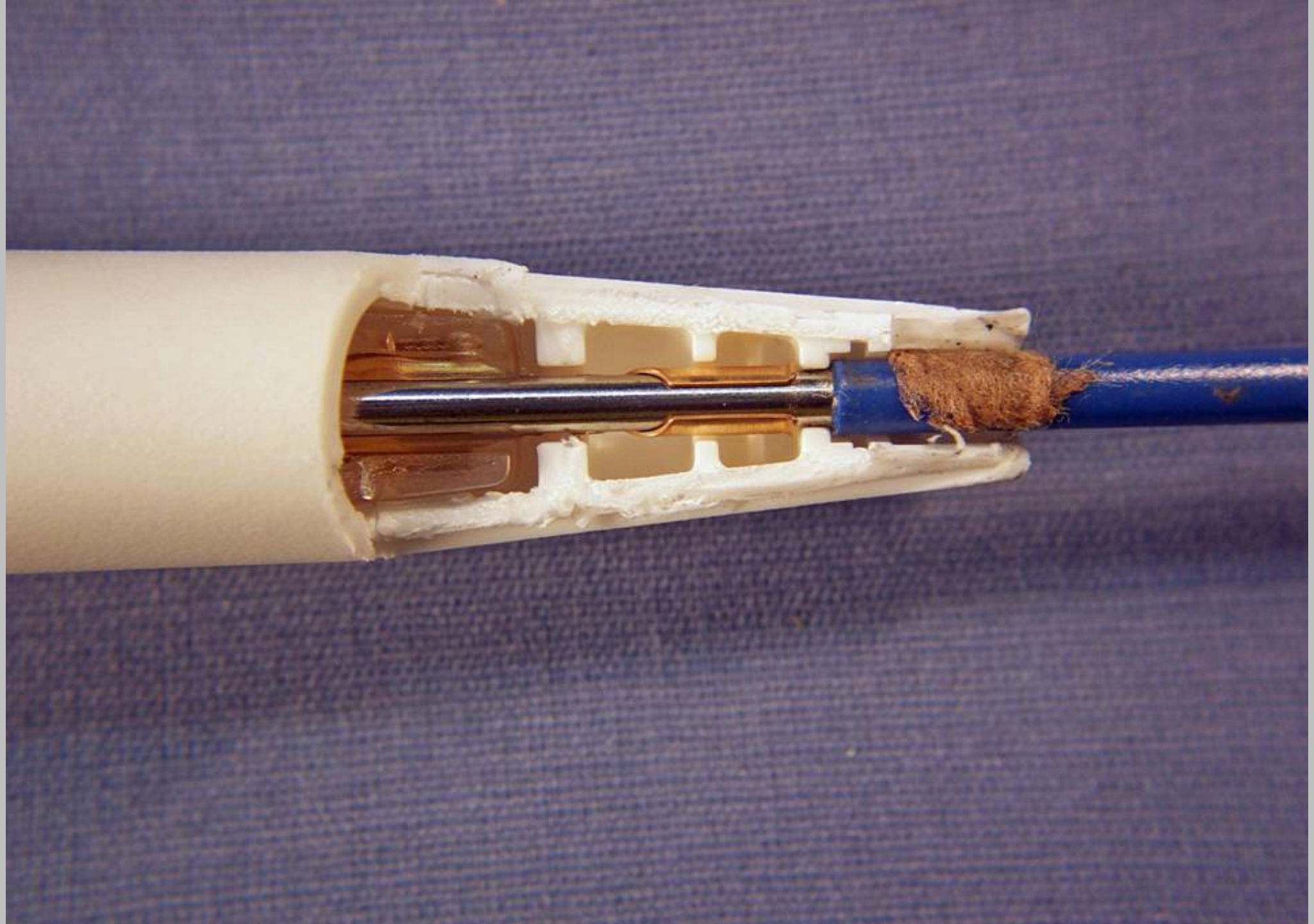
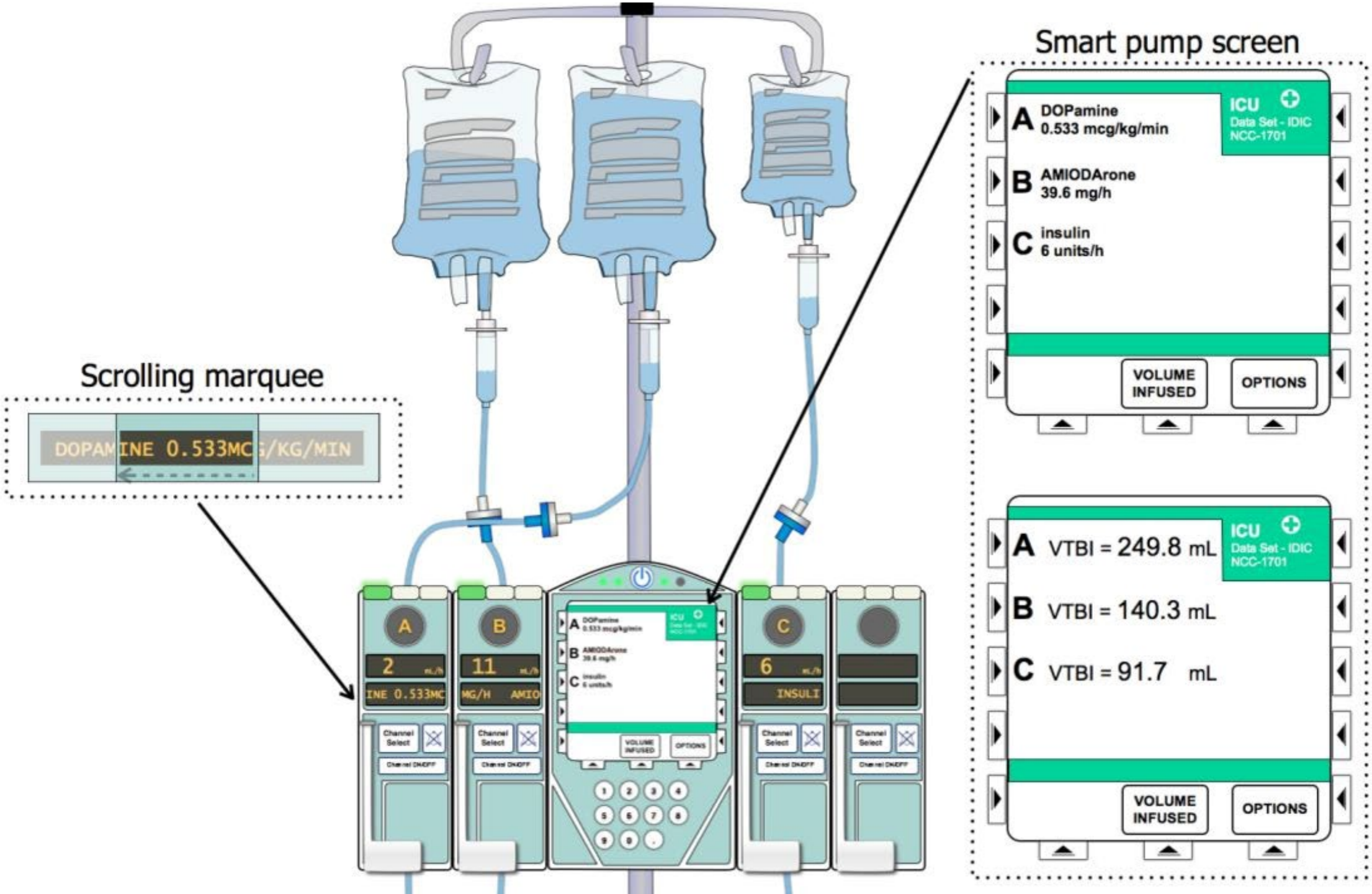
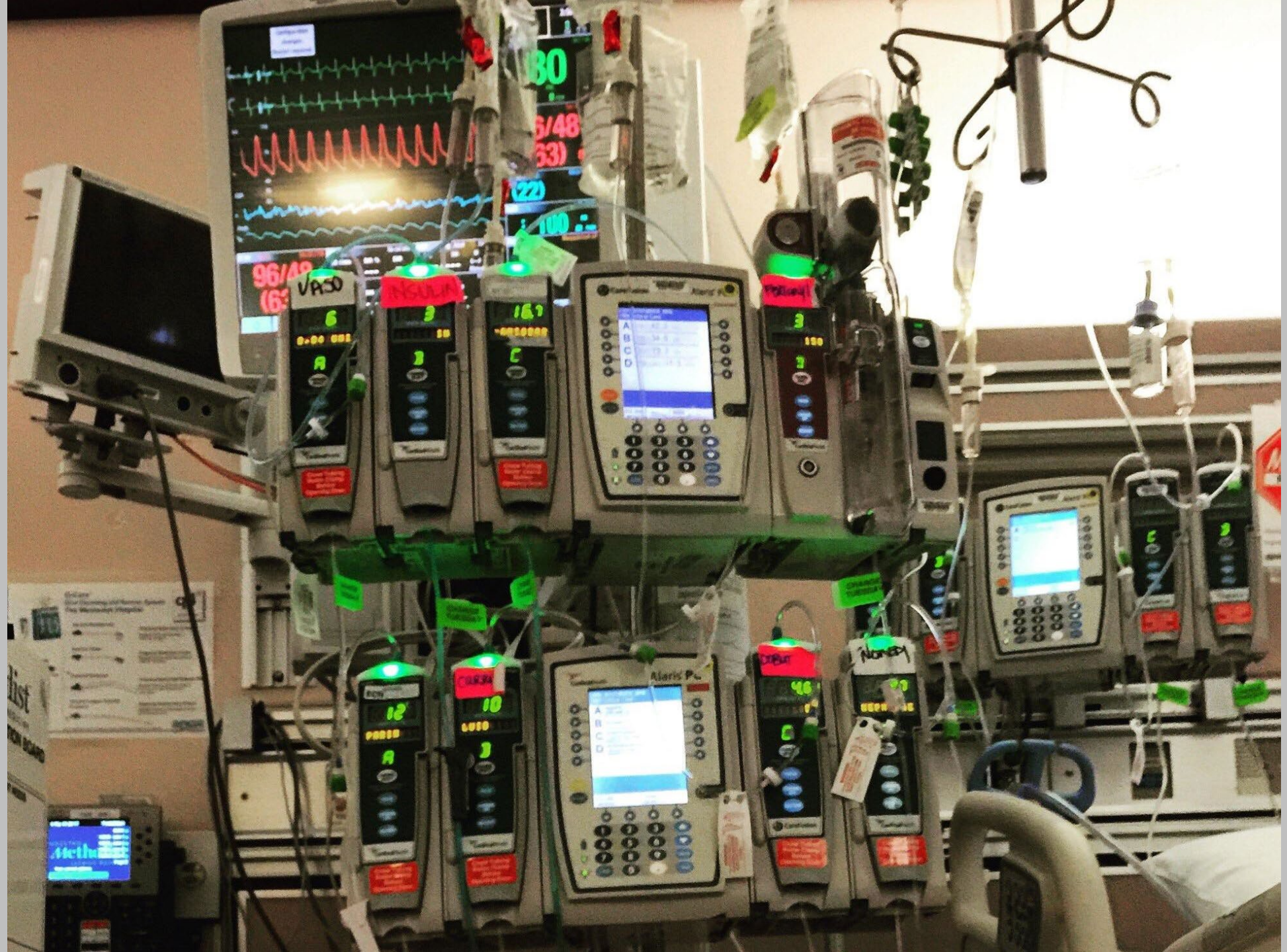


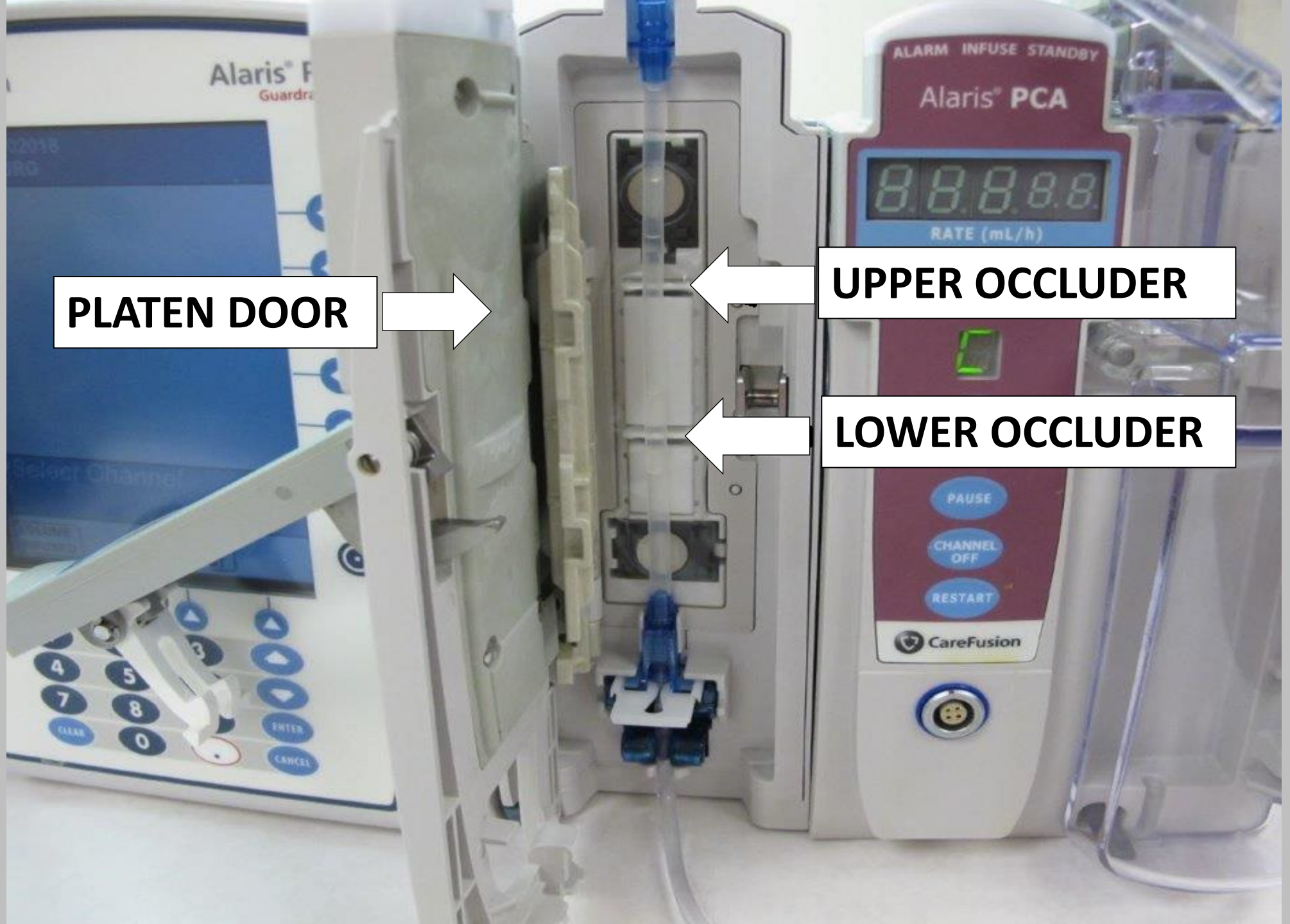


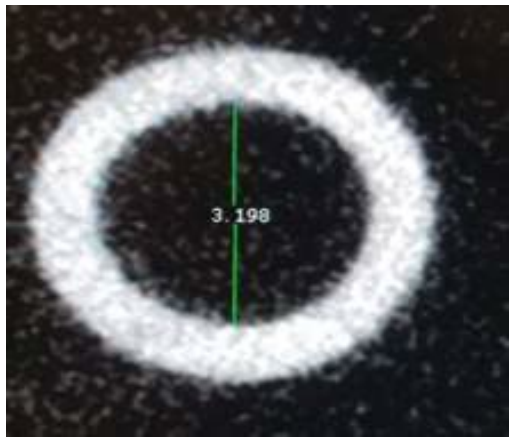


7. Avoid recurrences

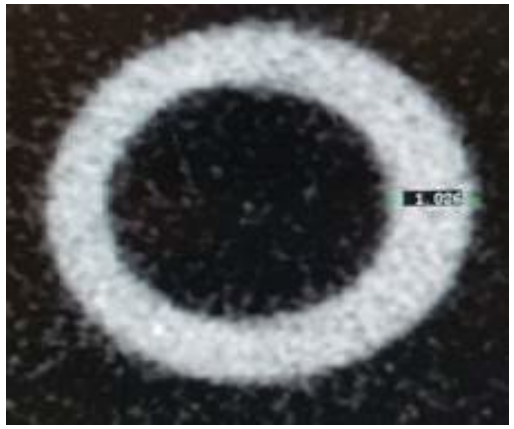

Scrolling marquee
DOPAMINE 0.533MCG/KG/MIN
Smart pump screen
A DOPamine
0.533 mcg/kg/min
ICU
Data Set - IDIC
NCC-1701
B AMIODArone
39.6 mg/h
C insulin
6 units/h
VOLUME INFUSED
OPTIONS
A VTBI = 249.8 mL
B VTBI = 140.3 mL
C VTBI = 91.7 mL


VASO
INSULIN
NOREPI


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

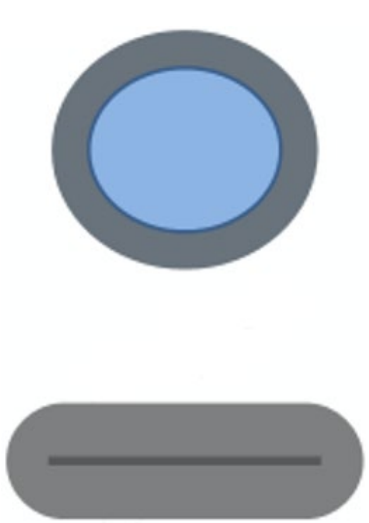


Exemplar Tubing: wall thickness is uniform (Good)

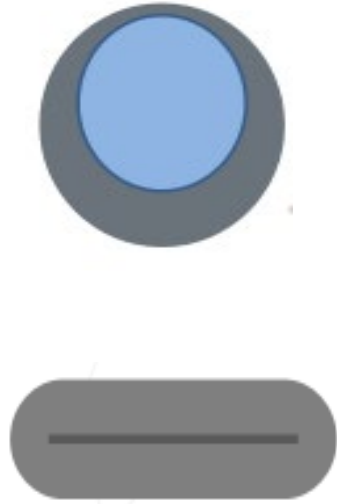


Incident Tubing: wall thickness is non-uniform (Bad)

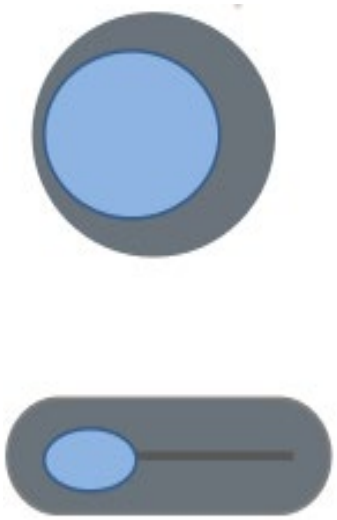
Uniform Wall Thickness



Non-Uniform Wall Thickness, Orientation 1



Non-Uniform Wall Thickness, Orientation 2



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

Questions & Discussions

Enter your questions to the Q&A window

Thank You

Please complete the online evaluation form at

https://www.surveymonkey.com/r/2023-2024_session4

or scan the QR code