GLOBAL CLINICAL ENGINEERING ALLIANCE™

With LIVE translated captions

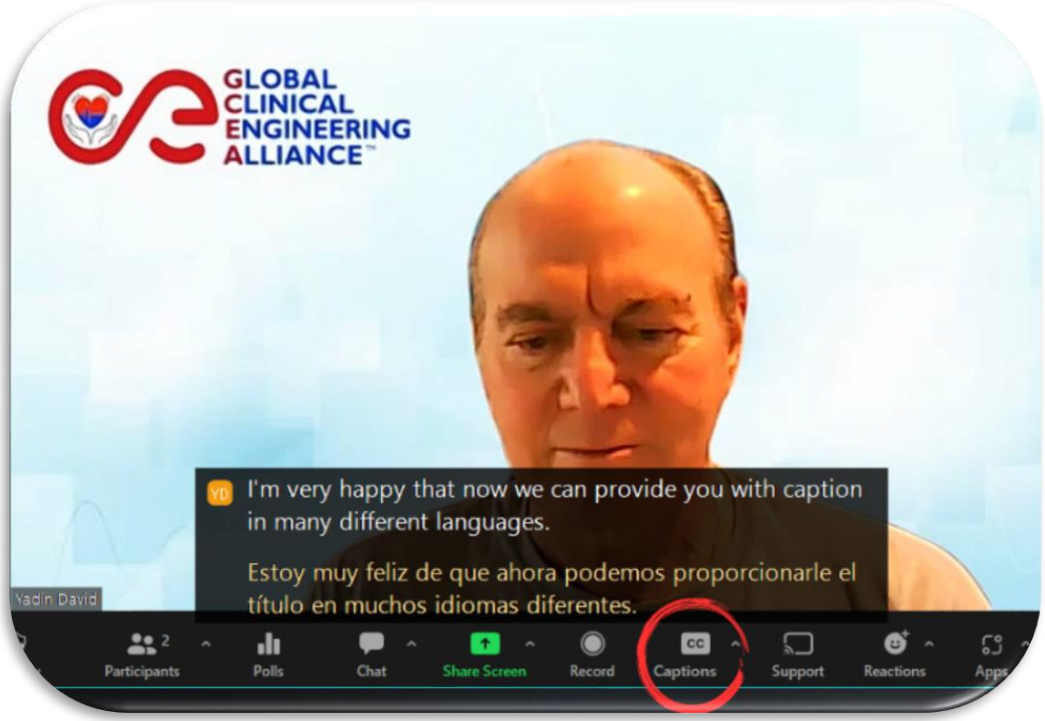
WEBINAR

Risk Management for Medical Technology in Home Healthcare

Wednesday
SEPTEMBER 6 | 2pm UTC | 10am NY

Register for free: https://tinyurl.com/GCEA-HomeMDs

GCEA is excited to announce the addition of a new **live translation** feature that we believe **will bridge the language gap and enhance your video conferencing experience** through Global Clinical Engineering Alliance programs even further. As part of our commitment to delivering innovative and educational video communications training, we have incorporated a new captioning option that facilitates the ability of our members to elevate their understanding of the spoken content during GCEA education and meeting events, by simultaneously customizing captions in their preferred language.



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English, Arabic (Beta), Chinese (Traditional) (Beta), Chinese (Simplified) (Beta), Czech (Beta), Dutch, Estonian (Beta), Finnish (Beta), French (France), Hebrew (Beta), Hindi (Beta), Hungarian (Beta), German, Italian, Japanese (Beta), Korean (Beta), Polish (Beta), Portuguese, Spanish, Romanian (Beta), Russian, Turkish, Ukrainian and Vietnamese.

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Risk Management for Medical Technology in Home Healthcare

Matt Baretich, Bill Gentles, Jani Mueller

September 6, 2023

Presentation outline

- Introduction and overview.
- Matt Baretich: Examples of risks related to home use of medical technology.
- Bill Gentles: Challenges to HTM for home healthcare devices.
- Jani Mueller: Patient advocacy for home use of medical technology.
- Questions, comments, discussion.

Philips CPAP Machines

Certain Philips Respironics Ventilators, BiPAP, and CPAP Machines Recalled Due to Potential Health Risks: FDA Safety Communication

November 12, 2021 Update: Certain Philips Respironics Ventilators, BiPAP, and CPAP Machines Recalled Due to Potential Health Risks: FDA Safety Communication

Date Issued: June 30, 2021

The U.S. Food and Drug Administration (FDA) is alerting people who use Philips Respironics ventilators, BiPAP, and CPAP machines and their health care providers that Philips Respironics has recalled certain devices (see table below) due to potential health risks. The polyester-based polyurethane (PE-PUR) sound abatement foam, which is used to reduce sound and vibration in these affected devices, may break down and potentially enter the device's air pathway. If this occurs, black debris from the foam or certain chemicals released into the device's air pathway may be inhaled or swallowed by the person using the device.

If you use one of these affected devices (see table below), talk to your health care provider to decide on a suitable treatment for your condition and follow the recommendations listed below

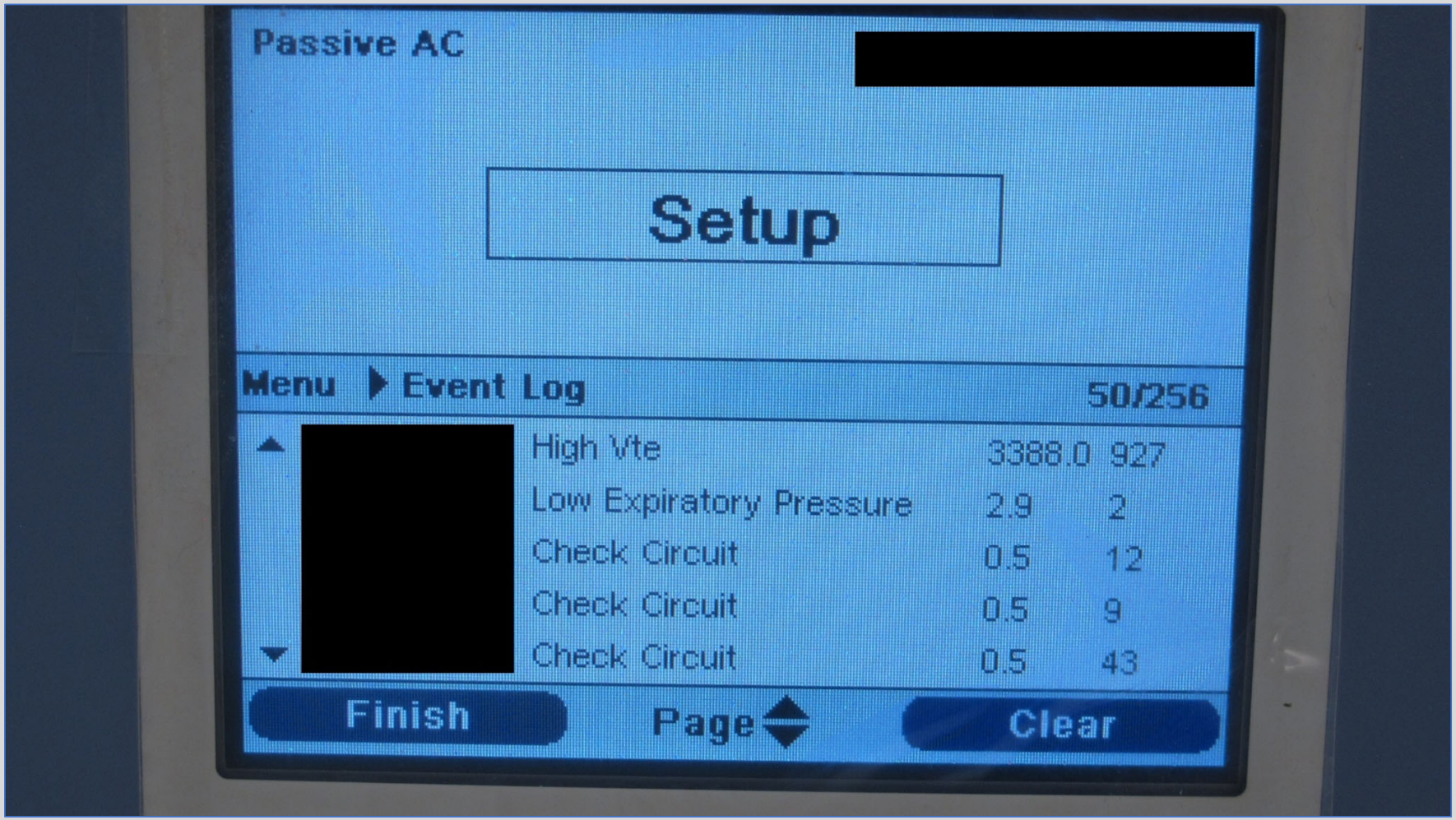
FDA Orders Philips Respironics to Notify Patients Regarding the Recall of Certain Breathing Assistance Machines

For Immediate Release: March 10, 2022

Today, the U.S. Food and Drug Administration issued a notification order to Philips Respironics requiring the company to notify patients and others of the company's June 14, 2021, recall of certain Philips Respironics ventilators, continuous positive airway pressure (CPAP) and bilevel positive airway pressure (BiPAP) machines, and the unreasonable risk of substantial harm to the public health posed by the degradation of the polyester-based polyurethane (PE-PUR) sound abatement foam used in those products. The FDA has determined that this order is necessary to eliminate the unreasonable risk of harm posed by the recalled products, because the company's notification efforts to date have been inadequate.

"The FDA has heard the frustration expressed by patients and durable medical equipment suppliers who are unaware of the recall and have received insufficient information on their next steps regarding the recall process," said Jeff Shuren, M.D., J.D., director of the FDA's Center for Devices and Radiological Health. "Taking this action today enables the FDA to mandate

Home Care for Ventilator-Dependent Patients


Passive AC
[redacted]
Setup
Menu
Event Log
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[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

	D	E
1	Event Log	
2	Time	Text A
296	02:40a	Check Circuit
297	02:39a	Check Circuit
298	02:37a	Check Circuit
299	02:35a	Audio Pause Pressed
300	02:34a	Check Circuit
301	02:34a	Audio Pause Pressed
302	02:33a	Modify Pressed
303	02:33a	Check Circuit
304	02:32a	Check Circuit
305	02:32a	High Insp Pressure
306	02:32a	Audio Pause Pressed
307	02:31a	Check Circuit
308	02:30a	High Insp Pressure
309	02:29a	Check Circuit
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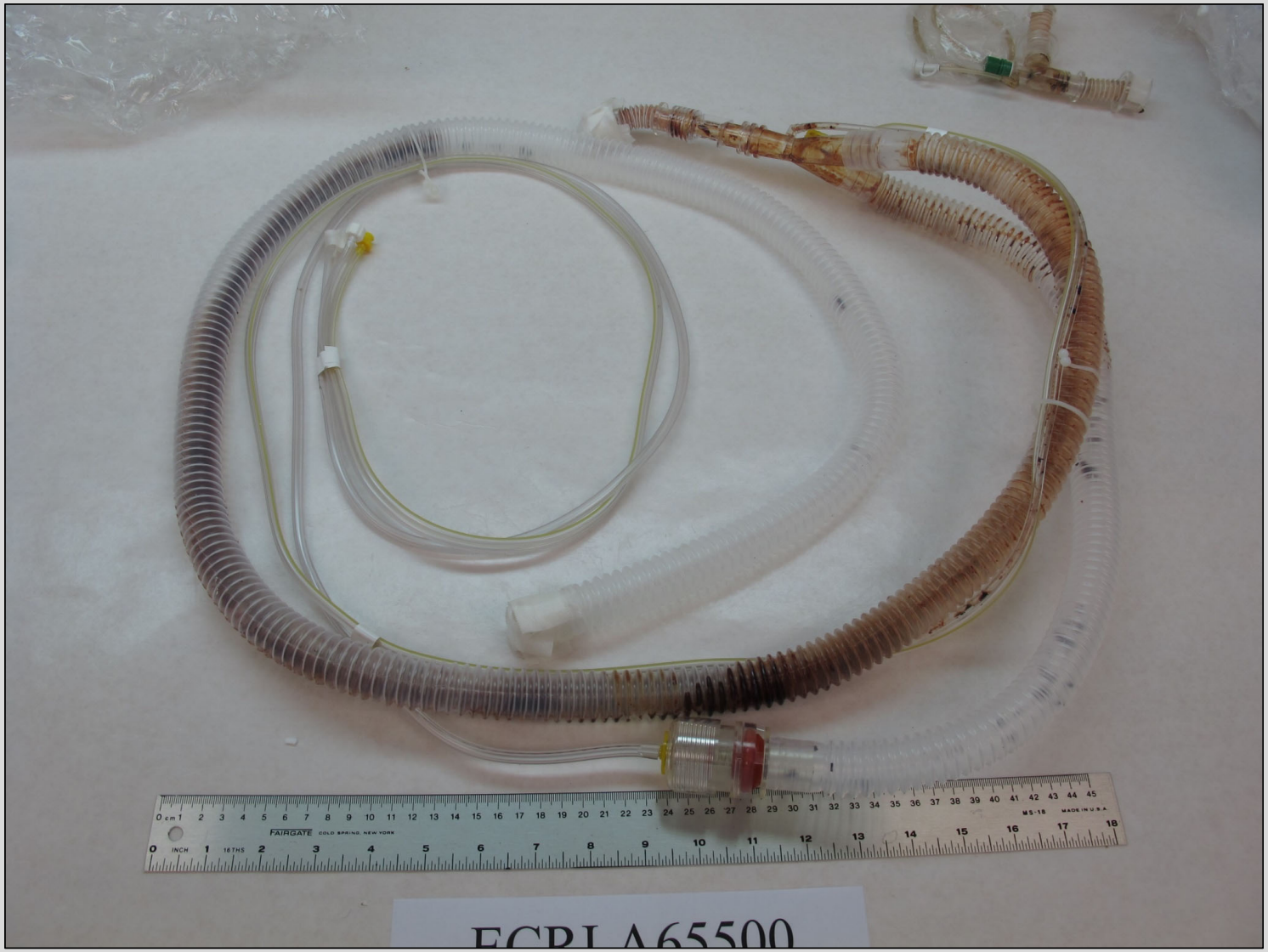
311	02:29a	High Insp Pressure
312	02:28a	High Insp Pressure
313	02:28a	High Insp Pressure



ECRI A65500

Medtronic MiniMed Insulin Pumps

Medtronic Recalls MiniMed Insulin Pumps for Incorrect Insulin Dosing

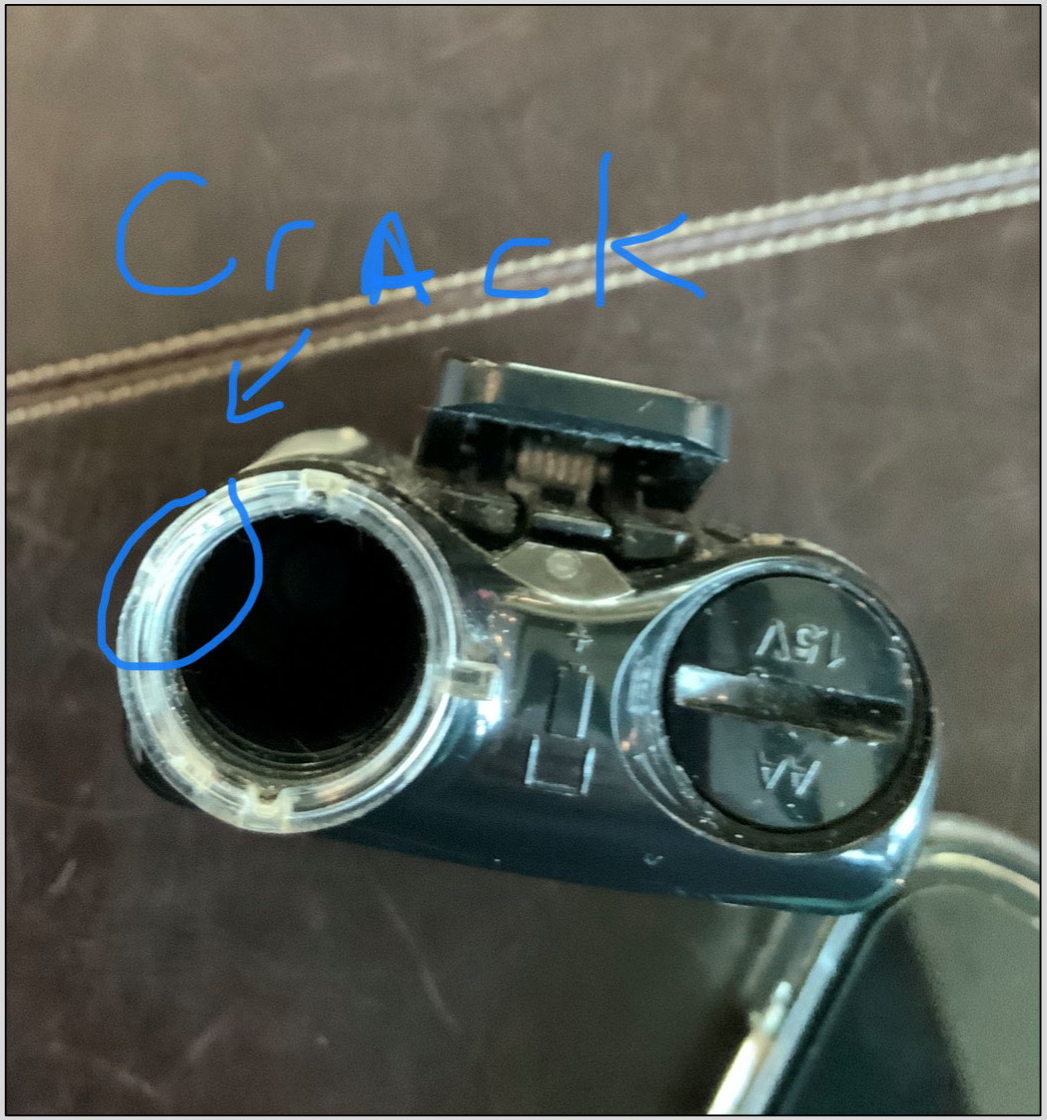
October 5, 2021 UPDATE: Medtronic updated this recall with information that Medtronic will replace any MiniMed™ 600 series insulin pump that has a clear retainer ring with one that has the updated black retainer ring at no charge. A replacement insulin pump will be provided even if the clear retainer ring is not damaged and regardless of the warranty status of the pump. If you have questions about this recall, call Medtronic's 24-Hour Technical Support line: 1-877-585-0166.

The FDA has identified this as a Class I recall, the most serious type of recall. Use of these devices may cause serious injuries or death.

Recalled Product

- MiniMed™ 600 Series Insulin Pumps
- Lot codes: Refer to the Medical Device Recalls database entry for each product.
- Distribution Dates:
  - Model 630G - September 2016 to February 2020
  - Model 670G - May 2015 to December 2020
- Devices Recalled in the U.S.: 463,464
- Date Initiated by Firm: November 21, 2019

CLEAR RETAINER RING PUMP (SUBJECT OF RECALL)	BLACK RETAINER RING PUMP (NOT AFFECTED BY RECALL)
 **Image:** Location of the retainer ring on the MiniMed™ 600 series insulin pump The images show a **normal** pump retainer ring vs a **damaged or missing** pump retainer ring.  **NORMAL** pump retainer ring  **DAMAGED** pump retainer ring  **MISSING** pump retainer ring	 Normal pump with black retainer ring


Crack

Top 10 Health Technology Hazards for 2023

Gaps in Recalls for At-Home Medical Devices Cause Patient Confusion and Harm

1

Challenges for Health Technology Management of Home Health Care Devices

Bill Gentles

HTM best practices in hospitals

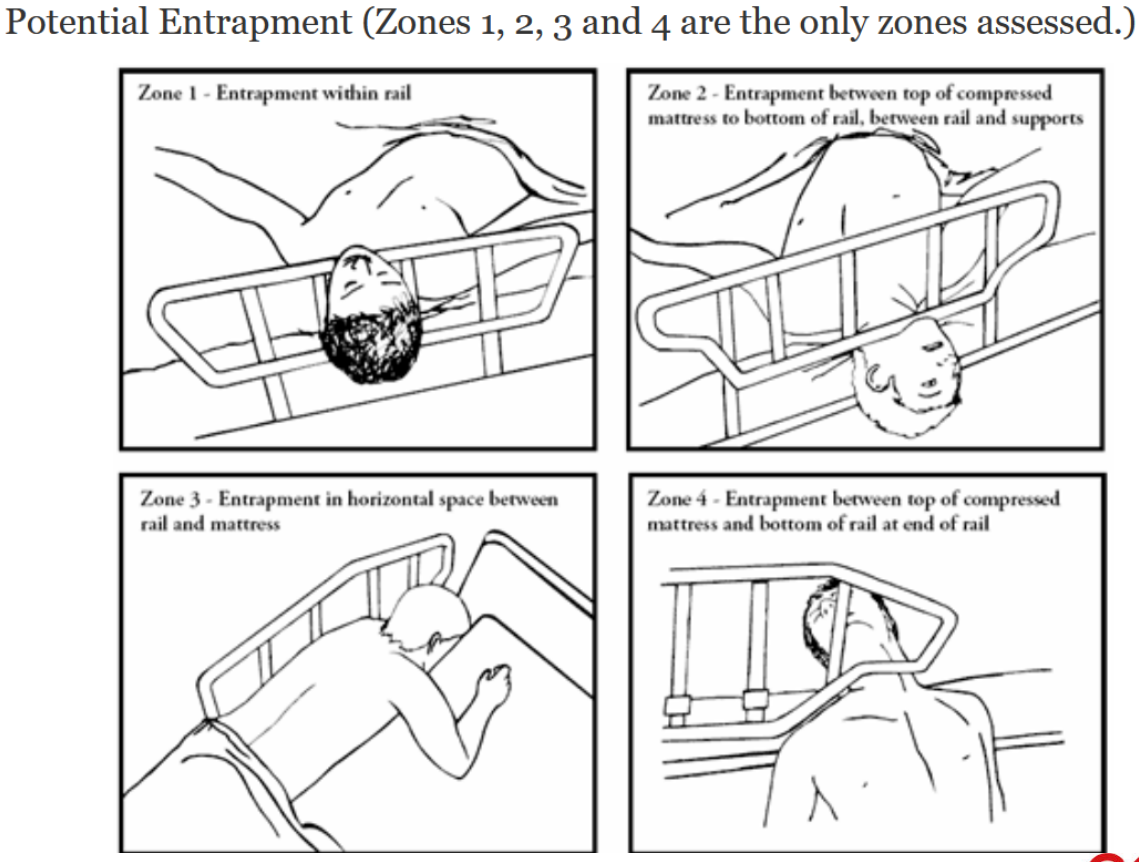
- Incoming Safety inspections of all devices
- Scheduled maintenance programs (sometimes called PPM)
- Unscheduled maintenance programs (repairs)
- Documentation of all service interventions on all devices in a CMMS
- Hazard alerts and recall management
- Incident investigation and reporting

Who is the owner of the medical device used at home?

- Medical devices may be provided to home health care clients from numerous sources
  - Retail stores (e.g. Shoppers Home Healthcare)
  - Online suppliers (e.g. Amazon)
  - Hospitals
  - Equipment rental companies
  - Companies that buy and sell used medical devices

Medical devices currently in use in home health care

- Hospital beds



Medical devices currently in use in home health care

- Hospital beds
- Accessories improperly installed causing entrapment

Medical devices currently in use in home health care

- Hospital beds
- Accessories improperly installed causing entrapment

Medical devices currently in use in home health care

- Hospital beds
- Patient lifts
- Wheelchairs
- Blood pressure monitors
- Blood glucose monitors
- Oxygen concentrators
- Home ventilators
- CPAP/BiPAP machines
- Pulse oximeters
- Insulin pumps
- Chemotherapy infusion pumps
- Haemodialysis machines
- Peritoneal dialysis machines

- This list is constantly growing

Standards that apply to the hospital environment

CSA Group Standards for Health Care Facilities	
CSA Z8000-18	Canadian health care facilities
CAN/CSA-Z8001-13 (R2018)	Commissioning of health care facilities
CSA Z8002:19	Operation and maintenance of health care facilities
CSA Z8003:21	Health care facility design research and evaluation
CSA Z8005	Special requirements for digital infrastructure in health care facilities (in development)
CSA Z317.1:21	Special requirements for plumbing installations in health care facilities
CSA Z317.2:19	Special requirements for HVAC systems in health care facilities
CSA Z317.5-17	Illumination design in health care facilities
CSA Z317.10:21	Handling of health care waste materials
CSA Z317.11-17	Area measurement for health care facilities
CSA Z317.12:20	Cleaning and disinfection of health care facilities
CSA Z317.13:22	Infection control during construction, renovation, and maintenance of health care facilities

Standards that apply to the hospital environment - continued

CSA Z317.14-17	Wayfinding for health care facilities
CSA Z10535.1:15 (R2021)	Hoists for the transfer of disabled persons – Requirements and test methods
CSA Z10535.2-17	Lifts for the transfer of persons – Installation, use, and maintenance
CSA PLUS 317	Guidelines for elementary assessments of building systems in health care projects
CSA Z32:21	Electrical safety and essential electrical systems in health care facilities
CSA Z7396.1-17	Medical gas pipeline systems – Part 1: pipelines for medical gases, medical vacuum, medical support gases, and anaesthetic gas scavenging systems
CAN/CSA-Z7396.2-02 (R2007)	Medical Gas Pipeline Systems – Part 2: Anaesthetic gas scavenging disposal systems

Standards that apply to the home health care environment

- National Building Code of Canada 2020

First Edition 1941
Second Edition 1953
Third Edition 1960
Fourth Edition 1965
Fifth Edition 1970
Sixth Edition 1975
Seventh Edition 1977
Eighth Edition 1980
Ninth Edition 1985
Tenth Edition 1990
Eleventh Edition 1995
Twelfth Edition 2005
Thirteenth Edition 2010
Fourteenth Edition 2015
Fifteenth Edition 2020

Standards that apply to the home health care environment

- Medical Electrical Equipment – Part 1-11: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Requirements for Medical Electrical Equipment and Medical Electrical Systems Used in the Home Healthcare Environment, CSA C22.2 No. 60601-1-11:15 (R2020), Canadian Standards Association
- Safe Installation and Operation of Hemodialysis and Peritoneal Dialysis in a Home Setting, CSA Z364.5-17, Canadian Standards Association
- National Healthy Housing Standard, National Center for Healthy Housing, American Public Health Association, Columbia, MD, USA, 2018. [Online]. Available: https://nchh.org/resource-library/national-healthy-housing-standard.pdf

Hazards in the home health care environment

- Buildings in disrepair, with rotting steps or crumbling ceilings;
- Faulty electrical wiring and circuit breakers or fuses and otherwise unsafe electrical systems;
- Lack of emergency sensors and alerts (e.g., smoke and carbon monoxide detectors and alarms);
- Lack of adequate heat, air conditioning, humidity, and ventilation;
- Lack of appropriate plumbing, running water, and a safe water supply;
- Lack of safe sanitation/waste disposal;
- Trip hazards in living, cooking, sleeping, entranceways or doorways, and common areas;
- Pets that may interfere with the operation of critical devices (e.g., pets may chew the device);
- Exposure to the outside elements from lack of repairs to the roof or exterior of the building; and
- Presence of pests, pollen, mould, chemicals, and other contaminants.

Risk management

- Quiz
- Is there an accepted procedure for reporting hazardous incidents or disseminating incident reports related to home health care devices?

Risk management

- Is there an accepted procedure for reporting hazardous incidents or disseminating incident reports related to home health care devices?
- Answer - NO

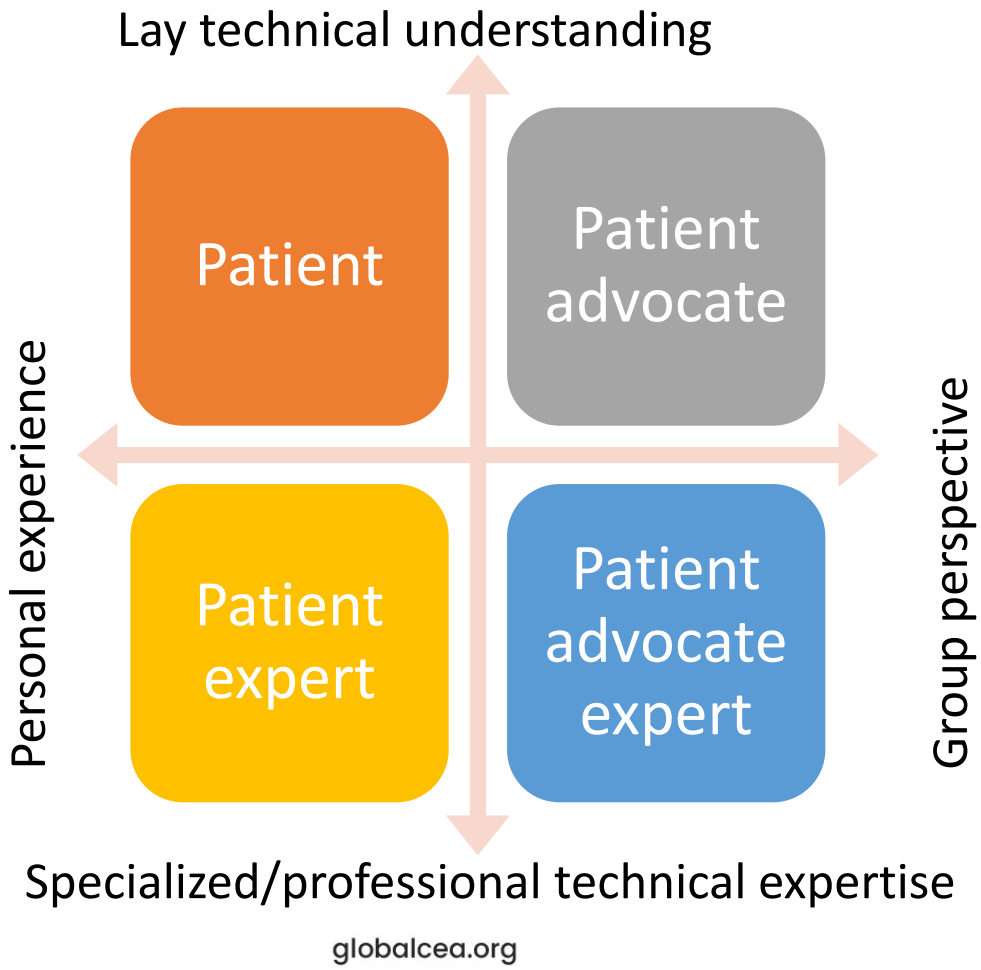
Conclusion

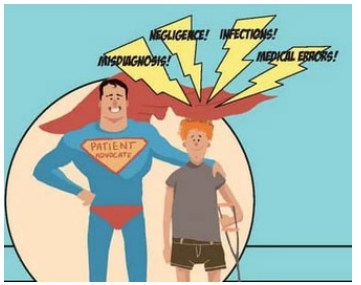
- Clinical Engineers are desperately needed to support the growing trend of using health care technologies in the home

Patient advocacy for home use of medical technology

Jani Mueller

What is patient advocacy?





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Responsibility

- Helping patients deal with clinicians and healthcare professionals in diverse settings
- Providing patients with guidance based on their conditions and treatment options
- Supporting patients with health insurance processes, including filing claims and preparing necessary forms

Role

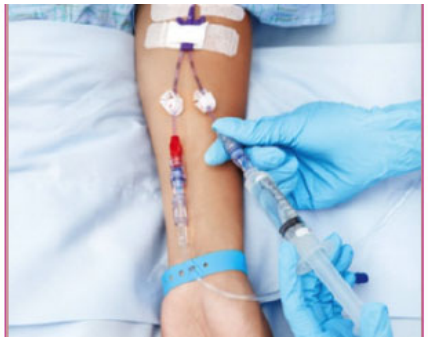
Respond to individual patient health needs and issues

Biological
Social /Political
Cultural/life-style
Financial
Psychological
Environmental

Technologies

Diagnosis & Screening

Interventions



Courtesy: WHO Compendium of innovative technologies for low-resource settings

Assessing at home medical technologies

HTA is a multidisciplinary **process** that uses explicit methods to determine the **value** of **health technology** at different points in its **lifecycle**. The purpose is to inform decision-making to promote an equitable, efficient, and high-quality health system.

O'Rourke B, Oortwijn W, Schuller T, the International Joint Task Group (2020). The new definition of health technology assessment. IJTAHC

Technical characteristics & safety considerations	• Configurations and features that may lead to unintended (dangerous) errors for home user
Effectiveness	• Reliable (changes in application etc) • Collection of data – hazard and safety
Economical aspect/Affordability	• Lifecycle cost (consumables, supplies etc) • Labor cost • Repair and operational costs

Organizational aspects

- Human factors needs with or without clinical or technical experience
- Site, user evaluation
- Training, troubleshooting etc

Ethical aspects

- Privacy
- Autonomy
- Ageism & Stigma
- Responsibility

Social & Patient aspects

- Physical and cognitive capabilities of the home user
- Safety & ability to live at home

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Questions?

Comments?

Thanks!


Q&A

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A list of additional topics and dates for next webinars will be soon announced through email campaign and on our website www.GlobalCEA.org

THANK YOU
for your participation