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.
Simply click on the Captions tab at the bottom of your screen and select the caption language you would like to read from the drop-down menu.

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With LIVE translated captions
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

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
<table>
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<tr>
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<tbody>
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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
<table>
<thead>
<tr>
<th>CLEAR RETAINER RING PUMP (SUBJECT OF RECALL)</th>
<th>BLACK RETAINER RING PUMP (NOT AFFECTED BY RECALL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>![Image](Image: Location of the retainer ring on the MiniMed™ 600 series insulin pump)</td>
<td>![Image](Normal pump with black retainer ring)</td>
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</tbody>
</table>

The images show a **normal** pump retainer ring vs a **damaged or missing** pump retainer ring.
ECRI

Top 10 Health Technology Hazards for 2023

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

<table>
<thead>
<tr>
<th>CSA Group Standards for Health Care Facilities</th>
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<tbody>
<tr>
<td>CSA Z8000-18</td>
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<tr>
<td>CAN/CSA-Z8001-13 (R2018)</td>
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<tr>
<td>CSA Z8002:19</td>
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<td>CSA Z8003:21</td>
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<td>CSA Z8005</td>
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<td>CSA Z317:1:21</td>
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<td>CSA Z317:2:19</td>
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Standards that apply to the hospital environment - continued

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

• National Building Code of Canada 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

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?

- Lay technical understanding
- Personal experience
- Specialized/professional technical expertise
- Group perspective

Patient

Patient advocate

Patient expert

Patient advocate expert

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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

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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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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