# Creating a Culture of Safety in Home Mechanical Ventilation

December 4, 2015

# Speaker Introductions

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  Vice President of Clinical Services / Owner,
  Mobile Medical Homecare

# Disclosures

- **Ronda Bradley**
  CareFusion, Medisize, SouthMedic, Percussionaire, Ohio Medical

- **Angela King**
  Breas Medical, Hamilton Medical, Mobile Medical Homecare, Ventec Life Systems

# Typical Homecare Ventilators

We will be focusing our discussion on ventilators FDA approved for home use as life support devices.

# Why RAD Devices are not Appropriate for Life Support

Devices commonly known as Bi-level/PAP/RAD (even those with a breath rate) are not appropriate for life-support:

- Not approved by FDA for life-support
- Most not approved by the FDA for application to the trach
- Most have no internal battery in case of power failure
- May not have adequate alarms for power loss, patient disconnect or other parameters
- Not intended for 24 hour per day use

# Circuit Types Offered in Home Vents

3 circuit types are available for home ventilators:

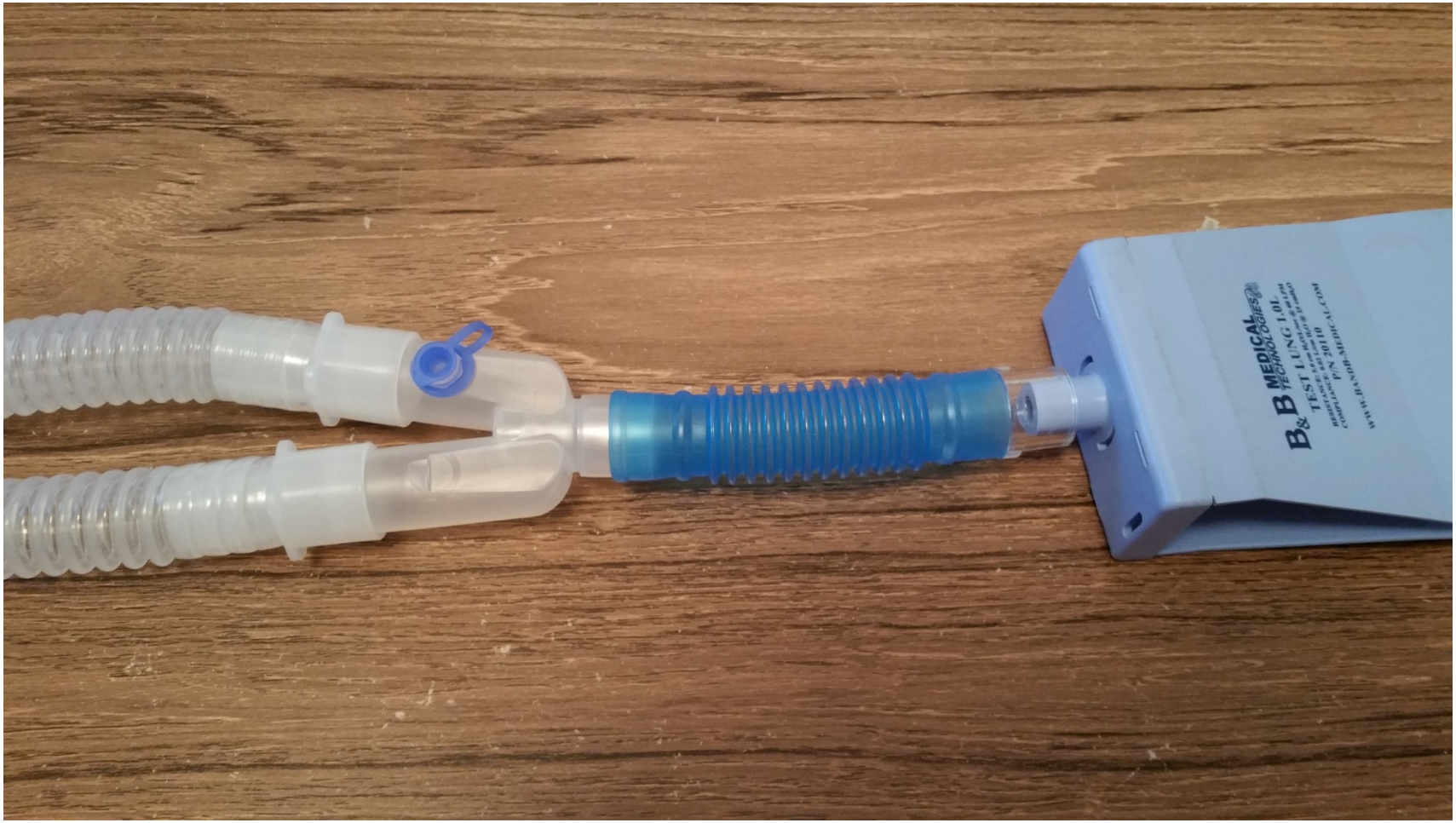
- Passive single limb circuit "Leak circuit"
- Active single limb circuit "Valve circuit"
- Active dual limb circuit "Valve circuit"

*Note: Many newer generation ventilators can be used with either a passive or an active circuit.*

# Passive Single Limb (Leak Circuit)

# Active Single Limb (Valve Circuit)

# Active Dual Limb (Valve Circuit)



| | Leak | Single Limb Valve | Double Limb Valve |
|---|---|---|---|
| **Actual Measurement of Exhaled Vt** | No--exhaled air is flushed out the intentional leak. | Only if there is a flow transducer on the single limb. | Yes—exhaled air is returned to the vent. This may be an important safety consideration. |
| **Allows setting of 0 Peep** | No--there must be some EPAP/PEEP to flush out the CO2 | Yes--Because valve opens to allow exhalation, EPAP/PEEP can be set to 0 | Yes--because valve opens to allow exhalation, EPAP/PEEP can be set to 0 |
| **Leak Compensation** | Generally considered optimal with leak circuit | Limited with valve circuits—patient synchrony may be compromised with large leaks | Limited with valve circuits—patient synchrony may be compromised with large leaks |
| **Allows higher FiO2** | No--the oxygen is diluted by the higher flow required for the intentional leak | Yes—not having the intentional leak keeps flow rates lower. | Yes—not having the intentional leak keeps flow rates lower. |
| **Optimal Heated Humidifier Efficiency** | No-- the intentional leak may make it more difficult for the heated humidifier to ensure optimal humidification | Yes--the valve helps to keep the flow rate down so heater can ensure optimal heated humidity | Yes--the valve helps to keep the flow rate down so heater can ensure optimal heated humidity |

*Adapted from ResMed handout*

| | Leak | Single Limb Valve | Double Limb Valve |
|---|---|---|---|
| **Acceptable with HME Use** | Controversial--some home ventilator Operator Manuals advise against using HME with leak circuits | Yes | Yes |
| **Promotes Battery Duration** | No-- intentional leak requires higher flows, draws battery down faster | Yes | Yes |
| **Allows Use of Standard NIV Interfaces** | Yes--most interfaces are designed with intentional leak | No--must use non-vented mask. Fewer mask choices (blue elbow mask) | No—must use non-vented mask. Fewer mask choices (blue elbow mask) |
| **Circuit Weight and Bulkiness** | The leak circuit is lightest weight and least bulky | The valve is near the patient which adds some weight and bulk | The valve is near the patient and the two circuit limbs add bulk and weight |

# Some Available Alarms

| Alarm | May Indicate |
|---|---|
| Circuit disconnect | Large leak |
| Low circuit leak | Passive leak port occluded, non-vented mask, incorrect circuit used |
| High pressure | Obstruction, patient needs suctioning |
| Low pressure | Leak, inadequate cuff pressure |
| Low minute volume | Large leak, deflated/no cuff, low breath rate, inadequate tidal volume, disconnection |
| Low peep | Large leak, deflated/no cuff |
| Hi peep | Valve sticking, inadequate exhalation time |
| Apnea | No breath or no spontaneous breath (depends on vent) |

# FDA MAUDE Database


AAMI FOUNDATION

# Serious Home Ventilator Incidents

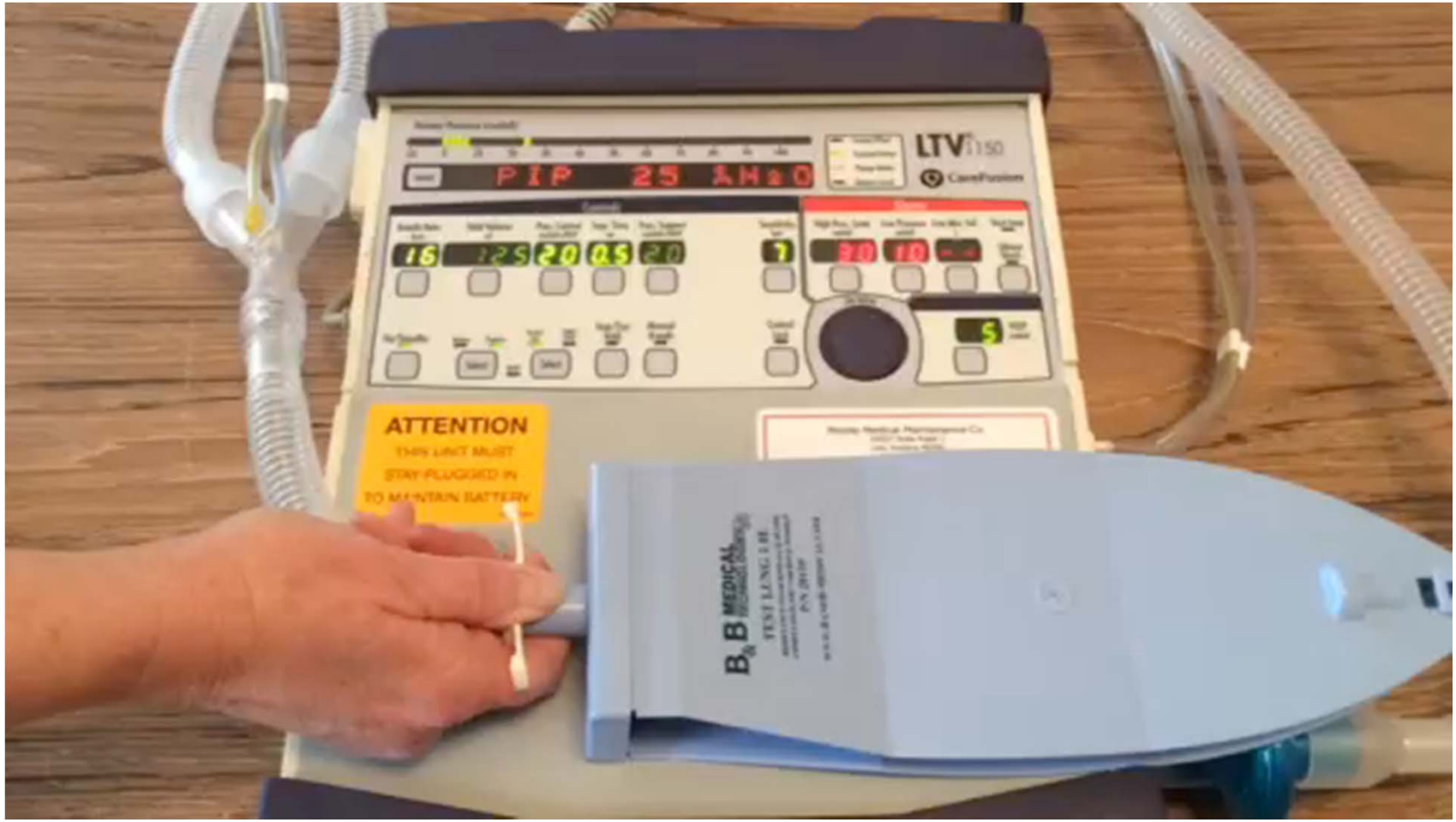
- Accidental disconnection or decannulation
- Mucus plug /obstruction
- Ventilator lost power
- Poor training re: emergency procedures

| 39 Children, 8 Deaths | | | | |
|---|---|---|---|---|
| **No.** | **Diagnosis** | **No. years on vent** | **Cause of death** | **No. years at home** |
| 1 | SCI<br>C2 Quadriplegia | 16 y | Ventilator disconnection, died at home | 15 y, 7 m |
| 2 | SCI<br>C2 Quadriplegia | 5 y | Cause unknown, found dead in bed at home | 3 y, 8 m |
| 3 | SCI<br>C2 Quadriplegia | 12 y, 10 m | Bowel obstruction, peritonitis, died in hospital | 6 y, 8 m |
| 4 | SCI<br>Quadriplegia | 8 y, 6 m | Unknown, died sitting in wheelchair after eating | 0 y, 5 m |
| 5 | SMA | 5 y, 1 m | Seizures, metabolic, died in hospital | 4 y, 8 m |
| 6 | Demyelinating neuropathy | 4 y | Fall-accident in wheelchair, died while living at home | 3 y, 1 m |
| 7 | Myotubular myopathy | 5 y | Overwhelming viral illness, died in hospital | 3 y, 0 m |
| 8 | Unknown myopathy | 11 y, 10 m | Ventilator disconnection, died at home | 10 y, 5 m |

# MAUDE Report # 3502341, Report Date 10/17/2013, Trilogy, Death

Mother went to check on patient at 4:15 pm and he was unresponsive. Mother stated patient was napping in a play-pen and had decannulated himself. Patient was on one end of the play-pen and his tracheostomy tube at the other end still attached to the ventilator circuit. Mother stated that the SIMV rate was set at 12. Mother also stated that ventilator was not alarming. Mother stated that ventilator started to alarm once she disconnected the tracheostomy tube from the ventilator circuit.

# Decannulation Video



# Alarm Issues

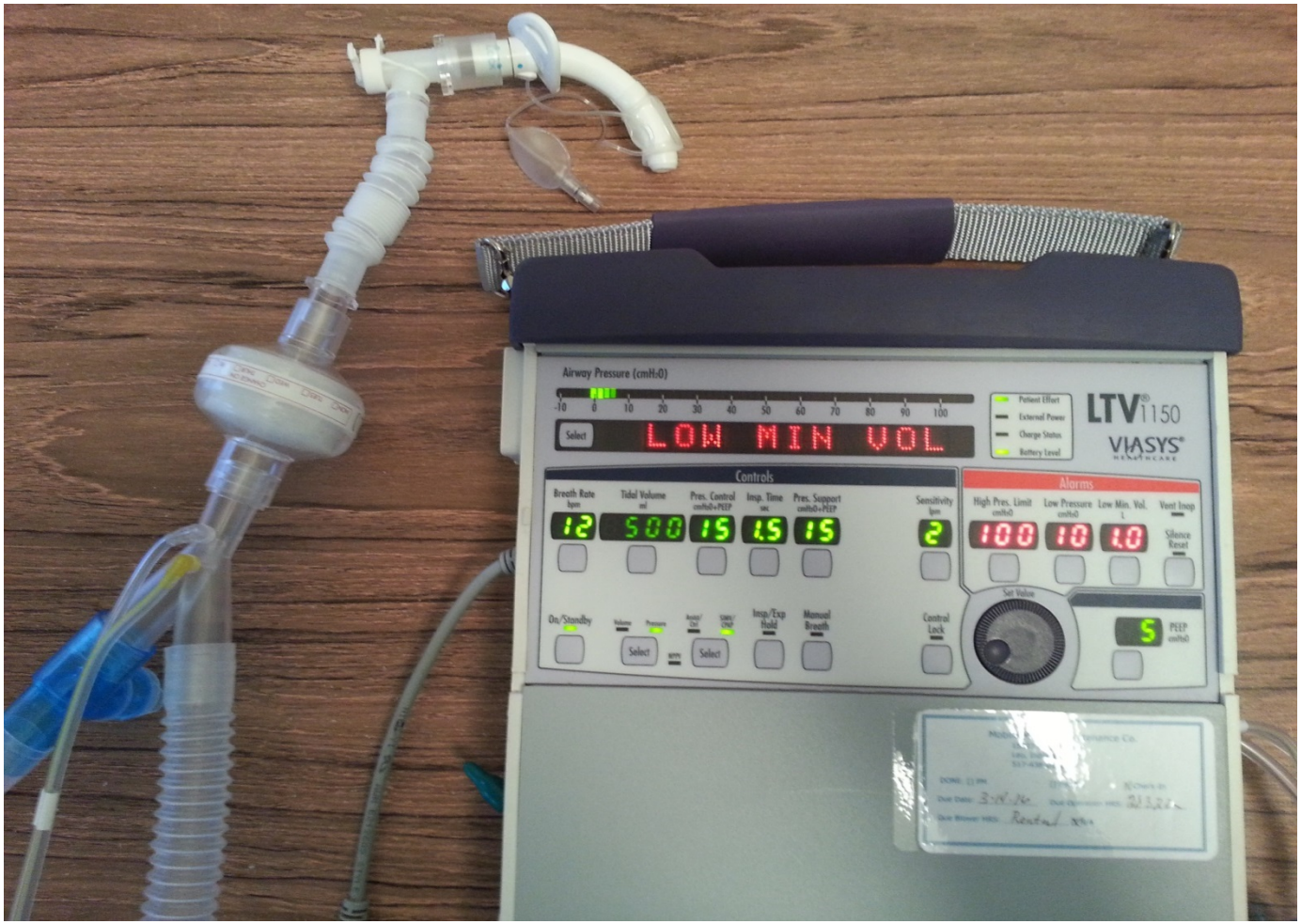
Chest. 2001 Feb;119(2):562-4.
**Kun SS. Home ventilator low-pressure alarms fail to detect accidental decannulation with pediatric tracheostomy tubes.**

**CONCLUSION**: We conclude that ventilator low inspiratory-pressure alarms fail to alarm during simulated decannulation with small tracheostomy tubes commonly used in children. We speculate that **low-inspiratory-pressure alarms set at 4 cm $H_2O$ below the desired PIP** will detect more decannulation than when set at 10 cm $H_2O$ below the desired PIP.

# How are Alarms Sometimes Fooled? Common Alarm Setting Mistakes which can Prevent Alarms from Sounding

1. Low pressure only with flow triggered vents in case of small ID tubes
2. Low pressure alarm set too low in situations of Speaking Valves

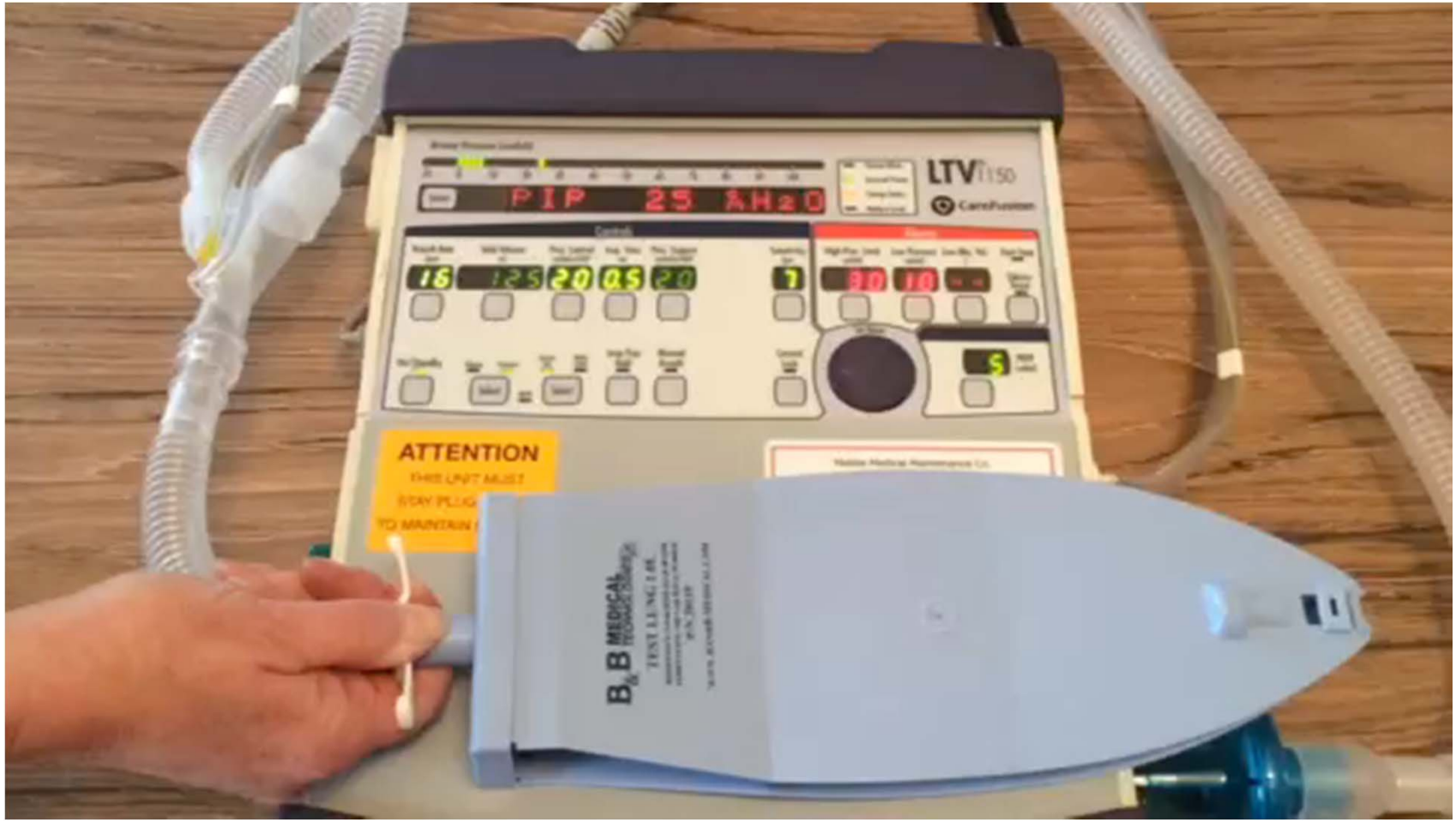
# Test by Simulated Decannulation



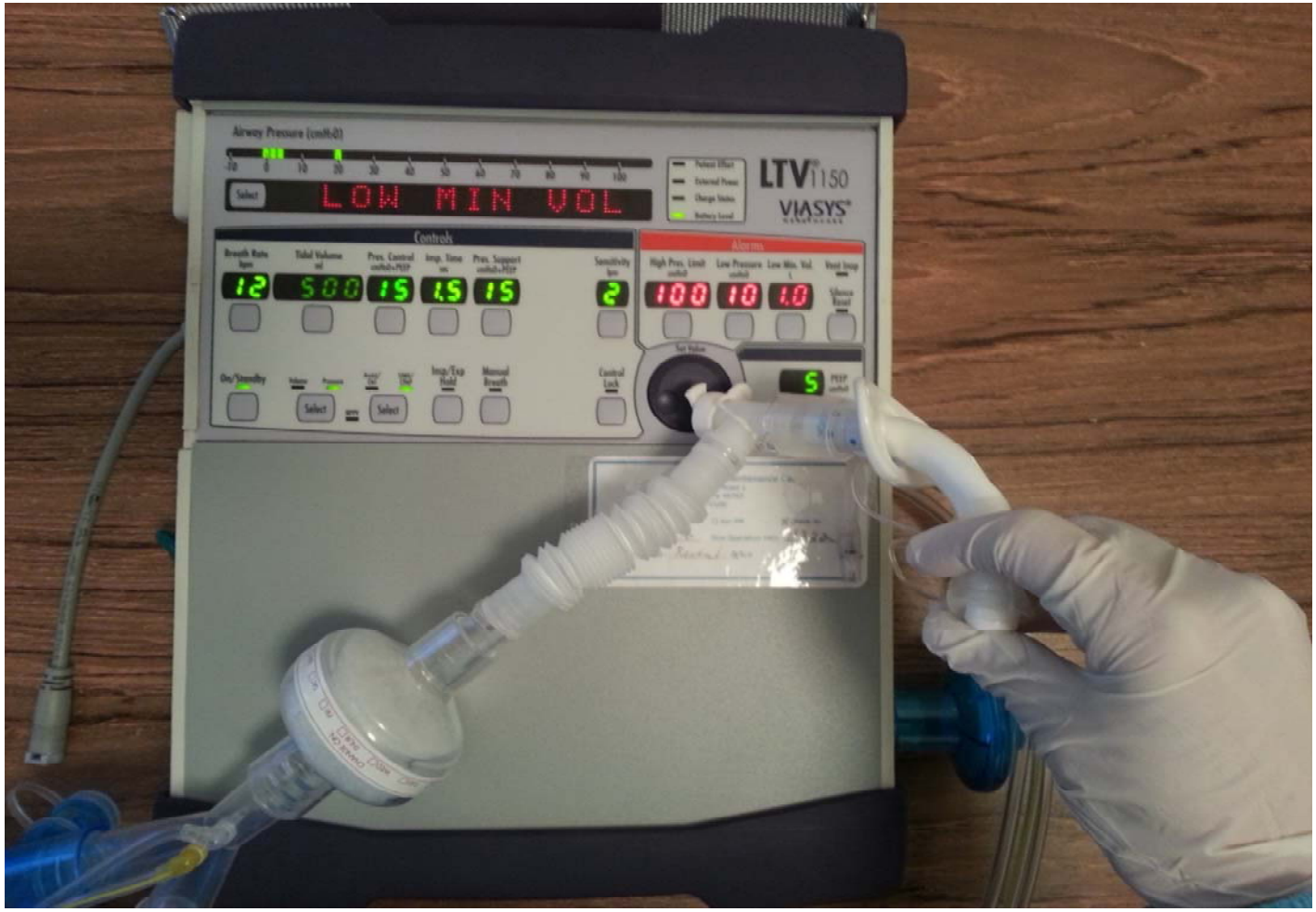
# MAUDE Report #2031702-2010-00060 , Report Date 4/8/10, LTV

It was reported that the patient had a mucus plug while connected to the ventilator, but the ventilator did not alarm. The patient passed away.

# Video– Simulated Obstruction

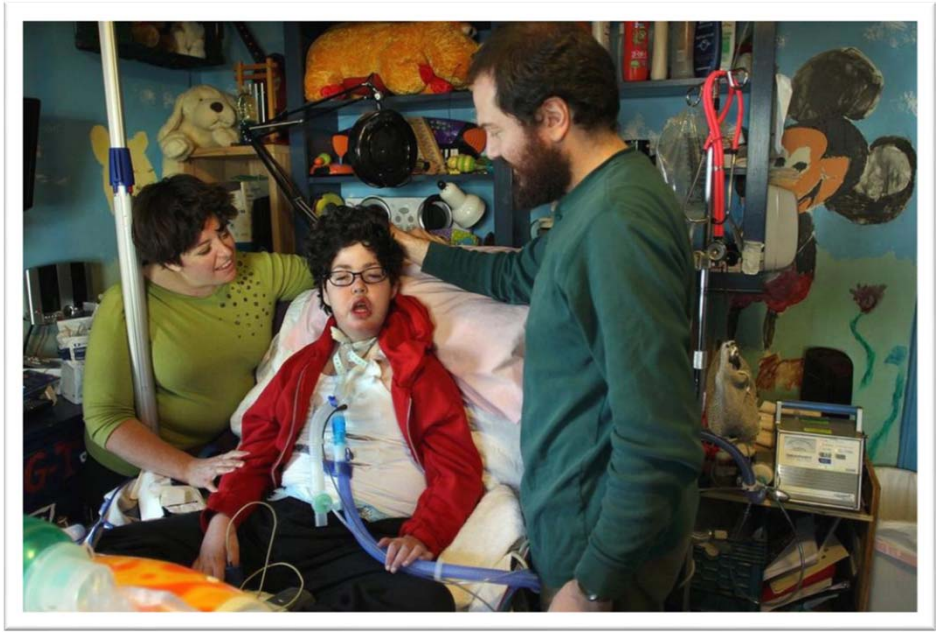


# Test by Obstruction



# Make Sure the Alarms Can Be Heard Over Household Noise

One day, when Liam was 3 years old, mucus blocked his breathing tube. Her husband was vacuuming and they aren't sure whether the alarm sounded or not, Ora Davis said. By the time they discovered he was not getting enough air, Liam had suffered a brain injury that limits his ability to move.



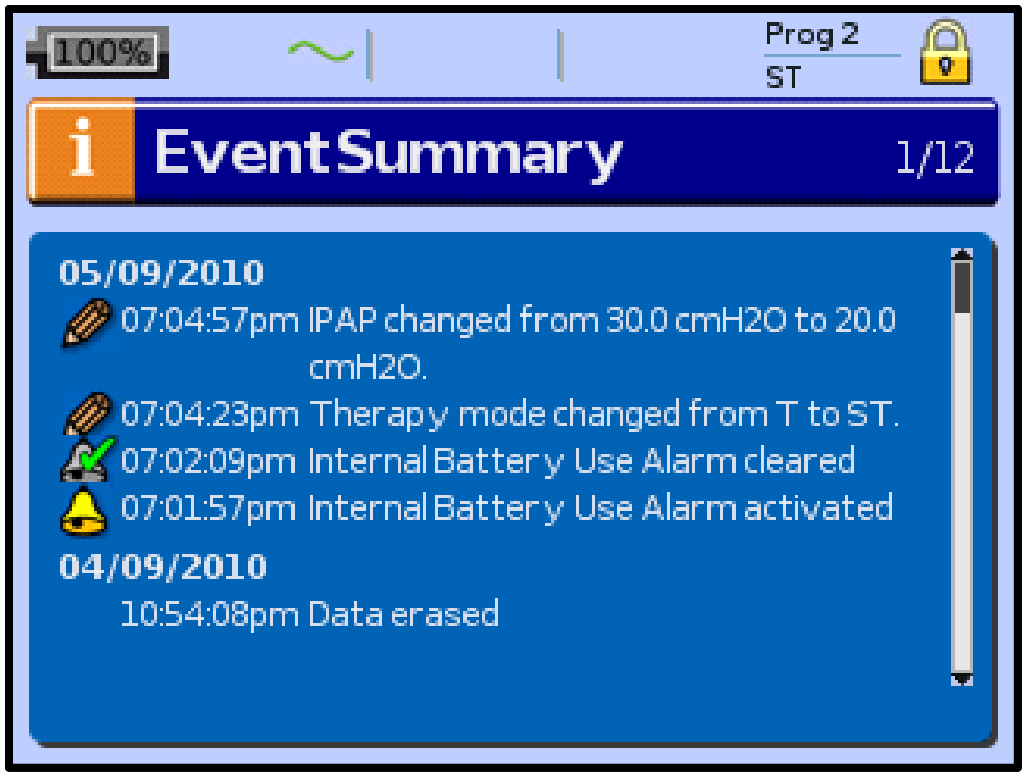
Liz Kowalczyk, Boston Globe, 12/11/2011

# Astral Remote Alarm

# Screen for Alarm Fatigue

"Nurses and other caregivers can become desensitized to audible warnings when they hear beeps all day long, many of them false alarms".

Liz Kowalczyk, Boston Globe, 12/11/2011




Minimize nuisance alarms when possible with delay or duration features!

# How to Address Alarm Fatigue

1. Eliminate Redundancy
2. Set Parameters appropriately for the type of patient.
3. Utilize features on ventilator to “customize” alarms.
4. Consider alarm package options when choosing a ventilator for a particular area
5. Create a culture of responsiveness to alarms

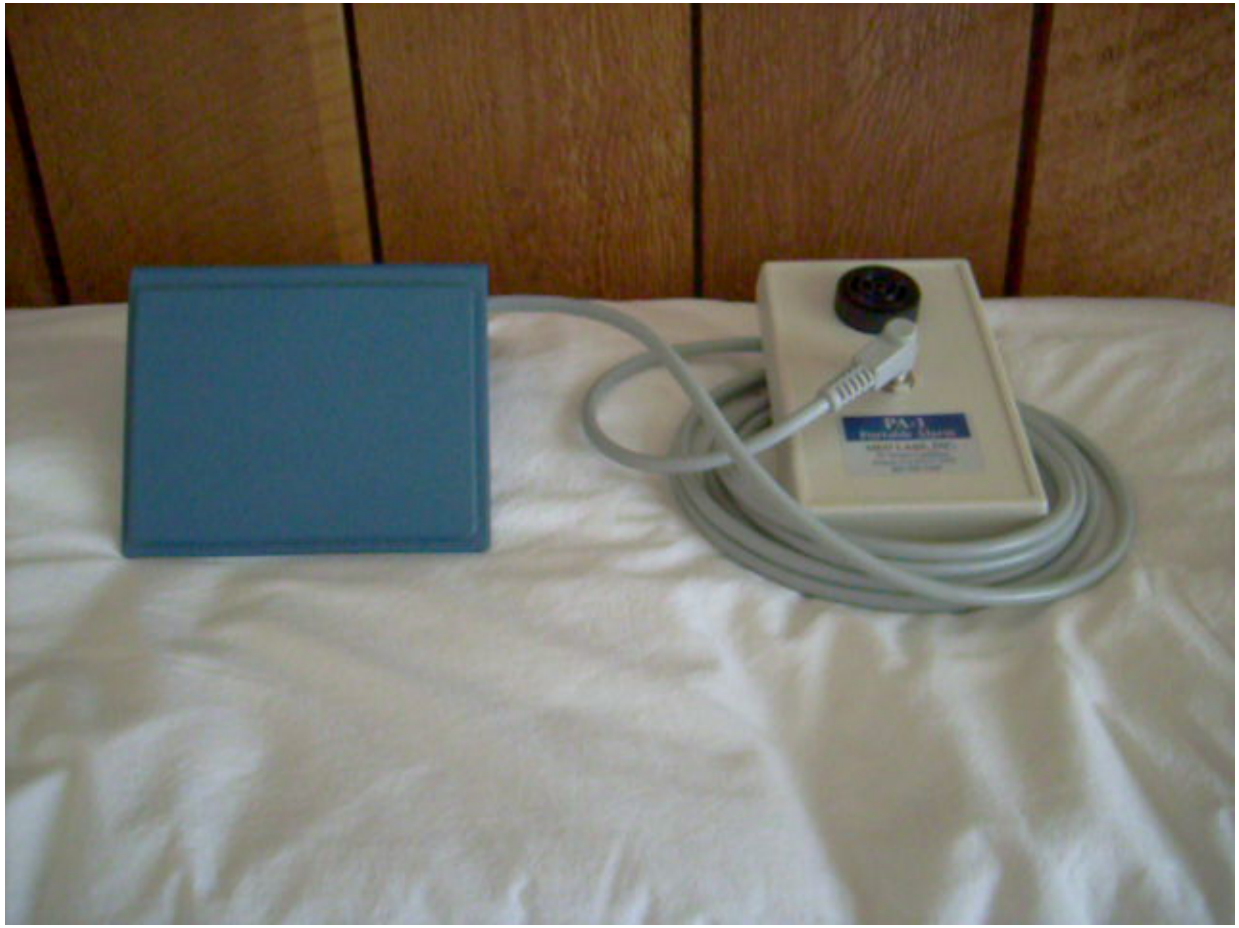
**MUST DO THE FIRST 4  Before #5 will be effective!**

# Examples: Alarm Configuration

- Reduce duplicate alarms: Disconnect alarm choice
- Utilize customizing features to reduce alarm fatigue.
  - HP Delay
  - Time delay on RR, High and low PEEP, VE

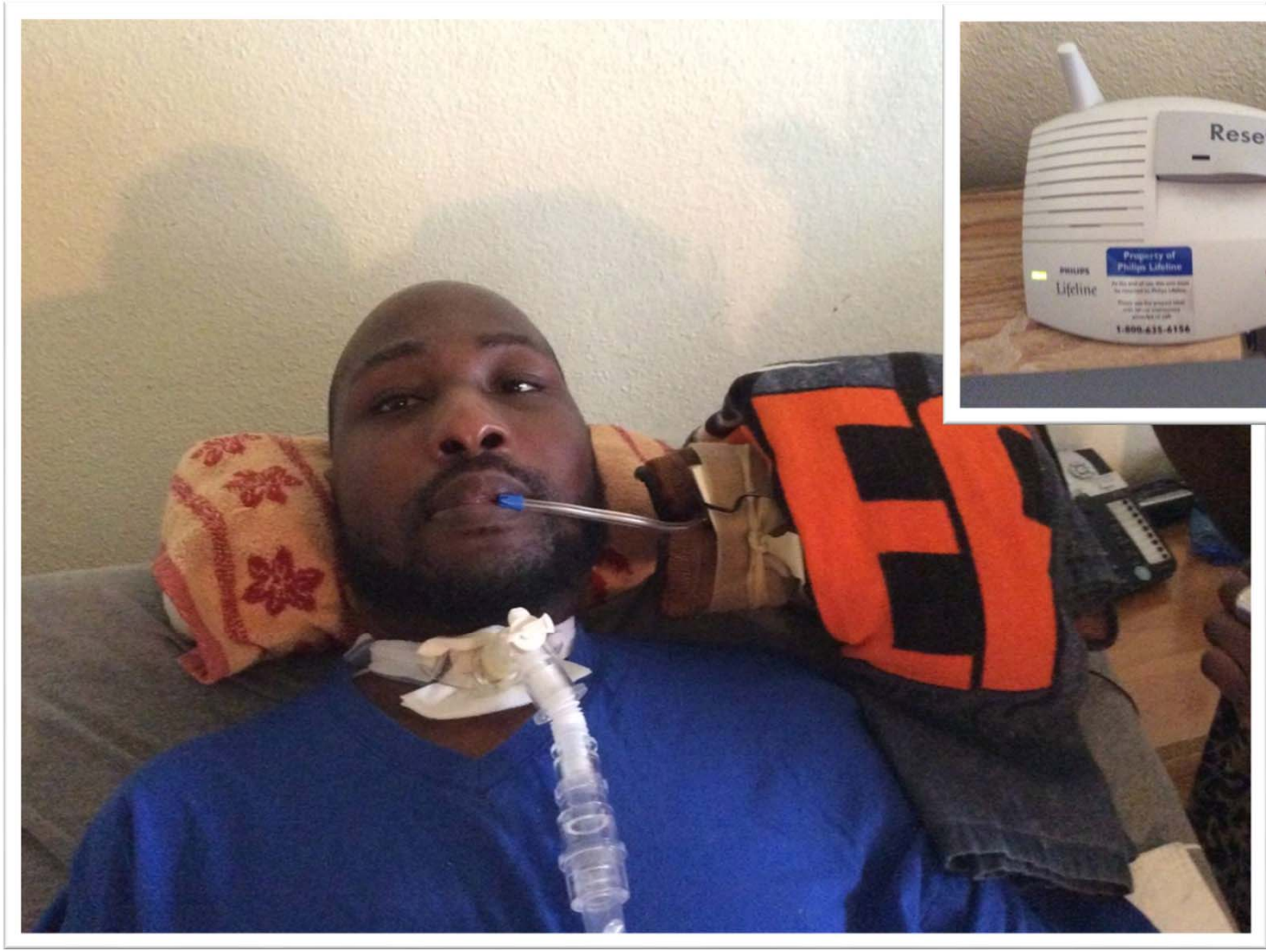
- When alarms are set correctly, the vent should NOT constantly alarm for no reason!

# Ensure that the Patient Can Call for Help



E-Z Call and PA-1 from Med Labs (Goleta, CA)

# Philips Lifeline System



# What are next JCAHO Requirements for Jan 1, 2016

- At minimum, address the following:
  - Clinically appropriate settings for alarm signals
  - When alarm signals can be disabled
  - When alarm parameters can be changed
  - Who in the organization has the authority to set alarm parameters
  - Who in the organization has the authority to change alarm parameters
  - Who in the organization has the authority to set alarm parameters to “off”

*http://www.jointcommission.org/assets/1/6/2015_NPSG_HAP.pdf*

# What are next JCAHO Requirements for Jan 1, 2016

At minimum, address the following:

- Monitoring and responding to alarm signals
- Checking individual alarm signals for accurate settings, proper operation, and detectability

- Must document: educate staff and licensed independent practitioners about the
  - purpose and proper operation of alarm systems for which they are responsible.

*http://www.jointcommission.org/assets/1/6/2015_NPSG_HAP.pdf*

# Summary

- Alarm safety is extremely important with both non-invasive and invasive ventilation in the home
- Choose the correct device
- Understand the differences between devices and circuits
- Ensure safety alarms
- Reduce alarm fatigue
- Ensure alarms can be recognized (heard and seen)
- Create P&P for alarms and alarm safety
- Train staff and caregivers

ALARM SAFETY IS EVERYONE'S RESPONSIBILITY

# Thank You to Our Industry Partners

This Patient Safety Seminar is offered at no charge thanks to funding from our National Coalition for Alarm Management Safety industry partners. The AAMI Foundation and its co-convening organizations appreciate their generosity. The AAMI Foundation is managing all costs for the series. The seminar does not contain commercial content.

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