MEDICAL DEVICE EVALUATION – PATIENT SAFETY PERSPECTIVE

CAHOCON 2023
LEADERSHIP IS THE KEY TO QUALITY
14-16 APRIL 2023,
HYDERABAD, INDIA

Ir. Dharmesh Doshi, ECRI Asia Pacific

Over 50 Years of Safe and Effective Healthcare


Health Devices

SUBJECT INDEX, VOLUMES 6-10

(ABBREVIATED INDEX, VOLUMES 1-5)

INDEPENDENT TESTING & EVALUATION LAB

The only independent medical device testing and evaluation lab in North America and Asia Pacific

ECRI

Patient Safety Organization

PATIENT SAFETY ORGANIZATION

Listed by the U.S. Department of Health & Human Services and now one of the largest in the U.S

EVIDENCE-BASED PRACTICE CENTERS

EVIDENCE-BASED PRACTICE CENTER

Designated as an Evidence-Based Practice Center by the U.S. Agency for Healthcare Research & Quality

OUR EVALUATION PROCESS

TEST CATEGORIES

Performance

- Test looks at the ability of the device to perform what it is designed to do.

Safety

- Any safety concerns that are associated with the primary purpose or design of the device. E.g alarms

Workflow

- how well a device fits into routine use. Note, several Workflow related features may also affect Safety. When that is the case, the feature should be evaluated as a Safety concern.
- Human factors assessments are included in Workflow testing.

Patient Experience

- Aspect of the device that is designed to improve patient experience, only applicable if the patient is aware/conscious

Interoperability

- Ability of the device to interact with other devices, either mechanically or electronically

Cybersecurity

- Manufacturer's precautions to address cybersecurity concerns. Manufacturers are requested to complete a cybersecurity questionnaire.

Maintenance

- Any issue affecting the maintenance and reliability of the device. E.g manufacturer maintenance procedures are reviewed to determine the recommended frequency and expected duration of scheduled maintenance.

User Experience

- Feedback from clinical users via survey regarding their interaction with both the device and the supplier.

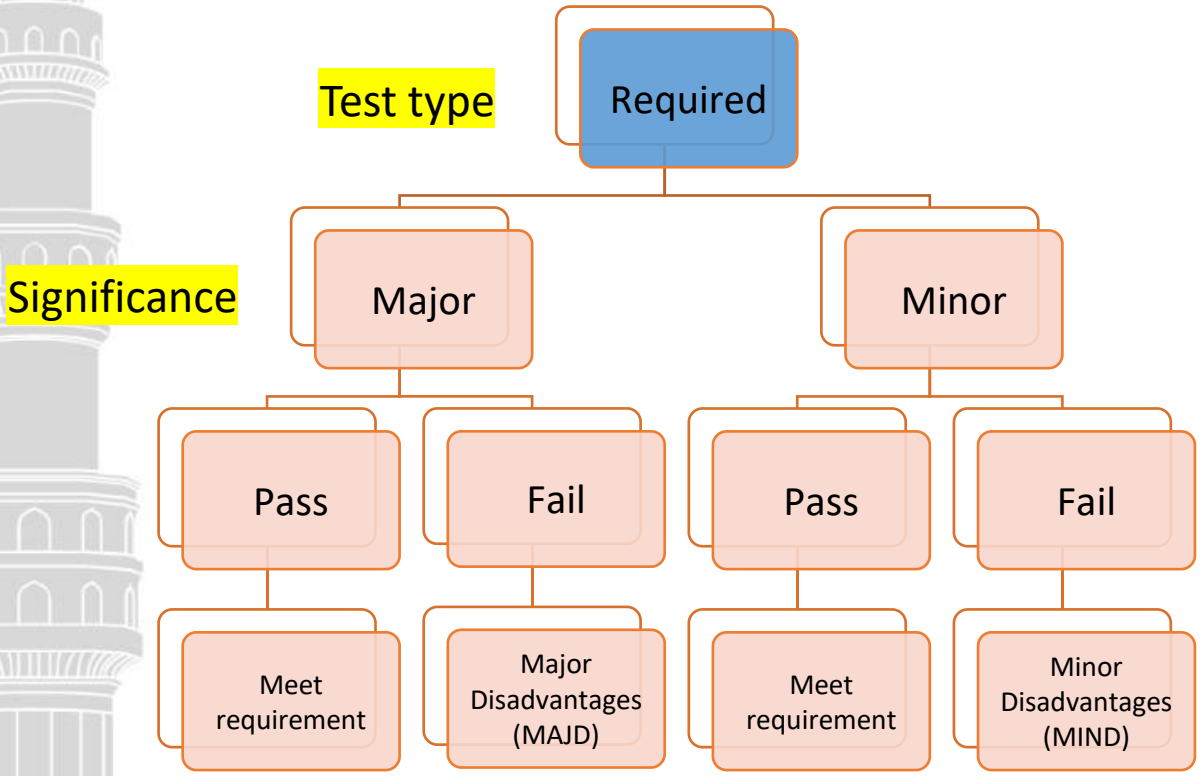
Total Cost of Ownership

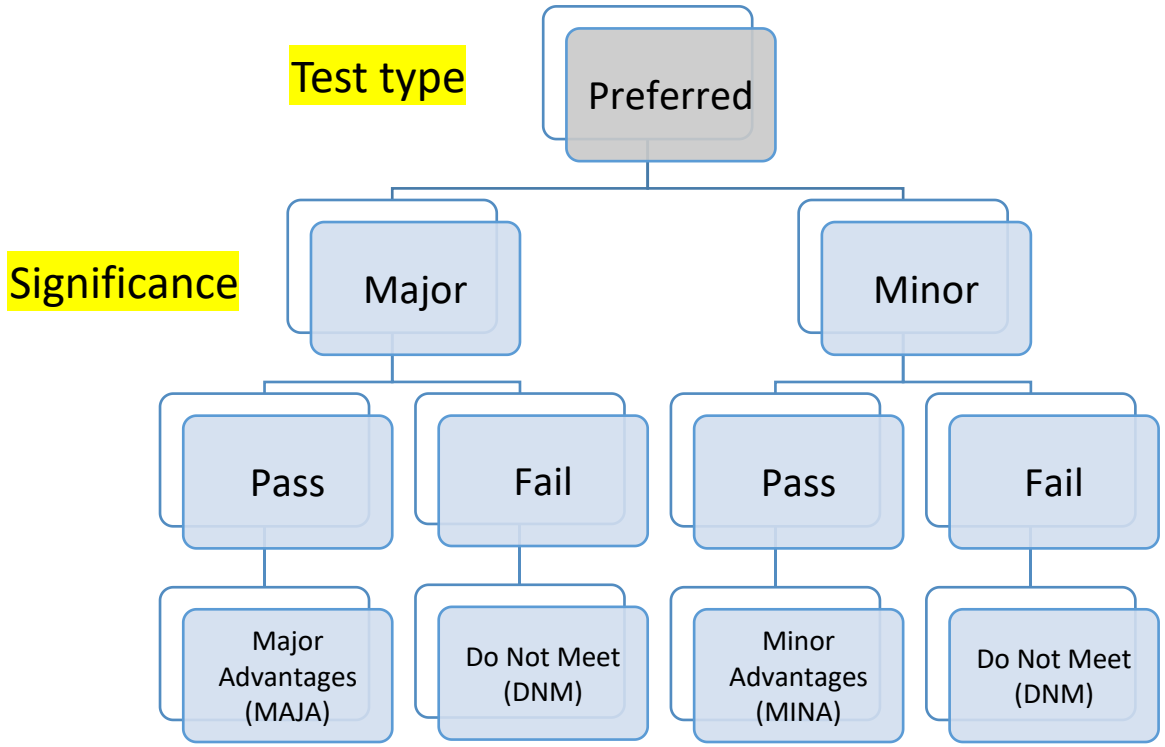
- Estimated cost of ownership provided by manufacturers or obtained from ECRI's capital pricing database. Features offered affects the cost of purchase or operation of the device.

Example of a Test Protocol

ID	Numb	Test Name	Test T	CC1 Type	Criterion	Test Method	Rationale
0001		Available Modes	1 Perf	Major Required	The ventilator should have modes that correspond to the following types: a. VC-CMV[s] b. VC-IMV[s,s] c. PC-CMV[s] d. PC-IMV[s,s] e. PC-CSV[s] CMV-continous mandatory ventilation IMV - intermittent mandatory ventilation CSV-continuous spontanous ventilation	Check for availability of these modes from the ventilator setting or from IFU: a. VC-CMV[s] b. VC-IMV[s,s] c. PC-CMV[s] d. PC-IMV[s,s] e. PC-CSV[s]	These modes capture most therapeutic needs of patients in a hospital transported to other areas fo the hospital.
000 046		Alarm limits display	2 Saf	Minor Required	Alarm limits should be displayed continuously next to the measured parameter	Check for presence of alarm limits on display.	Easy visualization of alarm limits helps the operator understand the safe ventilation parameters for the patient.
000 054		Remote operation	3 Wor	Major Preferred	Ventilators has external ventilator control panel, where the ventilator control panel is placed outside the intensive care room and can control the settings.	Check the IFUs and ask manufacturers if this can be done. If the control panel is connected wirelessly outside the patient room , ask manufacturer for documentation that proof that their wireless is not interered by EMI. Set it up with the control panel outside the room and observe the function with devices such as walkie talkie/ microwave is between. Observe any challanges.	This method enables respiratory therapist and respiratory physician to perform ventilator changes from outside the room, without having to go inside the room. Advantage of this method includes decreased utilization of PPE and exposure time inside the room.
000 060		Oxygen Enrichment	3 Wor	Minor Required	Oxygen enrichment shall be easy to activate, readily apparent on device display. High O2 concentration shall be reached in under 30 seconds.	Activate oxygen enrichment at delivered tidal volumes of 450 ml and 650 ml. Record times to reach 90% O2 and 100% O2. Record times above 90% and 100%. Assess overall operation per required criterion. Test Conditions: RR=12, PEEP=5, Starting O2=21. Mode=VC-AC	Oxygen enrichment is a frequently used feature. It should be easy to activate (minimal number of steps) and efficient.

TESTING JUDGEMENT FRAMEWORK





Significance	Notes
Major	The test is likely going to be a major consideration when selecting the device
Minor	The test is not likely to be a major consideration when selecting the device

Test Type	Notes
Preferred -Major	The related function is optional and is likely to be a major consideration when selecting the device. A device cannot receive a disadvantage for failing to meet the criterion
Preferred - Minor	The related function is optional but is not likely to be a major consideration when selecting the device. A device cannot receive a disadvantage for failing to meet the criterion
Required-Major	The related function is required and is likely to be a major consideration when selecting the device. A device cannot receive an advantage for meeting the criterion
Required-Minor	The related function is required but is not likely to be a major consideration when selecting the device. A device cannot receive an advantage for meeting the criterion

PERFORMANCE – ACCURACY OF PRIMARY VENTILATION PARAMETERS

Rationale

- Accuracy of delivered and measured parameters over a large range of PEEP settings is crucial to providing the best therapy.
- The primary ventilation parameters delivered should be **within 10% of the set values**;

(1) tidal volume (after correction for breathing circuit compliance to compensate for the volume of gas in the breathing circuit), (2) inspiratory pressure level (if available), (3) respiratory rate, and (4) I:E ratio or inspiratory time. The ventilator should meet the above criterion over a range of typical settings (including PEEP settings up to 15 cm H2O) without generating auto PEEP.

Flow analyzer and test lung used for ventilator testing

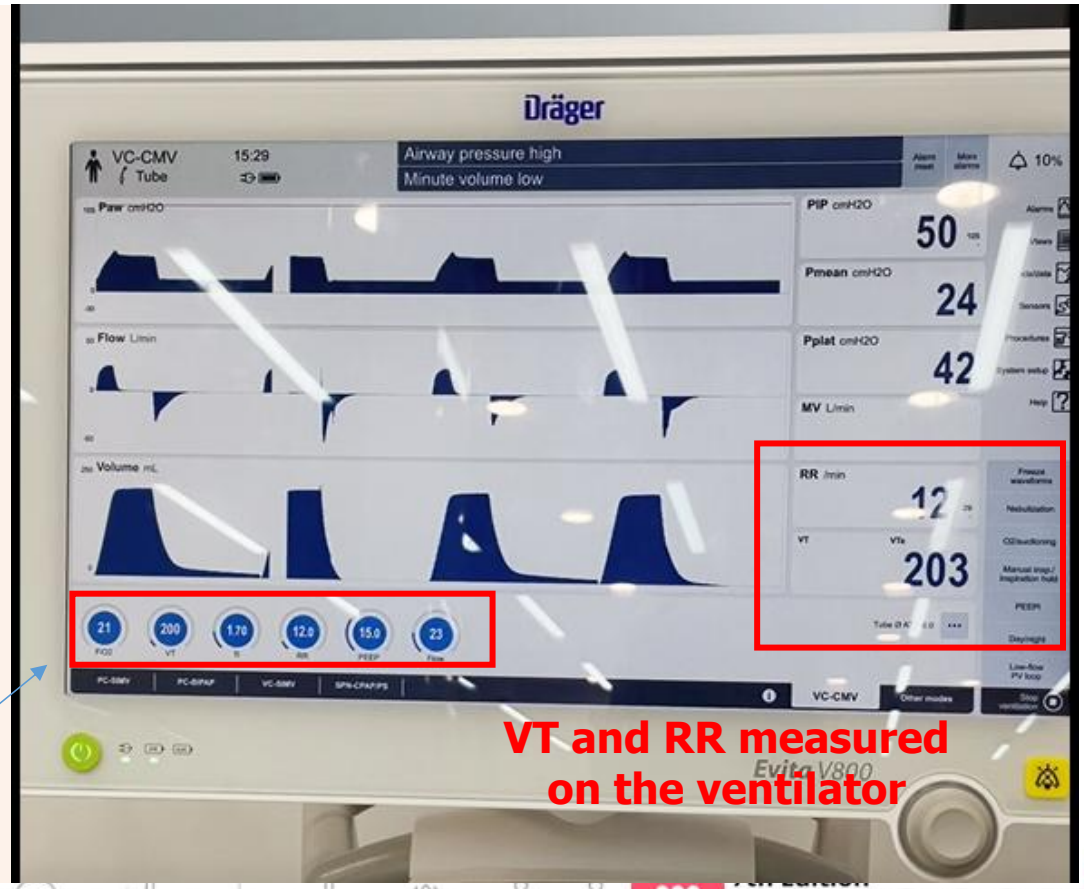
PERFORMANCE – ACCURACY OF PRIMARY VENTILATION PARAMETERS

Test Method

Tidal Volume (VT) accuracy test:

- Measure various tidal volume accuracy using flow analyzer and test lung at PEEP settings of 0cmH2O and 15cmH2O.
- We used Flowlab software to view the average tidal volume measured.
- Measured VT must be ±10% for it to meet the criteria.

Setting: VT=200ml, PEEP =15cmH2O, RR=12 bpm



VT and RR measured on the ventilator

PERFORMANCE – ACCURACY OF PRIMARY VENTILATION PARAMETERS

Findings from Flowlab Software

Measuring values	Unit	Value	Min	Max	Average	Setp
Flow High	l/min	0.0	-26.1	19.7	-0.8	
Flow Low	l/min	0.00	0.00	0.04	0.02	
Pressure (in Highflow)	cmH2O	15.73	15.65	24.14	17.89	
Flow High	l/min	0.0	-26.1	19.7	-0.8	
Temperature	°C	25.3	25.3	25.4	25.3	
Humidity	%	60	60	60	60	
Oxygen	%	19.9	19.8	20.0	19.9	
Pressure High	cmH2O	0	-1	1	0	

Respiratory Parameters	Unit	Value	Min	Max	Average	Setp
Rate	b/min	12.1	12.1	12.1	12.1	
I : E	---	7.4:1	7.4:1	7.4:1	7.4:1	
PEEP	cmH2O	14.6	14.6	14.6	14.6	
Ppeak	cmH2O	24.2	24.2	24.7	24.3	
Vte	ml	202	202	202	202	
Vti	ml	191	191	202	194	

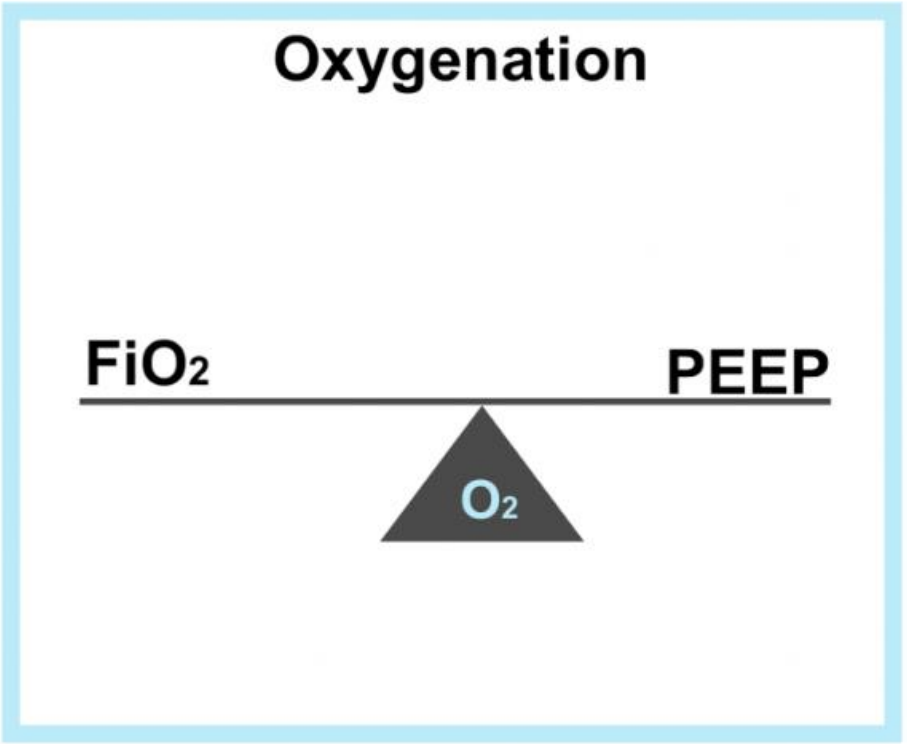
Measured VT

- Average VT measured on flow analyzer/ Flowlab software is ***202 ml (±1%).*** **Meets criteria.**
- Maintaining the appropriate tidal volume (VT) is important for success of lung protective ventilation (strategies that minimizes lung strain and stress, and prevention of recruitment-derecruitment injury.)

PERFORMANCE – ACCURACY OF AIR/OXYGEN MIXTURE

Rationale

- Accuracy of delivered FiO2 levels is important for oxygenation therapy.
- For instance, hypoxemia in the critically ill, has been shown to increase all-cause mortality. When oxygen consumption and supply are mismatched, cell damage and death occur.
- For units with an integral oxygen blender, oxygen-air mixtures should be accurate to within 4% across a variety of FiO2 settings.



Parameters that influence oxygenation : FiO2 and PEEP

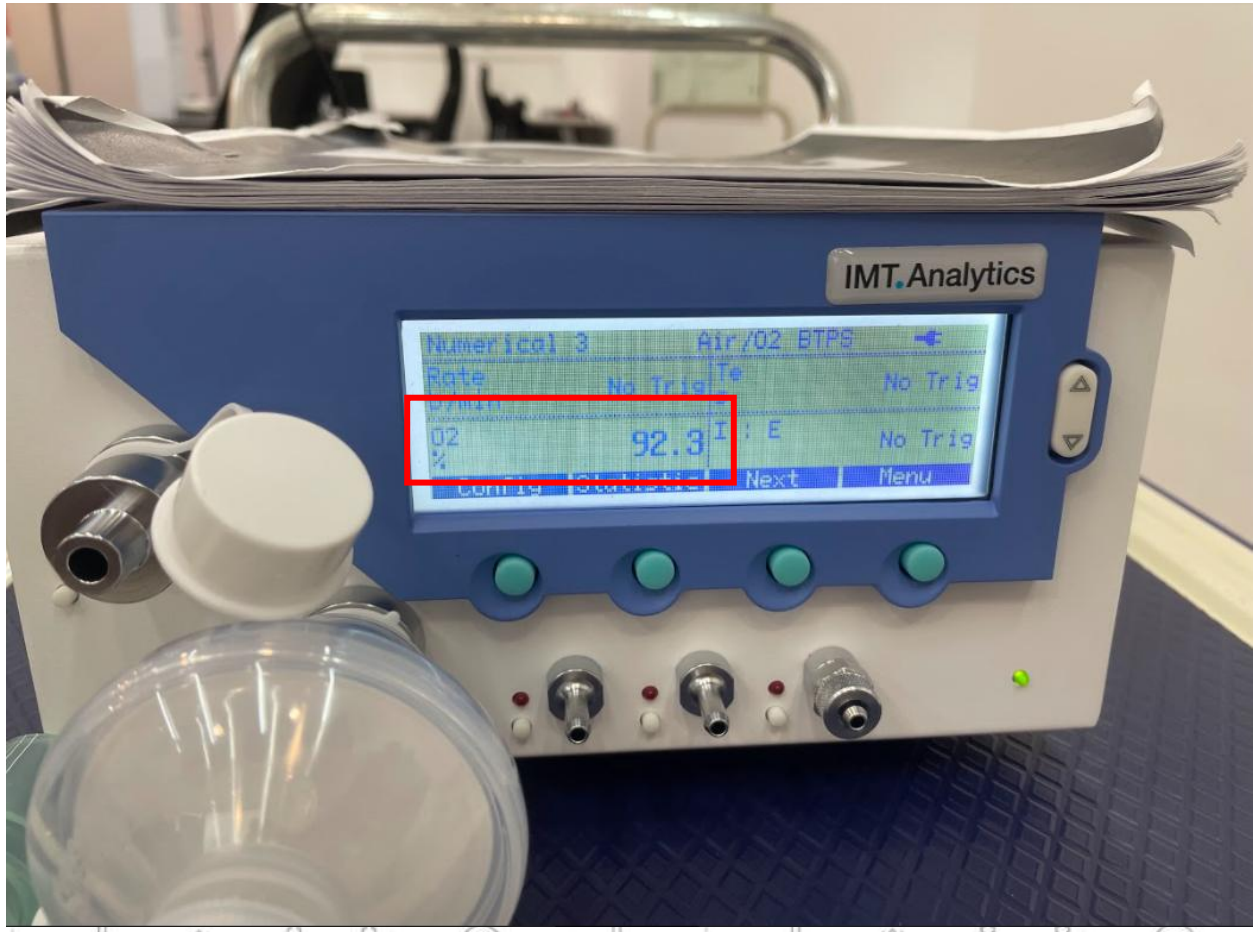
PERFORMANCE– ACCURACY OF AIR/OXYGEN MIXTURE

Test Methods

1. Use flow analyzer for this test.
2. Before testing, perform oxygen calibration for the flow analyzer at 100% and 21%.
3. Set FiO2 at the ventilator at 90% at VCV mode (or any other mode) and check the FiO2 readings at the ventilator (actual value) and at the flow analyzer (measured value). Take readings when the values are stable.
4. Repeat for 60% and 21%.

PERFORMANCE – ACCURACY OF AIR/OXYGEN MIXTURE

Findings



- Average FiO2 measured on flow analyzer is ***92.3% (±2.6%)*** **. Meets criteria.**

SAFETY – HIGH INSPIRATORY PRESSURE ALARM

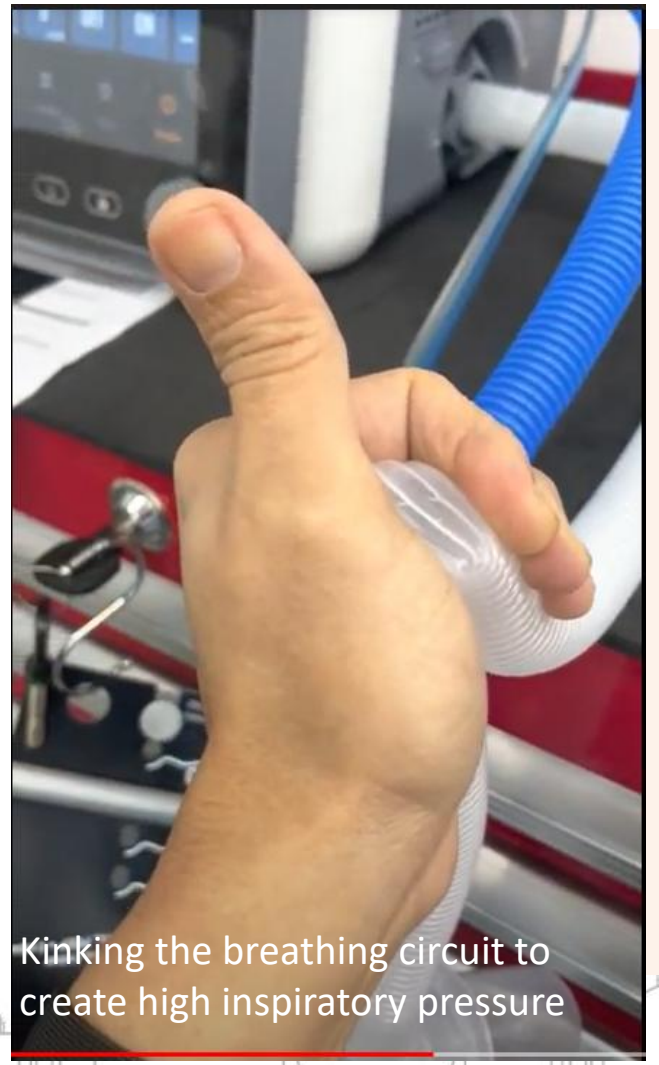
Rationale

- The ventilator should have adjustable alarm limits for high peak airway pressure. The preset high pressure limit for this alarm is typically set around 10 cmH2O above the peak inspiratory pressure (PIP).
- A high pressure alarm in mechanical ventilation is triggered whenever the circuit pressure exceeds a preset pressure limit during the inspiratory phase. When the ventilator pressure exceeds the set pressure limit, the ventilator immediately cycles into expiration and gas flow ceases.
- This alarm is caused by kink in the circuit, coughing, secretion accumulation, patient biting the ET tube, decrease lung compliance, increase airway resistance and water in the circuit.
- High pressures can cause barotrauma.

SAFETY – HIGH INSPIRATORY PRESSURE ALARM

Test Method

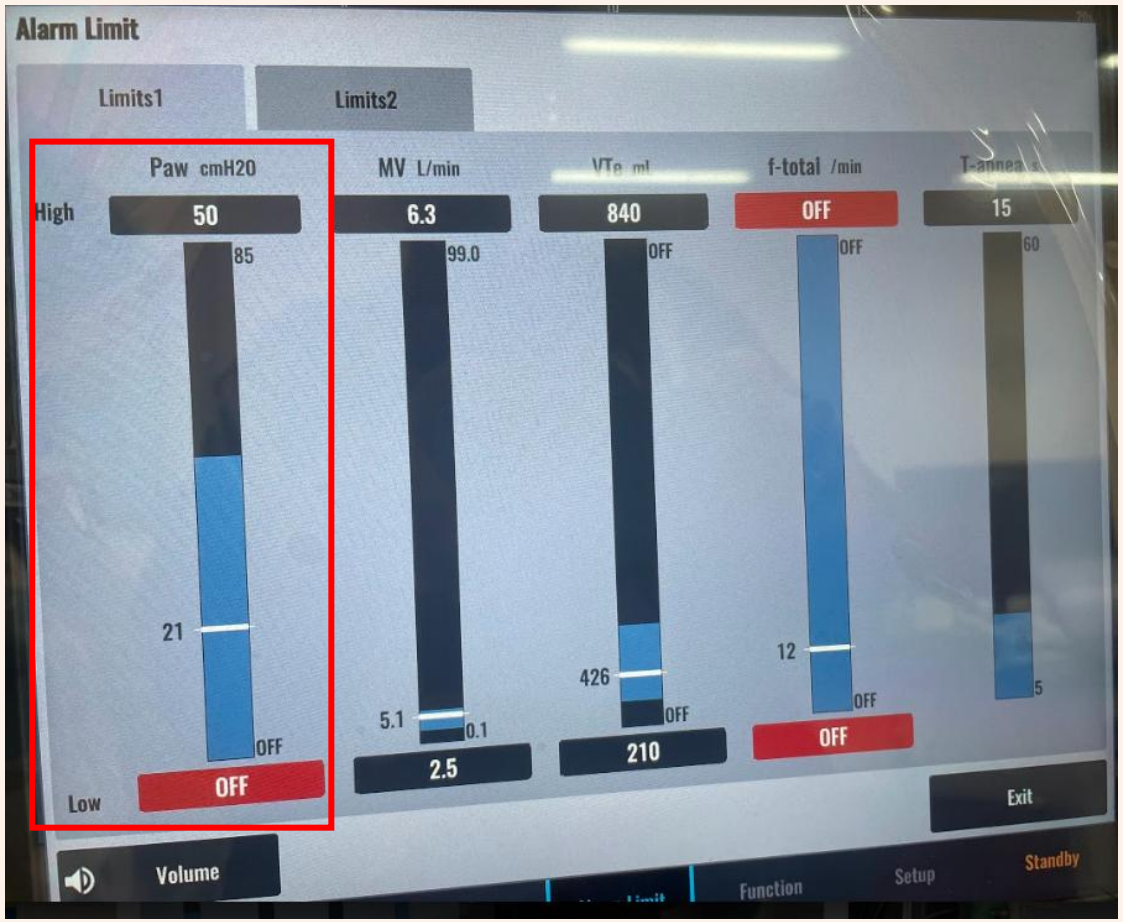
Squeezing the test lung to mimic coughing


Kinking the breathing circuit to create high inspiratory pressure

1. Select a pressure control mode on the ventilator.
2. Set Pinsp =15 cmH20 and adjust Paw high limit alarm to be 25.
3. Let it ventilate.
4. Check for presence and operation of high inspiratory pressure alarms by kinking the breathing circuit or by squeezing the test lung (to mimic cough).

Findings

In both simulation, the ventilator triggers audio and visual high pressure alarm.



The ventilator has adjustable alarm limit for high pressure alarm.

Anaesthesia Machine Safety Fix

ECRI's Finding – The identified problem is one we've observed repeatedly in units we evaluate—the **ability to set the default low-minute-volume alarm to zero**. Temporarily setting the low-minute-volume alarm to zero is a common practice, but allowing the default limit to be set to zero essentially turns off the alarm for one of the most critical measurements in anesthesia. Failure to detect a lack of respiration for many minutes can result in hypoxia and death. This scenario may seem far-fetched, but ECRI has investigated several fatalities that would likely have been prevented if the default low-minute-volume alarm limit been set at a reasonable value.

The Mindray A7, one of the products that received the software revision that resolved the low-minute-volume default issue. (Image courtesy of Mindray.)

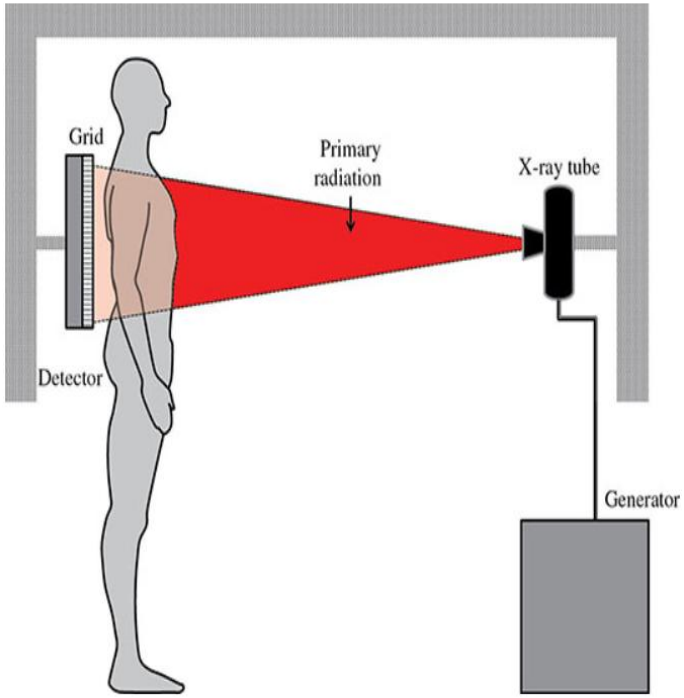
Anaesthesia Machine Safety Fix

End Result – During our Evaluation testing of Mindray's A5 Advantage and A7 Advantage in 2020, we made the company aware of the problem and the attendant risks, and encouraged them to implement a fix, as is our standard practice. The vendor was ultimately convinced, and updated the software on its entire product line. Since the update, the default limit cannot be set lower than 0.1 L/min. The user can still change the limits to zero during a case. In a follow-up to our Evaluation of the two Advantage units, published in May 2022 we judged the safety of both products to be excellent, with specific mention of the minute volume default alarm limits.

The Mindray A7, one of the products that received the software revision that resolved the low-minute-volume default issue. (Image courtesy of Mindray.)

Portable Radiography Design Improvements

- **ECRI's Finding** – While evaluating a portable radiography system we noted that, when the grid was used, the detector's status indicator is obscured. While the system will not allow an exposure if the detector is not ready, the operator will have to determine the problem and will likely have to reposition the patient unnecessarily.
- **End Result** – The manufacturer has updated the design, so the status indicator is no longer obscured by the grid and patient care improved.



Importance of Device Evaluations

- Improve patient safety and saves lives
- Makes product safer by modification of product
- Highlight issues that disrupt standard of care
- Guidance on selection and purchasing