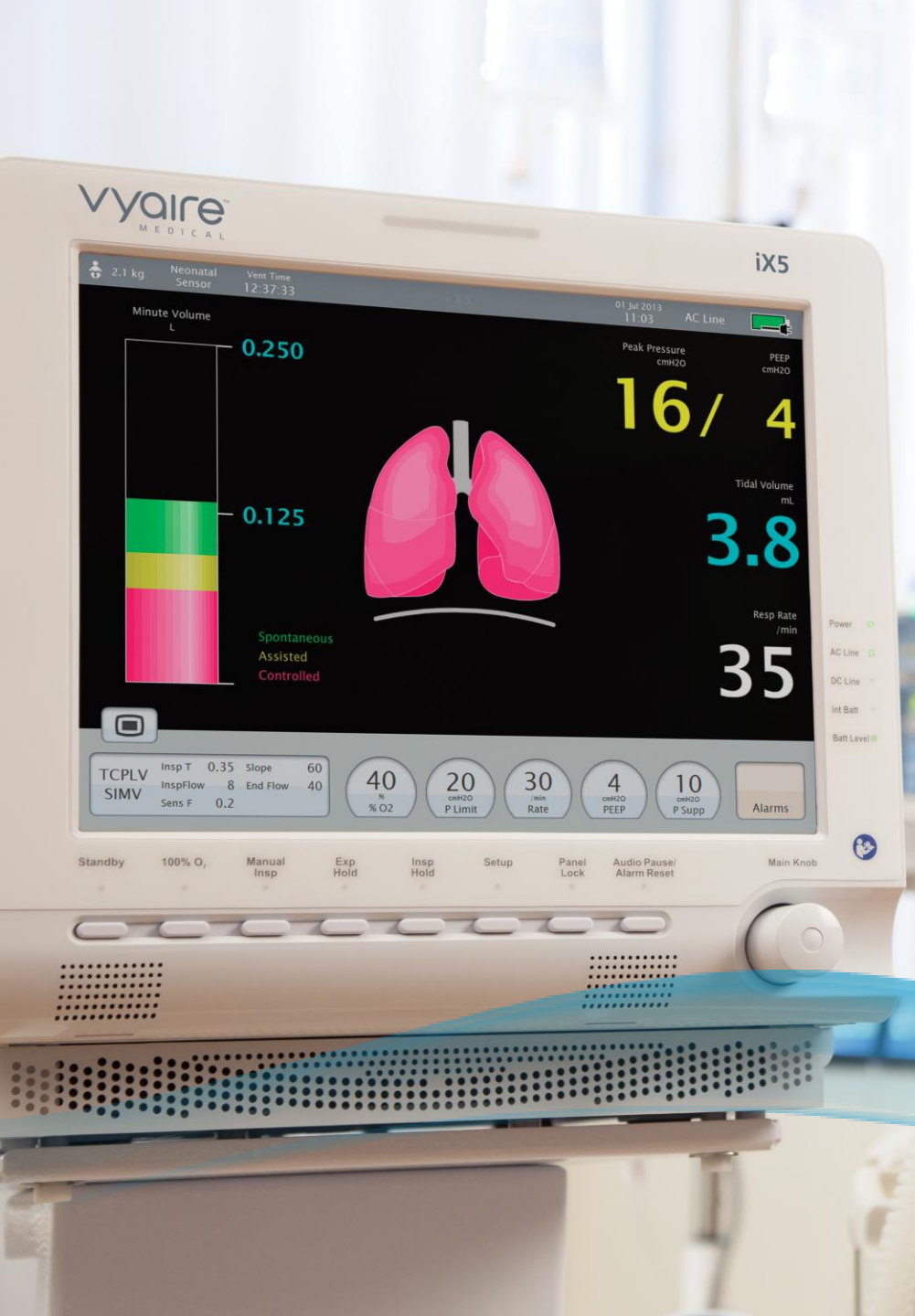

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iX5™ Ventilator

- **Overview**
- **Usability**
- **Safety**
- **Neonatology**
- **Lung Protection**

Product Overview

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iX5 new hardware

- RoHS
  - European regulation for restriction of dangerous substances, to protect the environment for future generations
- REACH
  - Prevent the human health against chemical substances that should cause cancer, respiratory diseases, etc.
- 4th edition
  - Adjusting parameters
- Profiles
  - International regulation that represents a shift in the philosophy of Medical Devices, with a greater emphasis on Risk Management and Essential Performance requirements (for software and hardware) and also introduces the evaluation of the entire development process

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Multi-purpose ventilation

Neonatal, Pediatric and Adult care areas – Invasive and non-invasive ventilation

- Usability in superior level including ClearView™ screen – cognitive load reduction
- Advanced alarm management – easy to identify high priority events
- Neonatal capabilities including: TCPL and VG (invasive); nCPAP and Biphasic (non invasive)
- Infant Flow LP compatibility
- Nebulization: synchronized with FiO2 and volume compensation
- TGI (Tracheal Gas Insufflation)
- Slow Flow (Slow PV) Maneuver
- Low TCO (Total Cost of Ownership):
  - Permanent Paramagnetic O2 sensor
  - Preventive Maintenance of less than USD 200 per year (parts only)

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Usability

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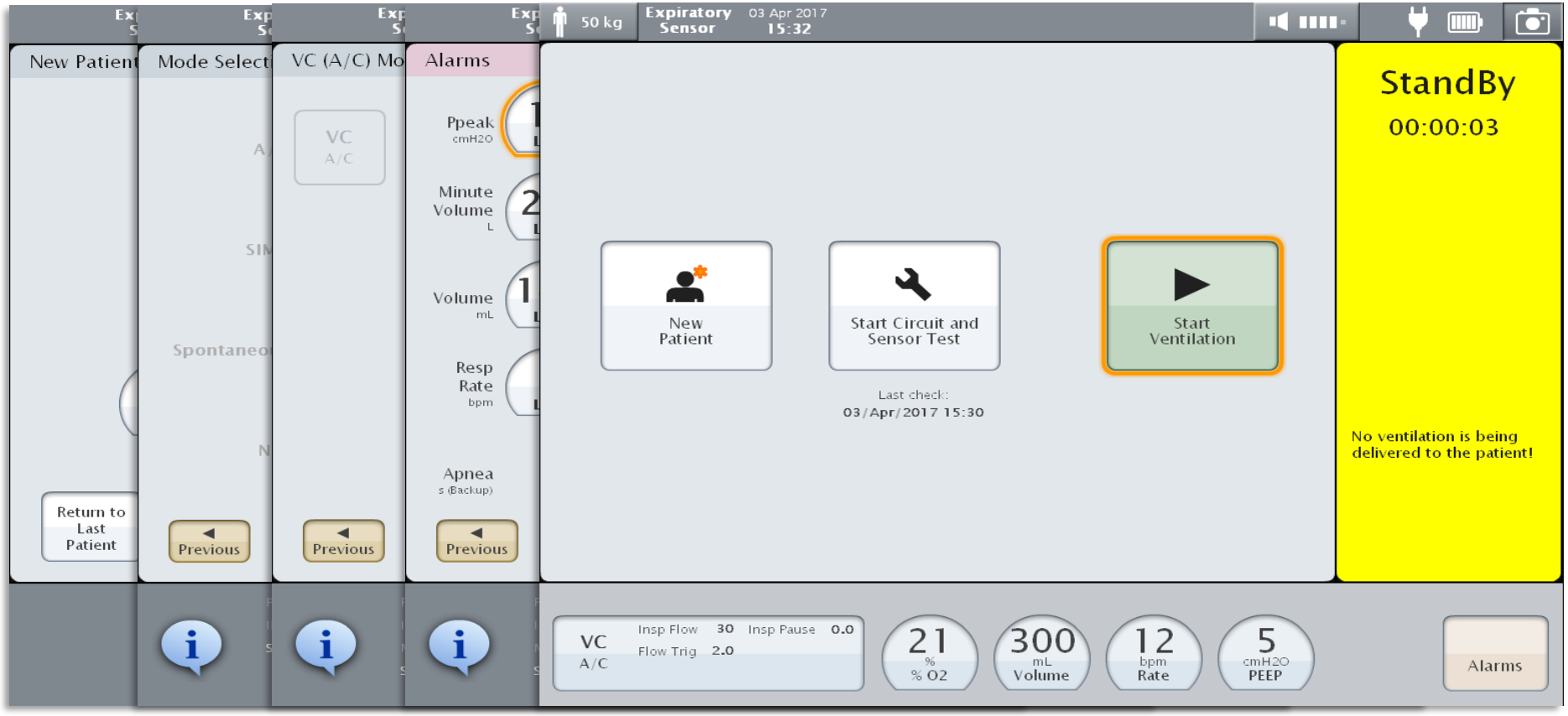
Usability

Easy setup in 5 steps



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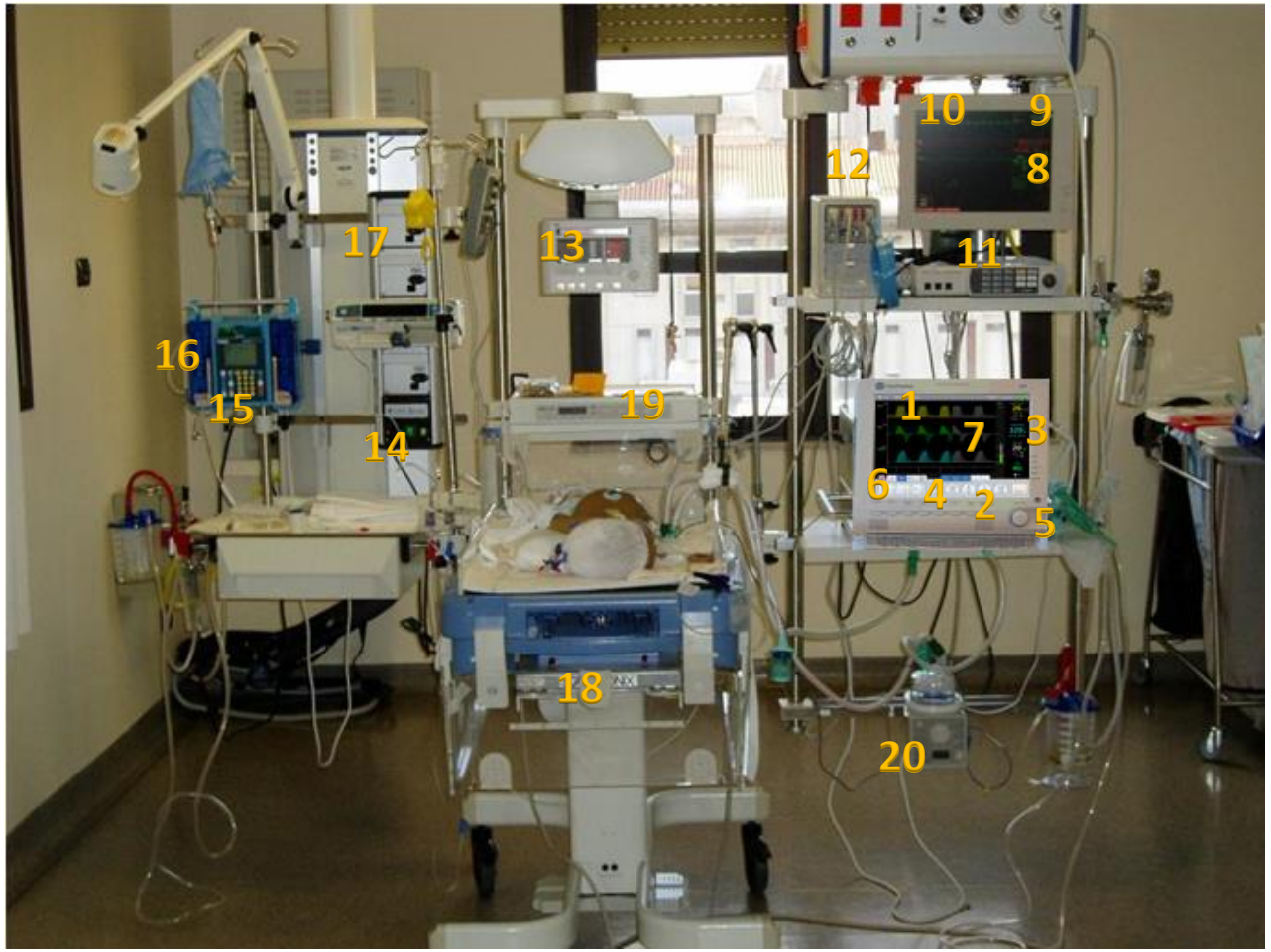
Usability

Cognitive load



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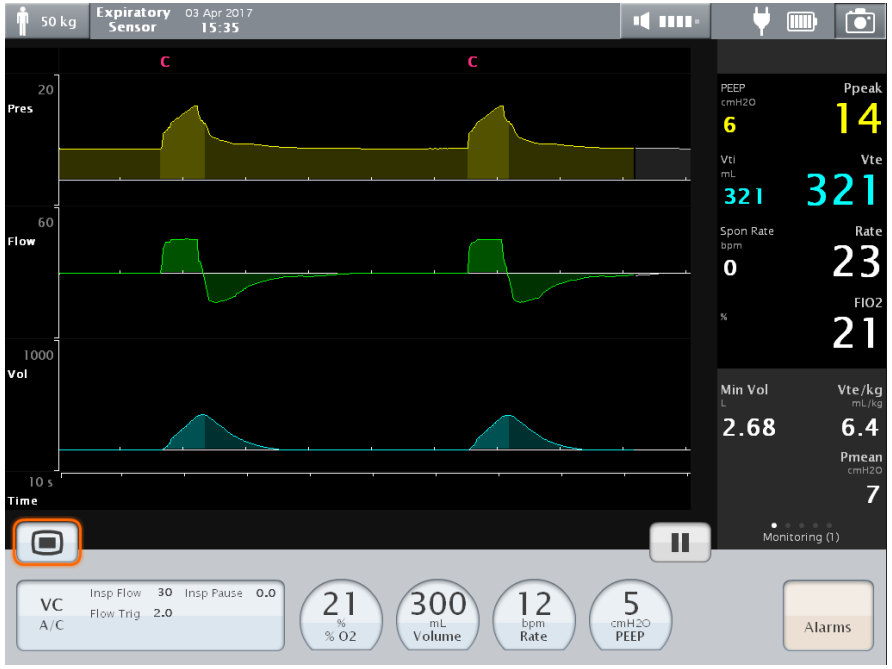
Usability

Main interface & ClearView™

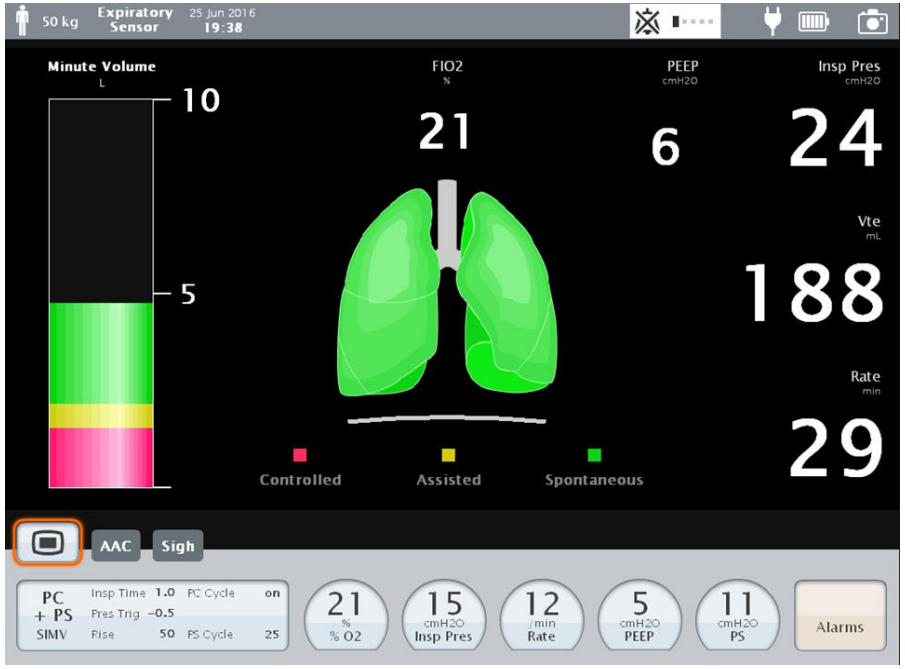
Main Interface

Critical patient's information – ideal visualization when interacting with device



ClearView™

Simplified visualization helps the user to process the information in a fast way at a distance



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Safety

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Alarm related hazards

According to the ECRI institute, from the top 10 health technology hazards, the alarm related ones have been figuring in the top of the list for years.

TOP 10 HEALTH TECHNOLOGY HAZARDS FOR 2013

EACH YEAR, ADVANCES IN HEALTH TECHNOLOGIES PROVIDE NEW WAYS TO IMPROVE PATIENT CARE. BUT SOME ALSO CREATE NEW OPPORTUNITIES FOR HARM. THUS, HOSPITALS MUST REGULARLY EXAMINE THEIR HAZARD-CONTROL PRIORITIES IN ORDER TO REMAIN FOCUSED ON THE MOST PRESSING RISKS. OUR ANNUAL LIST WILL HELP YOU MAKE SMART DECISIONS ABOUT YOUR SAFETY INITIATIVES IN THE COMING YEAR.

1. Alarm Hazards

Medical device alarms perform an essential patient safety function. Physiologic monitors, medical telemetry units, ventilators, infusion pumps, dialysis units, and a host of other medical devices sound alarms or issue alerts to warn caregivers of potential problems with the patient. The sheer number of alarms, however, has itself become problematic. The result is that caregivers can become overwhelmed trying to respond to the alarms, or they can become desensitized, which can lead to missed alarms or delayed response, placing patients at risk.

THE LIST FOR 2014

1. Alarm hazards
2. Infusion pump medication errors
3. CT radiation exposures in pediatric patients
4. Data integrity failures in EHRs and other health IT systems

www.ecri.org

THE LIST FOR 2016

1. Inadequate Cleaning of Flexible Endoscopes before Disinfection Can Spread Deadly Pathogens
2. Missed Alarms Can Have Fatal Consequences
3. Failure to Effectively Monitor Postoperative Patients for Opioid-Induced Respiratory
4. Inadequate
May Put Pa

The List for 2017

1. Infusion Errors Can Be Deadly If Simple Safety Steps Are Overlooked
2. Inadequate Cleaning of Complex Reusable Instruments Can Lead to Infections
3. Missed Ventilator Alarms Can Lead to Patient Harm
4. Undetected Opioid-Induced Respiratory Depression

The List for 2015

1. Alarm Hazards: Inadequate Alarm Configuration Policies and Practices
2. Data Integrity: Incorrect or Missing Data in EHRs and Other Health IT Systems
3. Mix-Up of IV Lines Leading
4. Inadequate Reprocessing of E

The List for 2018

1. Ransomware and Other Cybersecurity Threats to
2. Endoscope Reprocessing Failures Continue to Ex
3. Mattresses and Covers May Be Infected by Body Fluids and Microbiological Contaminants
4. Missed Alarms May Result from Inappropriately Configured Secondary Notification Devices and Systems

The List for 2019

1. Hackers Can Exploit Remote Access to Systems, Disrupting Healthcare Operations
2. "Clean" Mattresses Can Ooze Body Fluids onto Patients
3. Retained Sponges Persist as a Surgical Complication Despite Manual Counts
4. Improperly Set Ventilator Alarms Put Patients at Risk for Hypoxic Brain Injury or Death

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Alarm related hazards

The Joint Commission

Issue 25 - February 26, 2002

Preventing ventilator-related deaths and injuries

As of January 2002, the Joint Commission has reviewed 23 reports of deaths or injuries related to long term ventilation--19 events resulted in death and four in coma. Of the 23 cases, 65 percent were related to the malfunction or misuse of an alarm or an inadequate alarm; 52 percent were related to a tubing disconnect; and 26 percent were related to dislodged airway tube. A small percentage of the cases were related to an incorrect tubing connection or wrong ventilator setting. None of the cases were related to ventilator malfunctions. As the percentages indicate, ventilator-related deaths and injuries are often related to multiple failures that lead to negative outcomes. The majority of the cases occurred in hospital Intensive Care Units (ICUs), followed by long term care facilities and hospital chronic ventilator units.

- Third party device evaluators are focusing on usability and alarm hazards to help support patient safety

Healthcare Risk Control

Executive Summary
Critical Care 5

ECRI Institute
The Discipline of Science. The Integrity of Independence.

► VOLUME 4
May 2008

Table. Clinical-Alarm Reports Involving Patient Death

Description	Total Cases	Percent of Total (%)
Device, unpredictable failure	8	3.4
Device, deterioration	2	0.8
Environment, external	1	0.4
Operator error, education/ training	58	24.5
Operator error, distracted	67	28.3
Patient, active	3	1.3
Not analyzable	98	41.4
Total	237	100.0

Source: American College of Clinical Engineering Healthcare Technology Foundation (AHTF). Impact of clinical alarms on patient safety [white paper online]. 2006 [cited 2008 Jan 15]. Available from Internet: http://www.acce-htf.org/White%20Paper.pdf.

- Recent studies show that of 23 injury and death reports associated with mechanical ventilation, 65% were related to alarms

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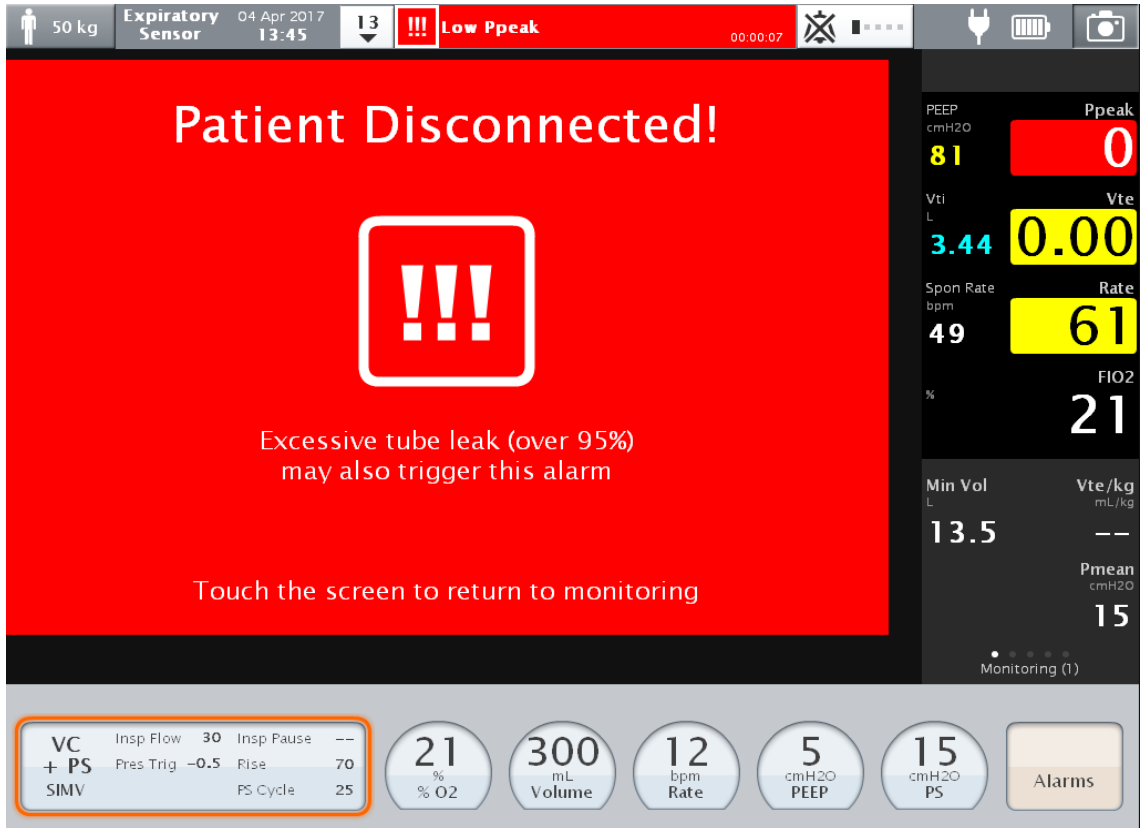
Safety

High priority alarm



- Problems are often associated with desensitization to alarms and alarm fatigue, delaying responses.
- iX5 presents prominent visual and audible alarms for high priority events so clinicians can easily identify an alarm that requires their immediate attention.

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CONVENTIONAL
or
NON INVASIVE?

WHAT ABOUT BOTH?

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Beyond conventional

Conventional	NIV	Advanced

Beyond conventional

Conventional	NIV	Advanced
PCV		
TCPL		
SIMV		
APRV		
PS		
CPAP		

Beyond conventional

Conventional	NIV	Advanced
	nCPAP nTCPL	

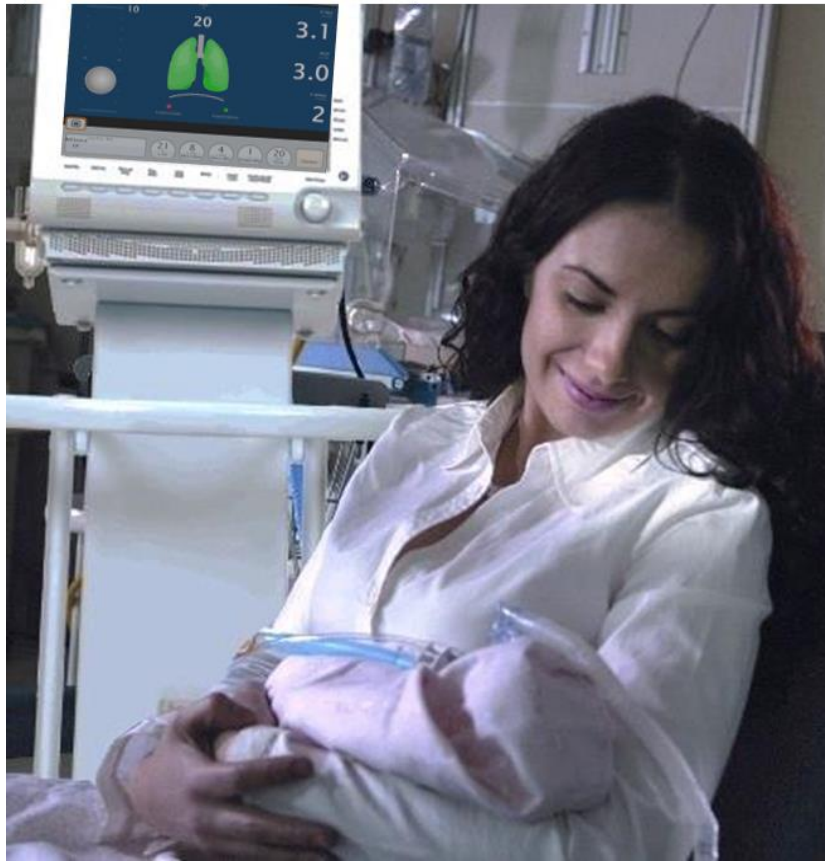
Beyond conventional

Conventional	NIV	Advanced
		IF LP modes
		Volume Guarantee

Benefits of NIV

The American Academy of Pediatrics and the European Consensus Guidelines on the Management of Neonatal Respiratory Distress Syndrome each recommend the early use of continuous positive airway pressure (CPAP).[1,2]

- NCPAP therapy when compared with CV may:
  - Significantly increase the weight[3]
  - Increase BINS (Bayley Infant Neurodevelopmental Screener) scores[3]
  - Decrease the incidence of ROP (Retinopathy of Prematurity) and Chronic Lung Disease (CLD)[3]
- Periodic increases of baseline CPAP (Bi-Level) may:
  - Stimulate respiratory drive[4]
  - Recruit more alveoli, potentially maintaining a stable Functional Residual Capacity (FRC)[4]
  - Stimulate surfactant production[4]



1 SUPPORT Study Group of the Eunice Kennedy Shriver NICHD Neonatal Research Network. Early CPAP versus surfactant in extremely preterm infants. N Engl J Med, May 2010, 362(21):1970–1979. /// 2 Sweet, D., et al. European Consensus Guidelines on the Management of Neonatal Respiratory Distress Syndrome in Preterm Infants, 2013 Update. Neonatology, 2013, 103:353-368. /// 3. Flesher SL, Domanico RS. Improved growth and development in premature infants with nasal continuous airway pressure; 2014. /// 4 Deakins, K. Non-invasive respiratory support in the neonatal intensive care unit. Clinical Foundations. 2009; 1-11.

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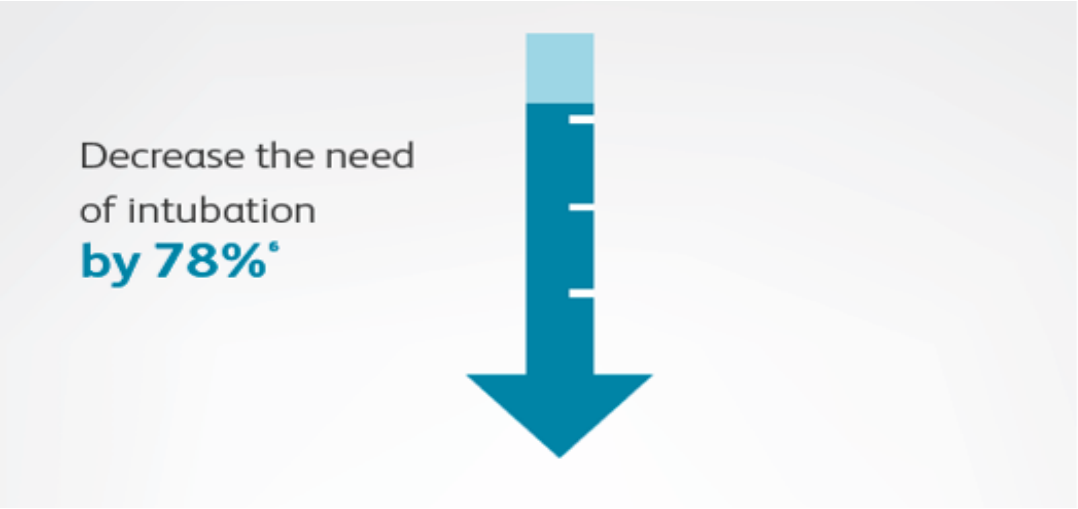
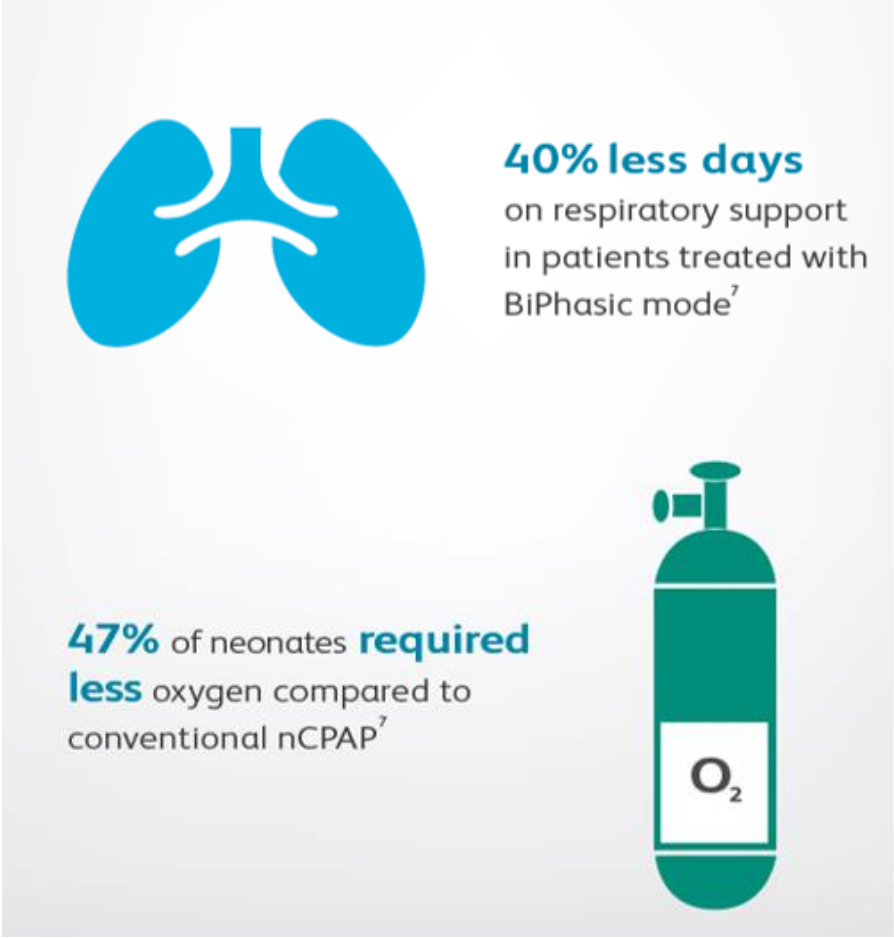
Infant Flow™ LP does even better





6. Swietlinski J., Pediatric Critical Care Medicine 2007;8(2):109–114. /// 7 Lista G., et al. Nasal CPAP vs. bilevel nasal CPAP in preterms with RDS: A randomized control study. Arch Dis Child Fetal Neonatal Ed, 2010;95:F85-F89.

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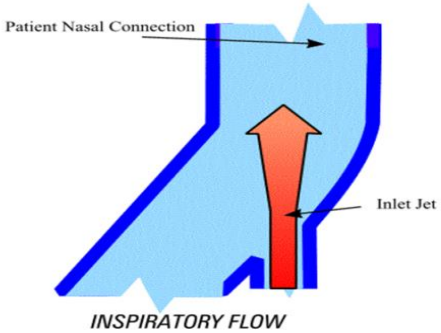
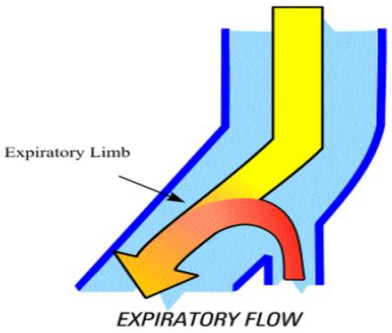
How does Infant Flow LP work





Inspiratory Flow

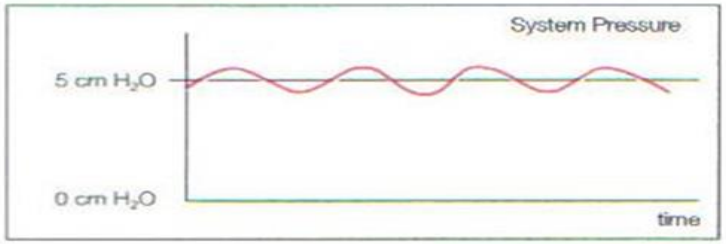
The flow provided by the Infant Flow™ nCPAP Driver is accelerated in the twin injector nozzles of the nCPAP Generator. When the patient makes a spontaneous inspiratory breathing effort, the Generator provides assistance by converting the kinetic energy of the flow to pressure energy, thereby reducing the added work of breathing of the infant.

Expiratory Flow

When the infant makes a spontaneous expiratory breathing effort, they apply pressure at the nasal attachment of the nCPAP Generator. This causes the flow to flip round and leave the Generator via the expiratory limb. CPAP is maintained at the nasal connection throughout. When the expiratory breathing effort stops, the flow instantly flips back to the inspiratory position.

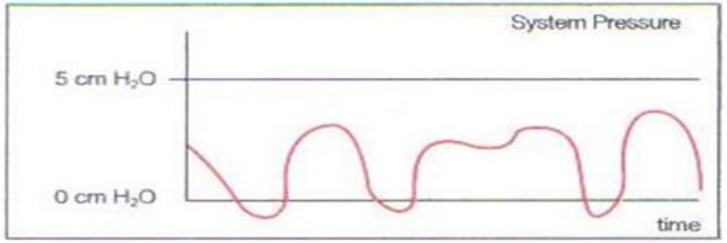
Infant Flow™

8Lts Flow, 5cm H_2O



Conventional CPAP

17Lts Flow, 5cm H_2O with 0.5 Lts reservoir bag



Patient born after 25 weeks gestation. Post natal age 5 weeks. Weight 840g. G.Moa/K.Nilsson.

The fluidic CPAP produces a very stable CPAP pressure compared to conventional CPAP.[1]

1 Moa, G., Nilsson, K. A new device for administration of nasal continuous airway pressure in the newborn: an experimental study. Critical Care Med. 1988; 16:1238-1242.

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The best interfaces…

… to prevent nasal injuries

- Types of nasal injuries[1,2]
  - Nasal excoriation
  - Scarring
  - Pressure necrosis
  - Septal distortion
- Leading factors[1,2]
  - Tight fitting interfaces
  - Frequency of assessment /adjustment
  - Duration of nCPAP
  - nCPAP level required
  - Birth weight

1 Deakins, K. Non-invasive respiratory support in the neonatal intensive care unit. Clinical Foundations. 2009; 1-11 /// 2. Squires, A., Hyndman, M. Prevention of nasal injuries secondary to NCPAP application in ELBW infants. Neonatal Network. 2009; 28(1):13-27.

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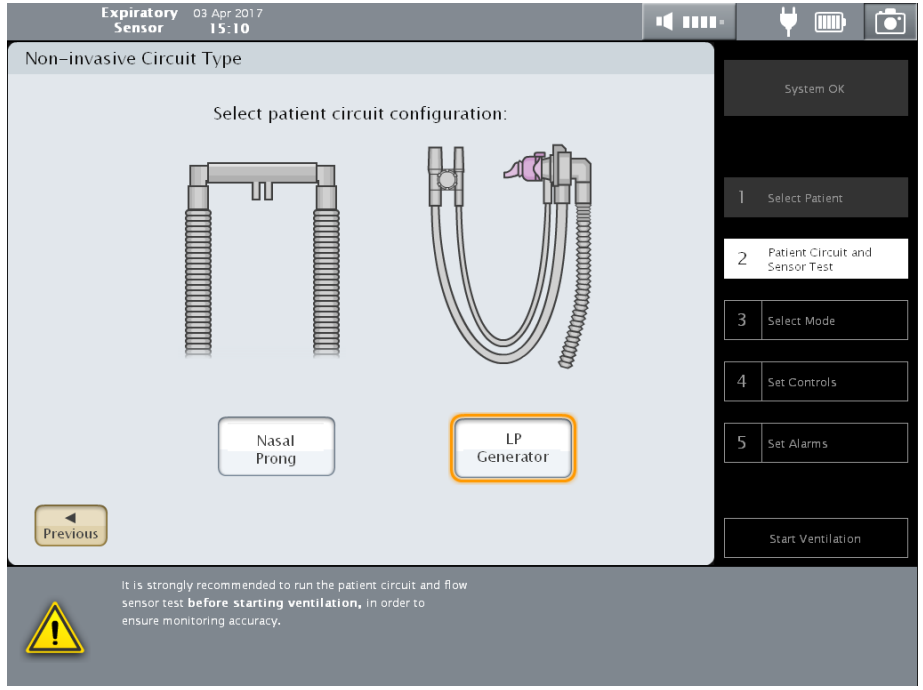
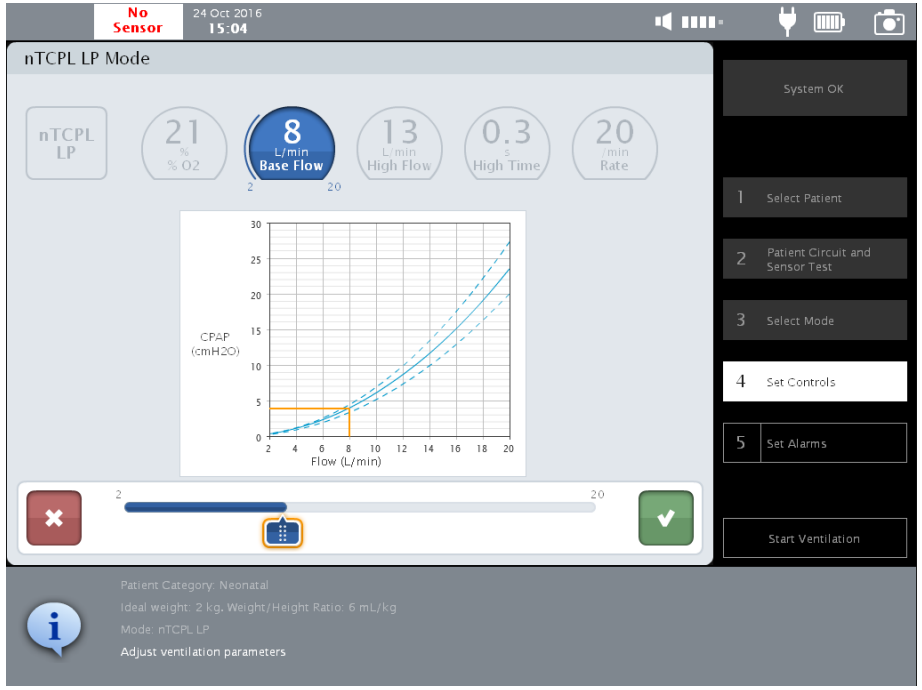
iX5 delivers both applications

- NIV with conventional nasal prong or Infant Flow LP option



- Setup similar to the SiPAP system
- Fast learning curve for SiPAP users and new users



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IF NIV FAILS?

SAME DEVICE, INVASIVE MODES

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Volume Guarantee

Mechanical ventilation is required to manage neonates with severe respiratory failure.

Pressure-limited ventilation (PLV), delivering a fixed-peak inflating pressure (PIP), has traditionally been used to control the arterial carbon dioxide ($PaCO_2$). During PLV the tidal volume (V_T) fluctuates widely due to the baby's breathing, changes in lung mechanics and variable endotracheal tube (ETT) leak.[1]

As high V_T (volutrauma), and not pressure per se, causes lung injury, controlling V_T rather than PIP is a logical strategy for ventilating preterm infants.[1]

1. C Klingenberg; K I Wheeler; P G Davis; C J Morley. A Practical Guide to Neonatal Volume Guarantee Ventilation. J Perinatol. 2011;31(9):575-585.

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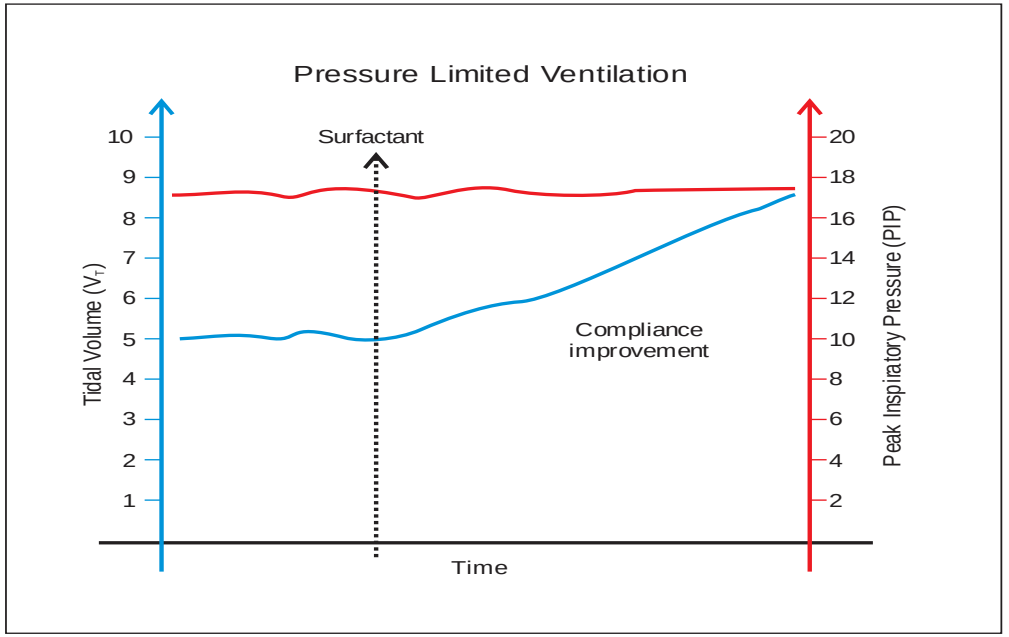

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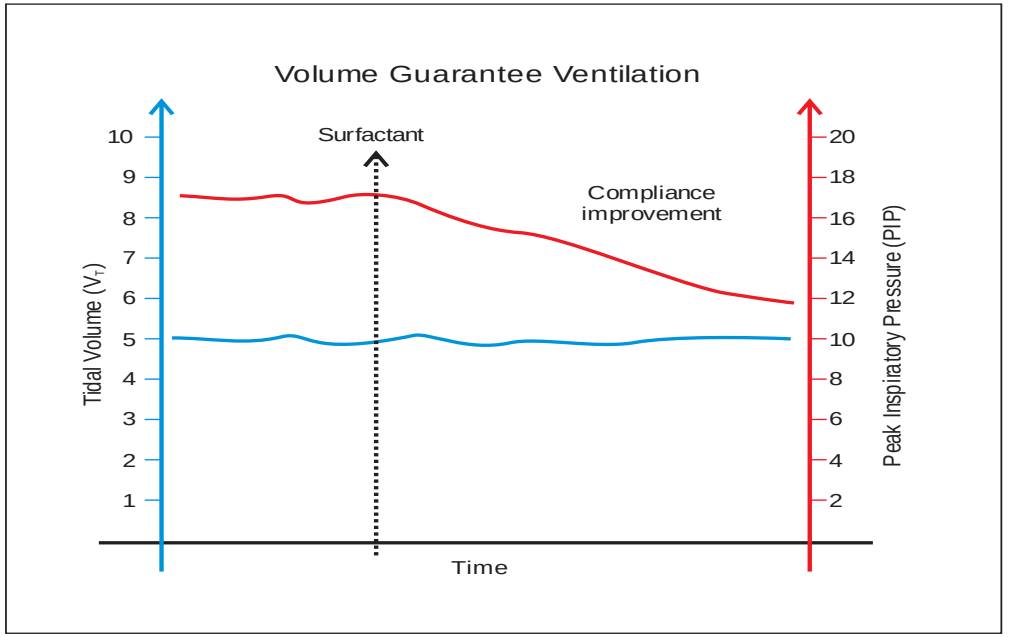

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High Performance Neonatal Ventilator

- Provides best NCPAP with Infant Flow LP
  - Reduces work of breathing
  - Might prevent intubation
- Biphasic adds additional functionality
  - Reduces number of apneas and desaturations
  - Reduces number of re-intubations
- But if intubation is needed…
  - Modern modes available including VG

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Lung Protection

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Effect of external conventional nebulization in the ventilation

Ventilator Settings

Tidal Volume	Breath Rate	I:E Ratio
200 mL	18 bpm	1:2

FiO2 adjusted
21%

Nebulization Settings

Neb Flow at 100% O2
6 L/m

Direct Effect

Resultant Tidal Volume	Resultant FiO2
311 mL	49%

Waste of O2 and medication with external nebulization

O2 not delivered to the patient during the Exp. Time per hour	240 L

Medication not delivered to patient during the Exp. Time (% of total)	67%

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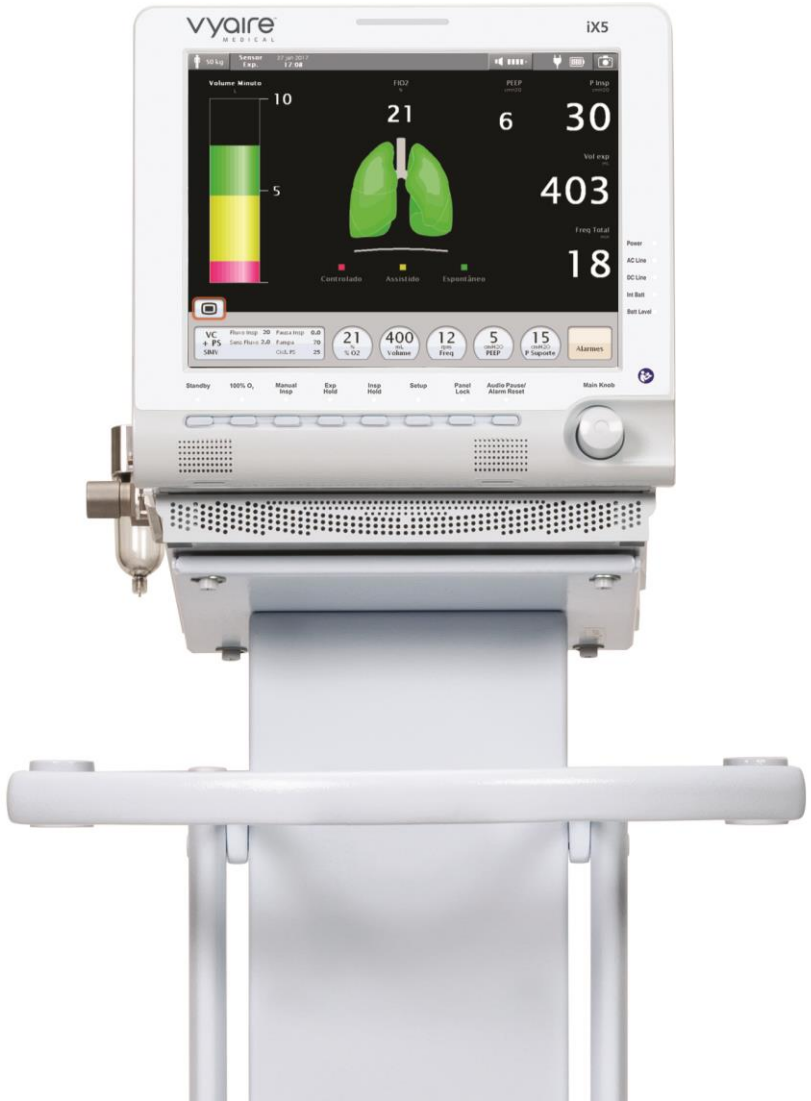
Nebulization on iX5



- Synchronized nebulization flow with the Inspiratory phase saves gas and medication
- Mixed nebulization flow doesn’t affect the FiO^2
- Volume compensation system doesn’t affect the Tidal Volume delivered

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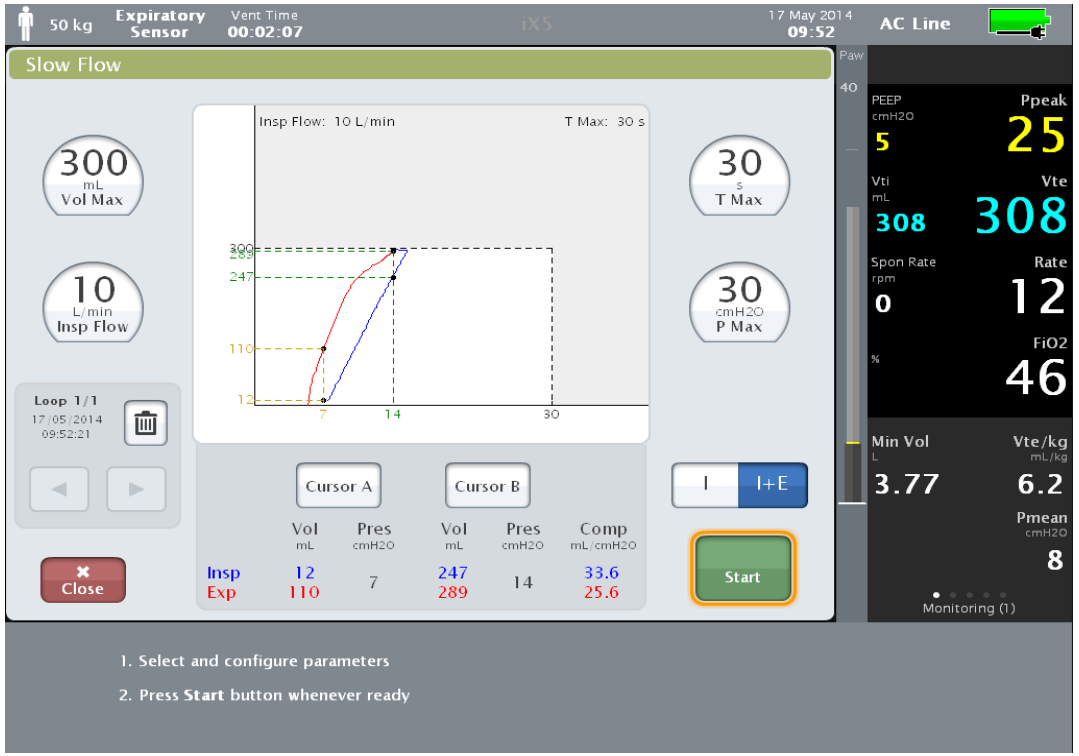
Slow flow maneuver

The Slow Flow could serves as an automatic lung recruitment maneuver and can be used to optimize ventilator settings.

The analysis of the PV loop may be helpful to:

- select the right PEEP level [1,2] to avoid cyclic recruitment and de-recruitment
- adjust inspiratory pressure or tidal volume to avoid over-distention of alveoli[1,2]



1. Hess D. Recruitment Maneuvers and PEEP Titration. Respiratory Care. 2015 Nov /// 2. Takeuchi M, Goddon S, Dolhnikoff M, Shimaoka M, Hess D, Amato M, Kacmarek R. Set Positive End-expiratory Pressure during Protective Ventilation Affects Lung Injury. Anesthesiology, V 97, No 3, Sep 2002

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Slide 24	*6. Swietlinski J., Pediatric Critical Care Medicine 2007;8(2):109–114. /// 7 Lista G., et al. Nasal CPAP vs. bilevel nasal CPAP in preterms with RDS: A randomized control study. Arch Dis Child Fetal Neonatal Ed, 2010;95:F85-F89.*
Slide 25	*1 Moa, G., Nilsson, K. A new device for administration of nasal continuous airway pressure in the newborn: an experimental study. Critical Care Med. 1988; 16:1238-1242.*
Slide 26	*1 Deakins, K. Non-invasive respiratory support in the neonatal intensive care unit. Clinical Foundations. 2009; 1-11 /// 2. Squires, A., Hyndman, M. Prevention of nasal injuries secondary to NCPAP application in ELBW infants. Neonatal Network. 2009; 28(1):13-27.*
Slides 29, 30 and 31	*1. C Klingenberg; K I Wheeler; P G Davis; C J Morley. A Practical Guide to Neonatal Volume Guarantee Ventilation. J Perinatol. 2011;31(9):575-585.*
Slide 37	*1. Hess D. Recruitment Maneuvers and PEEP Titration. Respiratory Care. 2015 Nov /// 2. Takeuchi M, Goddon S, Dolhnikoff M, Shimaoka M, Hess D, Amato M, Kacmarek R. Set Positive End-expiratory Pressure during Protective Ventilation Affects Lung Injury. Anesthesiology, V 97, No 3, Sep 2002*

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REFERENCES

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For Global distribution. The iX5 is not available for sale in the US and may not be available in every region, please contact a Vyaire representative for availability.

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