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Advanced Medical Technology Training and the APSF Recommendations: *Perspectives from my Vantage Point*

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Why are we here?

Improve patient care by ...

- Better utilizing advanced device capabilities
- Reducing equipment misuse
- Decreasing stress and cognitive burden on anesthesia caregivers
- Challenge is not “what” to do or “why” to do it, but “how” to effect change

Observations from MGH

- New anesthesia faculty are trained by biomed (clinical) engineers and monitoring nurses
- Often hire MGH-trained fellows, residents – that helps reduce knowledge gap
- Entire department has access to intermittent hands on “skill sessions” – e.g. Belmont Rapid Infuser, Infusion pumps, Hemocue
- Expert help is readily available (staff, anesthesia technicians, BME/Clinical Eng)

MGH - challenges

- Not enough time/opportunity to learn
- Not possible for everyone to participate in skill sessions
- If online – when?
 - Personal time?
 - Adequate without hands on?
 - Taken seriously or just “check the box”?

Recommendation #1

Reduce the need for lengthy training

- Through better design and monitoring device use/performance
- Example - AED concept. Once device has two modes of operation:
 - “Public” mode with voice assist
 - “Expert” mode with manual control

Will training alone ever be sufficient?

Ideal state – minimal to no training should be required

Standards recognize the complexity of modern equipment:

Symbol on the medical device
that means “read the manual”



“Caution” per ISO 7000-0434A

New symbol on the medical
device



Per ISO 7010-M002

Mandatory action safety sign: (It is a mandatory action to) Refer to instruction manual/booklet
Note: on me equipment “Follow instructions for use”

*How can we read instruction manuals that we can't find?
(Do YOU still read manuals for new consumer electronics?)*

Example: Belmont Rapid Infuser

- Pelvic fracture at 0300
- Belmont (or equivalent) could be life-saving
- Do I remember how to set it up?



*NB: This is an example of the need for better access to device information.
It is NOT intended to single-out Belmont or any manufacturer.*

I would start with the Belmont web site

[Home](#)[Products](#)[About Us](#)[News / Events](#)[Studies](#)[Contact Us](#)[Product Testimonials](#)[Scientific Studies](#)

The Belmont Rapid Infuser

The Belmont® Rapid Infuser has become the standard of care for rapid blood transfusion, by allowing precise control of intravascular volume while preventing hypothermia, air embolus and vessel trauma. The Belmont® Rapid Infuser uses patented electromagnetic induction heating to heat to target temperature in a single pass while intelligent software monitors and controls infusion. The touch screen allows for flow rate infusion from 2.5 to 1000ml/min with the touch of a button. The screen continuously displays total volume infused, infusion rate, fluid temperature and system pressure. The disposable set is designed for easy set up and active air evacuation.

There are more than 3,000 systems in use in more than 30 countries throughout the world. Widely used in major medical centers, community hospitals, and children's hospitals, The Belmont® Rapid Infuser is a proven life saver.

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First Name*

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Title

Institution*

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Address

City*

State

Zip

Country*

Deployed Military? ☐

[CLOSE](#)

Belme

Still looking ...

[PDF] [The Belmont Fluid Management System FMS2000 Operator's ...](#)
www.sh.lsuhs.edu/policies/policy_manuals_via_ms.../Belmont.pdf ▾

Belmont FMS2000 should not be used where **rapid** infusion is This chapter explains the procedure for **setting up** and initiating safe and effective operation.

[PDF] [Belmont Instrument Corporation - gd medical AG](#)
www.gdmedical.ch/.../Belmont%20Rapid%20Infuser_PP%20Presentatio... ▾

Belmont Rapid. Infuser ... **Setup.** Accessories. Specs. Features. Overview. ▫ Controlled Rapid Infusion ... **UP** and DOWN infuses from 2.5 to 750 ml/min.

[PDF] [The Belmont Rapid Infuser](#)
anesthesiology.unm.edu/_Docs/Resources/Belmont.pdf ▾

The **Belmont rapid** infuser is an induction heated, roller-pump driven instrument for ... Color coded **setup** ... Powering **Up**: Purge, Prime then Pump. Primero:.

belmont rapid infuser



Upload



Next, I try
YouTube ...
Without success

Video does not
Depict device setup



Dr. Herzlinger's Rapid Infuser



BelmontInstrument · 5 videos

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Uploaded on May 24, 2010

Dr. George Herzlinger talks about his product, the Belmont Rapid Infuser (FMS 2000)

Trauma Anesthesia

Avoiding the Lethal Triad

ABOUT

READ THIS FIRST

Posted by n6949u on February 22, 2012

Belmont Rapid Infuser

Posted in: Belmont Rapid Infuser. Tagged: Belmont, Belmont instructions, CNN death, Rapid Infuser, Transfusion.

Leave a Comment

Click on this link to view the Belmont instructional video:

http://spinalist.debunk-it.org/FMS%20Instructional%20Video_01_1.mp4

Click on this link to view the Belmont set up PDF:

<http://spinalist.debunk-it.org/Belmont%20Rapid%20Infuser%20-%20setup%20and%20use.pdf>

I have had problems loading the Belmont Rapid Infuser. The representative came to our institution and gave me tips on how to properly load the cassette and prime the infuser.

This is what I gleaned:

Before loading the cassette, close all clamps tightly and

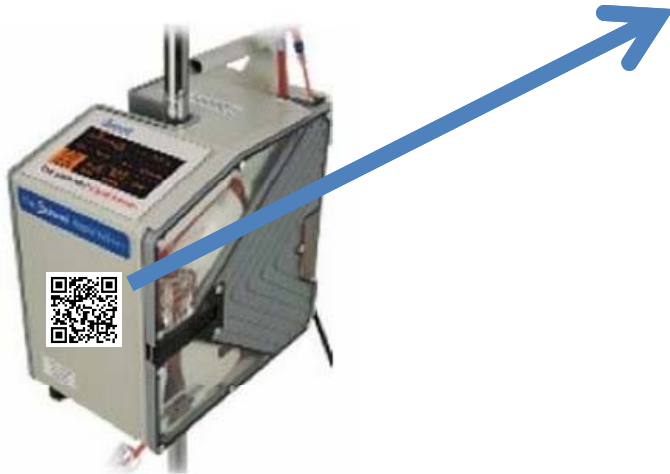
Be certain there are no kinks or twists here in the tubing that will

The need to educate users is a challenge for manufacturers and users:

"I have had problems loading the Belmont ..."
"rep came to our institution and gave me tips on how to properly load the cassette ..."

What if the device or cassette package had a “QR Code” that linked to information?

Audience: Read this QR code
with your smartphone now



Note – there are many free smartphone apps to read or create QR codes

What if QR code showed this?

FMS 2000 Fluid Management System - Belmont Rapid Infuser - setup and use.pdf

spinalist.debunk-it.org/Belmont Rapid Infuser - setup and use.pdf

qr code

This PDF document might not be displayed correctly. Open With Different Viewer


Page: 18 of 44 Automatic Zoom

Setup - Loading the Disposable: Step #2

- Features
- Setup
- Accessories
- Specs

- Snap the reservoir chamber into the reservoir support
- Load interlock block into air detector with the arrow pointing into the machine
- Thread pump tubing over pump head

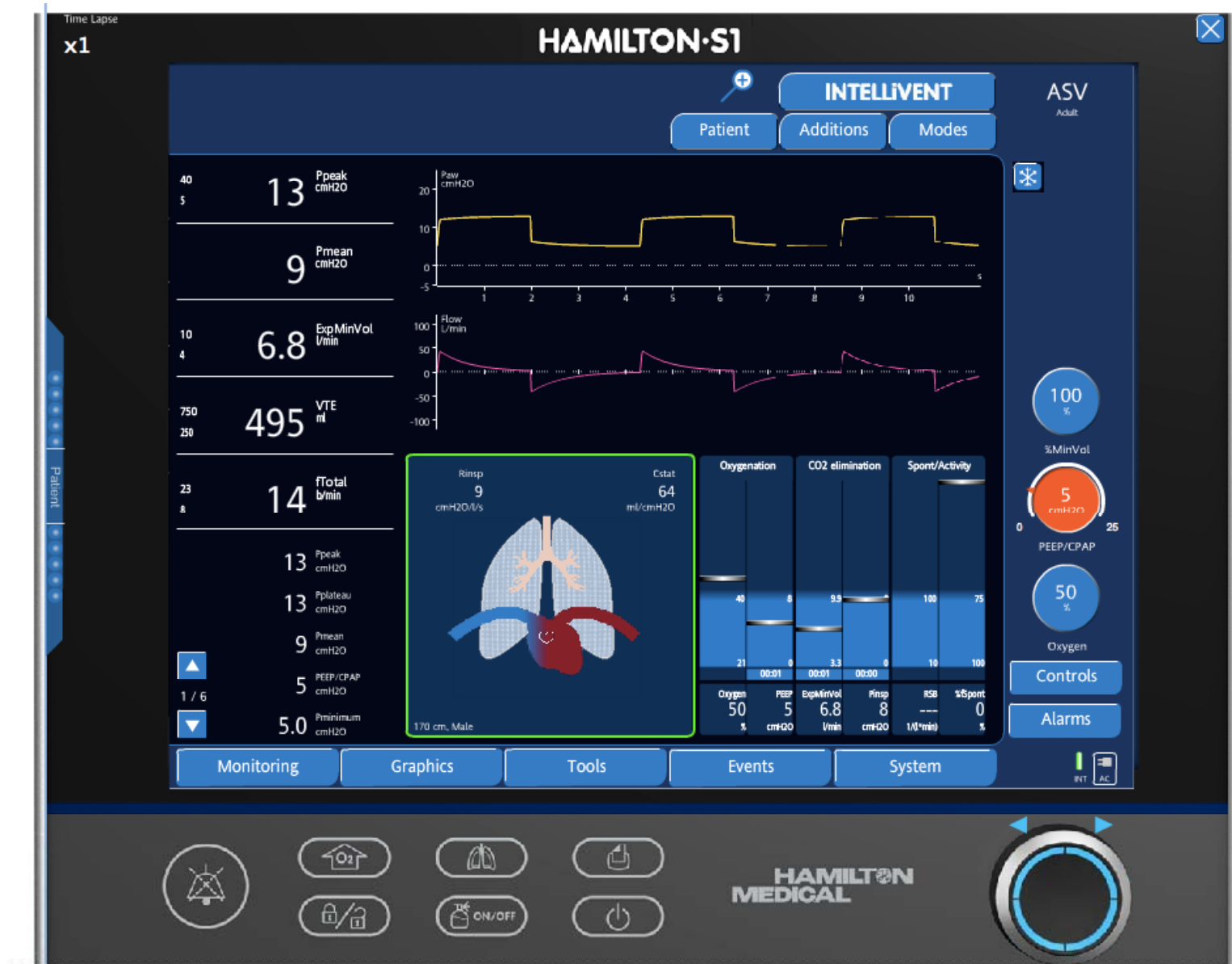
Arrow imprinted top of block



<http://spinalist.debunk-it.org/Belmont%20Rapid%20Infuser%20-%20setup%20and%20use.pdf>

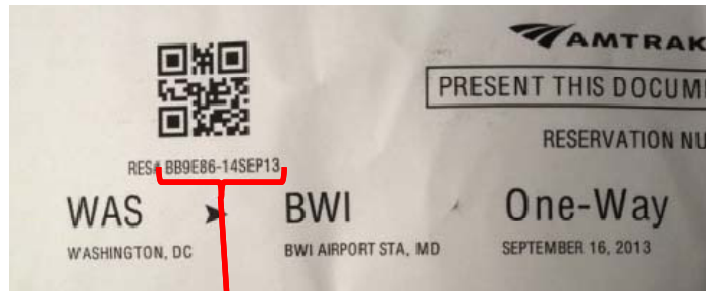
Or this ...

Interactive Ventilator Simulator (www)



- Invented 1994
- ISO standard
- Fast readability

QR Codes are widely used



QR App



Ticket number
and date



Recommendation #2

Improve access to training material

- Consider QR Code or similar approach for point-of-care access to key information
 - Point-of-care specific instructions
 - Informational web site
 - Current/updated warnings/cautions/recalls
 - Form to report problem, ask questions

Recommendation #3

Improve the usability of training material

- Recognize learning styles or “types” and diverse device features to be learned. Consider:
 1. Static Documents
 2. Videos/animations
 3. Interactive computer/web animations
 4. Hands-on training fairs
 5. Critical device setup information
 6. Devices can have “training” mode

Recognize that device are used within a system, not in isolation
Manufacturers and regulators must understand the use environment



Recommendation #4: A system perspective is needed



Automated data logging

How will we know if training was effective?

Was training the appropriate approach vs improved design?

- How can we identify equipment design improvement opportunities (use errors)?
- What if we could record/monitor device(s) in use
 - Button presses
 - Find confusing menus/submenus
 - Capture other contextual information from the SYSTEM of devices + patient
 - *Concept of black box recorder or system data logger
 - more than device-level logging]



*See standard ASTM F2761-09, and project on ICE data logger funded by DoD
http://mdpnp.org/MD_PnP_Program_DataLogger.html

Manual reporting of device/system issues:

Documenting the gaps and opportunities:
Clinical Scenario Repository Project at MGH

- **Clinical Scenario:** A brief description of a clinical situation or event. The purpose is to inform of the need for development of technical solutions.
- **Clinical Scenario Repository:** A web portal to allow clinicians, clinical engineers and other users to enter, revise and annotate clinical scenarios.

A place to document and share these scenarios will help to identify clinical and technical challenges, address healthcare needs to guide improvements in patient safety and quality of healthcare delivery.

Development supported by DoD – pilot go live in 2013.
Check www.mdnpn.org for updated info.

Manual reporting of device/system issues:

Scenario Unique ID: 198
SAVED

Background **Hazards** **Environments** **Equipment** **Proposed Solution**

Clinicians & Clinical Environments

Clinicians Involved:

- Chief Nurse
- CNA - Certified Nurse Assistant
- Critical Care Nurse
- CRNA - Certified Registered Nurse Asst
- HHN - Home Health Nurse
- Infectious Disease Nurse
- Labor-Delivery Nurse
- LPN - Licensed Practical Nurse
- LVN - Licensed Vocational Nurse
- Neonatologist
- Neurologist
- Nurse
- Nurse Assistant
- Occupational Health Nurse
- ORRN - Operating Room Registered Nurse
- RN - Registered Nurse

- Enter clinicians, clinical environments and equipment.
- Choose from a preselected array of options, or input your own.

Background **Hazards** **Environments** **Equipment** **Proposed Solution** **Benefits & Risks**

Equipment Utilized

Device Type	Manufacturer	Model	Rosetta ID	
PCA	Draegger			<input type="button" value="Delete"/>
				<input type="button" value="Delete"/>

[Add New...](#)

Project information
will be posted on
www.mdnpn.org

Scenario Unique ID: 99

SAVED

Background

Hazards

Environments

Equipment

Proposed Solution

Benefits & Risks

Proposed Solution

A specific solution implementing the Proposed State

Clinical processes required for new system:

[Example](#)

A patient is admitted into a non-acute care unit of the hospital. At the time of admission, clinical observations and vital signs are collected. The required values for each predetermined assessment are collected by the integrated system, which then calculates a Modified Early Warning System (MEWS) score. The MEWS score consists of respiratory rate, heart rate, systolic blood pressure, level of consciousness or sedation score, temperature, and hourly urine output. A bedside physiological monitor measures blood pressure at least every hour, at approximately the same time that the heart rate and respiration rate are collected. The nurse or clinical assistant performs a

Algorithm Description

SAVED

Background

Hazards

Environments

Equipment

Proposed Solution

Benefits & Risks

Benefits & Risks

Benefits:

[Example](#)

- a) Early warning of deteriorating patient condition.
- b) Decision support for the RRT to facilitate effective treatment.

Risks:

[Example](#)

- a) Poor data quality undermines the effectiveness of the MEWS-calculation algorithm, which could lead to under- or over-alerting of the RRT
- b) Staff dependency on the MEWS-calculation algorithm could lead to a reduction in clinical vigilance.

Submit for Approval

Save For Later

Add a **clinical concept of operations** to show the improvement in safety and effectiveness via a specific solution implementing the proposed state.

Describe the benefits of the proposed process and analyze its potential risks.

Project information will be posted on www.mdnpn.org

Health IT Policy Committee

Health IT Adoption Programs

Federal Advisory Committees (FACAs)

► Health IT Policy Committee

- Health IT Policy Committee Meetings: How to Participate

- Health IT Policy Committee: Recommendations

FDASIA

The Food and Drug Administration Safety Innovation Act (FDASIA) Workgroup is charged with providing expert input on issues and concepts identified by the Food and Drug Administration (FDA), Office of the National Coordinator for Health IT (ONC), and the Federal Communications Commission (FCC) to inform the development of a report on an appropriate, risk-based regulatory framework pertaining to health information technology including mobile medical applications that promotes innovation, protects patient safety, and avoids regulatory duplication.

The FDASIA Workgroup is expected to build on prior work such as the Institute of Medicine (IOM) report, *Health IT and Patient Safety: Building Safer Systems for Better Care* and *ONC's Health IT Patient Safety Action and Surveillance Plan*; FDA's mobile medical applications guidance and *Medical Device Data Systems Rule*; FCC's *National Broadband plan* and other relevant work. Specifically the three agencies will seek input on issues relevant to the report, which include:

<http://www.healthit.gov/policy-researchers-implementers/federal-advisory-committees-facas/fdasia>

http://www.healthit.gov/facas/sites/faca/files/FDASIARRecommendationsDraft030913_v2.pdf slide 41

Recommendation #5

Must align national patient safety interests with the use of clinical technology: consider “HITSA”

- Need - a national approach for evolving the safety and capabilities of healthcare system technologies
- Centralized reporting, analysis, recommendations, shared solutions. Regulatory enforcement + Market incentives
- Health IT Safety Administration or Board (HITSA) modeled on other national reporting initiatives (NHTSA, ASRS, MedSun, NTSB, ASTERD, PSO, etc.):
 - Adverse event reporting (expanded definition)
 - Include FDA Regulated and non-regulated (IT) devices
 - Multi-stakeholder
 - Regulators, clinical representatives, manufacturers, etc.

<http://www.mdnpn.org/HITSA.html>

Summary:

Essential elements for success:

- Data is required on equipment use/*misuse/training effectiveness (ongoing basis)
- Technology should assist in its safe and effective use of devices; reduce training needs; support use information
- Research must be performed using above
- Policy is needed to align healthcare incentives
- Training should be effective and efficient

My contact info

