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

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V2

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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

Belmont Instrument Corporation

Home | Products | About Us | News / Events | Studies | Contact Us

Product Testimonials

Scientific Studies

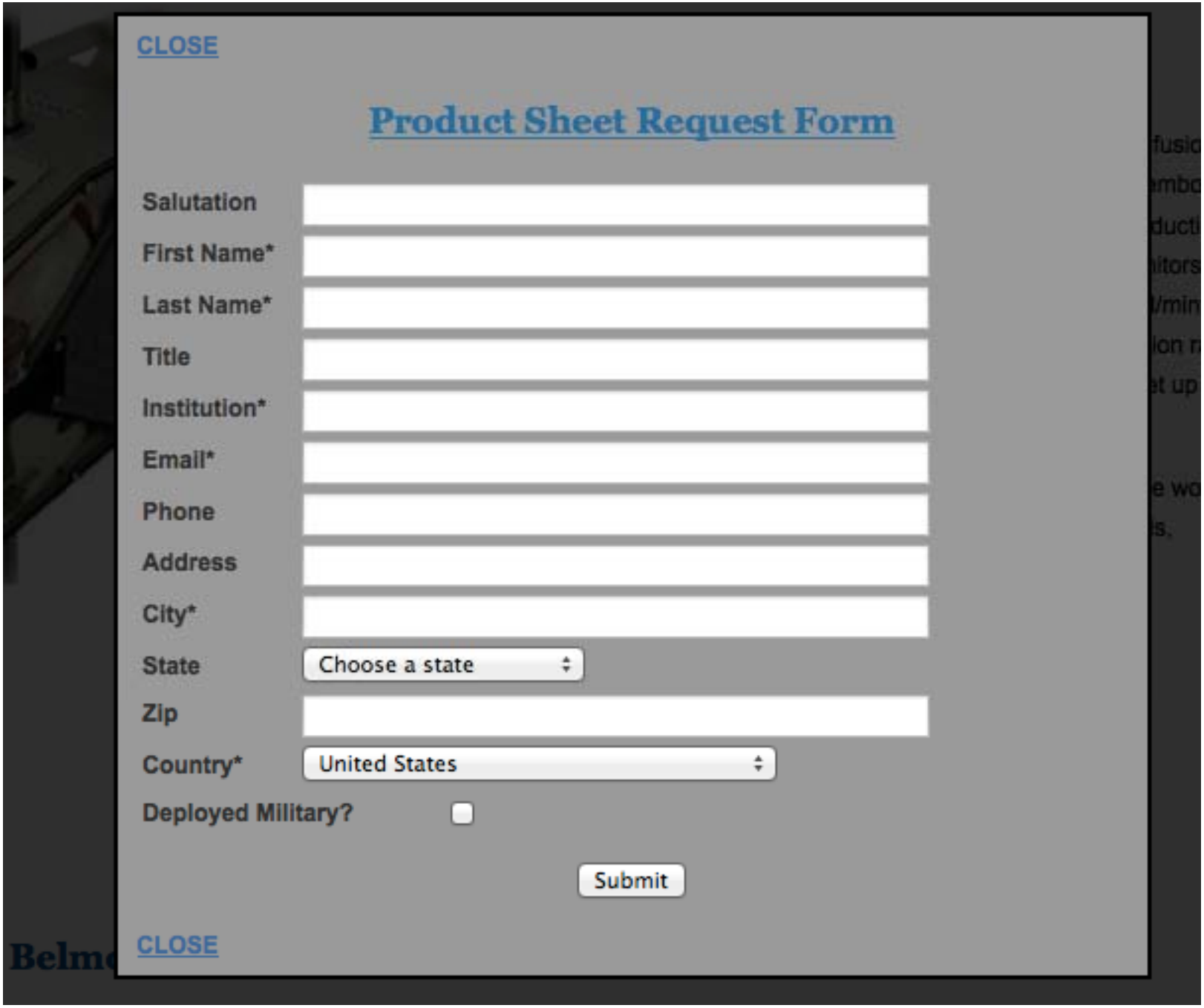
The Belmont Rapid Infuser

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.

DOWNLOAD PRODUCT SHEET | REQUEST INFORMATION

To Request Product Information, complete this form:



CLOSE

Product Sheet Request Form

Salutation

First Name*

Last Name*

Title

Institution*

Email*

Phone

Address

City*

State — Choose a state

Zip

Country* — United States

Deployed Military?

Submit

CLOSE

Still looking …

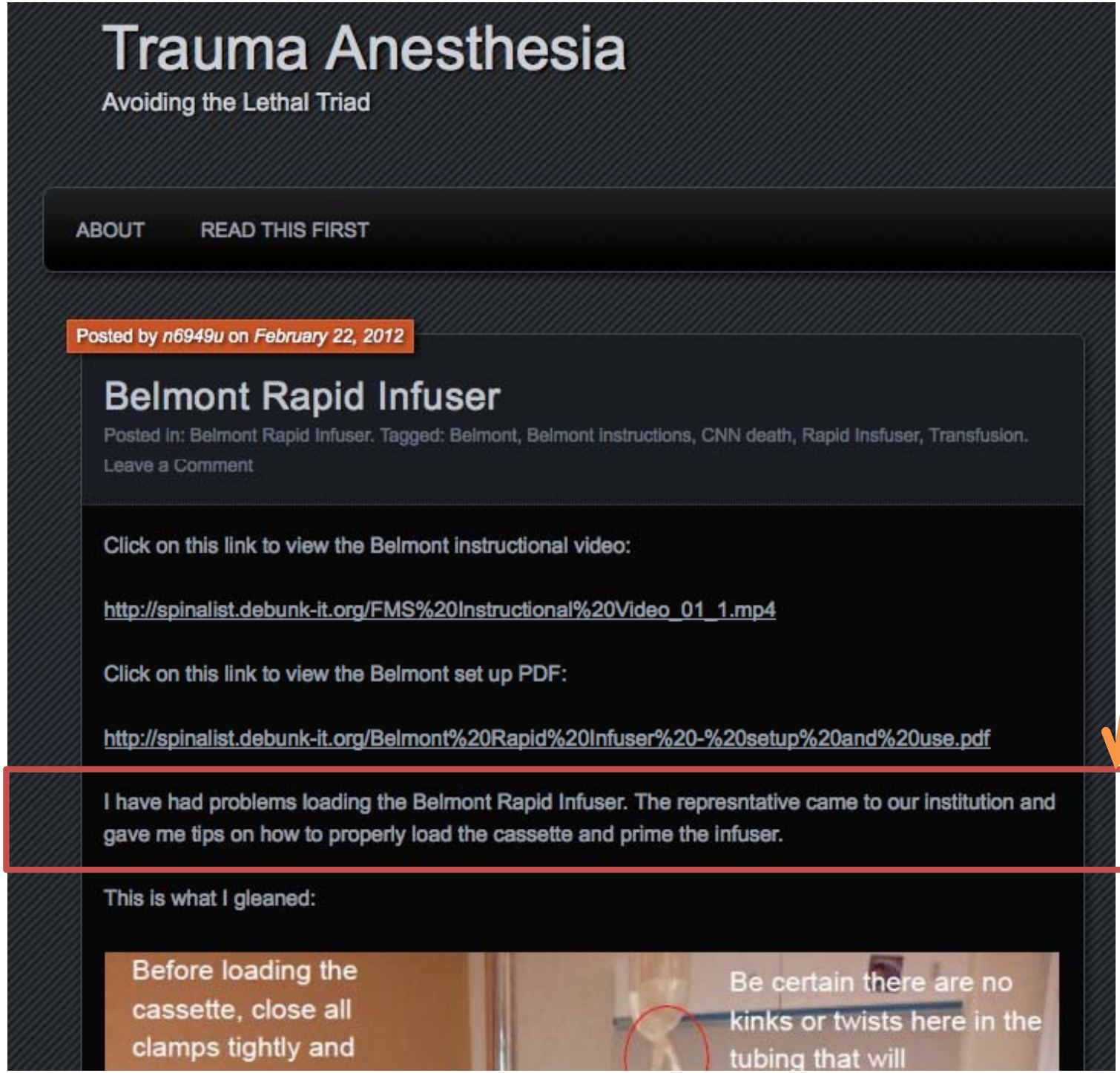
[PDF] The **Belmont** Fluid Management System FMS2000 Operator's ...
www.sh.lsuhsc.edu/policies/policy_manuals_via_ms.../**Belmont**.pdf
Belmont FMS2000 should not be used where **rapid** infusion is ..... This chapter explains the procedure for **setting up** and initiating safe and effective operation.

[PDF] **Belmont** Instrument Corporation - gd medical AG
www.gdmedical.ch/.../**Belmont**%20**Rapid**%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:.

Next, I try
YouTube …
Without success

Video does not
Depict device setup

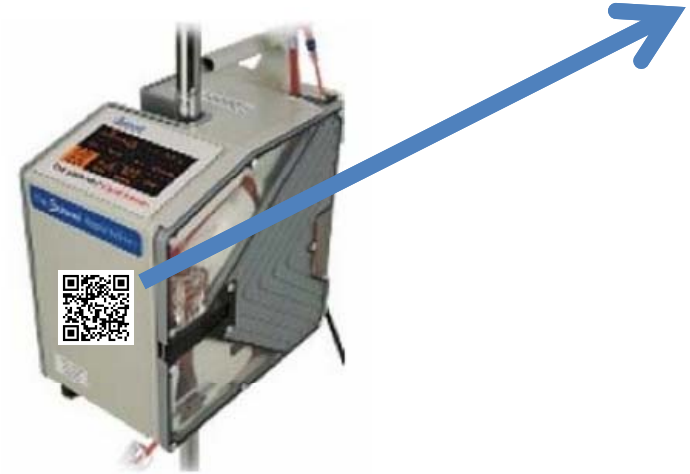


The need to educate users is a challenge for manufacturers and users:

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

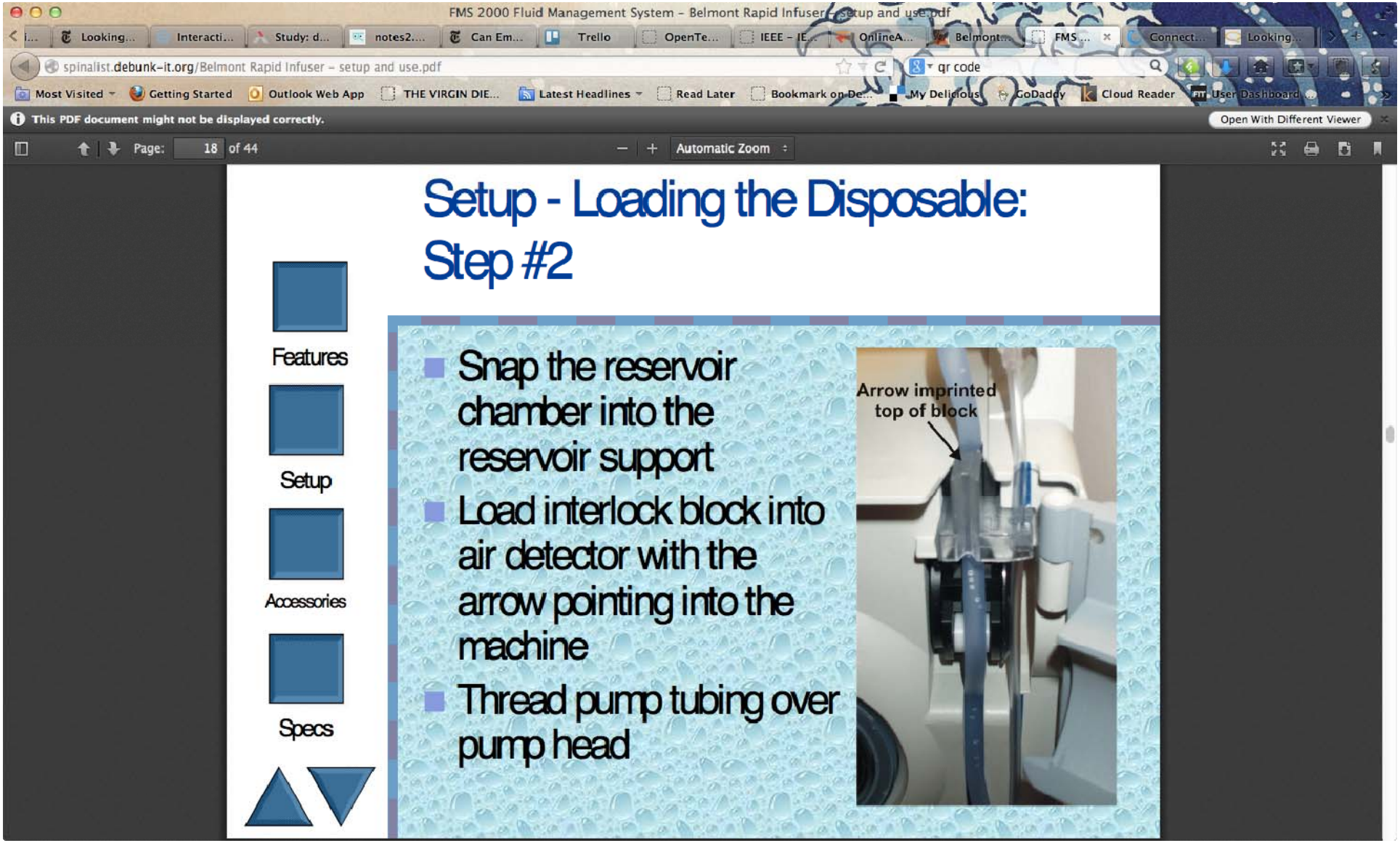
What if the device or cassette package had a “QR Code” that linked to information?

Audience: Read this QR code with your smartphone now



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

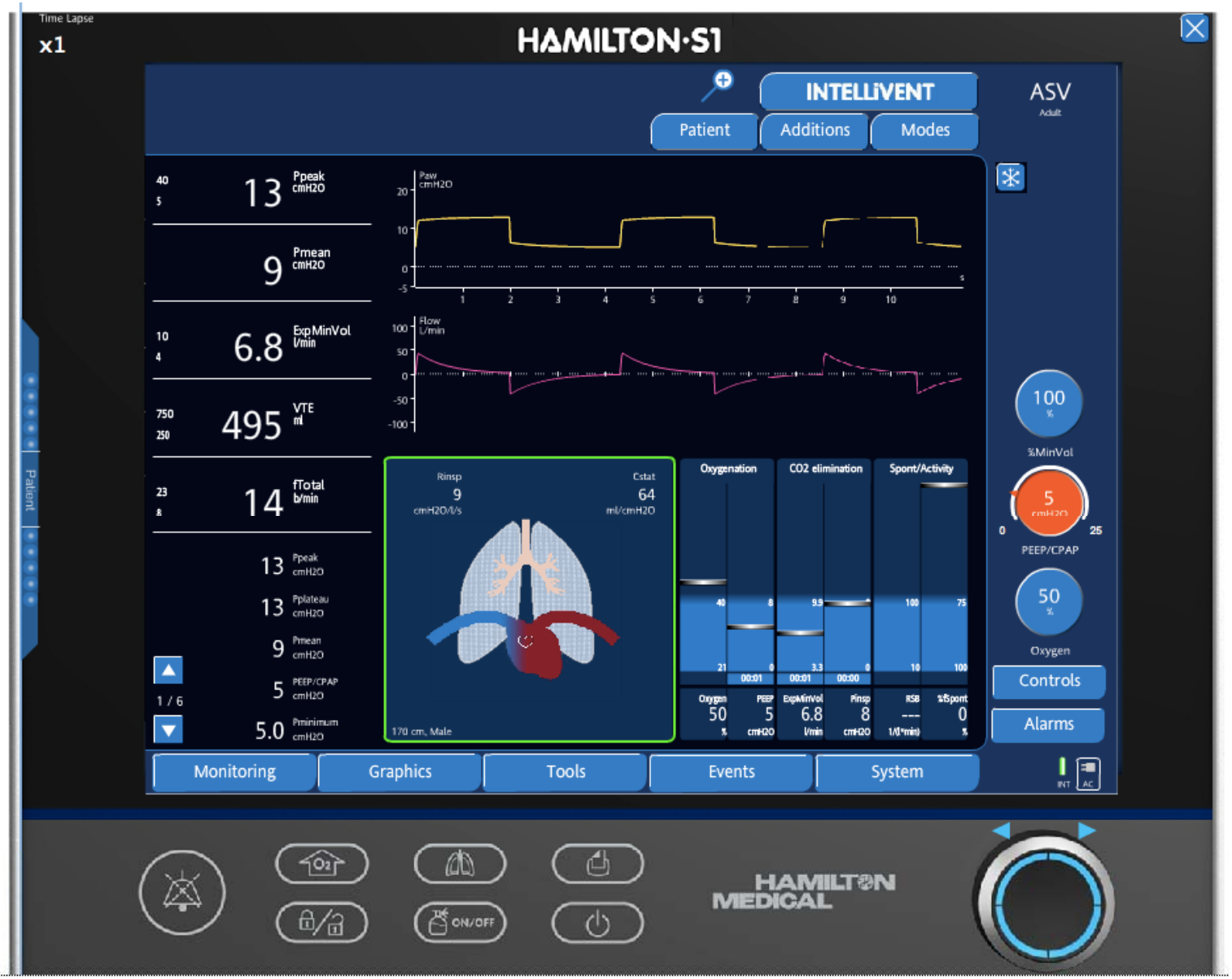
What if QR code showed this?



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

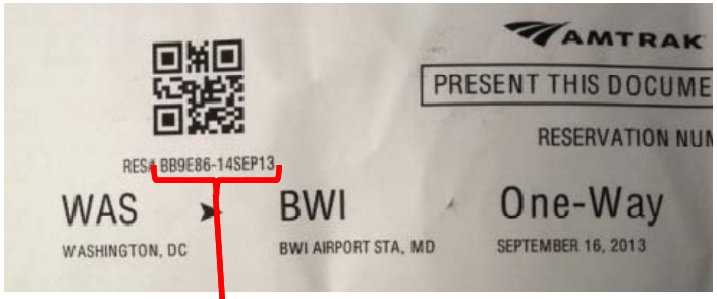
Or this …

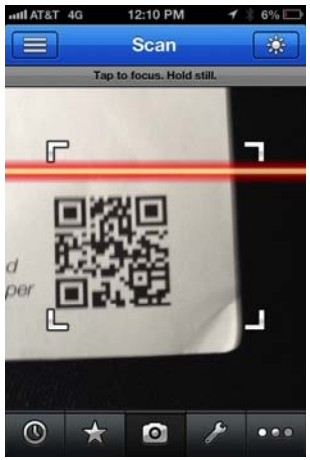
Interactive Ventilator Simulator (www)



- Invented 1994
- ISO standard
- Fast readability

QR Codes are widely used





QR App

Ticket number and date

Recommendation #2
Improve <u>access</u> 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.mdpnp.org for updated info.

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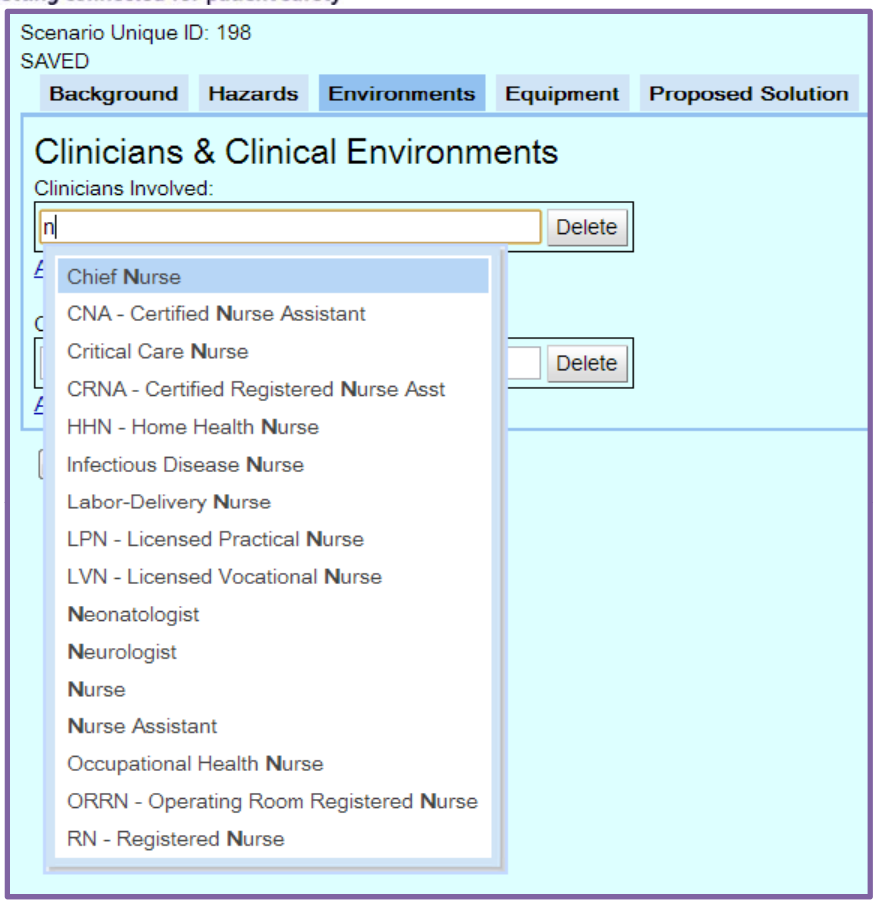
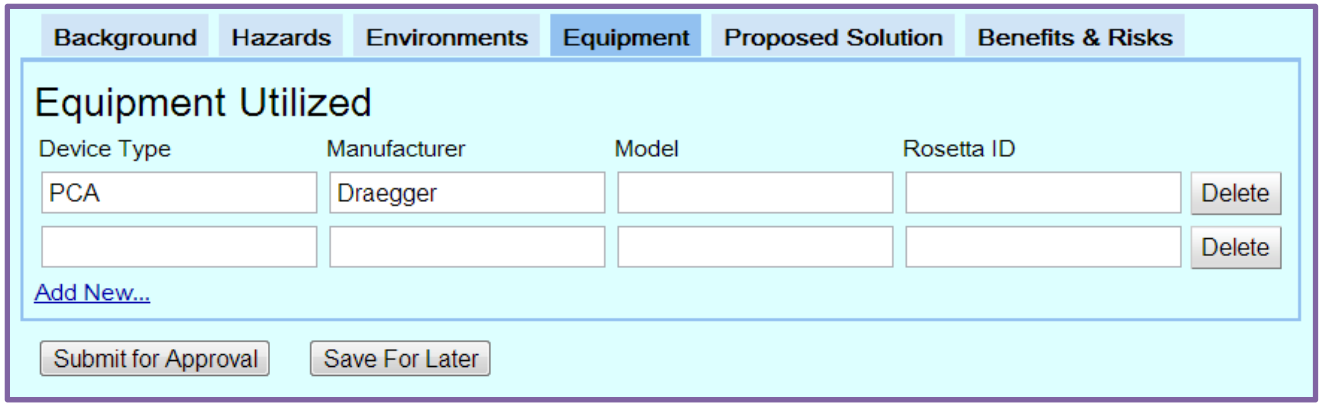
Getting connected for patient safety™

Manual reporting of device/system issues:





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

Project information will be posted on www.mdpnp.org

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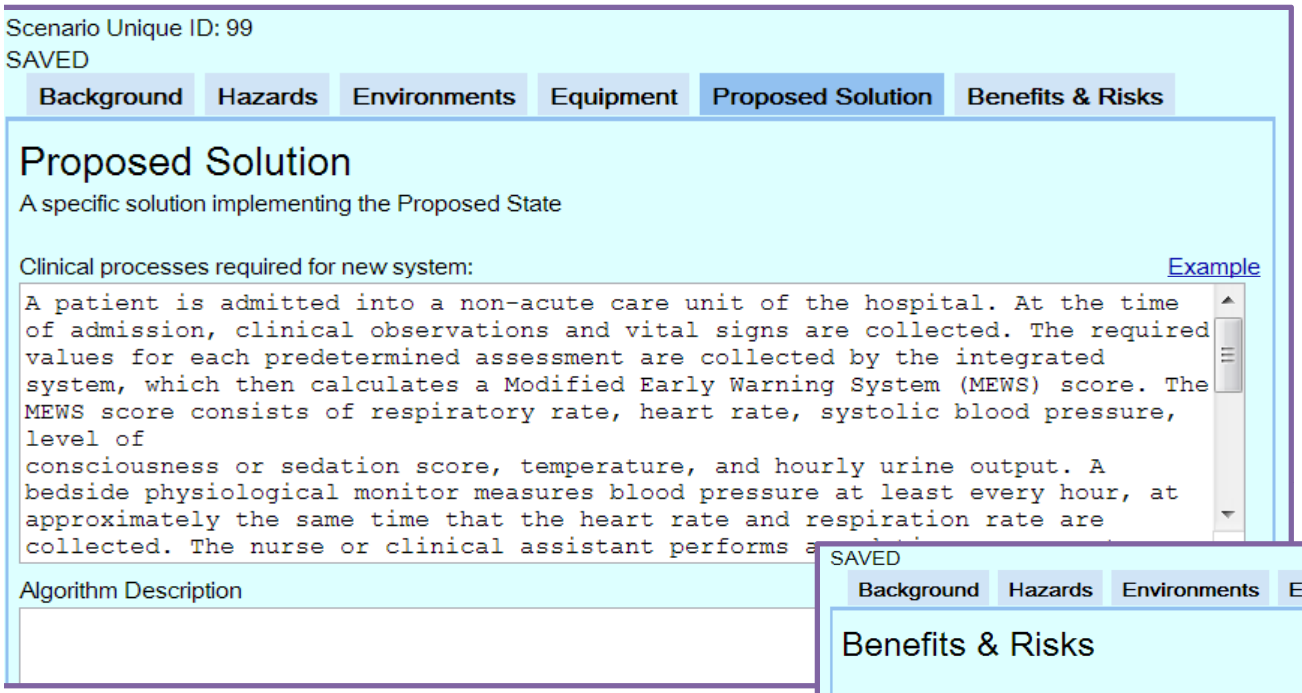
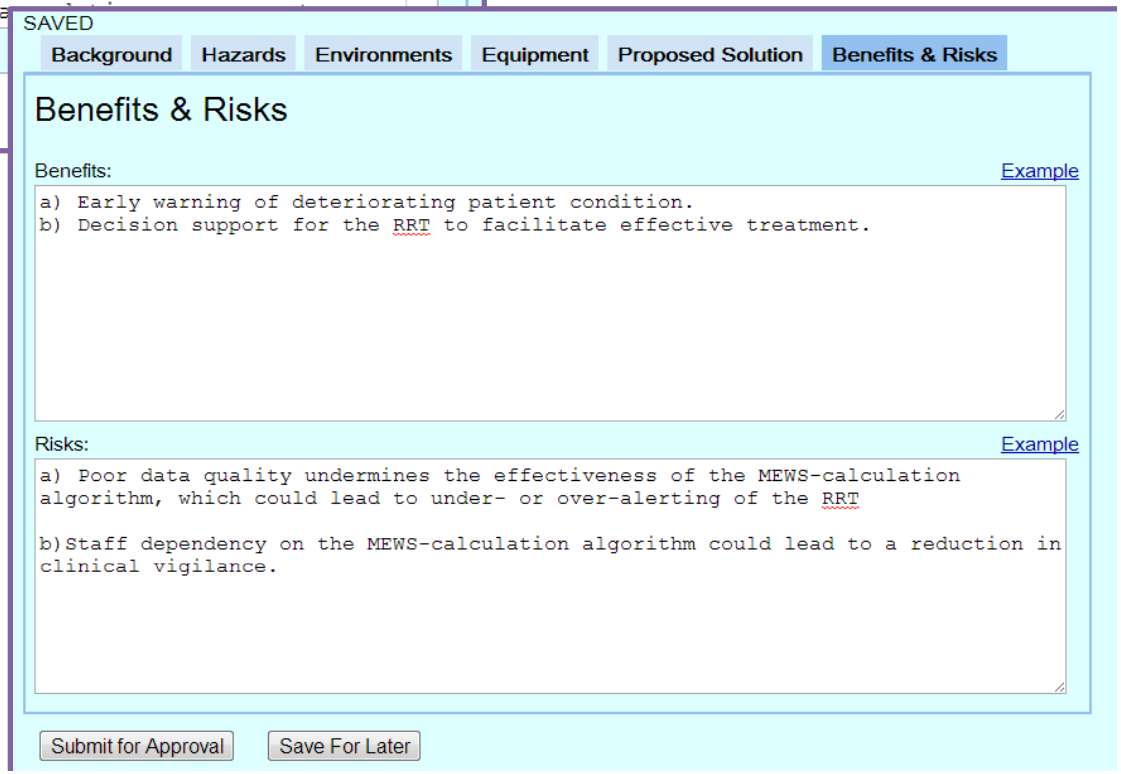


Add a **clinical concept of operations** to show the improvement in safety and effectiveness via a specific solution implementing the proposed state.



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

Project information will be posted on www.mdpnp.org

http://www.healthit.gov/policy-researchers-implementers/federal-advisory-committees-facas/fdasia
http://www.healthit.gov/facas/sites/faca/files/FDASIARecommendationsDraft030913_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.mdpnp.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

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My contact info