The Challenges Of Medical Device Technology: Design, Usability, Standards And Regulation Or Let's Try Not To Kill The Patient!

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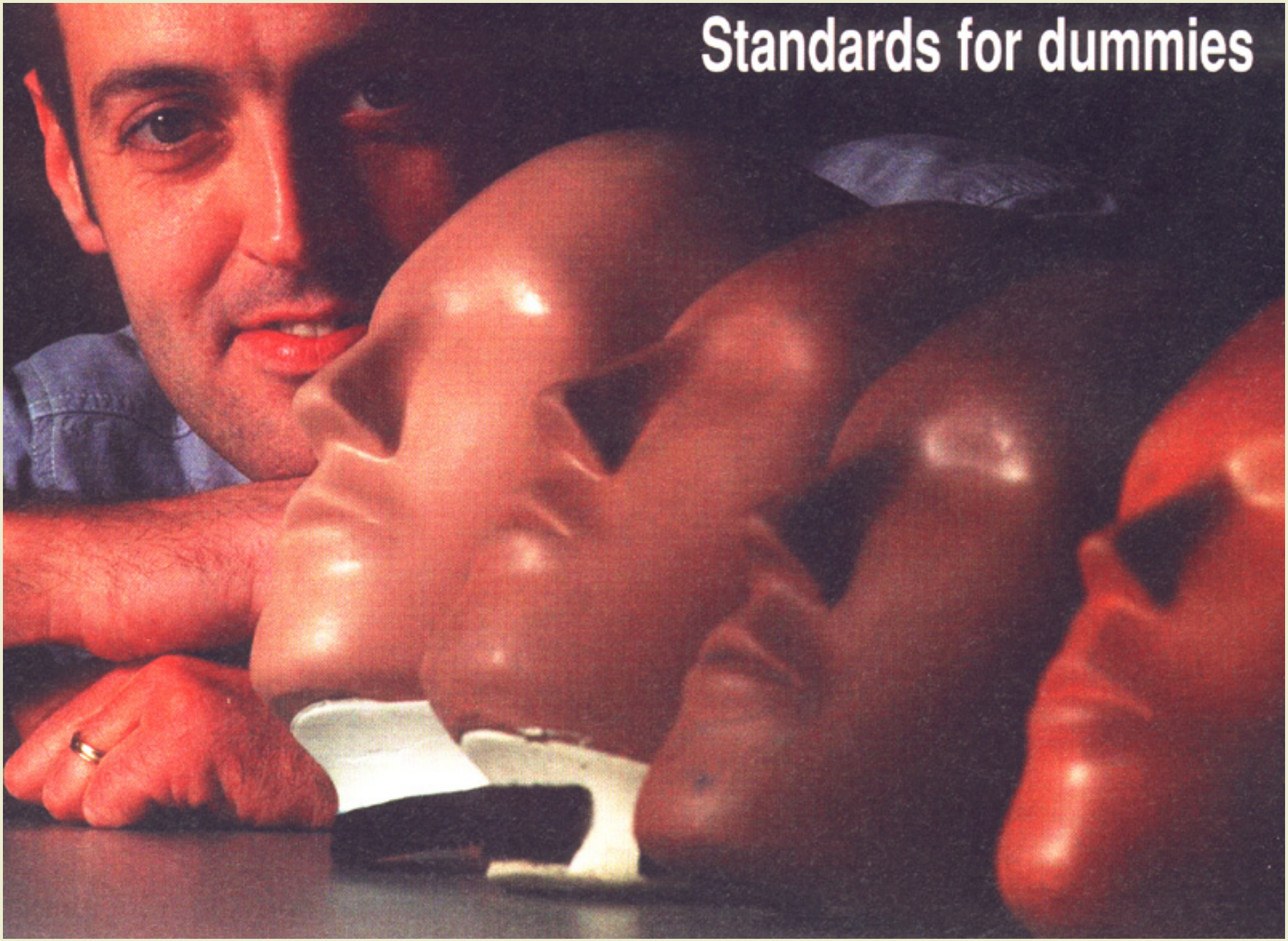
OBJECTIVES

- What do you need to know to start designing and building medical devices
- What are standards and what do I need to know about them
- Usability engineering-application to medical devices
- Some examples of equipment
- What regulatory hoops do you need to jump through

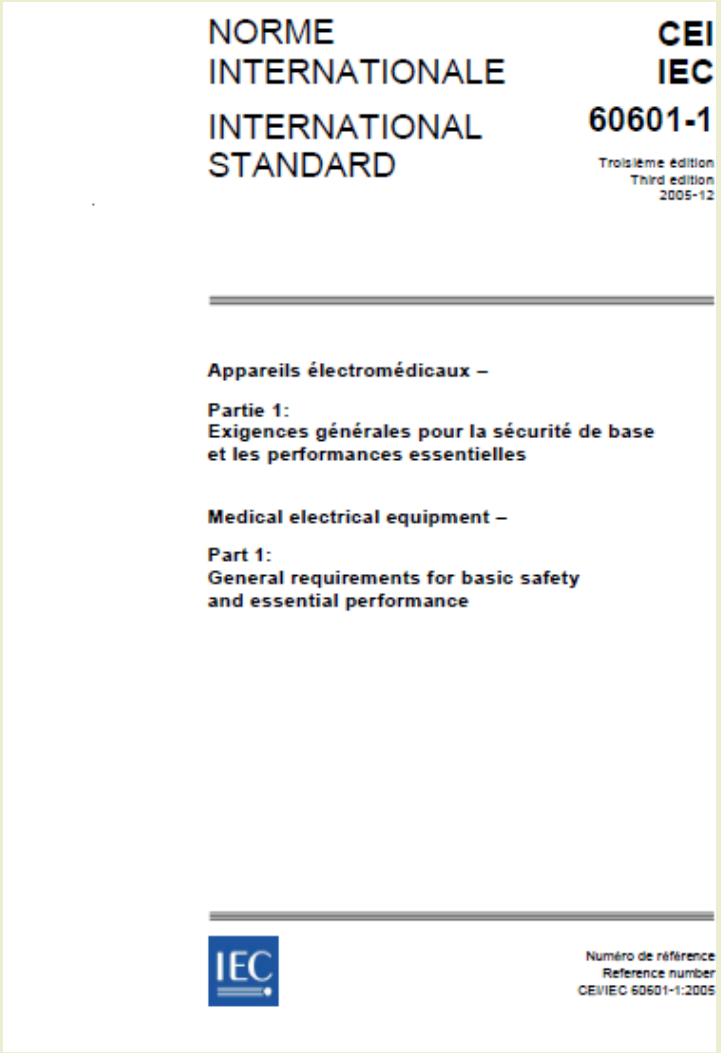
MEDICAL DEVICES

- Design and construction is very regulated
- Needs to be electrically safe within the hostile environment of the operating room or ICU
- May have a direct connection with conductors into the heart-microshock
- May have to survive the shock of a defibrillator or electrocautery machine
- Needs to be easy to use-prevention and mitigation of errors


Standards for dummies

IEC 60601

IEC 60601-1:2005-Ed.3.0
Medical electrical equipment - Part 1: General requirements for basic safety and essential performance



NORME INTERNATIONALE
INTERNATIONAL STANDARD

CEI IEC 60601-1

Troisième édition
Third edition
2005-12

Appareils électromédicaux –

Partie 1:
Exigences générales pour la sécurité de base et les performances essentielles

Medical electrical equipment –

Part 1:
General requirements for basic safety and essential performance

IEC

Numéro de référence
Reference number
CEI/IEC 60601-1:2005

MEDICAL DEVICES

medical device
any instrument, apparatus, implement, machine, appliance, implant, *in vitro* reagent or calibrator, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of

— diagnosis, prevention, monitoring, treatment or alleviation of disease,

— diagnosis, monitoring, treatment, alleviation of or compensation for an injury,

— investigation, replacement, modification, or support of the anatomy or of a physiological process,

— supporting or sustaining life,

— control of conception,

— disinfection of medical devices,

— providing information for medical purposes by means of *in vitro* examination of specimens derived from the human body,

and which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means

NOTE 1 This definition has been developed by the Global Harmonization Task Force (GHTF). See bibliographic reference [38].

[ISO 13485:2003, definition 3.7]

MEDICAL ELECTRICAL EQUIPMENT

- Medical device with one or more parts connected to the patient
- Connected to Mains

AC CURRENT & THE HEART

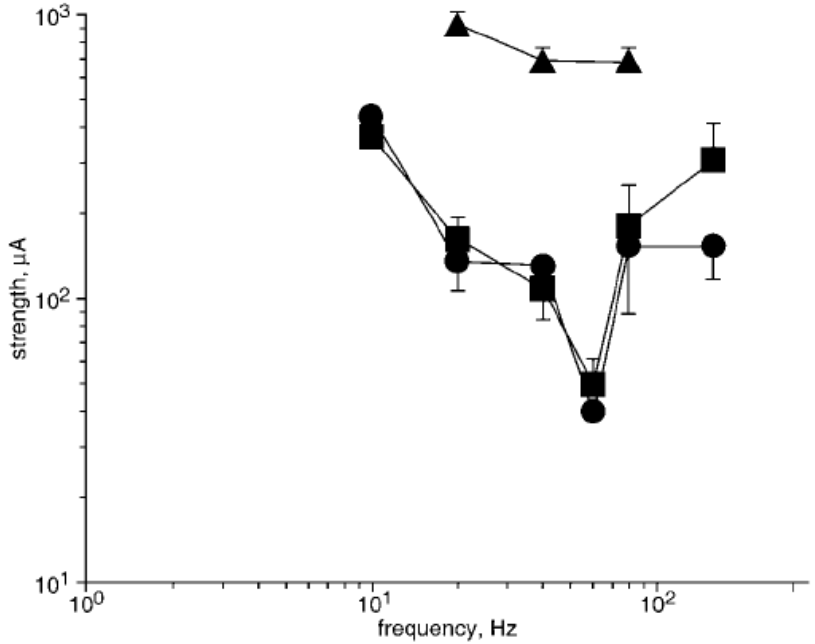


Fig. 3 *Unlike EFFECT threshold for AC stimulation, threshold for VF in dogs follows bowl shape with minimum at 60 Hz and significant increase below ($p < 0.05$) and above ($p < 0.05$) this frequency. (–●–) Sine wave; (–■–) square wave; (–▲–) 1 ms pulse*

Weirich J, Hohnloser S, Antoni H.1983 . Factors determining the susceptibility of the isolated guinea pig heart to ventricular fibrillation induced by sinusoidal alternating current at frequencies from 1 to 1000 Hz. Basic Res Cardiol. 1983 Nov-Dec;78(6):604-16.

IEC 60601

- Family of standard for basic safety and essential performance

IEC 60601-1-2

- Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic phenomena - Requirements and tests

IEC 60601-1-4

- Medical electrical equipment - Part 1-4: General requirements for safety - Collateral standard: Programmable electrical medical systems

IEC 60601-1-6

- Medical electrical equipment - Part 1-6: General requirements for safety - Collateral standard: Usability IEC 60601-1-8:2006-Ed.2.0

IEC 60601-1-8

- Medical electrical equipment - Part 1-8: General requirements for safety - Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems

ISO 14971

INTERNATIONAL STANDARD

ISO 14971

Second edition
2007-03-01

Medical devices — Application of risk management to medical devices

Dispositifs médicaux — Application de la gestion des risques aux dispositifs médicaux

Compliance is checked by inspection of appropriate documents.

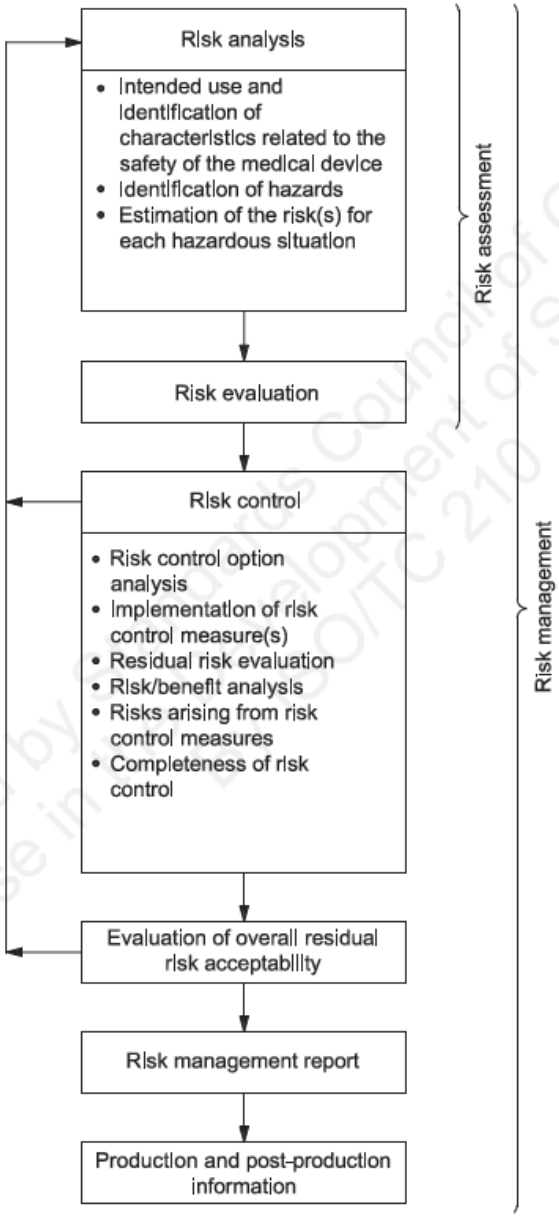


Figure 1 — A schematic representation of the risk management process

QUALITY SYSTEMS

- ISO 13485:2003 specifies requirements for a quality management system
- an organization needs to demonstrate its ability to provide medical devices and related services that consistently meet customer requirements and regulatory requirements
- applicable to medical devices and related services
- Based ISO 9001

RECOGNIZED STANDARDS

- Health Canada Website
- http://www.hc-sc.gc.ca/dhp-mps/md-im/standards-normes/md_rec_stand_im_norm_lst-eng.php


TECHNOLOGY
NO PLACE FOR WIMPS
DILBERT

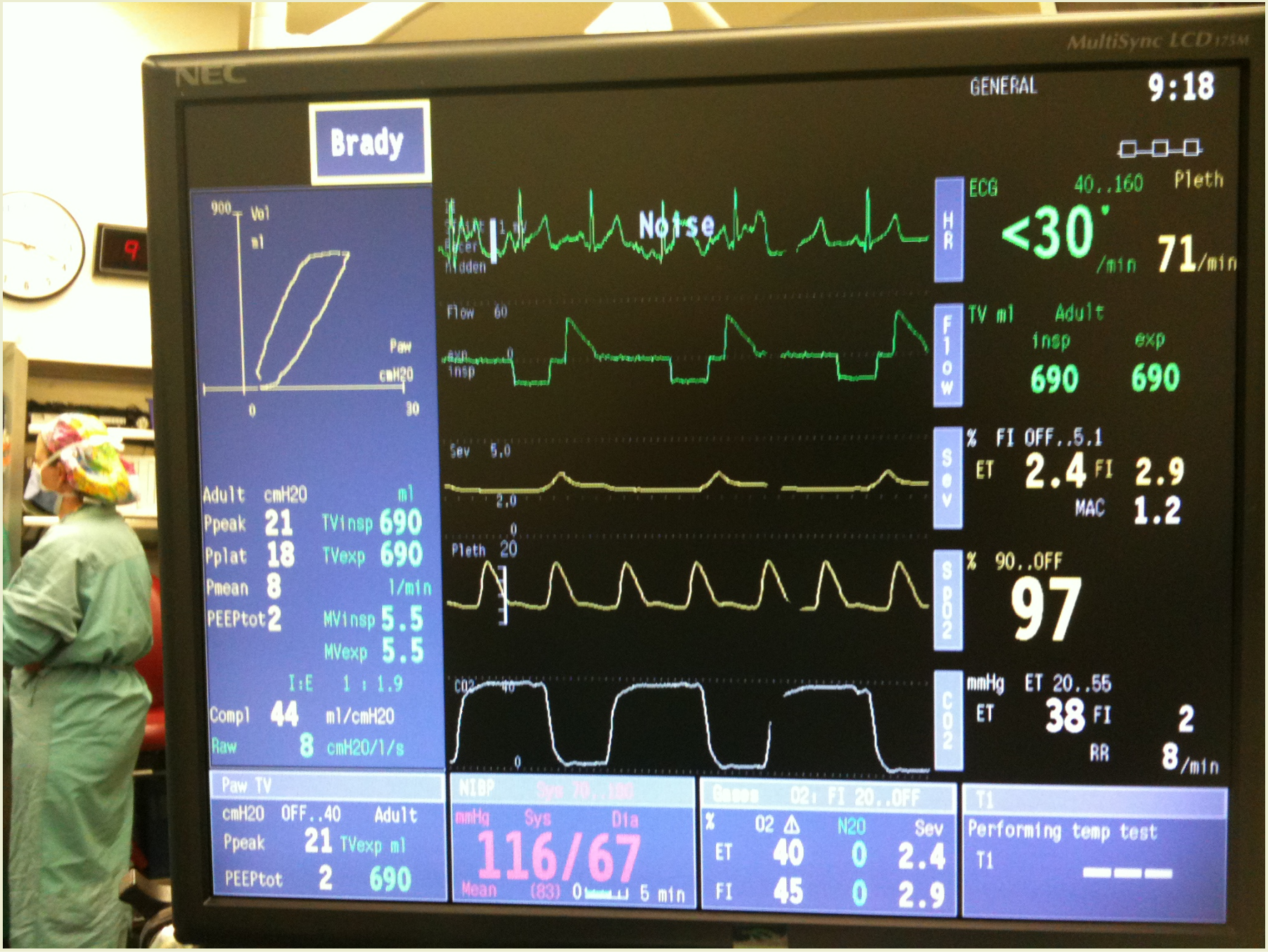
PROBLEMS WITH CURRENT DEVICES

PROBLEMS WITH CURRENT DEVICES

- Artifact
- Usability
- Alarms


GENERAL
8 34
ECG
40..160
67
/min
Pleth
66/min
% 90..OFF
100
HR
SPO2
CO2
mmHg ET 20..54
ET
FI
35
0
RR
8
/min
Pleth 5
CO2 40
240
120
0
100
90
80
50
40
30
0
102/65
Sys
Dia
5 min
41
46
5.0
2.0
1.0
2.5


NEC
MultiSync LCD
GENERAL
8:56
Brady
ECG
HR
68
/min
Arrh. analys: Severe
Sev 5.0
2.0
0
Sev
ET 2.6 FI 3.0
MAC 1.3
Pleth
SpO2
100
CO2
mmHg
ET 41 FI 0
RR 8 /min
Gases
% O2 N2O Sev
ET 40 0 2.6
FI 45 0 3.0
mmHg Sys Dia
131/80
Mean (97)
5 min
°C
T1
35.5
Adult
cmH2O
Ppeak 25 TVexp ml
PEEPtot 2 630


NEC
MultiSync LCD175M
GENERAL
9:18
Brady
Noise
ECG
40..160
Pleth
<30
/min
71/min
HR
Flow
TV ml
Adult
insp
exp
690
690
Sev
% FI OFF..5.1
ET 2.4 FI 2.9
MAC 1.2
SpO2
% 90..OFF
97
CO2
mmHg ET 20..55
ET 38 FI 2
RR 8/min
Vol
ml
Paw
cmH2O
Adult cmH2O ml
Ppeak 21 TVinsp 690
Pplat 18 TVexp 690
Pmean 8 l/min
PEEPtot 2 MVinsp 5.5
MVexp 5.5
I:E 1 : 1.9
Compl 44 ml/cmH2O
Raw 8 cmH2O/l/s
Paw TV
cmH2O OFF..40 Adult
Ppeak 21 TVexp ml
PEEPtot 2 690
NIBP
mmHg Sys Dia
116/67
Mean (83)
5 min
Gases
O2: FI 20..OFF
% O2 N2O Sev
ET 40 0 2.4
FI 45 0 2.9
T1
Performing temp test
T1

The Problem of Artifacts in Patient Monitor Data During Surgery: A Clinical and Methodological Review

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Artifacts are a significant problem affecting the accurate display of information during surgery. They are also a source of false alarms. A secondary problem is the inadvertent recording of artifactual and inaccurate information in automated record keeping systems. Though most of the currently available patient monitors use techniques to minimize the effect of artifacts, their success is limited. We reviewed the problem of artifacts affecting patient monitor data during surgical cases. Methods adopted by currently marketed patient monitors to eliminate and minimize artifacts due to technical and environmental factors are reviewed and discussed. Also discussed are promising artifact detection and correction methods that are being investigated. These might be used to detect and eliminate artifacts with improved accuracy and specificity.

(Anesth Analg 2006;103:1196–1204)

ARTIFACTS-CAUSES

ECG	Electrosurgical Unit knife interference Cardiopulmonary bypass machine interference Power-line interference Movement artifact (Surgical preparation, patient movement, etc.) Electrode instability and electrode distortion due to external forces EMG interference Improper lead contact or connection Pacing or defibrillation Abnormally tall T-waves mistaken as QRS complex Intraoperative MRI scanners (59)	Heart rate ST values Arrhythmia detection

ARTIFACTS-CAUSES

Non-invasive Blood Pressure (Oscillometric)	Movement artifact (14) Improper cuff size or position Kinked cuff tubing and leaking cuff bladder Compression of cuff by extrinsic forces such as a surgeon or a piece of equipment pressing against the cuff	Systolic, diastolic, and mean NBP values NBP pulse rate
Spo_2 signal	Movement artifact Injection of contrast dye Occlusion of blood flow due to NBP cuff constriction Ambient light interference	O_2 saturation Spo_2 pulse rate

ARTIFACT-PREVENTION

- Need for better artifact detection and signal extraction
- Improvements in biological sensors
- Better electronic filtering
- Improved digital signal processing
- Combining information from multiple sensors
  - Heart rate from ECG, SpO_2, arterial lines

CONCLUSIONS

- Artifacts remain a significant problem for processing and displaying correct clinical information
- Most current devices still use simple linear filters that are often ineffective
- Need for improved methods of artifact prevention, detection and elimination

USABILITY ENGINEERING

USABILITY ENGINEERING

The application of knowledge about human behavior, abilities, limitations, and other characteristics to the design of equipment, systems, tasks, jobs, and environments to achieve productive, safe, comfortable, and effective human use.

KISS PRINCIPLE

HUMAN FACTORS DESIGN PROCESS

KEEP IT SIMPLE & SAFE!

SO EASY……

USABILITY MYTHS

- Usability testing is the same as Functional Testing.
- We can't involve users in the design because they'll want to change the functionality and scope of the product.

USABILITY MYTHS

- The design is finished.
- We'll handle that problem in the help documentation.
- We'll handle that problem in the training.

HUMAN FACTORS DESIGN PROCESS

- Product Idea
- Target user and environment
- Focus Groups

HUMAN FACTORS ENGINEERING

- Usability goal setting, ergonomics
- Design and Prototype development
- Usability testing
- Further design and iterative testing

USABILITY TESTING

- Frequent use scenarios
- Critical use scenarios
- Does the equipment do what I want, is it easy to learn, easy to remember, easy to use, and intuitive?

HCI DESIGN GOALS

- Learnability
- Memorizability
- Efficiency
- Errors
- Satisfaction


Julian

ERRORS

- Design the equipment to minimize errors
- If an error is made, design equipment for easy and safe recovery from the error
- Risk Analysis Process

DEADLY DESIGN ERROR

AECL radiation therapy machine

- Text based operator interface
- Operator made typing mistake, thought she corrected it, but machine delivered a lethal dose of radiation

NUISANCE AND POTENTIAL HAZARD

Baxter syringe pump AS50

- Must turn off pump and reprogram pump if patient's weight wrongly entered


BAIRD INFUS O.R.
60cc syringe
Label: L02
Infusion Rate
mcg/kg/min
Body Weight
kg
Bolus
mcg/kg
purge
off
Alaris/Cardinal
infuse
Bolus start
Volume Total (mL)
Infusing
Alternator
Balancing
Manual
Baxter
ALERT
BATTERY
ON CHARGE
STANDBY
LOCK
SYSTEM
START
STOP
PAG
CA
MAG
INF
MIX
SUFENTAN

SATISFACTION

- Enjoyment of use
- Want to use equipment vs fear or hating to use equipment

HUMAN EQUIPMENT INTERFACE

- GUI Design
- Expected persons to use equipment
- Expected Environment of use

EXPECTED PERSONS OF USE

- Age – adults, teens, children, the elderly
- Height and Weight
- Eyesight -- presbyopia
- Colour blindness –red/green
- Other common diseases – diabetes, rheumatoid arthritis

INSULIN PUMP

MiniMed Paradigm® Veo™ Insulin Pump and CGM System

Features FAQ

Get ahead of diabetes with Continuous Glucose Monitoring (CGM)

With the MiniLink® transmitter and glucose sensor; CGM allows you to read your glucose levels at any time- keeping you informed around the clock and giving you the jump on information you need to take action sooner.

Get Started

CGM is always alert.

The Veo Insulin Pump and CGM System is the world's only insulin pump engineered with a Low Glucose Suspend (LGS) function. LGS is designed to help prevent severe hypoglycemia day and night.

Take Advantage of the Evidence.

CGM can help you:

What Our Pumpers Say

http://www.medtronicdiabetes.ca/en/paradigm_veo.html

EXPECTED PERSONS OF USE

- Level of Education
- Technical Knowledge

EXPECTED ENVIRONMENT OF USE

- Inside/Outside - Temperature
- Hospital
- Clinic
- Ambulance/Helicopter
- Homecare

EXPECTED POSITION

- Sitting
- Standing
- Operators –Height/Weight

A Cool Interface is not always Usable

Usable = Cool

Need to design equipment that is so foolproof that it can't be brought to its knees by a well-intentioned novice.

Thank-you

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ALARM SYSTEMS

PROBLEMS

- It is estimated that alarm signals annunciate in the operating room every 4-5 minutes during each general anesthetic

Kestin IG, Miller BR, Lockhart CH. Auditory alarms during anesthesia monitoring. Anesthesiology 1988; 69:106-109

ALARM STANDARDS

60601-1-8 General requirements and guidelines for the application of alarms in medical electrical equipment

ALARM SYSTEMS

Number of pulses in burst[1)]	**5** 	**3** 
Pulse spacing(t_s) [2)]		
Between 1st and 2nd pulses	**x [3)]**	**y [3)]**
between 2nd and 3rd pulses	**x**	**y**
between 3rd and 4th pulses	**2 x**	**not applicable**
between 4th and 5thpulses	**x**	**not applicable**
Burst spacing(t_b)	**2 s +/- 0,2 s**	**not applicable**

ALARM SYSTEMS

- Pleasant sounds
- Easy to identify and read
- Disable, Mute, Suspend, Silence
- Latching or non-latching
- Able to disable separate functions

ALARM SYSTEMS

- One of the largest sources of irritation in the OR and ICU's
- Anesthesiologists tend to disable alarm systems in the OR
- Prompted by poor design of alarm systems in existing equipment

CURRENT PROBLEMS

- Loud
- Annoying, irritating
- Too many artifacts
- Recognition of auditory alarm signals
- Continuous sounds

Current Medical Equipment

Alarm Process

Alarm condition

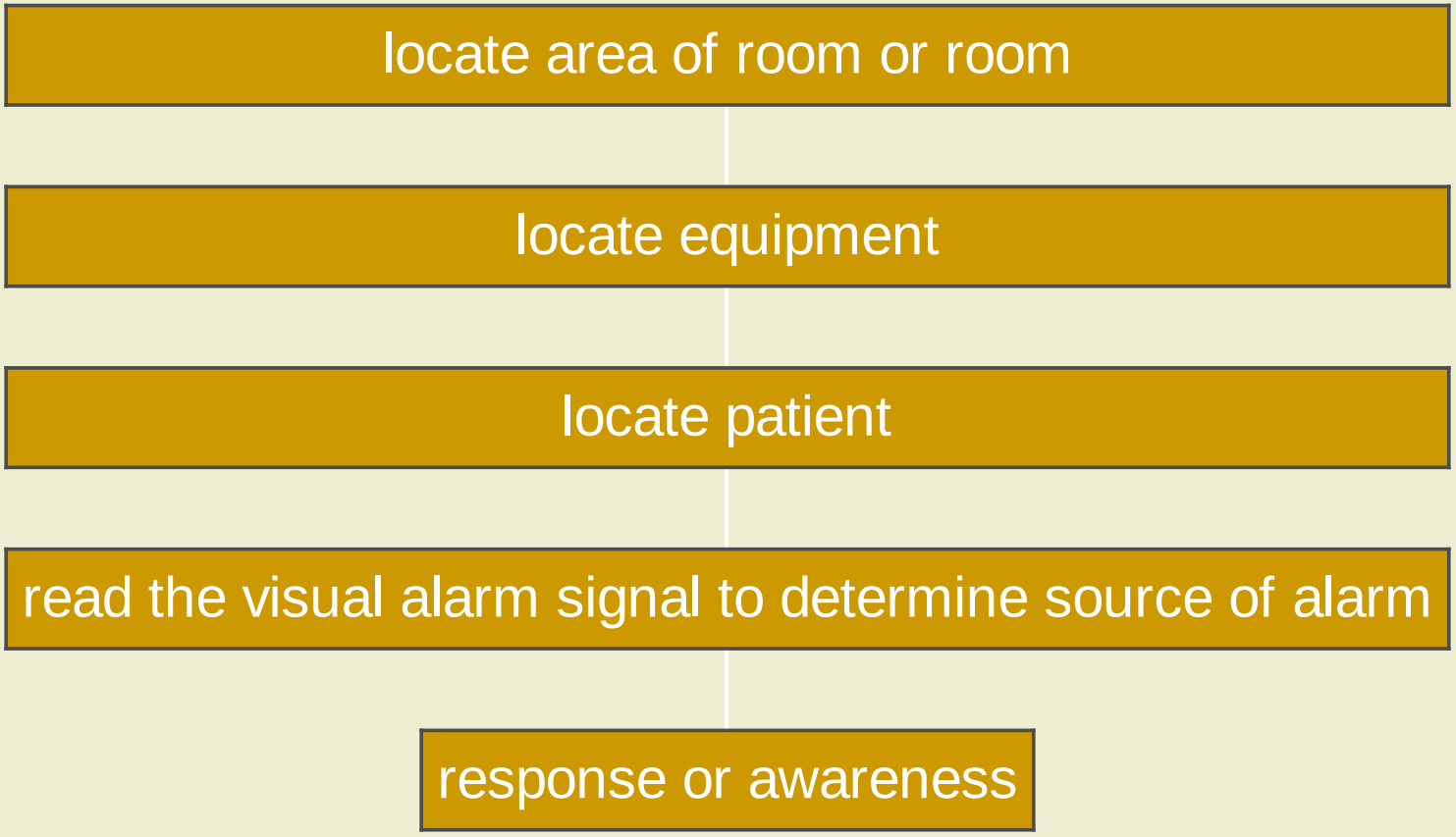
what alarm and when to annunciate

Is the system disabled, silenced or suspended?

Alarm signal
(auditory,visual, verbal, vibratory)

Priority of alarm signal--urgency of response required

Alarm Process



Philosophy of Alarm Design

- Pleasant non-startling sounds
- non-continuous
- not overly loud
- recognition of device
- urgency mapping/encoding

LEARNABILITY

- Is it easy to learn
- Is there a rapid learning curve

  -easy to learn vs rapid to use

MEMORIZABILITY

- Once learned, is the knowledge retained
- Frequent use
- Intermittent use

EFFICIENCY

- Intuitive, minimal number of steps for frequently used functions
- Preferably one menu deep
- Never more than 3 deep
- Short-cuts for expert users