GLOBAL CLINICAL ENGINEERING ALLIANCE

WEBINAR

# Safety and Quality of Medical Equipment

Global Clinical Engineering Perspectives

WEDNESDAY MAY 11

6 PM UNIVERSAL TIME (UTC)

2 PM NEW YORK TIME (ET)

REGISTER FOR FREE

https://bit.ly/3KVHHqo

## MODERATOR

**STEFANO BERGAMASCO**
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## PRESENTERS

**KEVIN TAYLOR**
Territorial Manager of Biomedical Engineering for the Northwest Territories.(Canada)

**KEIKO FUKUTA**
Associate Professor, Medical Center for Translational and Clinical Research Department of Medical Innovation, Osaka University Hospital & GCEA Founder Council Member (Japan)

**NIRANJAN KHAMBETE**
Manager – Clinical Engineering, Deenanath Mangeshkar Hospital and Research Centre, Pune (India)

# Safety and Quality

## Health Technology Management in the Northwest Territories, Canada

Kevin Taylor

Territorial Manager of Biomedical Engineering for the Northwest Territories, Canada

# Background – Geography and Environment


- Geographic Area of about 1/5 the US.
  - From Yellowknife to Sanikiluaq is > 2000km.
- Remote Communities
- Harsh Environments
- Problematic Utilities
- Limited local remote troubleshooting / support resources

# Background – Demographics

- NTHSSA Biomedical Engineering supports health technology in all NWT and 2/3rds of Nunavut.
  - NWT – 33 communities
  - Nunavut (Kivalliq and Kitikmeot Regions) – 12 communities
  - Population
    - NWT – 45,000 - 51% Indigenous comprising
    - Kivalliq and Kitikmeot Regions of Nunavut – 17,000 - 86% Indigenous
  - Access
    - Approximately 40% of NWT communities are fly in or winter ice road only
    - All Nunavut communities are fly in only.

# NWT Health Technology Management

- Northwest Territories Health and Social Services Authority
  - Biomedical Engineering
    - Part of Informatics and Health Technology Division
    - 1 Territorial Manager – Professional Engineer
    - 7 Biomedical Engineering Technologists
    - Manage service on health technology – in-house service on vital signs through to dialysis, anaesthesia, community x-ray in-house
    - Manage all Territories health technology service contracts
- Department of Health and Social Services
  - Health Technology Planning
    - Part of Infrastructure Planning Division
    - 1 Manager – Professional Engineer
    - 3 Health Technology Planners
    - Manage all NWT health technology evergreening

# Quality and Safety Challenges

- Prior to 2018
  - NWT had a solid Health Technology Management foundation
    - Territorial In-house Biomedical Engineering program (1 Engineer and 4 Technologists)
    - Evergreening Planning Team at DHSS (1 Engineer and 2 to 3 Planners)
- Core Quality and Safety Challenges Identified in 2018
  - In-house Biomedical Engineering resources hadn’t changed since 2005
    - Complexity and quantity increased substantially
  - Service contracts not managed and divided between regions
  - Information, communication and collaboration challenges between NTHSSA and DHSS
  - Increasing number of vendors not providing manuals or parts
  - Nunavut and NWT separate systems each with limited resources
    - Nunavut had recruitment challenges
    - One region had no community service for two years

# Quality and Safety Initiatives

- DHSS and NTHSSA Collaboration
  - Created Territorial Health Technology Management Committee
  - Full inventory and assessment of all health technology
    - Shared full access to Territorial Health Technology Database
  - Collaborated on re-creating health technology management tools
    - Medical Equipment Replacement Score System
  - Loaned resources and support to each other to maximize system needs
    - COVID – purchased 1 years capital equipment in 1 month
    - Resource gaps – loaned and shared resources
- Right to Repair
  - Set Requirement in Territorial level Health Technology Policy
  - DHSS and NTHSSA created and refining mandatory procurement clauses to align with Territorial policy.
  - Work started to implement Right to Repair as a standard Nationally

# Quality and Safety Initiatives

- Consolidated all Service Contracts
  - Ensured service contract compliance
    - Repatriated community x-ray gaining additional staff
  - Ensure standardized Terms and Conditions
    - DHSS supporting contract terms during procurement process
- Partnered with Nunavut
  - All policies and procedures were aligned
    - Developed collaboratively
  - Share health technology database
  - Formed partnership agreement to support all Kivalliq and Kitikmeot combined
    - Staffed resource to support Nunavut regions
    - Shared access to Nunavut and NWT resources

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# Thank you !

**Kevin Taylor**
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# Medical Equipment QA and Safety

## With a Clinical Perspective

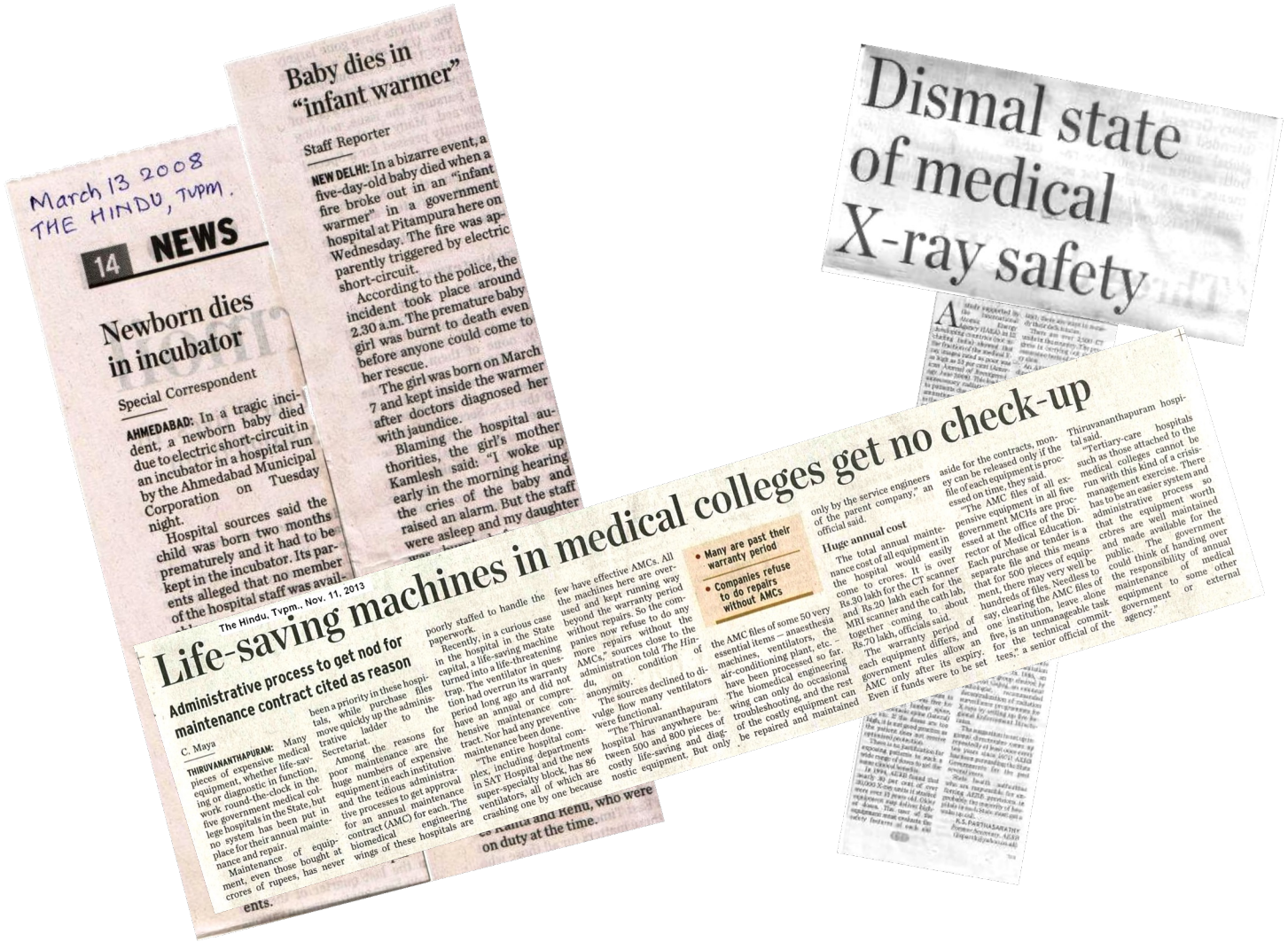
Dr. Niranjan D. Khambete

**Manager, Clinical Engineering**,
Deenanath Mangeshkar Hospital and Research Centre, Pune, India

# Outline of the talk

- Medical Equipment QA and Safety – The need
- Medical Equipment Safety Demystified
- Electrical Safety – Getting the basics right
- Performance Evaluation – The ‘Glucometer Story’
- Training – Empowering the frontline clinical staff

# Not a very happy scenario



March 13 2008
THE HINDU, TVPM.

14 NEWS

Newborn dies in incubator

Special Correspondent

AHMEDABAD: In a tragic incident, a newborn baby died due to electric short-circuit in an incubator in a hospital run by the Ahmedabad Municipal Corporation on Tuesday night.

Hospital sources said the child was born two months prematurely and it had to be kept in the incubator. Its parents alleged that no member of the hospital staff was avail-

ents.

Baby dies in "infant warmer"

Staff Reporter

NEW DELHI: In a bizarre event, a five-day-old baby died when a fire broke out in an "infant warmer" in a government hospital at Pitampura here on Wednesday. The fire was apparently triggered by electric short-circuit.

According to the police, the incident took place around 2.30 a.m. The premature baby girl was burnt to death even before anyone could come to her rescue.

The girl was born on March 7 and kept inside the warmer after doctors diagnosed her with jaundice.

Blaming the hospital authorities, the girl's mother Kamlesh said: "I woke up early in the morning hearing the cries of the baby and raised an alarm. But the staff were asleep and my daughter

Rama and Renu, who were on duty at the time.

Dismal state of medical X-ray safety

The Hindu, Tvpm., Nov. 11, 2013

Life-saving machines in medical colleges get no check-up

Administrative process to get nod for maintenance contract cited as reason

C. Maya

- Many are past their warranty period
- Companies refuse to do repairs without AMCs

THIRUVANANTHAPURAM: Many pieces of expensive medical equipment, whether life-saving or diagnostic in function, work round-the-clock in the five government medical college hospitals in the State, but no system has been put in place for their annual maintenance and repair.

Maintenance of equipment, even those bought at crores of rupees, has never been a priority in these hospitals, while purchase files move quickly up the administrative ladder to the Secretariat.

Among the reasons for poor maintenance are the huge numbers of expensive equipment in each institution and the tedious administrative processes to get approval for an annual maintenance contract (AMC) for each. The biomedical engineering wings of these hospitals are poorly staffed to handle the paperwork.

Recently, in a curious case in the hospital in the State capital, a life-saving machine turned into a life-threatening trap. The ventilator in question had overrun its warranty period long ago and did not have an annual or comprehensive maintenance contract. Nor had any preventive maintenance been done.

"The entire hospital complex, including departments in SAT Hospital and the new super-specialty block, has 86 ventilators, all of which are crashing one by one because few have effective AMCs. All the machines here are overused and kept running way beyond the warranty period without repairs. So the companies now refuse to do any more repairs without the AMCs," sources close to the administration told *The Hindu* on condition of anonymity.

The sources declined to divulge how many ventilators were functional.

"The Thiruvananthapuram hospital has anywhere between 500 and 800 pieces of costly life-saving and diagnostic equipment. But only the AMC files of some 50 very essential items — anaesthesia machines, ventilators, the air-conditioning plant, etc. — have been processed so far. The biomedical engineering wing can only do occasional troubleshooting, and the rest of the costly equipment can be repaired and maintained only by the service engineers of the parent company," an official said.

**Huge annual cost**

The total annual maintenance cost of all equipment in the hospital would easily come to crores. It is over Rs.30 lakh for the CT scanner and Rs.20 lakh each for the MRI scanner and the cath lab, together coming to about Rs.70 lakh, officials said.

"The warranty period of each equipment differs, and government rules allow an AMC only after its expiry. Even if funds were to be set aside for the contracts, money can be released only if the file of each equipment is processed on time, they said.

"The AMC files of all expensive equipment in all five government MCHs are processed at the office of the Director of Medical Education. Each purchase or tender is a separate file and this means that for 500 pieces of equipment, there may very well be hundreds of files. Needless to say, clearing the AMC files of one institution, leave alone five, is an unmanageable task for the technical committees," a senior official of the Thiruvananthapuram hospital said.

"Tertiary-care hospitals such as those attached to the medical colleges cannot be run with this kind of a crisis-management exercise. There has to be an easier system and administrative process so that the equipment worth crores are well maintained and made available for the public. The government could think of handing over the responsibility of annual maintenance of medical equipment to some other government or external agency."



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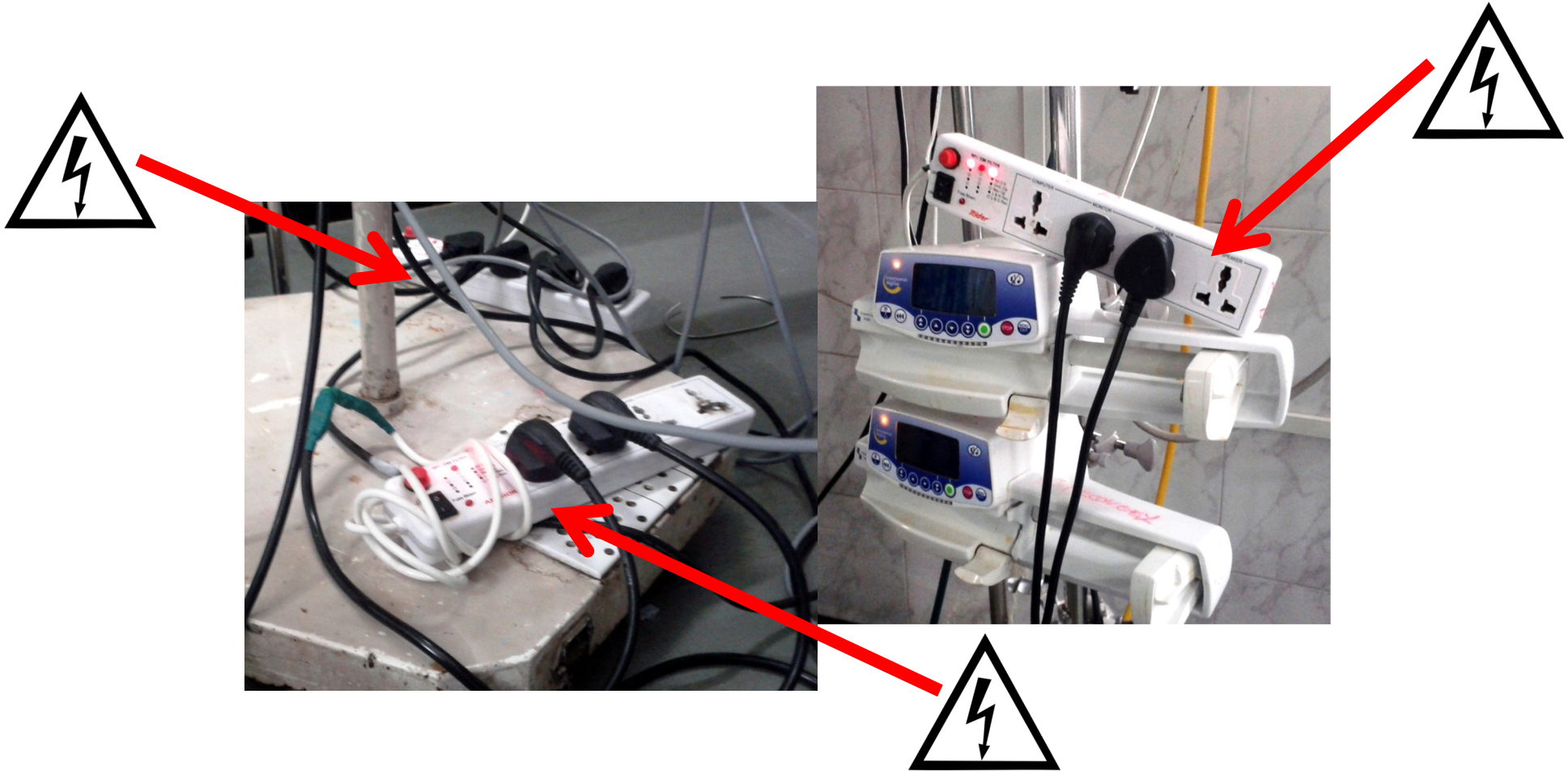
# Medical Equipment in Clinical Use !!!

# Electrical Extensions – a Hazard !!!



# National initiatives for awareness creation

2007

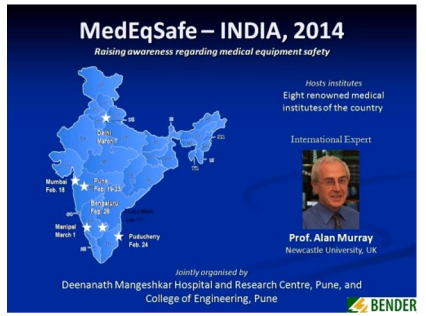
2012

2008


2013


2009

2011




2014

# Equipment QA and Safety Demystified

## Surgical Scalpel

Functional Requirement
- Sharpness

Safety Requirement
- Sterility
  (An independent requirement)


Functional **and Safe**

Functional **BUT Unsafe !!!**

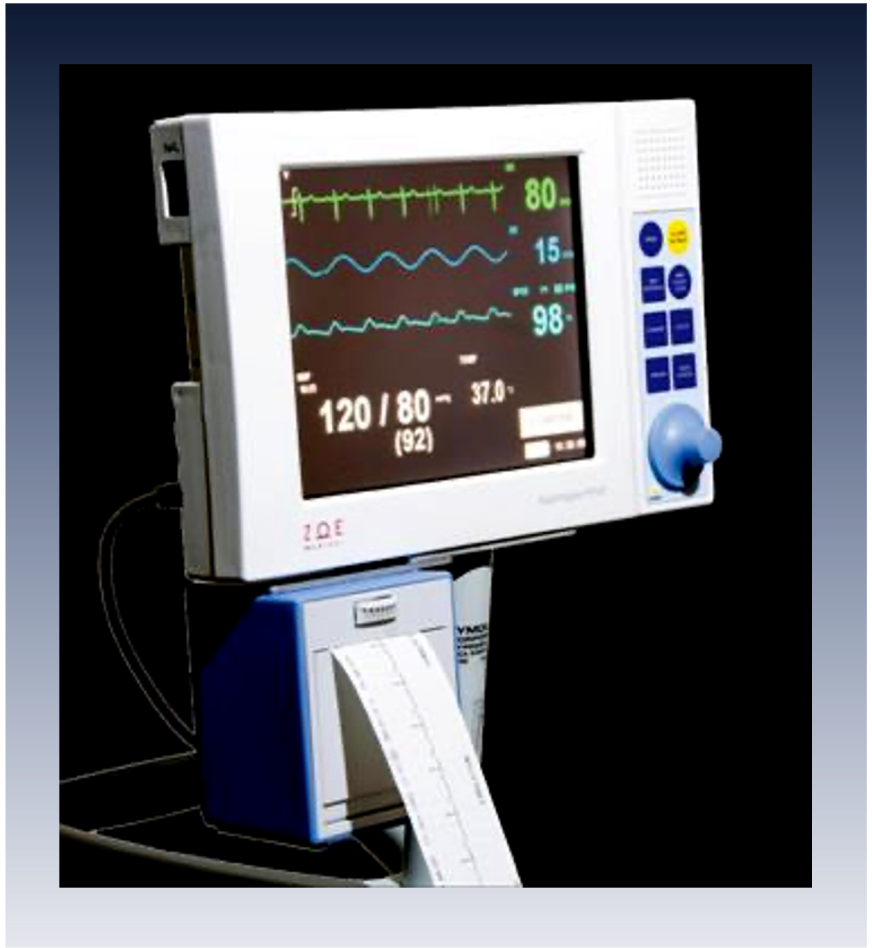
Clinical professionals will **NOT** use this device in this condition

# Equipment QA and Safety Extrapolated

## Patient Monitor

Functional Requirement
- Monitor patient parameters

Safety Requirement
- **Electrical Safety**
- Calibration and QA **(An independent requirement)**




Are clinical professionals **aware** of these requirements?



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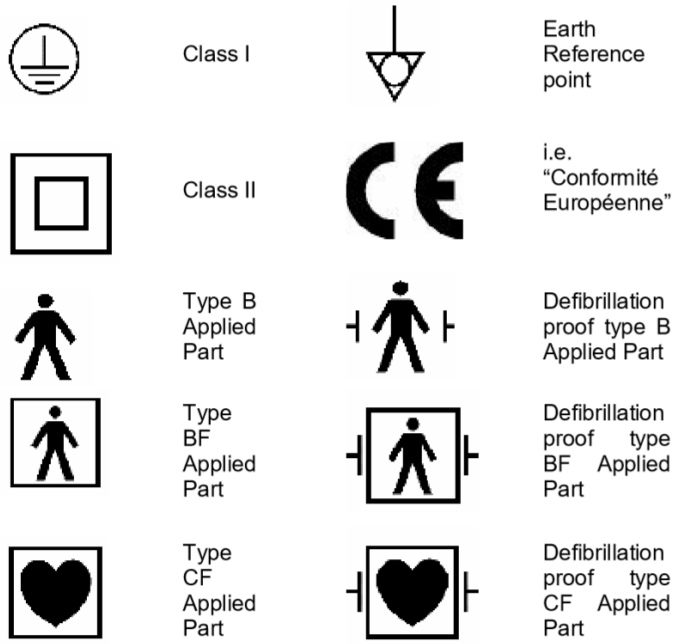
# Electrical Safety Testing

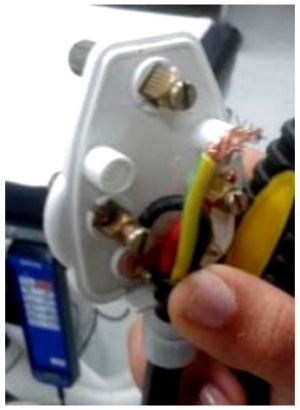
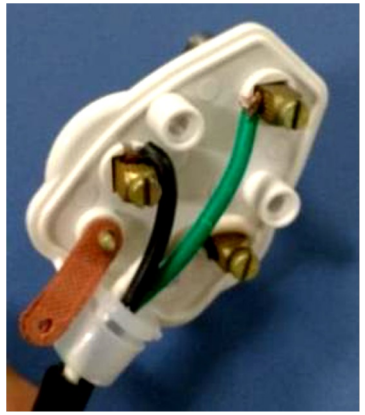
# Electrical Safety Testing - IEC 62353(2014)

**Medical electrical equipment – Recurrent test and test after repair of medical electrical equipment**

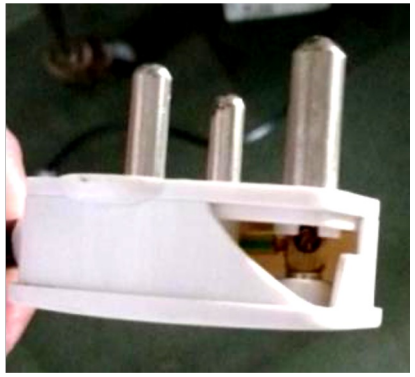
- **Periodicity – <u>6 months / 12 months</u>**
- **Earth bonding – an essential first !!!**
- **What is the situation in clinical use?**



# Sub-optimal **earth bonding** in clinical use

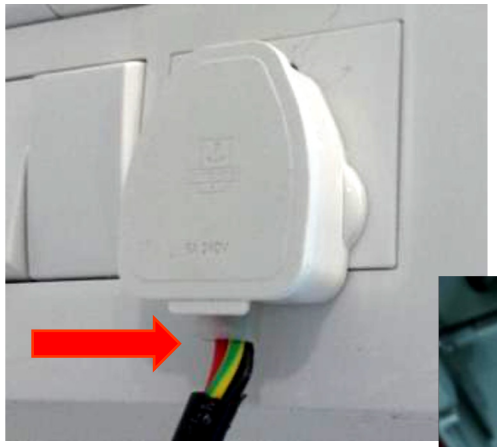



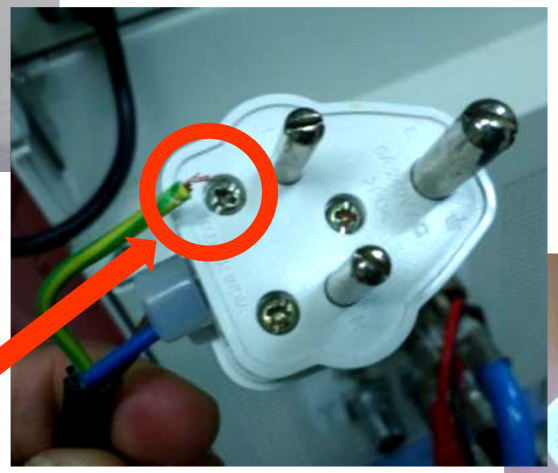




Lack of reliable **Earth Bonding** - a chronic problem !!!

# Poor Earth Bonding – investigating the root cause



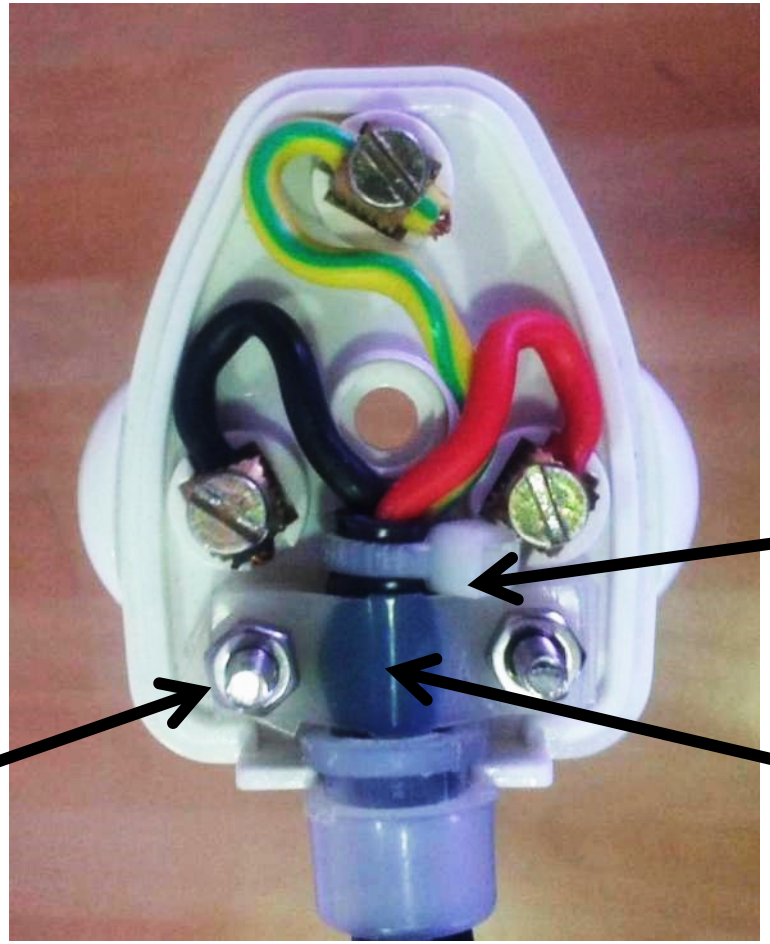


Disconnected Earth

Weak Retainer clip

European pin top in an Indian socket - **No earth connection possible**

# Solution - securing the cable and earth connection



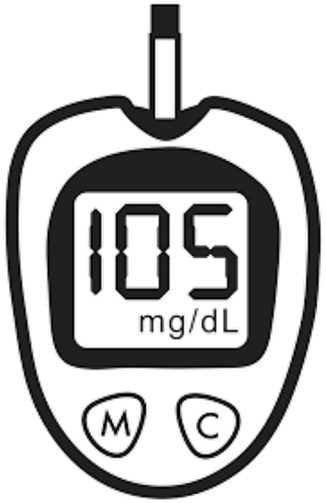
A **simple** and **cost-effective** solution

Interlocking with cable tie

SS Ny-lock nuts and bolts

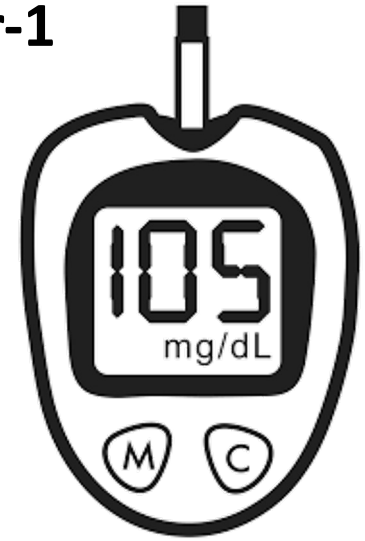
Strong nylon retainer clip

# The ‘Glucometer Story’



# The ‘Glucometer Story’

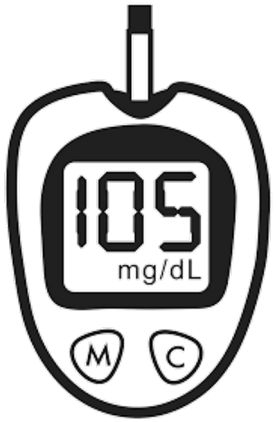
- A call from Obstetrics ward at **8 p.m.** to Clin. Engg. Dept.
  - Neonate having **low blood glucose** as shown by **Glucometer-1**
  - Shifted to Neonatal IC (NICU)
  - **Glucometer-2** in NICU showed **normal blood glucose**
  - **Was there a real need to shift the neonate to NICU?**
- Which of the two **Glucometers** was correct?




- **Can the field Clinical Engineer find an immediate answer?**

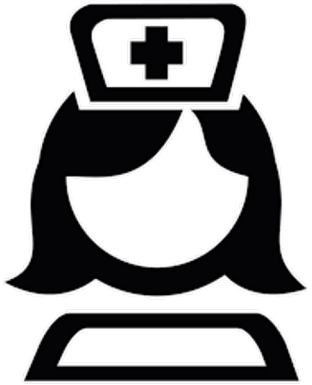
# Isolating the source(s) of the error

- Medical Device
  - The Glucometer and the strips?



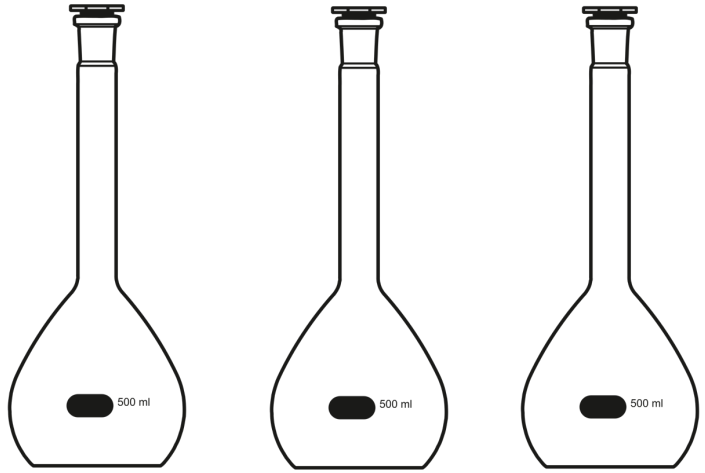

OR

- In-correct use
  - Untrained user?



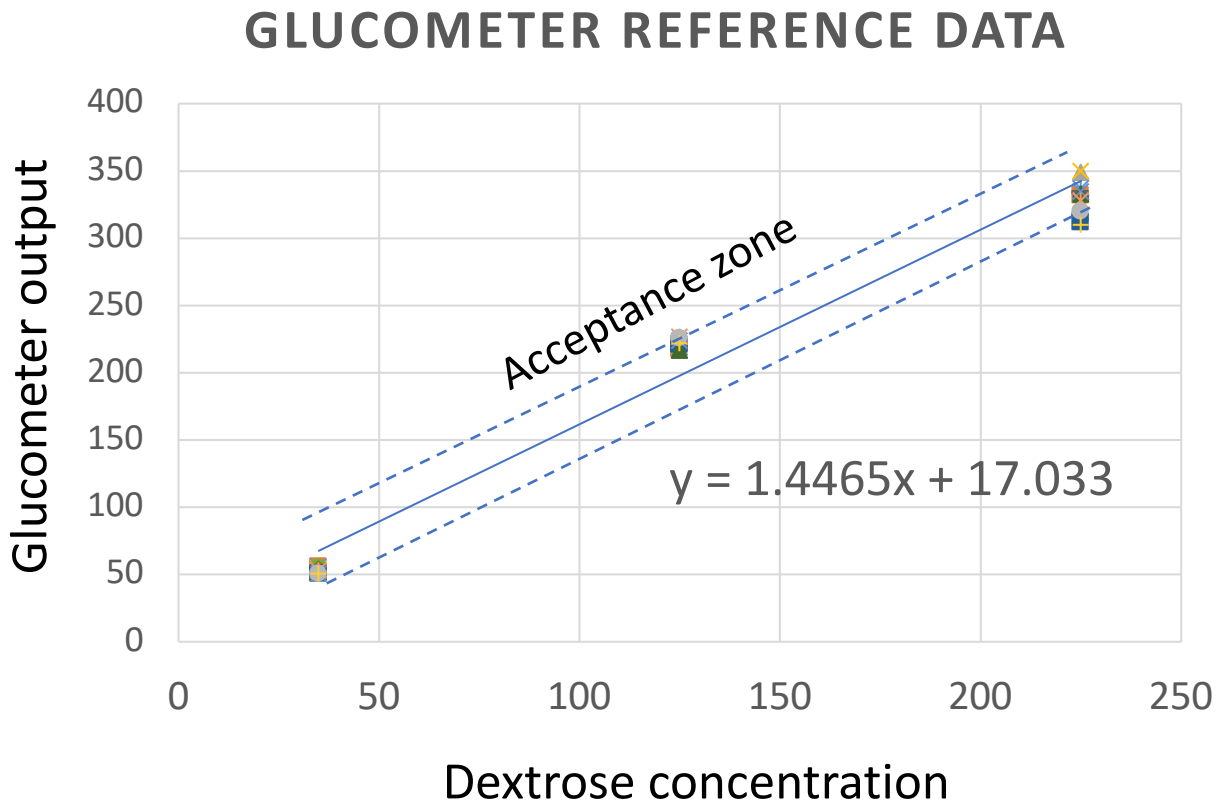
**Clinical Engineer needs to isolate the source?**

# In-house generation of ‘Reference data’




35 mg/dl 125 mg/dl 225 mg/dl

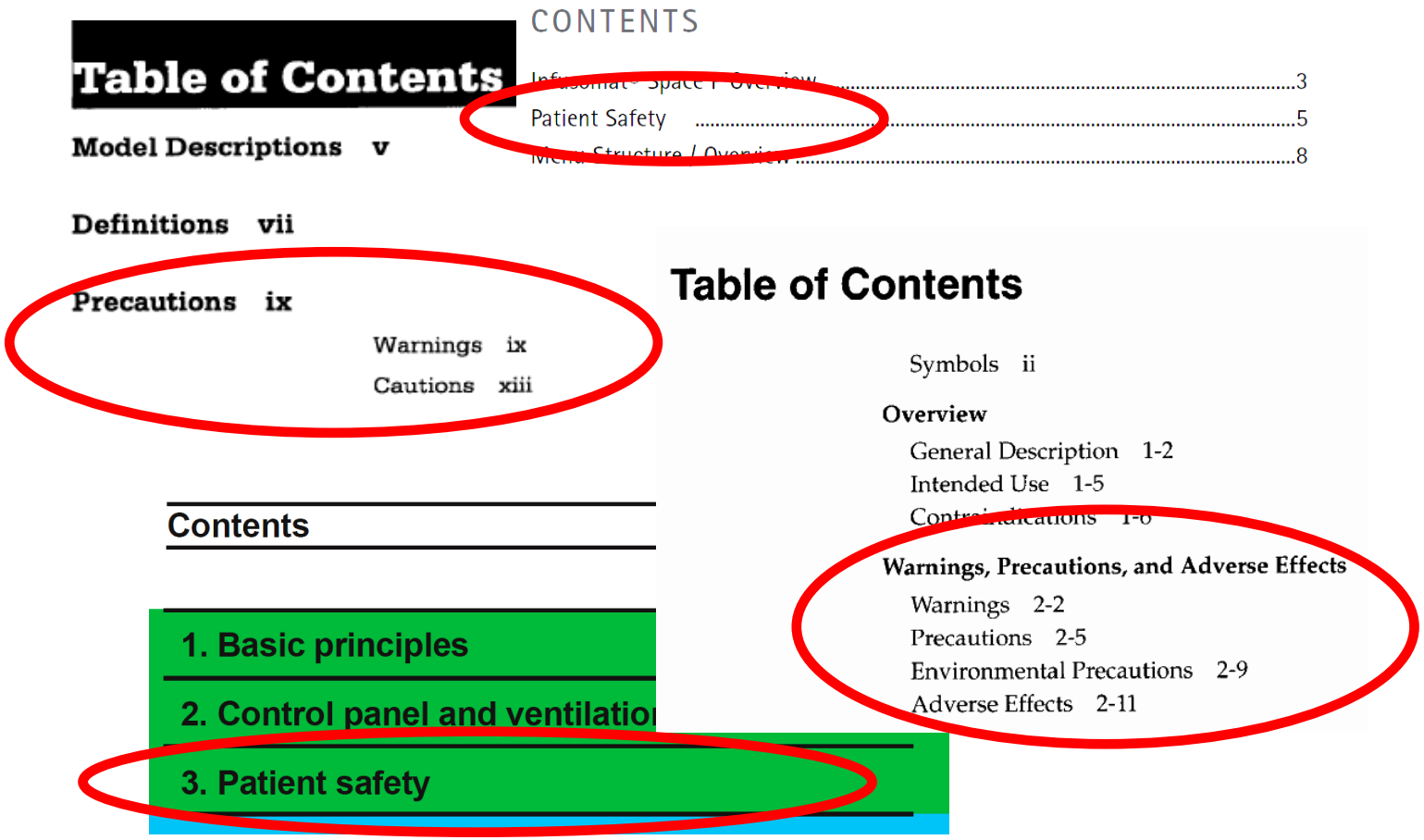
Reference Dextrose solutions with 3 different concentrations



# Empowering the clinical staff through training

# Training of clinical staff – an essential step

# Medical Equipment Literature – a key resource



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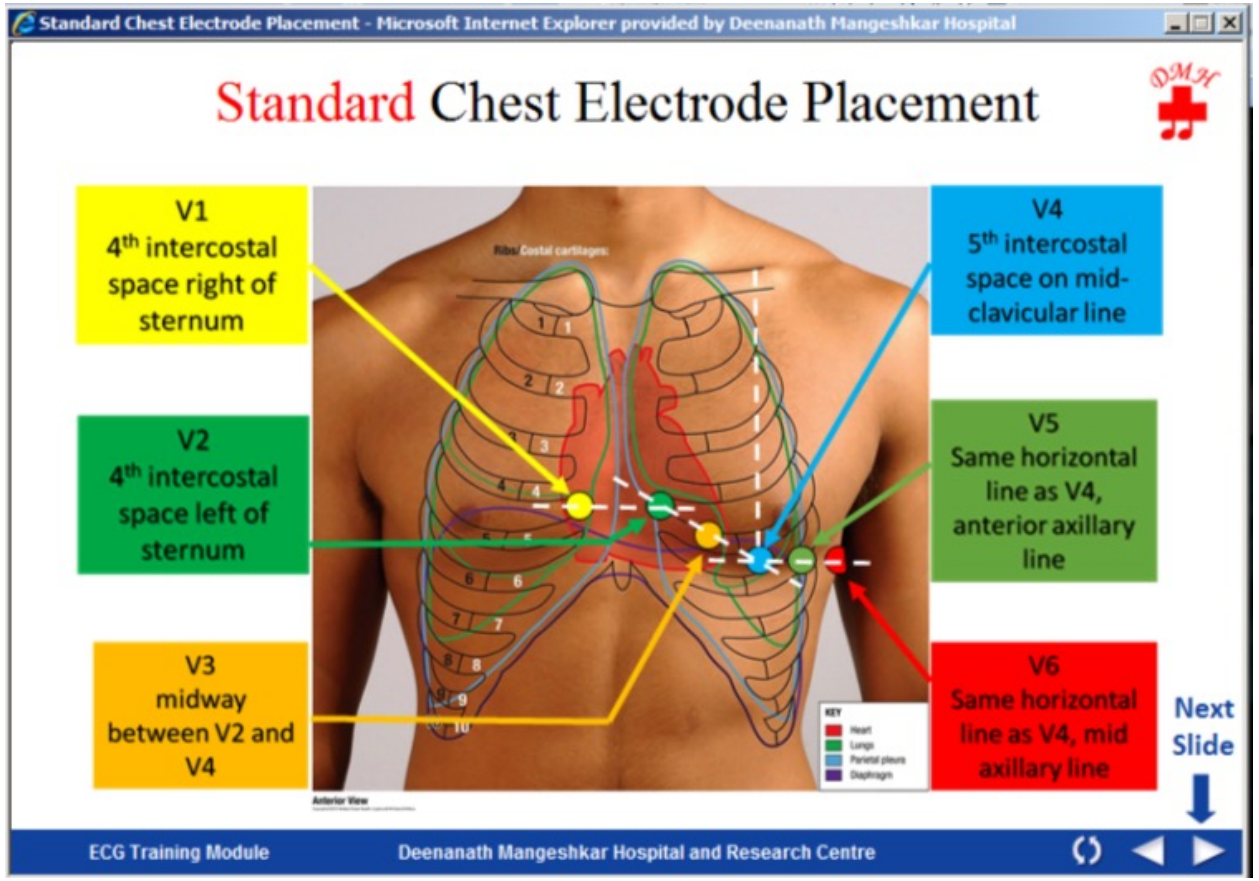
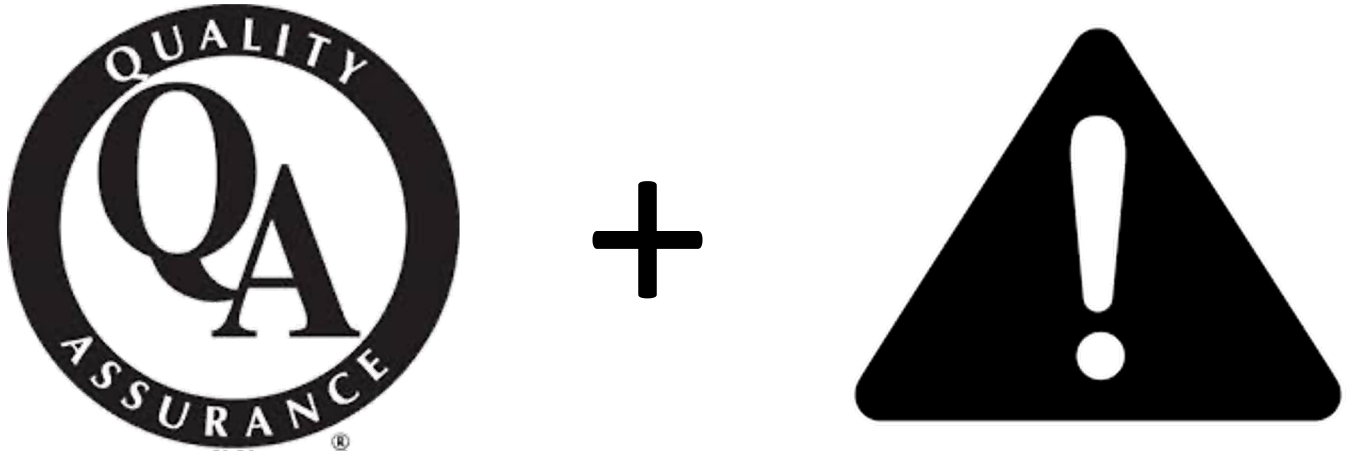
# E-learning – an effective tool



# In Summary .....



# The **take home** message

- Engage
  - with the clinical staff
- Observe
  - with a keen eye
- Investigate
  - with a scientific mind
- Innovate
  - with simplicity
- Implement
  - a cost-effective solution
- Follow-up
  - on its effectiveness

# A **BIG** thank you to ……

- Global Clinical Engineering Alliance
- Deenanath Mangeshkar Hospital and Research Centre

All my colleagues and friends
who continue to encourage us
as well as
contribute in these efforts to offer
**Safe and Quality care to patients**

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# Thank you !

**Niranjan D. Khambete**
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Q&A

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A list of additional topics and dates for next webinars will be soon announced on our website www.GlobalCEA.org

THANK YOU
for your participation