MIND THE GAP

Facing the standards gap

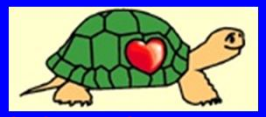
Focus on sterilization of medical supplies in developing world

A sterilizer for the rest of us

STERILTEKNISKA FÖRENINGEN

Sterildagarna 2022

Stockholm 26-10-2022



HEART Consultancy

Healthcare through **A**ppropriate and **R**eliable **T**echnology

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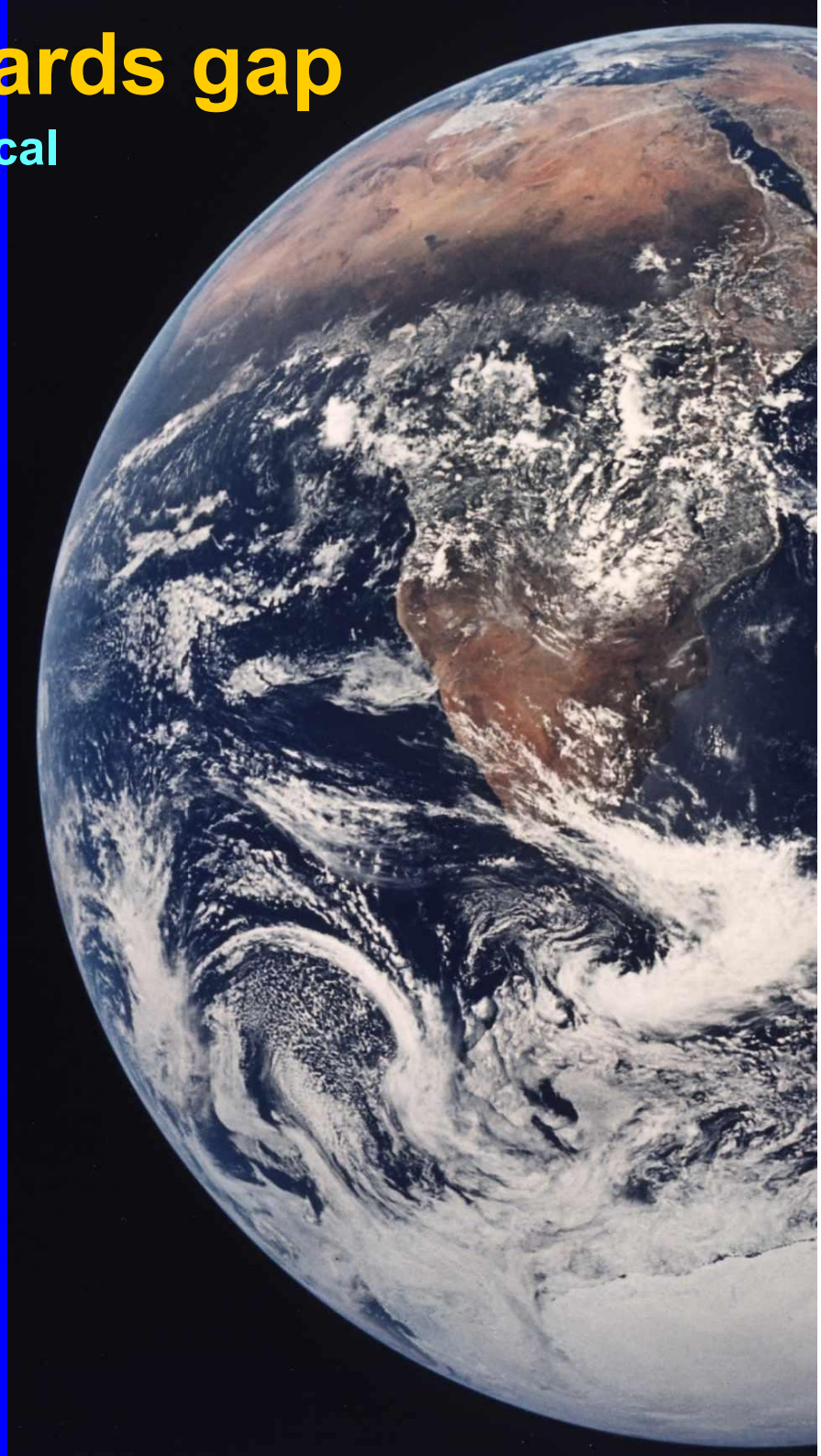
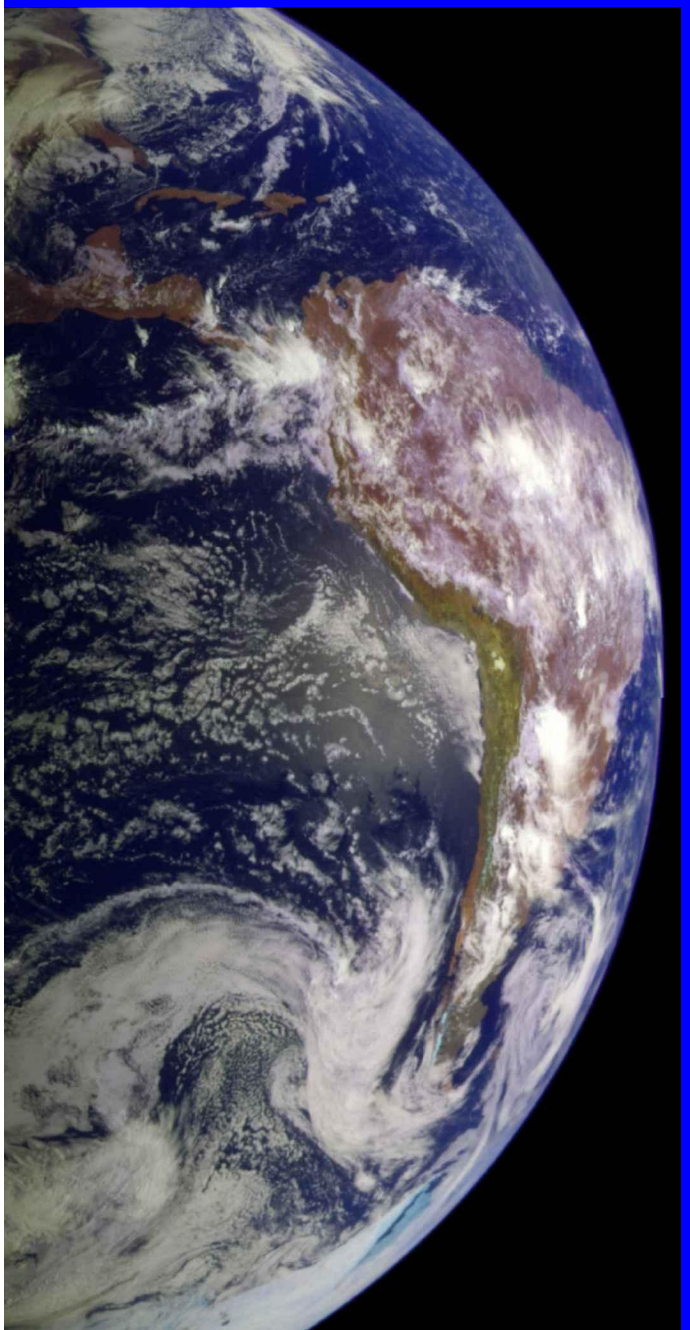
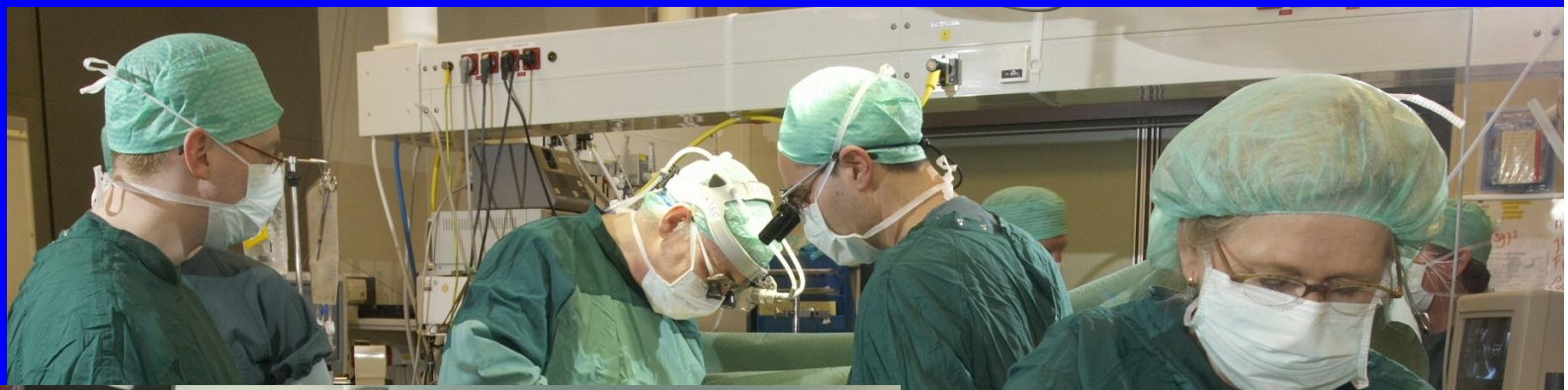


Facing the standards gap



- Technology in health care
- Focus on sterile supply
- Local reality/constraints
- Situation analysis: sample cases; sterilization and cleaning
- Objectives of standards
- Problems caused by standards
- Bridging the gap: Toward a solution
- Concept for sterile supply
- General design considerations for medical devices for LMIC's

Modern healthcare has become dependent on advanced technology



Advanced technology in the CSSD (Central Sterile Supply Department)

Advanced technology in the CSSD (Central Sterile Supply Department)

Introduction of Packaging robot: UMC Nijmegen NL

Technological infrastructure

A few hours flying from here . . .

MIND THE GAP

Arrival

Arrival


50
ABUJA
LEADERSHIP
friday
Uncompleted Buildings In Abuja For Demolition

MIND THE GAP

Arrival

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Health post: first line of care

Health facilities with limited resources

Typical District Hospital in Africa.
Approx. 100 beds. Catchment population: 100.000
With Out Patient Department, Maternity, Surgery, Laboratory, Radiology service and Wards.

Reliable sterile supply is indispensable!

Local context: Constraints of Supplies/Infrastructure

Electricity supply

Water supply

Access roads

Local context: Operational constraints

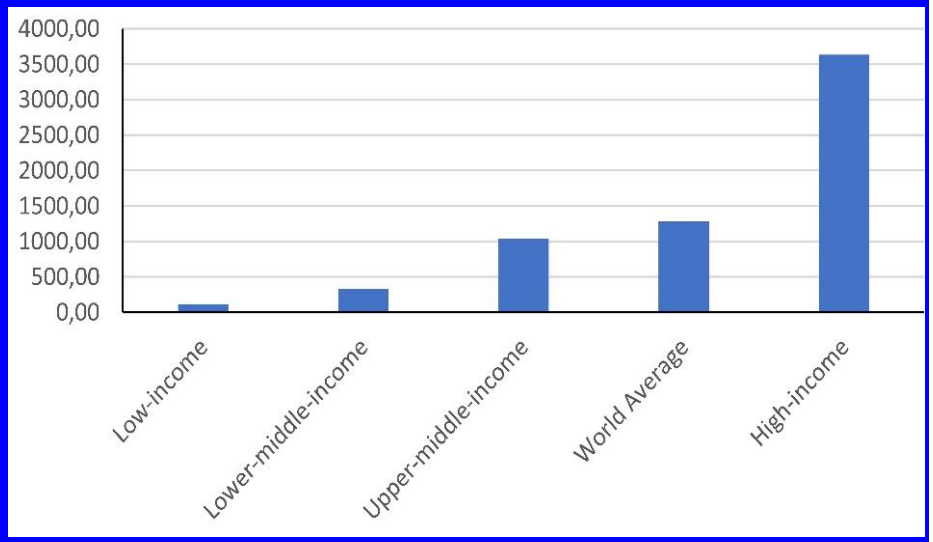
Operating Staff

Technical Support

Limited budgets

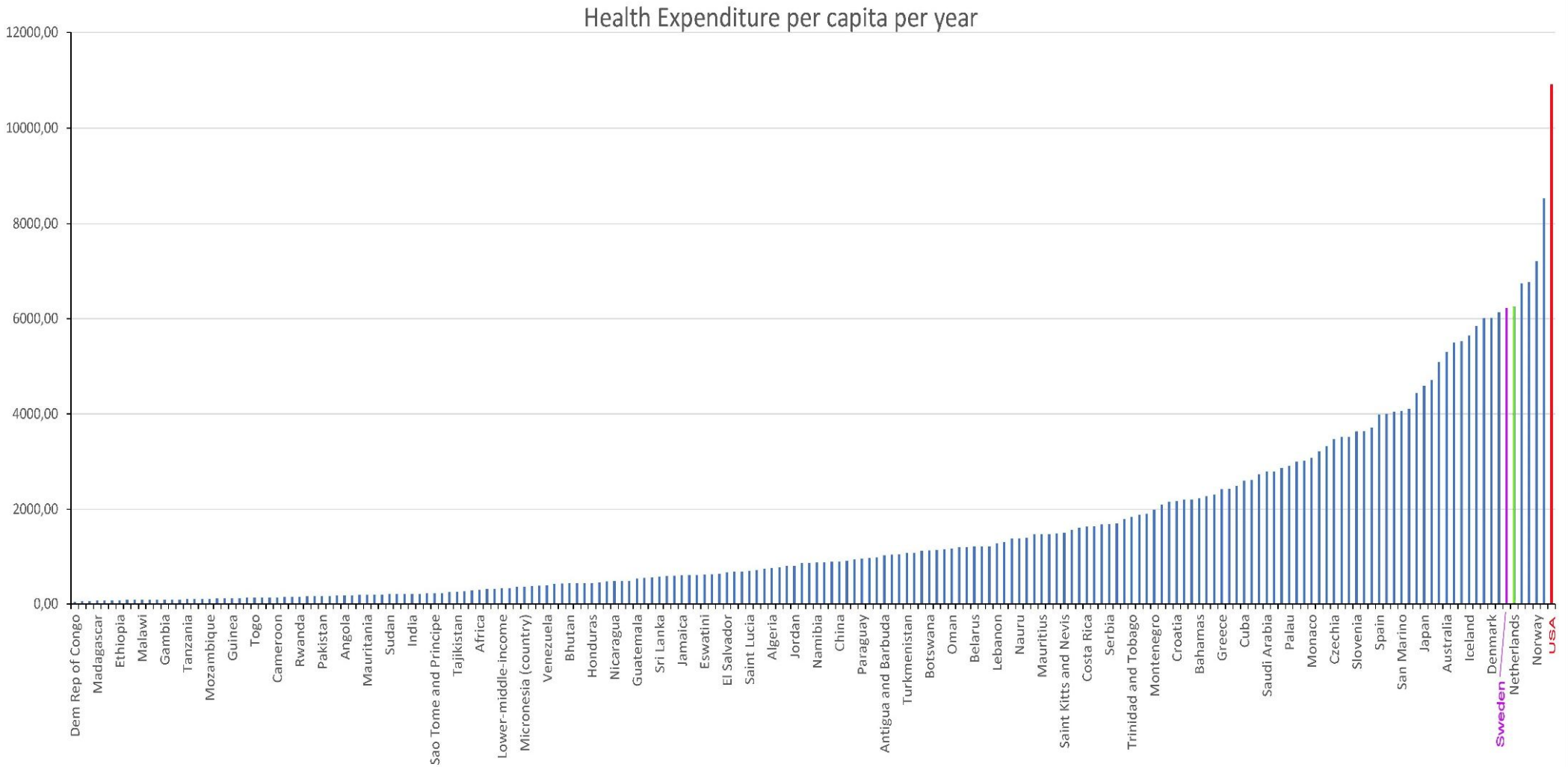
Medical technology is embedded in industrialized societies

Well trained operating staff and technicians is essential, but scarce!



Annual per capita expenditure on health care

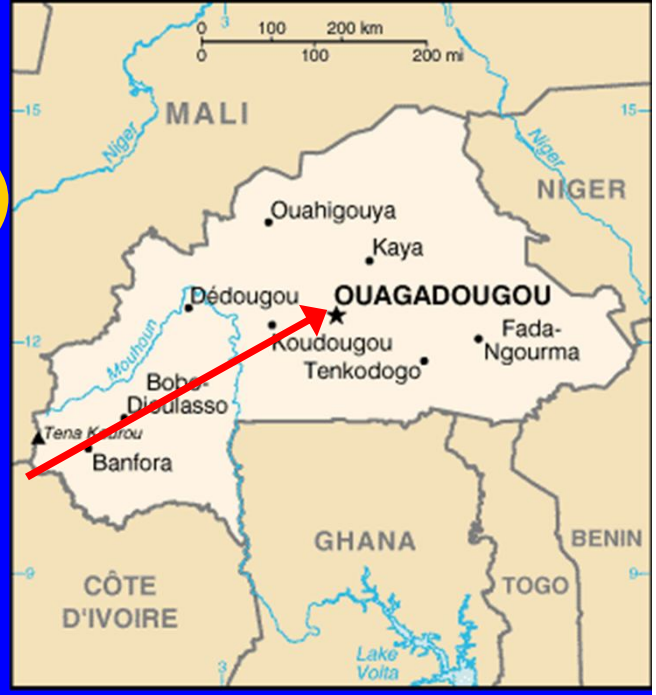
Local context: Limited budgets
Per capita spending on health care per year



Dem Rep Congo: 41 ***Ghana: 193*** ***Poland: 2.200*** ***Sweden: 6.300*** ***USA: 11.000***

Figures: WHO 2019

Case 1: CMA de Kossodo, Ouagadougou, Burkina Faso. (2005)



Case 1: CMA de Kossodo, Ouagadougu, Burkina Faso. (2005)

Case 2: Hopital Communautaire de Bangui, CAR (2009)

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Case 3: Bungudu General Hospital
Zamfara state, Nigeria (2012)

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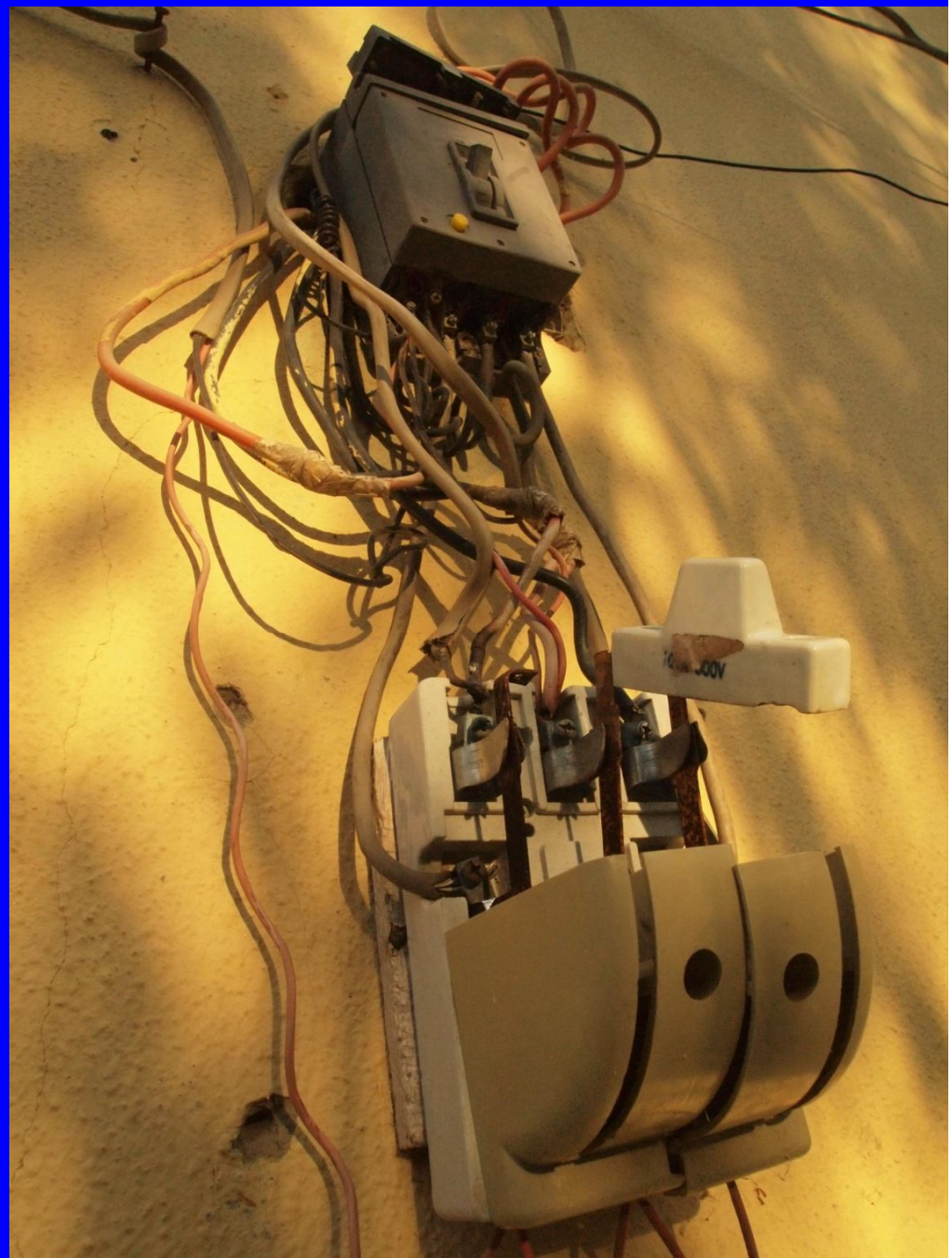

Case 3: Bungudu General Hospital, Zamfara state, Nigeria (2012)

Case 4: JF Kennedy Medical Centre, Monrovia, Liberia (2015)

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Deutsches Rotes Kreuz

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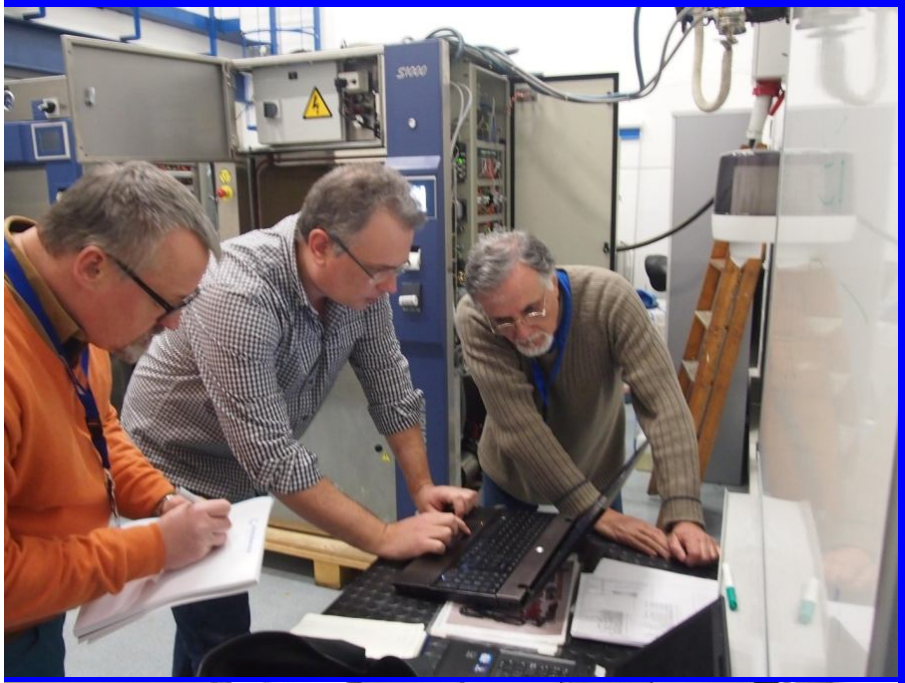

Case 4: JF Kennedy Medical Centre, Monrovia, Liberia (2015)

Case 5: University Teaching Hospital Orlu, Imo State, Nigeria (2015)

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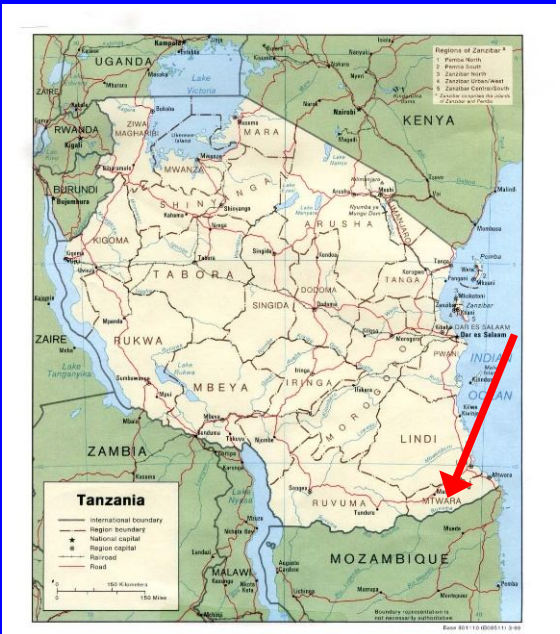
Case 6: St Benedict Hospital, Ndanda, Tanzania. (2019)



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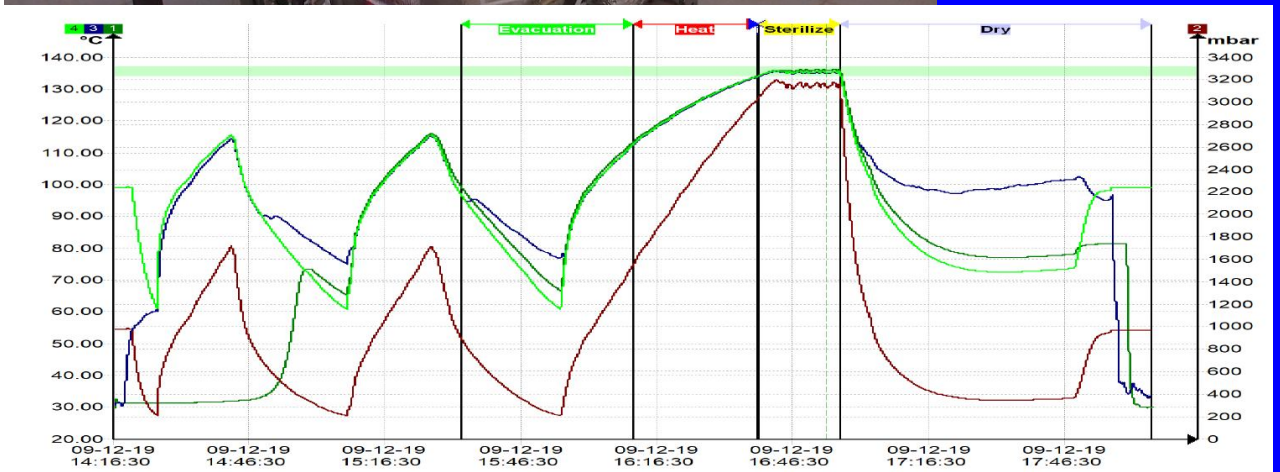
Case 6: St Benedict Hospital, Ndanda, Tanzania. (2019)



Case 6: St Benedict Hospital, Ndanda, Tanzania. (2019)

Case 7: Bugando Medical Centre Mwanza, Tanzania. (2019)

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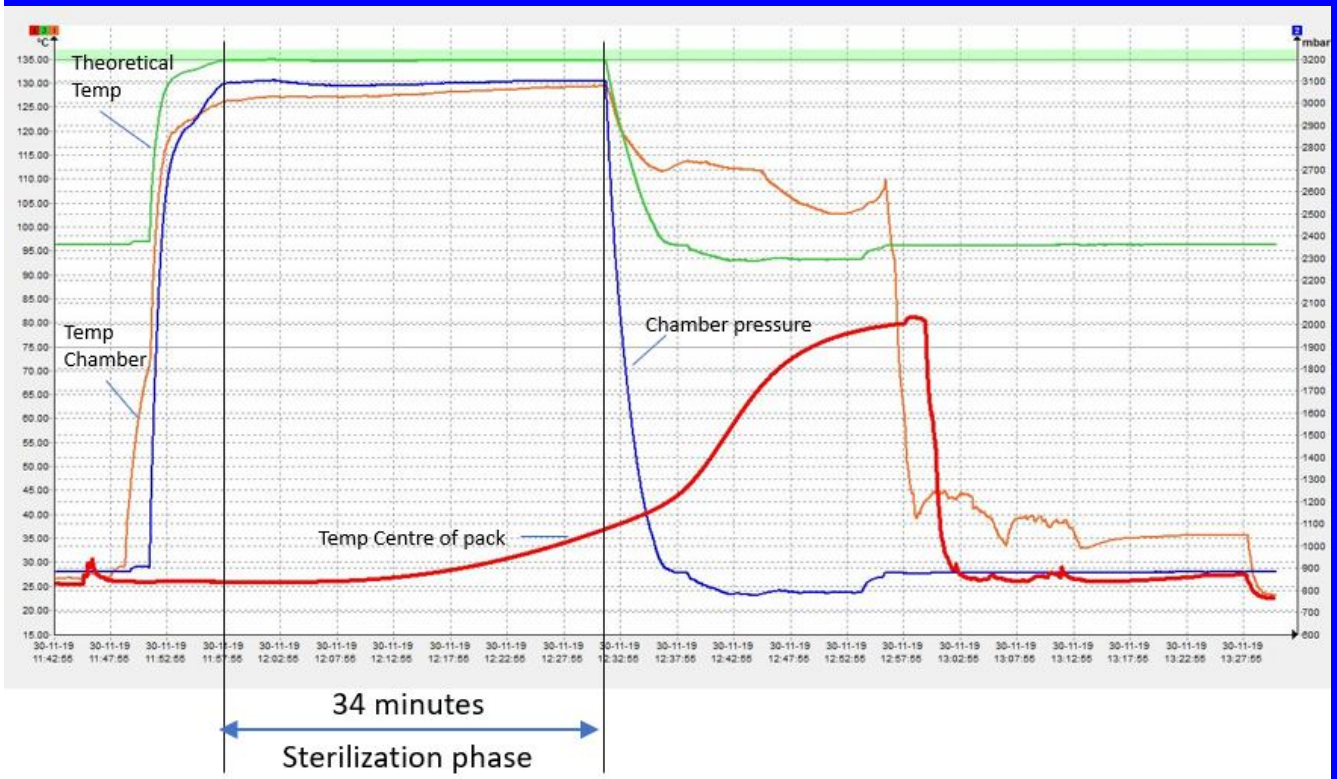

Case 7: Bugando Medical Centre Mwanza, Tanzania. (2019)

Case 8: Maiduguri University Teaching Hospital Maiduguri, Nigeria. (2022)

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Local context: Sterilizer acquisition

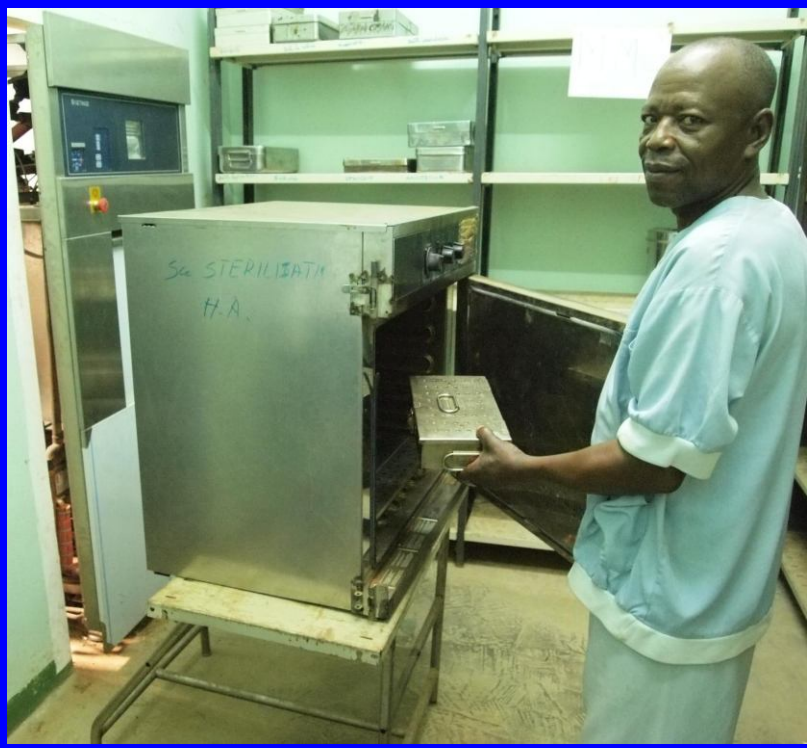
- Driven by low cost: ➔ procurement of cheap, substandard equipment
  - **Poor performance**
  - **Poor safety**




Cheap, but poorly performing and poor quality sterilizers

Local context: Sterilizer acquisition

- Driven by (western) standards:
  ➔ procurement of high-tech equipment.
  - High-tech is embedded in high-income economies with all required resources.
  - Transfer of high-tech to low-income economies without considering the context is bound to fail.
  - Donor/procurement community tends to supply equipment meeting the standards. Very limited know-how about actual conditions in the field
- **Standards thus may lead to non functioning equipment**



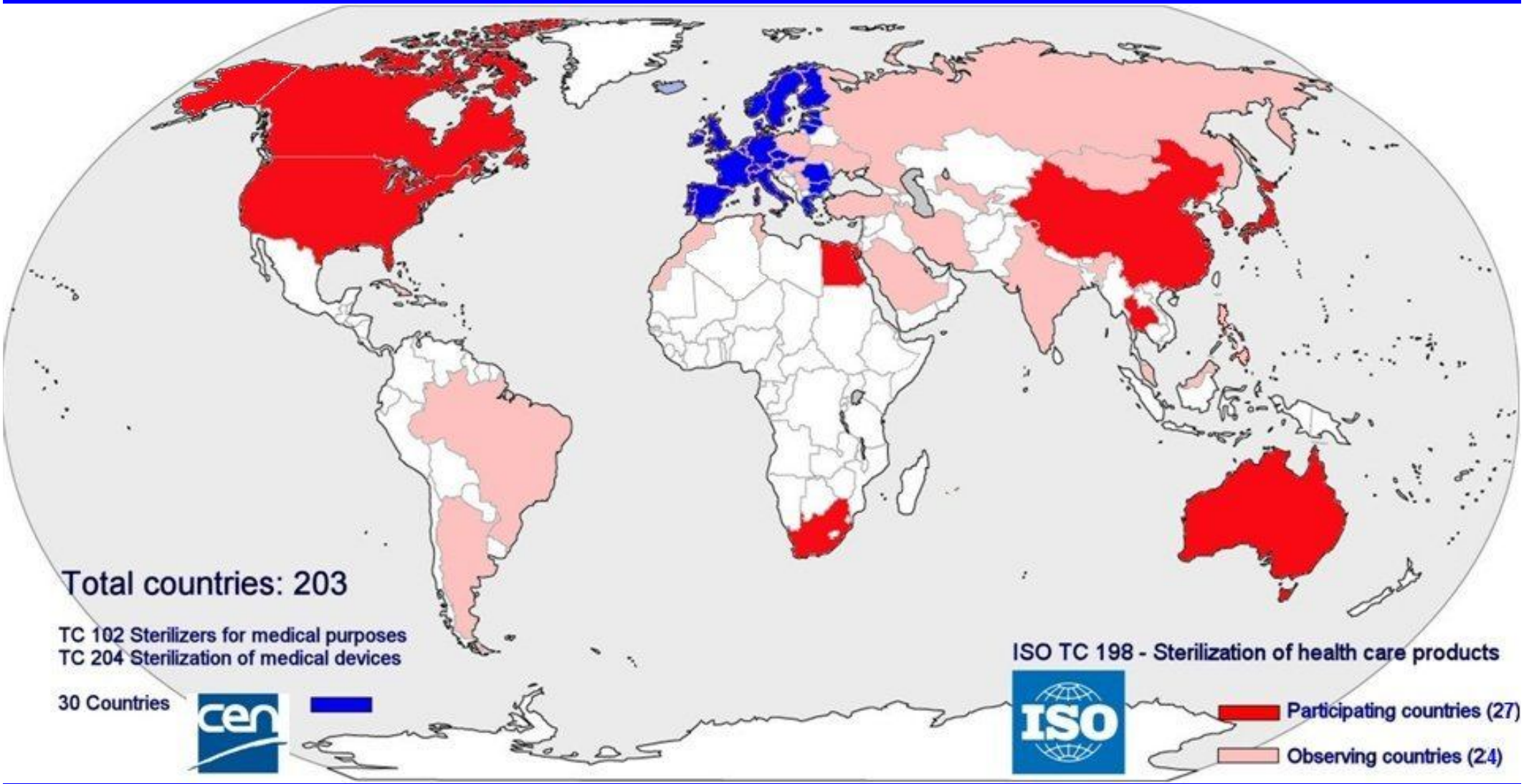
Broken down high-tech sterilizers in regional hospitals.

International standards for sterilization Objectives

- Ensure safety and health of the users and patients
- Ensure minimum standards of quality

- Facilitate interchangability of products and services between nations: reduce trade-barriers
- Legal requirements: responsibility: traceability

Membership of CEN/ISO sterilization-related Technical Committees

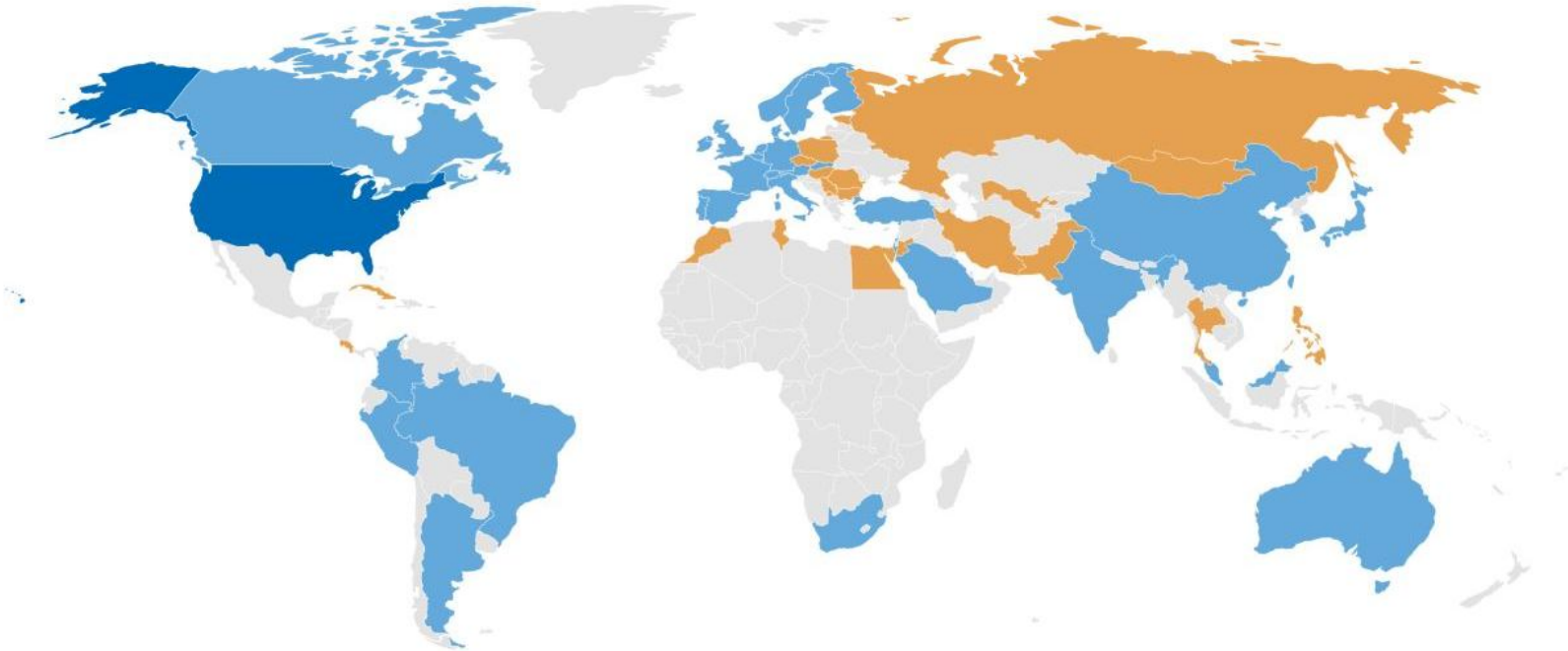


Membership of ISO TC 198 (2021)
Sterilization of healthcare products

Standards | About us | News | Taking part | Store | EN

ISO/TC 198

PARTICIPATION



This map is designed to visually demonstrate the geographic distribution of our Members. The boundaries shown do not imply an official endorsement or acceptance by ISO.

- Participating members (34)
- Observing members (21)

Membership of WFHSS (2022)

- Participating members (79)
- Countries (66)

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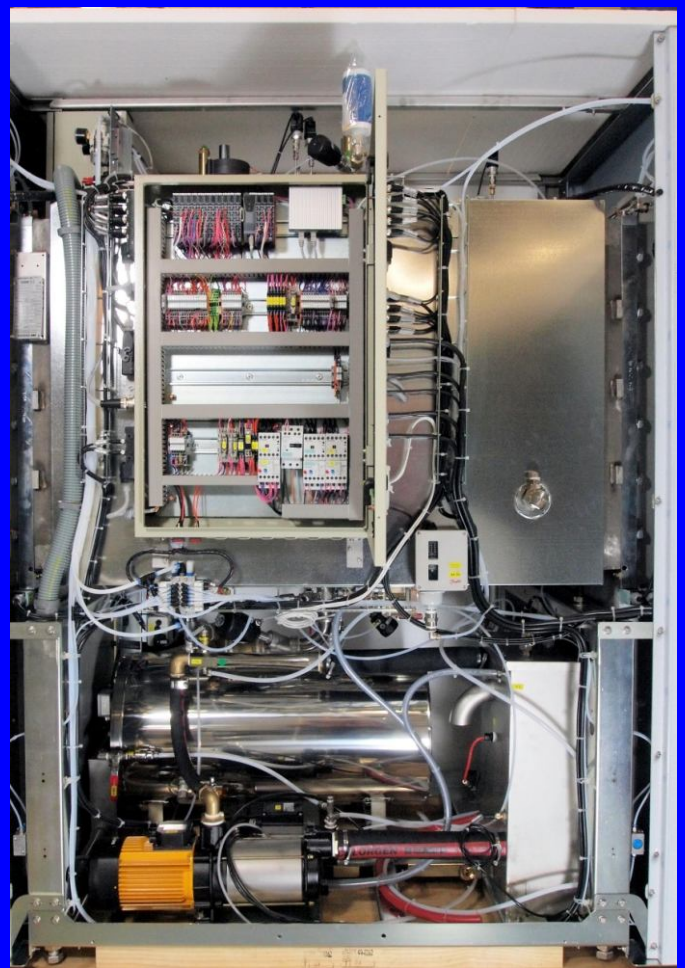
The current standards result in

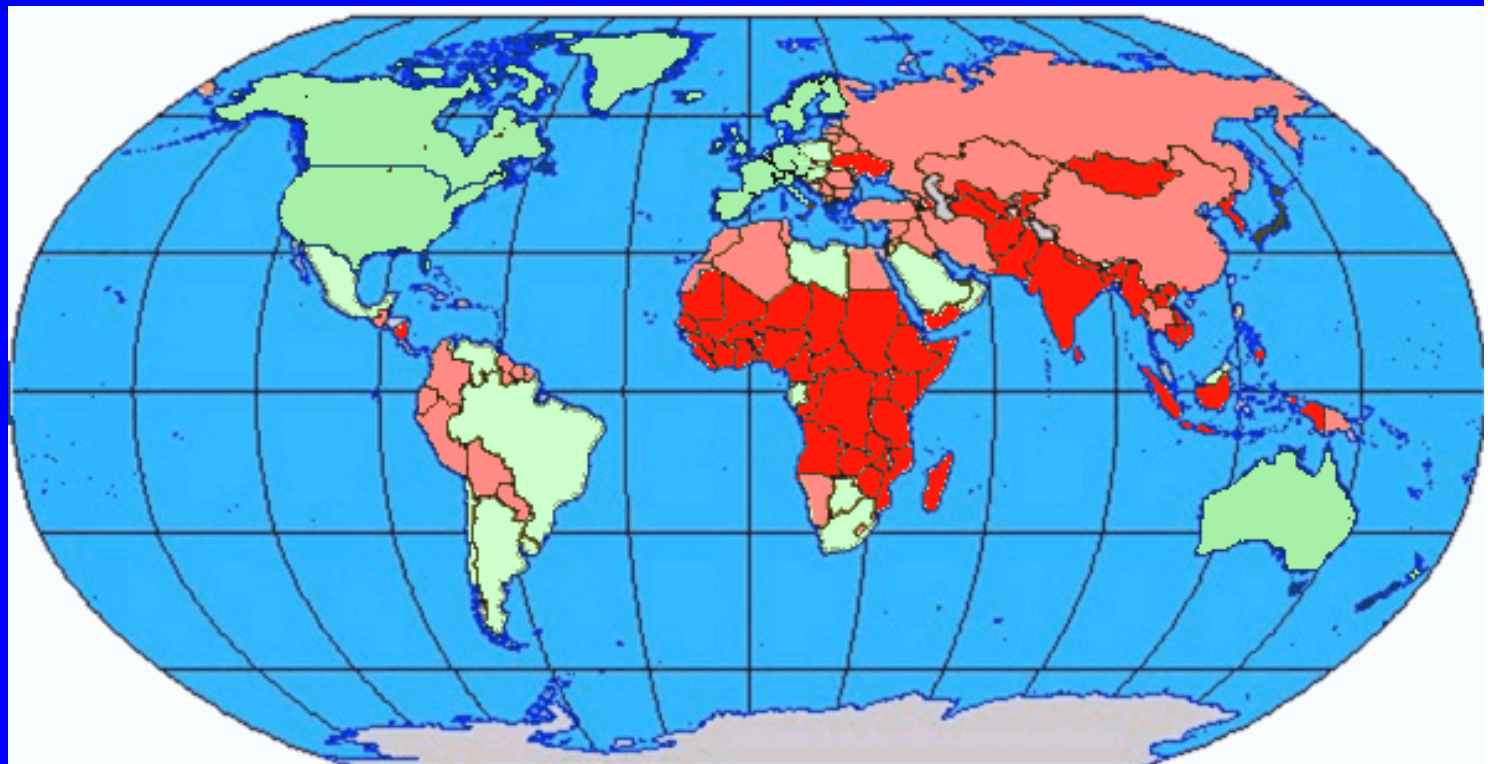
- High performance automatic sterilizers; human intervention is virtually ruled out
- Require advanced technology
- Requires advanced infrastructure, support and thus: money.



Situation in developing countries

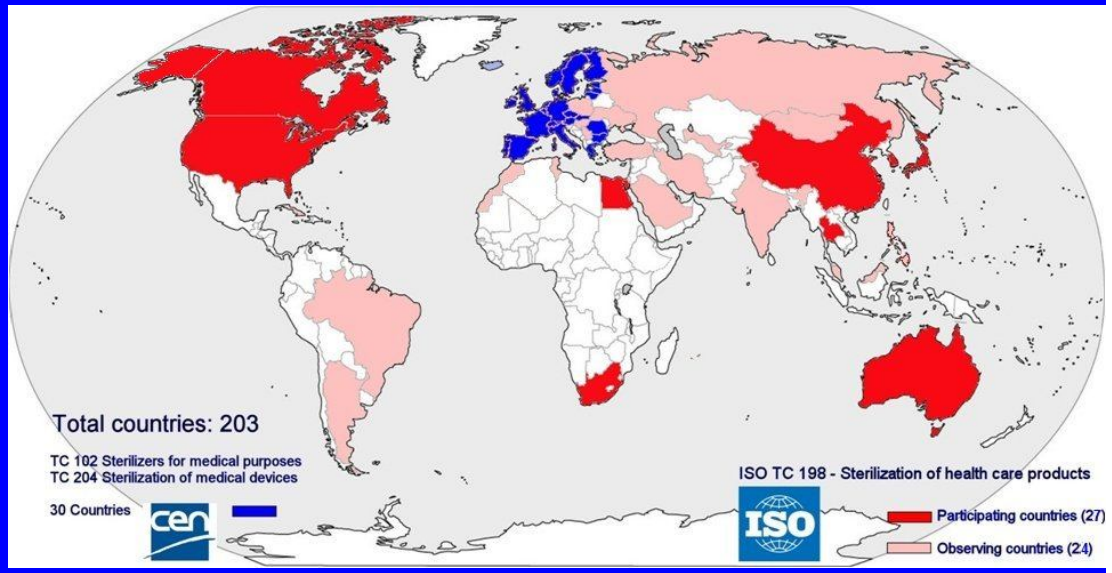
- Majority of world population (6.9 billion) lives in low/middle income countries (approx 4 billion)
- Health authorities seek to follow developments
- Eager to improve situation
- Want guidance to improve
- Want to use of international standards as reference

Total: 6.9 billion
Low/medium income:
4 billion



Bridging the standards gap
Case: sterilization of medical supplies

- Consider local economy: Compatible with socio-economic background
- Facilitate that developing countries become members of standards committees
- Identify relevant standards: e.g. No concessions to ISO/CEN standard for sterility of products (CEN/ISO 554)
- Interim solution: Provide binding guidelines for emerging markets through authorative bodies such as WHO, Red Cross, MSF



Bridging the standards gap
Case: sterilization of medical supplies

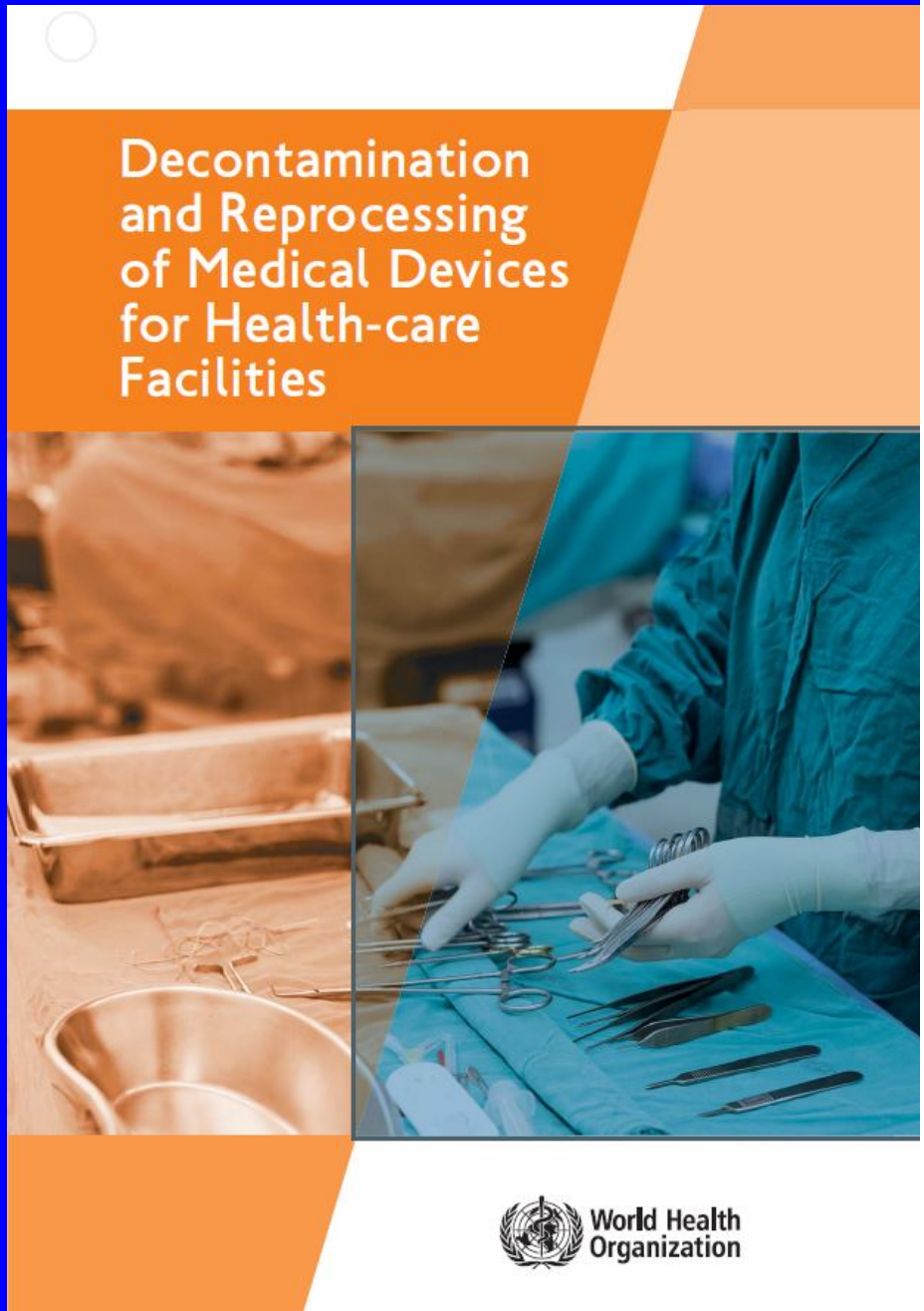
- Validation of all steps of reprocessing cycle
- Introduce quality assurance

- Development of products appropriate for this (huge) market based on guidelines

- Education/Training at all levels

Bridging the standards gap
Case: sterilization of medical supplies

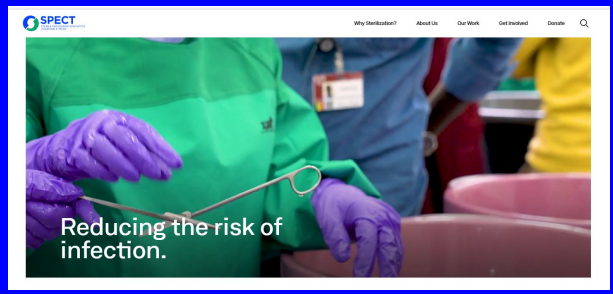
- Need for legal framework that considers the socio-economic reality in a respective country
- Need for standards the are compatible with the legal framework
- Industry can develop products within the criteria, and have a reasonable chance for a market
- Initiatives: WHO-guidelines for sterile supply. Note: issues related to equipment not addressed!



Bridging the standards gap
Case: sterilization of medical supplies

- Initiatives related to training :
  SPECT, Canada: Christina Fast

SPECT
STERILE PROCESSING EDUCATION CHARITABLE



Bridging the standards gap
Case: sterilization of medical supplies

- 2019: WFHSS Working group: sterilization in developing world

World Federation for Hospital Sterilisation Sciences

Still great needs for support/training!

- Request from Cameroon for 3 Hospitals under the Evangelical Church of Cameroon
- Training sessions on sterile supply

Conclusion

- World wide standards should be world wide!
- Developing countries want to develop!
- Need of appropriate equipment that meets essential functional requirements and local conditions
- Role for standards organizations ISO and CEN; WHO
- Instability in many regions increases demands for equipment that can function with very limited conditions and infrastructure