GLOBAL CLINICAL ENGINEERING ALLIANCE™

WEBINAR

Oxygen concentrators for individual patients and health facilities

Technology, usage, service

WEDNESDAY JULY 6

6PM UNIVERSAL TIME (UTC)

2PM NEW YORK TIME (ET)

REGISTER FOR FREE

https://bit.ly/395UVDP

MODERATOR

STEFANO BERGAMASCO

Member of the Italian Clinical Engineering Association, GCEA Founder Council Member, and CEO at MedTech Projects Srl. (Italy)

PRESENTERS

ALEXANDRE H. HERMINI

Hospital Equipment Advisor at CAISM UNICAMP Women's Hospital. (Brazil)

JOSE R. BALOTE

Owner at Enimed Engineering and Hospital Facilities Ltda and Dental-Medical Committee Secretary at Hospitalar (Brazil)

LEANDRO PECCHIA

Prof of Biomedical Engineering at Università Campus Bio-Medico di Roma and University of Warwick - IUPESM, EAMBES, ABSPIE. (Italy)

STEFANO POLVI

CEO at Logic Srl, Logic Africa Ltd, Logic Senegal Ltd. and Visped doo (Italy)

GCEA Awards

A recognition program to promote knowledge sharing, excellence in international collaboration, exceptional clinical engineering or technical service, leadership, and stewardship.

GLOBAL CLINICAL ENGINEERING ALLIANCE™

2020 CE PERFORMANCE AWARD

2021 COLLABORATIVE CAPACITY BUILDING AWARD

Have you ever nominated a colleague for an award?

The Global Clinical Engineering village hosts many individuals and associations that can serve as ~~a~~ professional model. Now, as you think about these individuals or associations make the effort to nominate them for an award. Go to the site below and nominate them.

https://www.globalcea.org/clinical-engineering-awards

GCEA Collaborative Capacity Building Award

This award recognizes groups or societies for their contribution toward collaboration with other countries to improve their knowledge, education, capacities, and status in the Clinical Engineering field.

Find more information and nominate your candidate here:

https://www.globalcea.org/collaborative-capacity-building-award?hsLang=en

Frequency: Yearly; once in the ICEHTMC or once on the CE Day.

GCEA Technologist/Technician Leadership Award

This award recognizes a Technologist or Technician who practices in healthcare those functions and demonstrates outstanding efforts to contribute toward the promotion of the clinical engineering field through their leadership skills and service.

Find more information and nominate your candidate here:

https://www.globalcea.org/technician-technologist-leadership-award?hsLang=en

Frequency: Yearly; once in the ICEHTMC or once on the CE Day.

"Impact of the Oxygen in Health Technology "

July 6th 2022

Alexandre Henrique Hermini, PhD. – State University of Campinas

José Roberto Balote, EE. – Enimed

São Paulo Brasil

WHY DO CLINICAL ENGINEERING TALKING ABOUT“OXIGEN” IF OUR BUSSINESS IS HEALTH TECHNOLOGY?

BECAUSE NO MORE
CE GOES BEYOND EQUIPMENT

- *CE FOCUS ⇒ "PATIENT HEALTHCARE"*

  "PATIENT OUTCOME"

- *NOW: CE GOAL IS TO REACH HEALTHCARE EXCELLENCE*
- *TO THIS GOAL, NO MATTER "THE VENTILATOR", "THE MRI", "THE GAS"*
- *REALY MATTER THE "FULL HEALTHCARE SYSTEM"*

GEAR MACHINE MODEL

OXIGEN AS A GEAR TOOTH

IMPACT

- ***REMEMBER, ONE BROKEN GEAR TOOTH COMPROMISES THE WHOLE MACHINE***
- ***ESPECIALLY IN THE PANDEMIC, OXIGEN WAS "CRUCIAL GEAR TOOTH"***
- ***WHICH ONE CAN BE SUPPLIED:***
  - ***LIQUID CRYOGENIC TANK – GAS CILYNDER - OXIGEN CONCENTRATOR***
- ***AND TO TALK ABOUT OXIGEN CONCENTRATOR, I'D LIKE TO INVITE ENG. JOSÉ ROBERTO***

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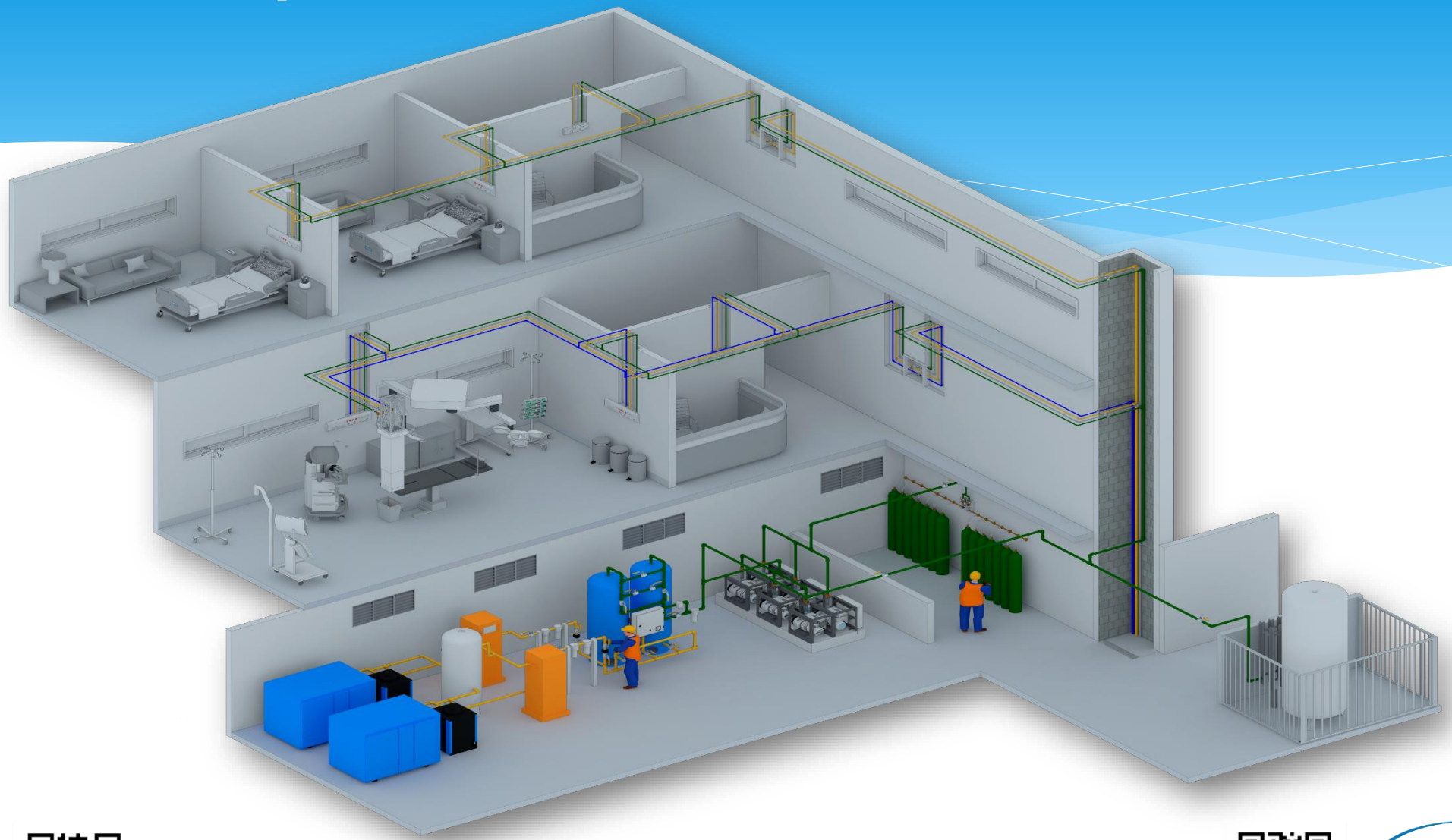
“Oxygen Concentrator – PSA”

José Roberto Balote, EE

PSA Central Detail

“Example of PSA plant and its components”

“Diagram of Hospital Medical Gas Distribution Network”



In the hospital, Is Oxigen only a gas?
No, it is a medicament

Presentation june 2022

Brazilian Regulatory Affairs

Since 1990, Brazilian Agency had established that oxygen used in patient must treated as medicament.

Standardization, Resolutions and Regulatory Affairs

Each Country has its “laws”

In Brazil:

Brazilian Standard ABNT NBR 12188: Centralized medical gas, medical device gas and vacuum supply systems for use in healthcare services

Brazilian Standard ABNT NBR 13587: Health Service - Oxygen Concentrator System (SCO) for use in centralized medicinal oxygen system

Brazilian Health Regulatory Agency RDC 50⁄2002: Hospital project criterias

Oxygen quality criteria
In Brazil: ABNT NBR 13587

Concentration

- As said earlier, the oxygen can be delivered by cryogenic tank, gas cylinder or PSA
- Cryogenic tank, gas cylinder are referred as "OXYGEN 99“
- Oxygen concentrator (PSA) are referred as "OXYGEN 92”
- The safety and performance requirements for oxygen concentrator (PSA): must be provided "OXYGEN 92”, ie, 92% of O_2 concentration in this medical gas.
- Oxygen concentrator systems can be used to provide "OXYGEN 92" to a medicinal gas distribution network as a substitute for "OXYGEN 99".
- But: Oxygen concentrator (PSA) systems may also be combined with sources of supply containing "OXYGEN 99" (cryogenic tanks／cylinders).

Pressure

The minimum pressure value delivered by oxygen concentrator system (PSA) must be 4.5kgf/cm² to 5kgf/cm²

COST BENEFIT

- For the correct decision, must be considered all factors of “Oxygen Delivery”, for example:
- CAPEX of system, if acquired
- OPEX of system, if rented
- Power supply $
- Water (if used for cooling)
- Building needs
- Back up source $

We appreciate the attention

Alexandre H. Hermini, PhD.
Medical Equipment Assessor
Woman Hospital
State University of Campinas
Brazil

Impact of the oxygen in Health Technology

Alexandre Henrique Hermini and José Roberto Balote

Brazil

3D-printed activated charcoal inlet filters for oxygen concentrators: A circular economy approach

Leandro Pecchia

Professor of Biomedical Engineering, Università Campus Bio-Medico, Italy
Professor of Biomedical Engineering, University of Warwick, UK
Innovation Manager, R&D Blueprint and COVID-19, World Health Organization, Swizzerland
President, *EAMBES* (2021-23)
Secretary General, *IFMBE* (2022-2025)

How can we improve Medical Devices in Africa?

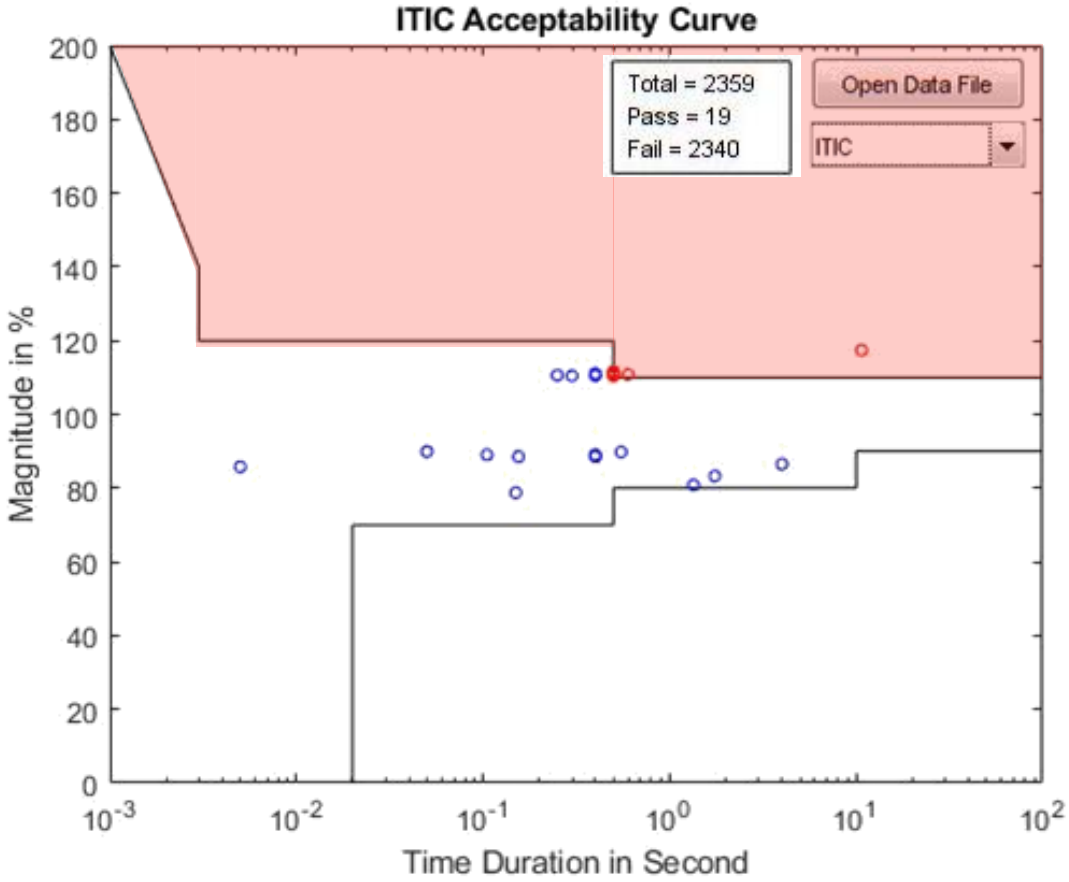
Improve medical device effectiveness and safety in Africa requires to overcome the Cartesian Fragmentation of Knowledge (i.e., no silos).

Therefore, we focus on:

- Design
- Regulation
- Management
- Assessment

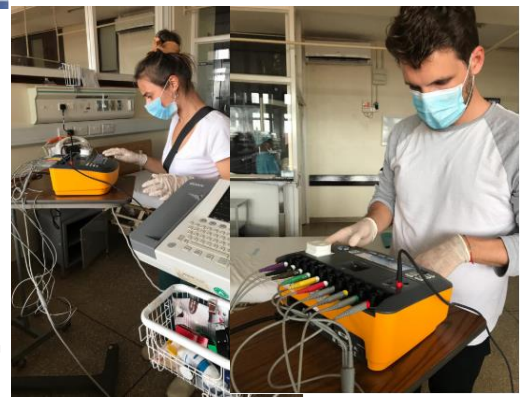
8 field studies in 24 months: Benin, Ethiopia, South Africa, Nigeria, Uganda

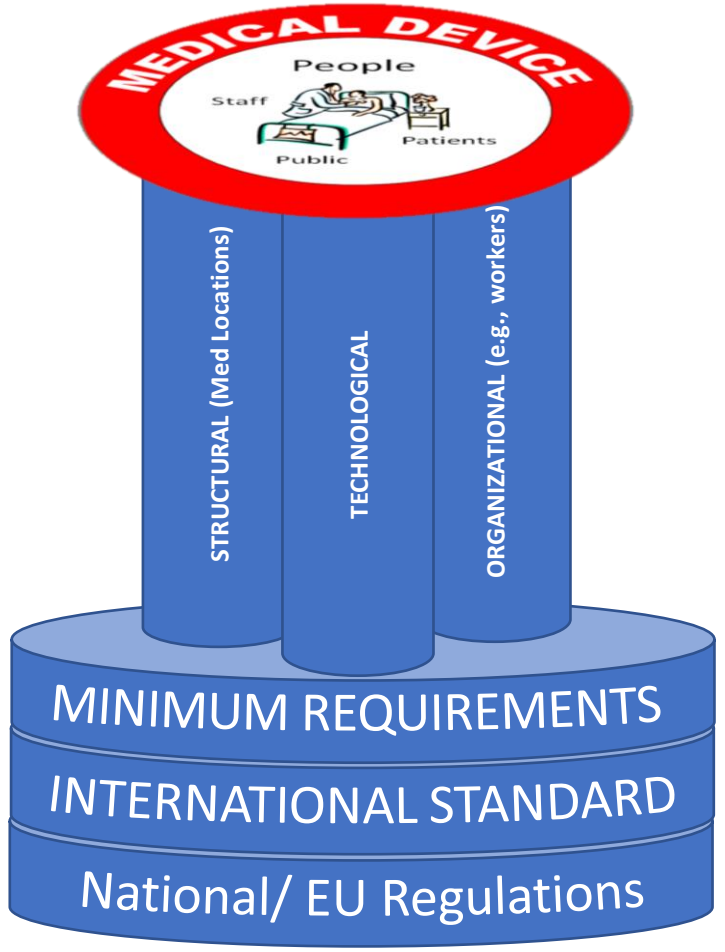
Step1: understand the real needs to provide evidence-based info



...99%!

Step1: understand the real needs to provide evidence-based info

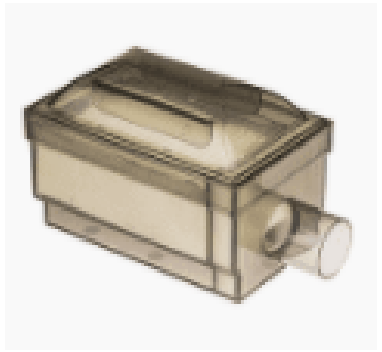




*

The filter Dilemma: should I stay or should I go?

A nurse from new-born unit noticed that the device was performing consistently (moving the control from 1 to 2, the output was not doubled as expected)



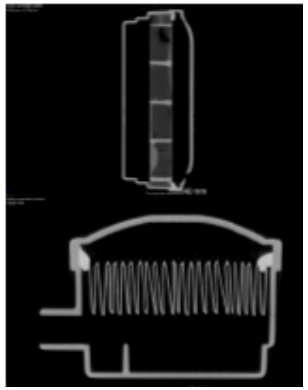
- *Long-term technical implications?*
- *Legal implications?*
- *Moral implications?*
- *Ethical implications?*

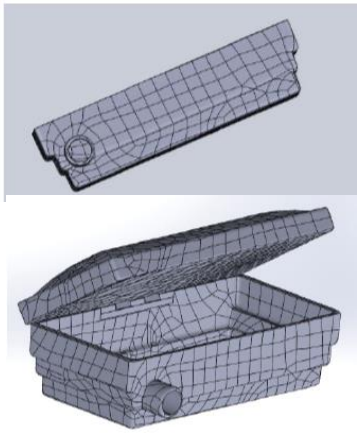
Pecchia, L., et al. "Health Technology Assessment and Biomedical Engineering: Global trends, gaps and opportunities." *Medical engineering & physics* 72 (2019): 19-26.

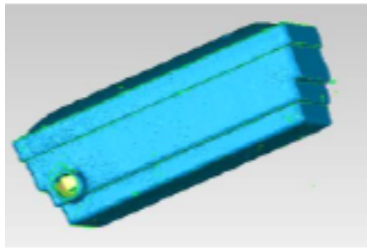
The filter Dilemma: should it be locally manufactured?

Local manufacturing of filters

XR, CAD, 3D printing and DIY active coil, (wood and calcium chlorite)





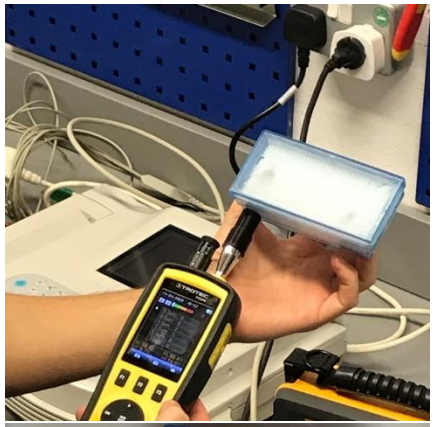


*Williams, E., Piaggio, D., Andellini, M., & Pecchia, L. (2022). 3D-printed activated charcoal inlet filters for oxygen concentrators: A circular economy approach. Development Engineering,7:100094. doi: 10.1016/j.deveng.2022.100094. Epub 2022 Jan 19.

The filter Dilemma: should it be locally manufactured?

Local manufacturing of inlet filters -unpublished-

Preliminary results



	# particles per m³*	
Particle size	**Original Filter**	**Warwick Filter**
10.0µm	117.7	594.6
5.0µm	78.4	1837.8
2.5µm	3725.5	28054.1
1.0µm	17686.3	215081

*average values

Warwick filter avg filtering power: **38.8% (VS 96.8% original filter)**
Warwick filter avg filtering power (>= 1 micron): **64.2% (VS 96.4% original filter)**

We could not find standards or references for inlet filters.
The only avaiable standards are related to the gas outputted by the oxygen concentrators: i.e., after double filtering (inlet filter + microdisk filter). The ISO 80601-2-69:2014.
«[...] filter particles greater than 1.0 µm to ISO Class 5 levels, as specified in ISO/DIS 14644-1:2010 [...]»
Threshold (per m^3): 830 particles >0.1

WARWICK
THE UNIVERSITY OF WARWICK

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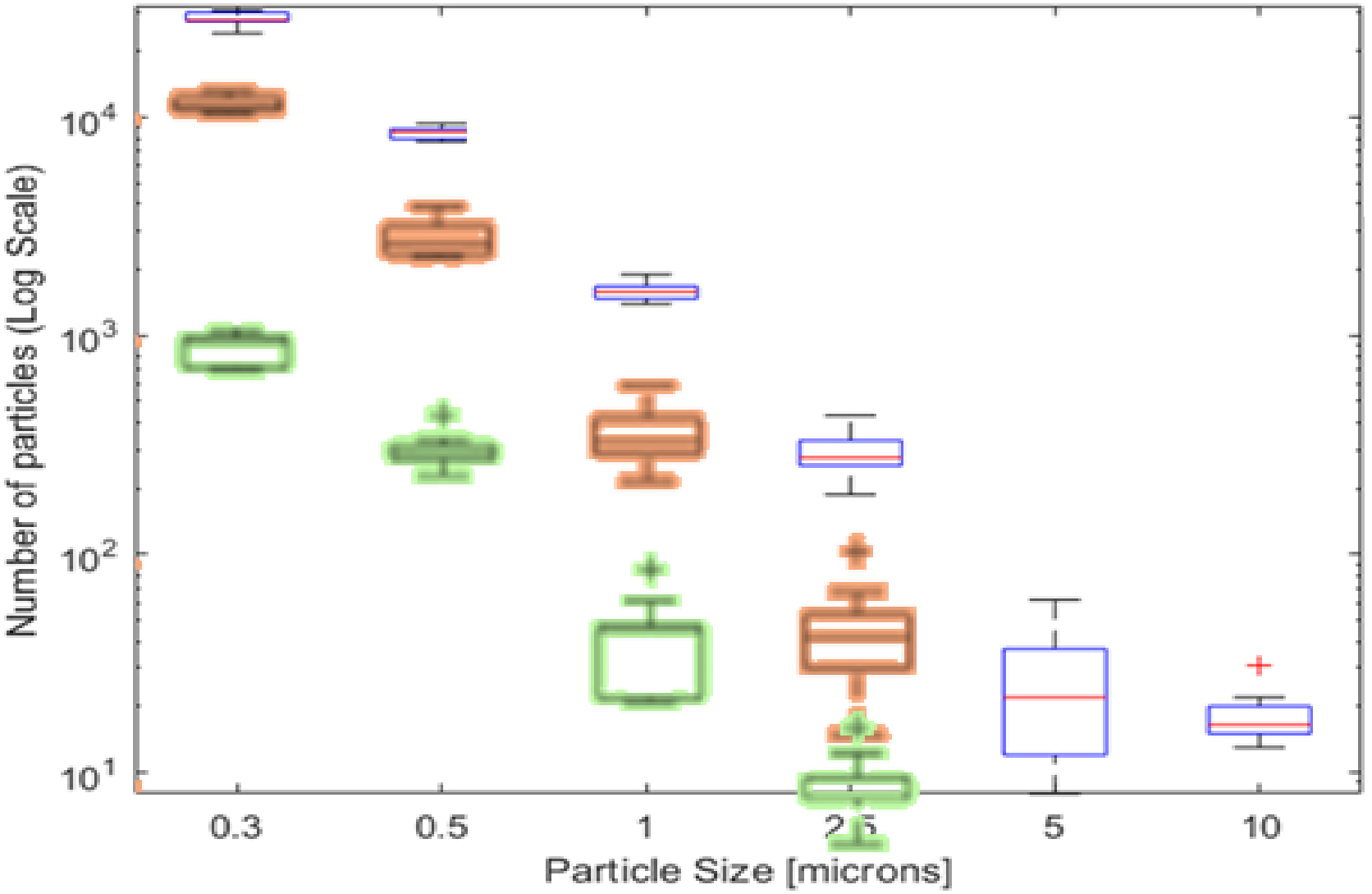
Average particle distribution per liter -unpublished-



Room Particles

Warwick Filter

Original Filter

How can we enhance Medical Devices?

- We have identified the main challenges, issues and needs (first of all denial must be fought, otherwise there will be no progress)
- AI can improve the sensing capability of the mobile phone
- Enhance information extraction from the acquired data
- Support the Decision of non-specialised healthcare professionals
- Support data presentation to lay-users

Next Step

- We are now studying the relevant standards to see how far we are from legal requirements and state of the art
- We are now discussing those results with the WHO (Infection Prevention and Control Unit, Medical Devices Unit, Emergency Unit) to explore how to scale-up our approach

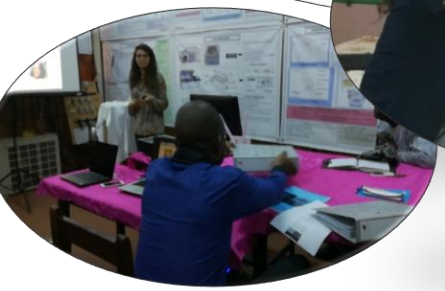
Open Challenges

- Lack of (reliable) data
- Poor evidence…
- Ethical issues arising

Thank you! …normal life will be back soon…






PORTABLE O2 CONCENTRATORS SERVICE ISSUES IN LMIC

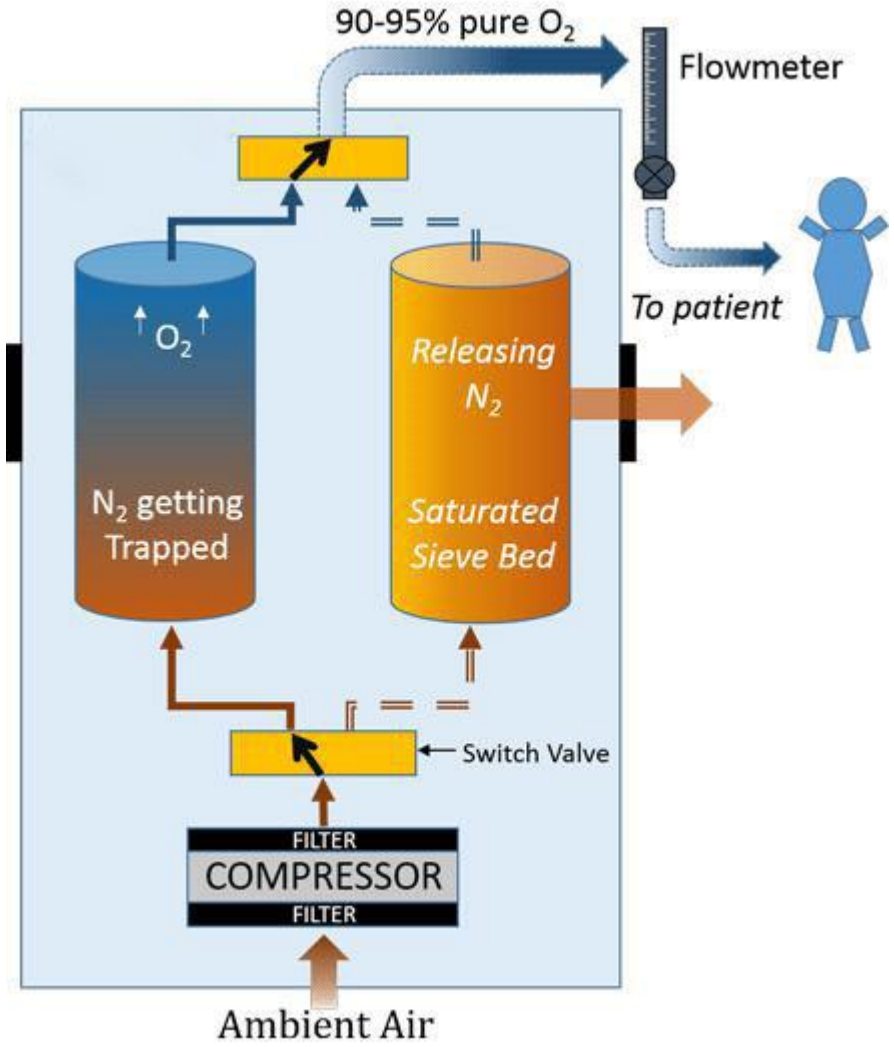
STEFANO POLVI

CEO of Logic S.r.l.

Portable O2 concentrators in LMIC

- Very popular, also in hospitals (in Africa approximately 1 unit/10 beds or more)
- Actual quantity is unavailable due to unreliable inventories and large stock of equipment in non working conditions
- Poor preventive maintenance
- Dusty environments
- Unstable power supply
- Prices range from US$ 400,00 up to US$ 3.000,00 depending by quality, brand reputation and flow (L/min)

How does a portable O2 concentrator work?



Service issues

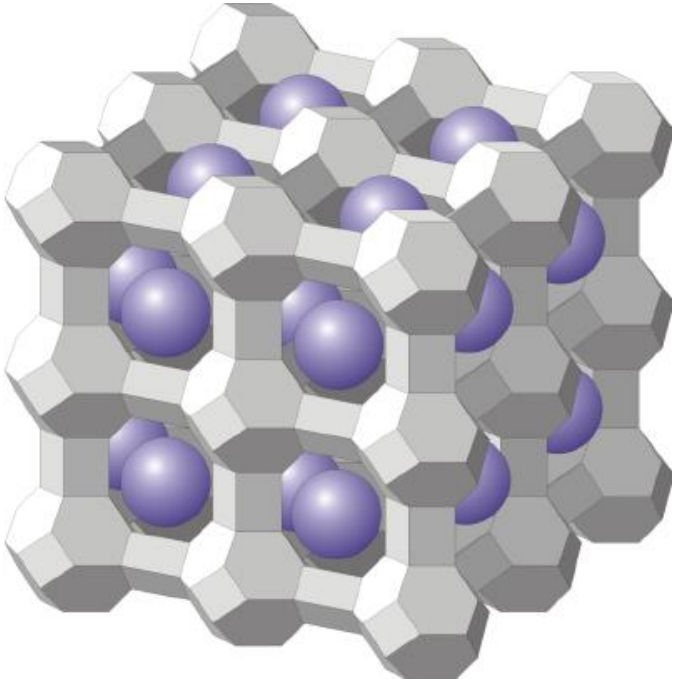
- Filters
- Compressor
- Other components (switches, valves, connectors, etc.)
- Sieve beds

A COUPLE OF SIEVE BEDS IS USUALLY REQUIRED

Inside the sieve beds

Zeolite: aluminosilicate crystal able to “ADSORB” N2 allowing O2 to pass.

Pressure Swing Adsorbtion (PSA) - a process based on the phenomenon that under high pressure, gases tend to be trapped onto solid porous surfaces



Causes for molecular sieve beds failures

- Dust
- Moisture
- No preventive maintenance (filters)
- Air/O2 leakage

EXPECTED LIFE FOR PORTABLE O2 CONCENTRATORS SIEVE BEDS: 5 YEARS
ACTUAL LIFE FOR PORTABLE O2 CONCENTRATORS SIEVE BEDS: 2 YEARS OR LESS

Costing

- PRICES FOR BRAND NEW SPARE SIEVE BEDS RANGE FROM US$ 150 UP TO US$ 500,00.
- REPOUR WITH BRAND NEW ZEOLITE RANGE FROM US$ 75,00 UP TO US$ 150,00 + SHIPPING, DUTIES, VAT, DHL ROUNDTRIP...
- NO REPOURING FACILITIES IN EU (IN USA ONLY)
- SHOULD WE BE ABLE TO OPEN A REPOURING FACILITY IN THE LMIC, IT WOULD GREATLY REDUCE THE WORKING COSTS
- SHOULD WE BE ABLE TO REGENERATE THE OLD ZEOLITE IN THE LMIC AND RE-USE IT FOR REPOURING… IT WOULD BE...

Technical issues

- Do we have or can we acquire the technology to properly open the sieve beds cylinders without damaging?
- Can we get on the market the full range of gaskets, seals, O-rings, connectors, tubes, etc. to make the sieve beds ready for repouring?
- Can we locate on the market certified suppliers for medical zeolite or can we regenerate the old zeolite?
- Can we arrange the repour without compromising the quality of the zeolite?
- Can we test the repoured sieve beds and prove that their performances are the same as the brand new OEM sieve beds?

Regulatory issues

- What about exhausted zeolite? Should it be considered as a contaminated hospital waste?
- What are the applicable international normes and rules (IEC 62353 or more?)
- What are the tests and how should they be performed after the repour?
- In case of regenerated zeolite, what are the applicable reference normes, also in terms of safety.
- Any local FDA special norm?

What’s new on the market?

- Logic Srl - Trieste and University Campus Biomedico – Rome recently launched a joined R&D program to assess the pending technical and regulatory issues on the regeneration of zeolites
- Including a detailed evaluation on the possible use in agriculture of exhausted zeolites
- Including a detailed evaluation of the effectiveness of the methods
- Including a detailed evaluation of the compliance to the existing normes
- Including a detailed evaluation about safety and contamination of the materials involved

Our goal is to establish in the short-medium term a chain of repouring centres in selected African countries. Involving local partners in a win to win strategy and increasing the availability of pure O2 for medical therapies.

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Thank you !

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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