

ECMO Equipment Selection: Circuit Components and Managing Backorders Post-Covid

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CHOP Cardiology 2024

The Dreaded News...



May 18, 2023

URGENT MEDICAL DEVICE – Removal

Reference Number: : 8010762-03/27/2023-001-R and 8010762-03/27/2023-002-R

QUADROX-iD / QUADROX-iR / QUADROX-i Oxygenators and Cardiotomy Reservoirs

ITEM	ITEM DESCRIPTION	UDI (Single device)
701050330	QUADROX-iD Pediatric- BEQ-HMOD30000-USA	4037691670164
701070397	QUADROX-iD Pediatric- BEQ-HMOD30000-USA	4058863154435
701067840	HMOD 70000-USA/ QUADROX -iD Adult	4058863019000
701067859	BEQ-HMOD70000-USA/ QUADROX -iD	4058863019024
701067905	BEQ-HMO 50000-USA / QUADROX -i Small	4058863019079
701067891	HMO 50000-USA /QUADROX-i Small Adult	4058863019055
701067895	HMO 51000-USA /QUADROX-i Small Adult	4058863019185
701067820	HMO 70000-USA /QUADROX-i Adult	4058863019147
701067823	HMO 71000-USA /QUADROX-i Adult	4058863017341
701067829	BEQ-HMO 71000-USA /QUADROX-i Adult	4058863017372
701070412	HMO 10000-USA /QUADROX -i Neonatal	4058863154473
701070416	HMO 11000-USA /QUADROX -i Neonatal	4058863154558
701070384	HMO 30000-USA /QUADROX-i Pediatric	4058863153681
701070388	HMO 31000-USA /QUADROX-i Pediatric	4058863154299
701070441	VKMO 10000-USA /Venous Hardshell Cardiotomy Reservoir	4058863153889

Overview

Advances in ECMO technology



Multiple platforms



Backorders/Recalls



Using substitute products

Advances in ECMO Technology



CIRCUIT COMPONENTS
MORE INTEGRATED AND
STREAMLINED



EASIER TO ASSEMBLE AND
PREPARE



ADVANCED FEATURES AND
SAFETY MECHANISMS



MORE EFFICIENT
MEMBRANES

Advances in ECMO

Quadrox-ID

- First PMP membrane
- Oxyplus fiber technology
- Unique interwoven mat
- Parallel channels
- Efficient gas exchange
- Low pressure gradient
- Rapid prime

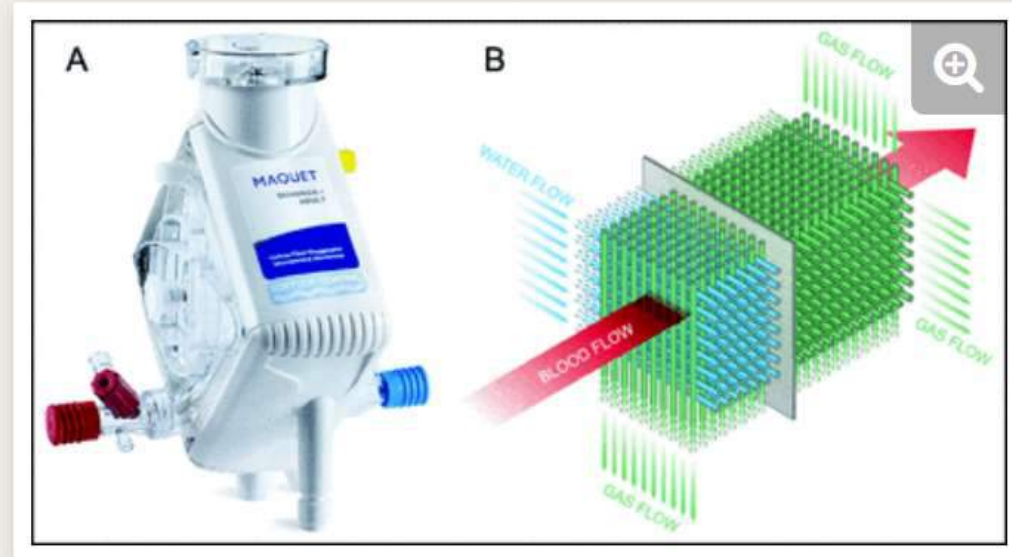


Fig. 1.

[Download figure](#) | [Open in new tab](#) | [Download powerpoint](#)

The Quadrox-iD (A) and cross-section of diffusion membrane showing blood, water, and gas flow through a mat of hollow fibers (B). Courtesy of Maquet.

Advances in ECMO

Medos Hilite LT

- 3 sizes
- Cylindrical shape
- Efficient gas exchange*
- Higher pressure gradient

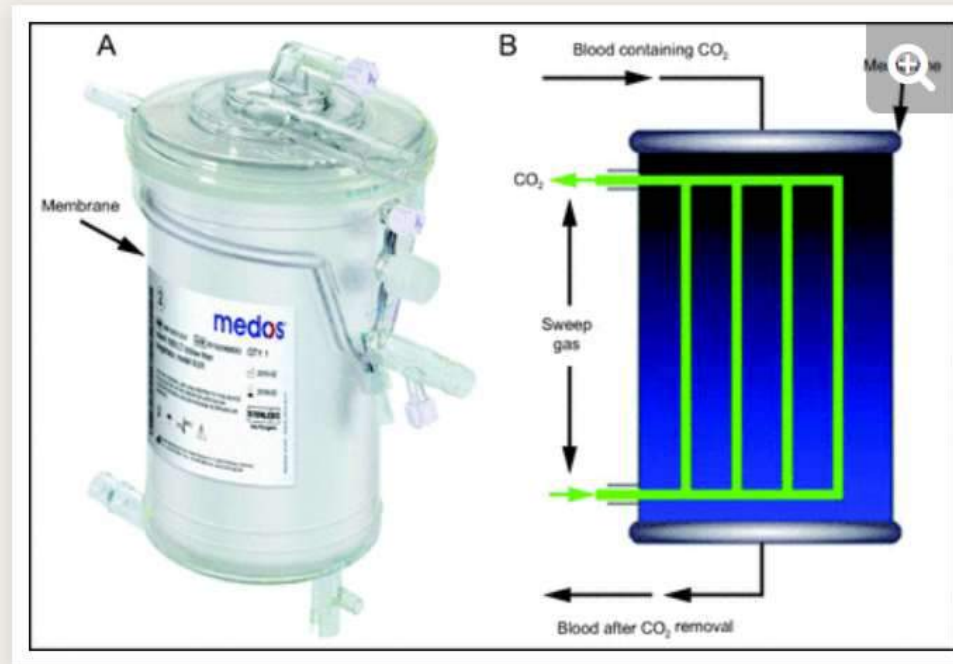


Fig. 2.

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Image of the Medos Hilite LT (A) and diagram of flow through blood and sweep gas channels (B). Courtesy of Xenios.

Advances in ECMO

Euroset

- PC Coated
- Cylindrical shape
- Higher pressure gradient
- Plasma leakage



Advances in ECMO

Spectrum Medical

- 4 sizes-large adult, small adult, pediatric, neonate
- No heat exchanger
- Hypobaric ventilation
- Biocompatible coating
- DEHP free



Advances in ECMO

Spectrum Medical

- Heat exchanger
- Biocompatible coating



Advances in ECMO

Medtronic Nautilus

- Adult size
- Circular flow path
- Low pressure drop
- Higher price point



Advances in ECMO

Medtronic Nautilus *Smart*

- Interactive touch screen
- Pressure In/Pressure Out/ Δ P
- O₂ Saturation In/O₂ Saturation Out
- Temperature Out
- Set alarm limits
- Receive visual and audio alert notifications



Advances in ECMO

CentriMag/PediMag

- CentriMag approval for up to 30 day
- PediMag only approved for <6hrs
- Higher price point



Advances in ECMO

Cardiohelp

- Combined system
- Larger prime volume
- Pressure, temp, flow, venous sat, Hgb, Hct
- Lightweight
- Ideal for transport
- Higher price point



Advances in ECMO

Spectrum Medical

- CP20/CP22 Quantum Centrifugal Motor Drive system
- Biocompatibility coating



The Charlotte Perfusion System

The Charlotte Perfusion System is Spectrum Medical's most compact Perfusion ECLS System. Designed to maximize mobility within the I.C.U. and yet offering the ultimate in patient safety technologies for all ECLS therapies in the I.C.U.



In its standard configuration the Quantum ECLS system includes the Quantum Workstation Elite, an integrated stainless-steel Space Frame, and a secondary Power Pack which optimizes patient safety with extended battery life and system redundancy. System flexibility is further enhanced with the optional Quantum Ventilation Lite, a range of therapy based disposable mounting solutions and the capability to operate both centrifugal and roller pump technologies.



How Do We Choose?

- Features
- Ease of use
- Cost

Nationwide Children's Hospital

- Centrimag <10kg
- CardioHelp >15kg in the CTICU
- CardioHelp >10kg in the PICU





Boston Children's

- Pedimag <8kg
- Spectrum roller <8kg cardiac ICU
- Cardiohelp >8kg

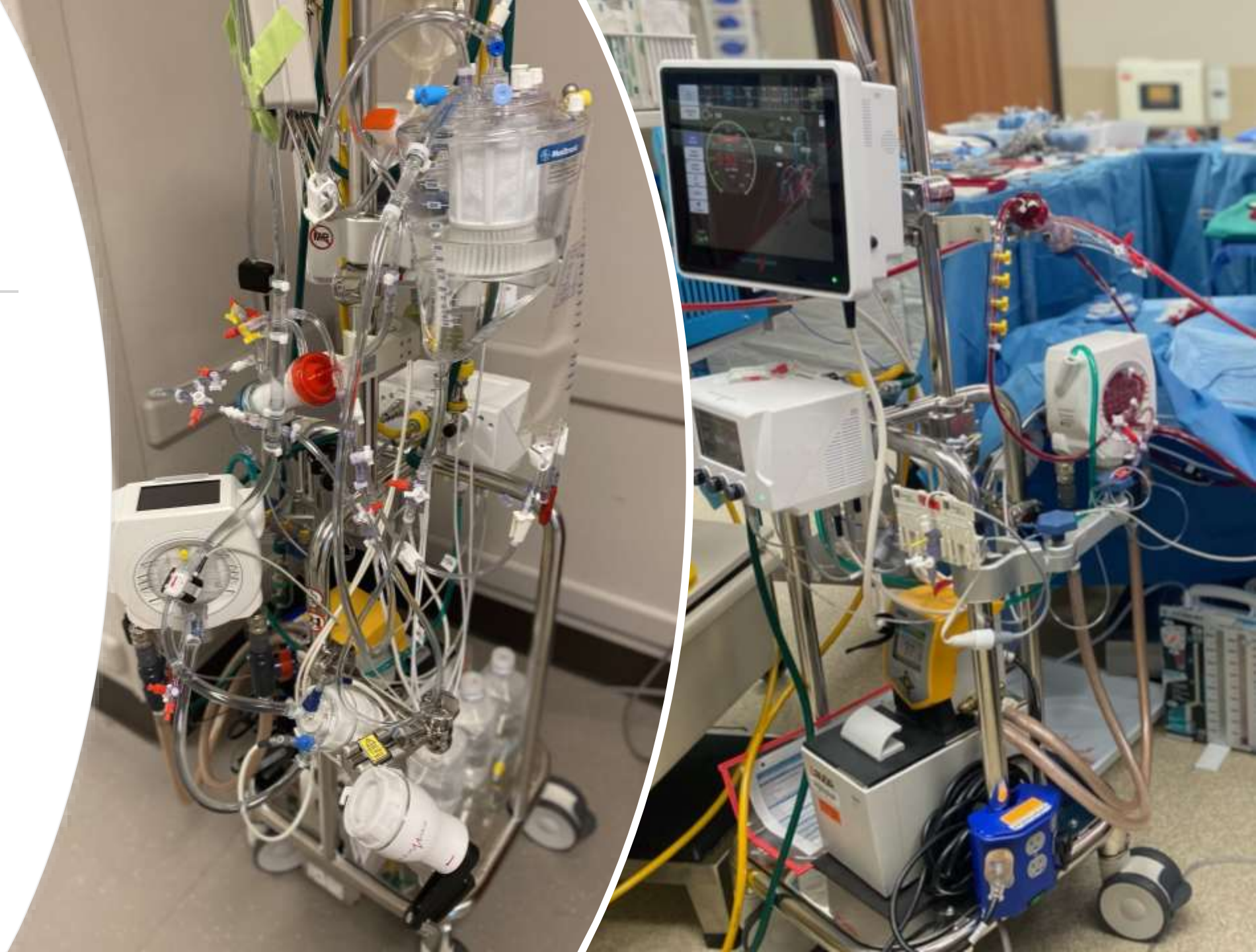
Penn State Health Children's Hospital

- Pedimag with Infant Euroset <8kg
- Centrimag with Pediatric Euroset 8-20kg
- Centrimag with Nautilus >20kg



Children's of Alabama

- Spectrum CP22
Centrifugal with
Nautilus
- All size patients



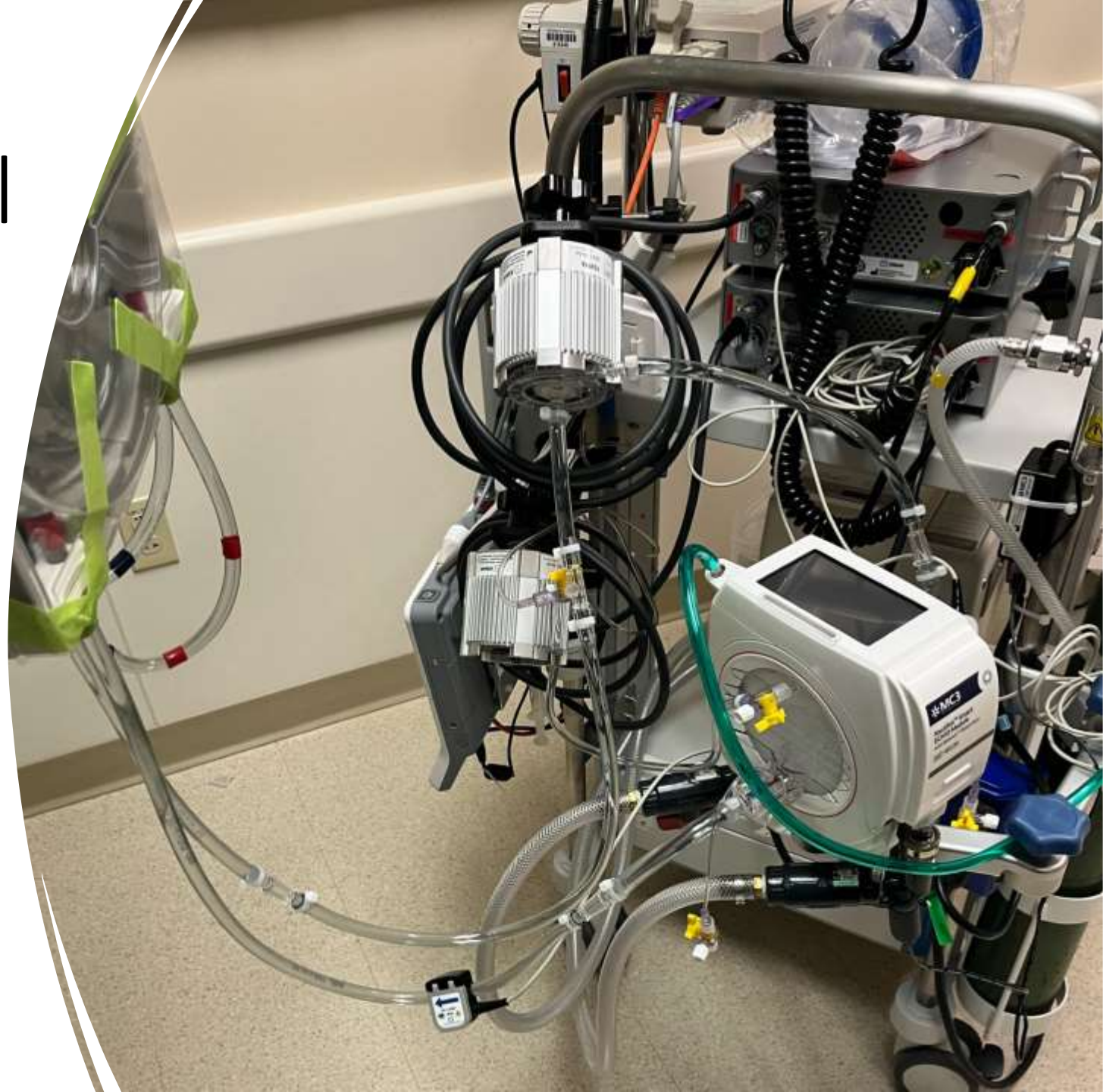
Phoenix Children's

- Spectrum <15kg
- Cardiohelp >15 kg



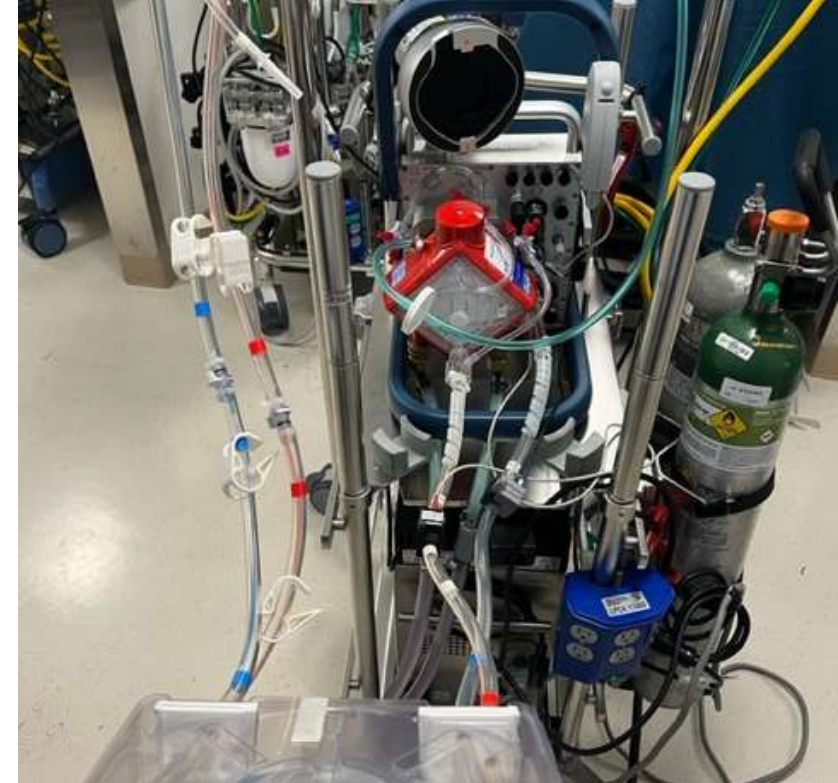
Children's Hospital of Wisconsin

- Pedimag with Nautilus <10kg
- Centrimag with Nautilus >10kg



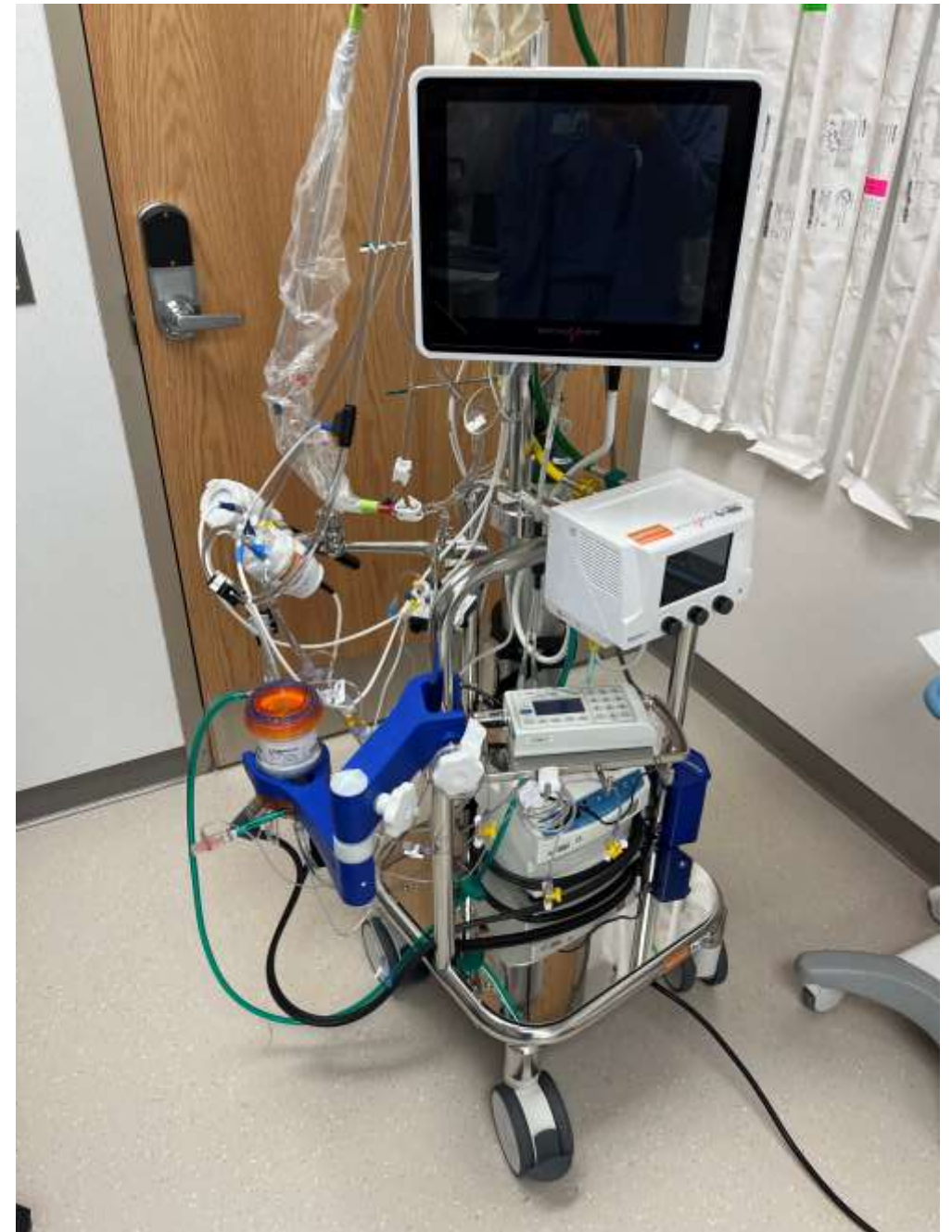
Stanford Children's Hospital

- Roller with Nautilus 0-5kg
- Spectrum centrifugal with Nautilus 5-20kg
- Cardiohelp >20kg

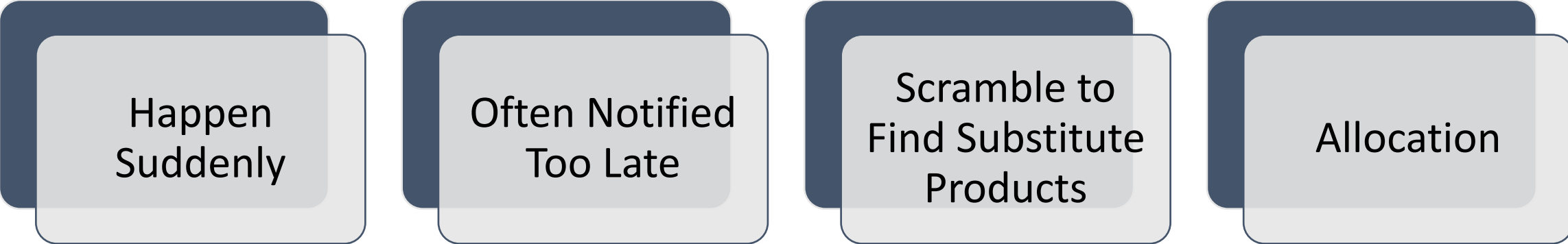


Children's Hospital of Philadelphia

- Spectrum centrifugal with Euroset <13kg
- Cardiohelp >13kg



Backorders And Recalls



Happen
Suddenly

Often Notified
Too Late

Scramble to
Find Substitute
Products

Allocation



ELSO Equipment Survey Data

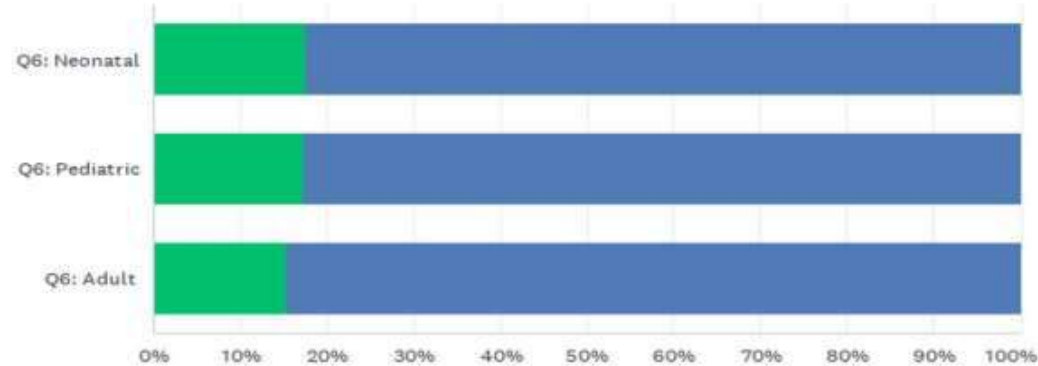
Getinge Equipment Recall
June 2023

- Survey to assess the impact of the Getinge ECMO equipment recalls
- Open to all centers
- Questions specific to impacted products
- 267 Responses
- Hypothesis:
 - In certain regions, access to ECMO care may be a significant issue
 - For those that typically use the recalled products, anticipated limitations in access to ECMO increase over time

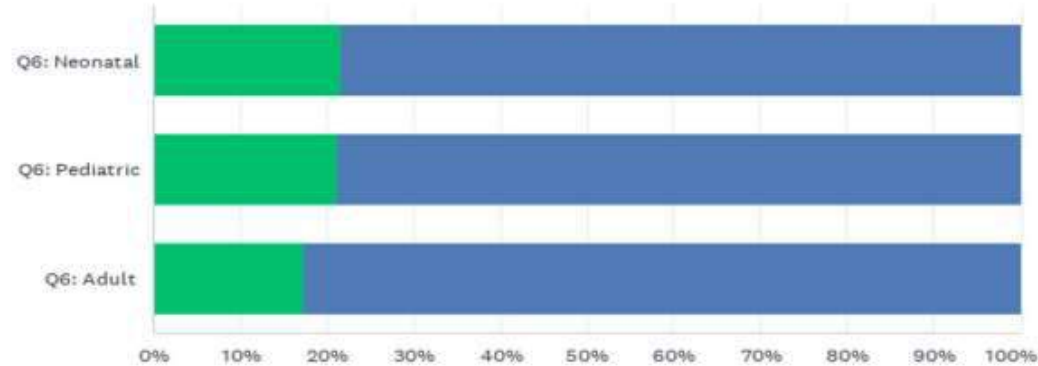
Quadrox ID Oxygenator: Future Anticipated Access

In the **next 6 months**, about 22% of **neonatal and pediatric** ECMO care access in the **US** is anticipated to be limited for centers who **typically utilize** this product.

3 Months
(August 2023)



6 Months
(November 2023)

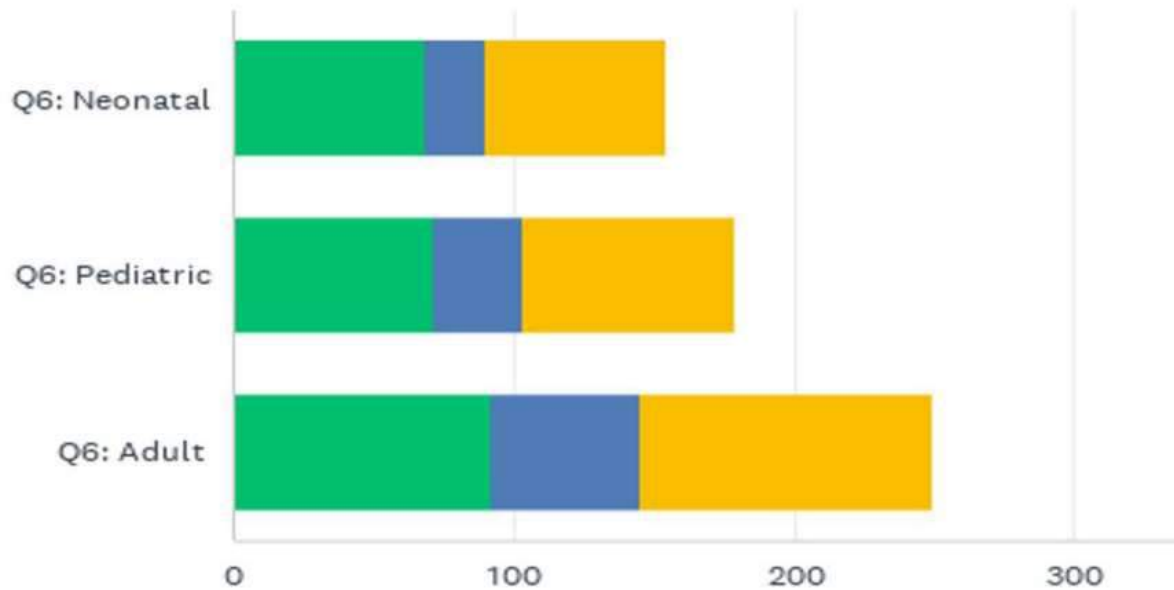


Yes No

ECMO Equipment Recall | June 2023



Quadrox-iD Oxygenator: Actions in Response to Recall



Other Actions

- Borrowing oxygenators
- Ignoring the recall
- Using adult oxygenator with a shunt
- Using a different oxygenator other than Getinge

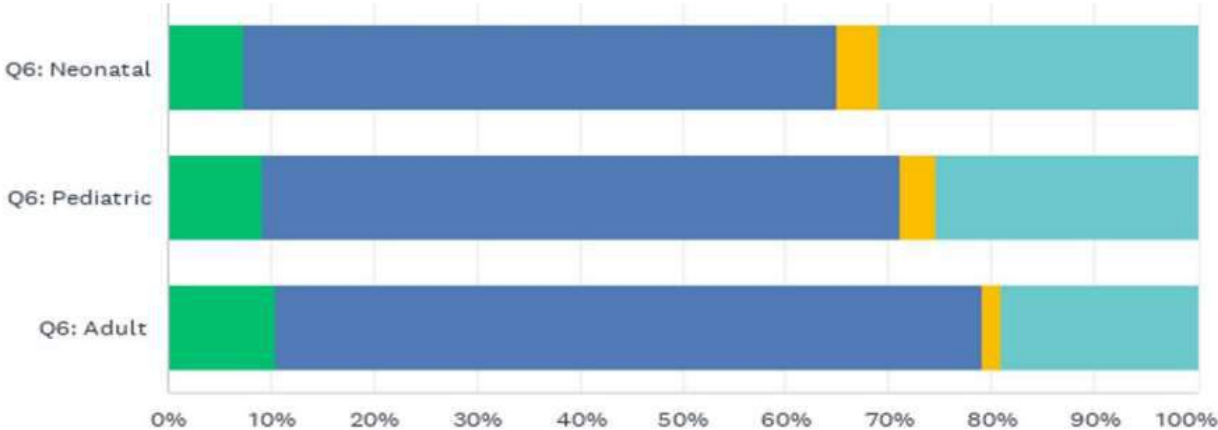
Using non-preferred circuit components

Contacting regulatory agencies for help to maintain access as a medical necessity

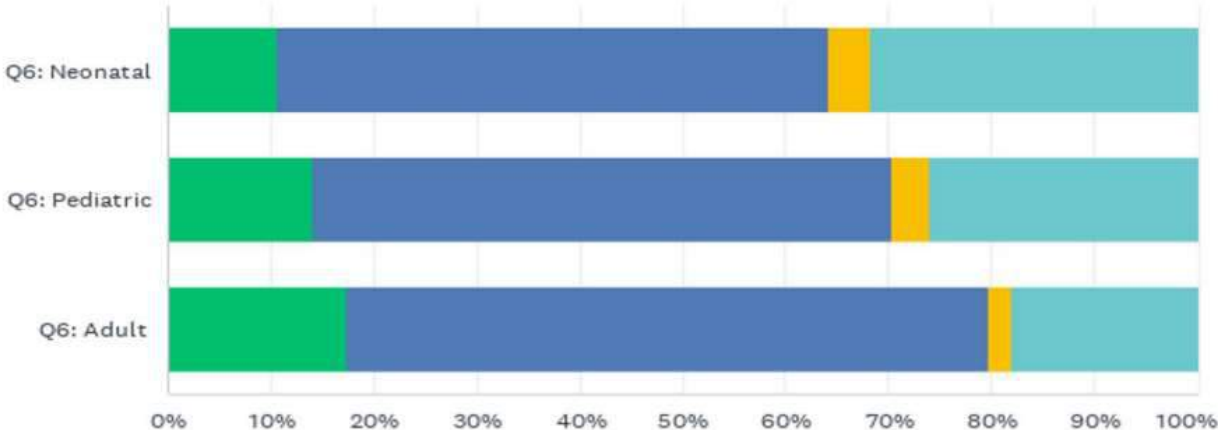
Other

Cardiohelp: Current and Anticipated ECMO Access

Current

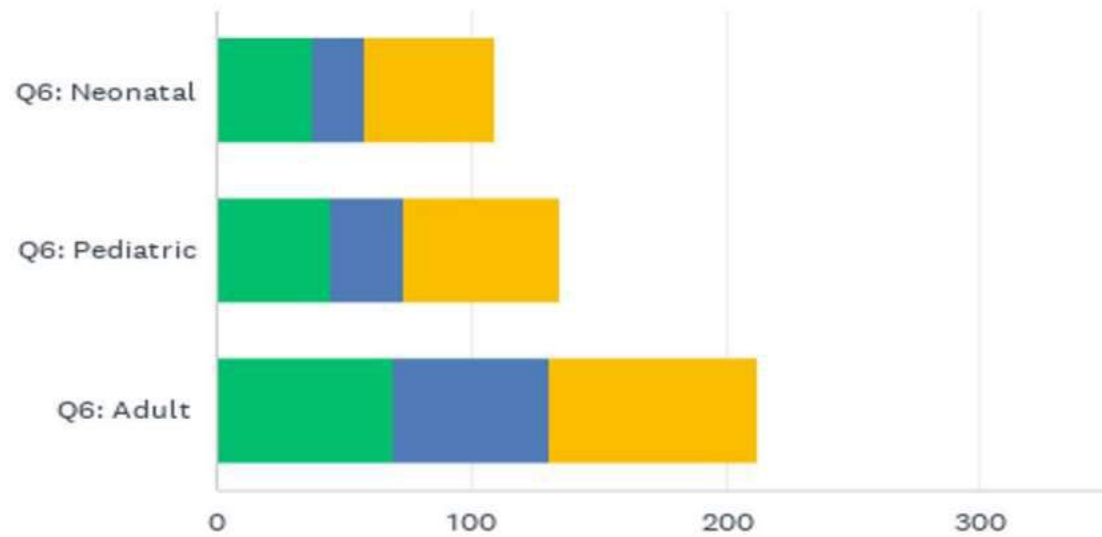


3 Months (August 2023)



Cardiohelp: Actions in Response to Recall

Other Actions



- Use alternative product other than Getinge
- Inspect packaging and continuing to use
- Equipment sharing with other hospitals in the region
- Limiting HLS set use to patients less than 10 kg
- Coordinating with local Getinge reps
- Force Getinge to have transparent communication via national medical societies
- Contacting regulatory agencies for help to maintain access as a medical necessity

■ Using non-preferred circuit components

■ Contacting regulatory agencies for help to maintain access as a medical necessity

■ Other

ELSO Action Items

Respondents agreed with the following **actions** from ELSO:



Share concerns with regulatory agencies



Communicate updates related to the recall

- Emergency virtual meeting
- WhatsApp group for updates
- Website, email updates



Support communication between ECMO centers

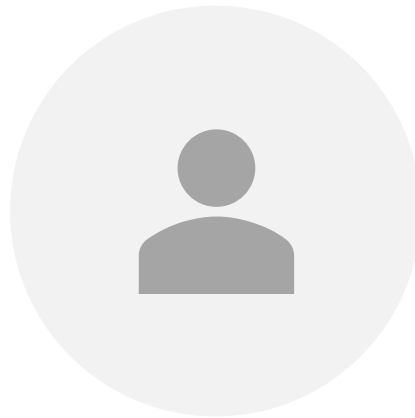


Partner with industry to improve supply availability

Being Proactive



INCREASING STOCK ON
HAND



MULTIPLE VENDORS



MAINTAINING MULTIPLE
PLATFORMS

Challenges With Substitute Products

Price

Quality

Availability

New Training Might be Needed

Potential for Error



Allocation

“The process of distributing the right amount of products to be sold among a company's multiple locations to match customer demand”

- Decreasing ability to stock pile
- Prioritizing children's hospitals

Future...



Industry/Professional
society assistance with
FDA



Strong preparation for
using substitute products



Good communication
with vendors



Help each other