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Methodology for Calculating Greenhouse Gas Reductions from the Use of R-SUDs II April 2024

Introduction/Background

The overwhelming majority of greenhouse gas emissions from hospitals come from what researchers categorize as "Scope 3." This includes indirect emissions, like those from the millions of supply chain products that are purchased by hospitals, many of which are labelled for single-use.

Beginning in the 1970s and 80s, hospitals turned to "single-use" products, heavy on plastic content, for use in patient procedures. The Medical Device User Fee and Modernization Act of 2002 created a framework for the commercial reprocessing of select single-use medical devices. Reprocessing companies, which use discarded single-use devices (SUDs) in the manufacture of renewed, single-use devices, must validate a safe and effective process to collect, label/track, decontaminate, clean, inspect, disinfect or sterilize, package and return these products to hospitals.

Reprocessed SUDs must meet or exceed the same regulatory standards for cleanliness, sterility, and performance as their original counterpart. When hospitals use reprocessed SUDs they reduce cost, waste, greenhouse gas emissions, and add resilience to the supply chain. They drive a circular economy where the alternative is more medical waste.

Calculating and comparing greenhouse gas emissions requires careful analysis of the entire life cycle of comparable products. That's why life cycle assessments (LCAs) are so important. Researchers break down the "cradle to grave" environmental impact of the materials and processes used to create, ship, use (and reuse if applicable), and discard comparable products to determine which product has a preferable environmental profile in terms of carbon emissions and other key environmental metrics.

By creating this free, publicly available greenhouse gas emissions calculator to measure emissions reductions from the use of reprocessed SUDs, AMDR hopes to demonstrate the environmental benefits of reprocessed SUDs to health and environmental policy-makers, as well as to help hospital purchasing decision-makers and sustainability coordinators to calculate emissions savings from their reprocessing programs.

To achieve this, AMDR evaluates relevant, peer-reviewed LCAs comparing reprocessed SUDs to their original device counterparts to power the emissions savings formulas used by the calculator. Because LCAs use dozens of inputs for the particular devices, manufacturer and processes studied, these formulas result in estimated savings only. However, they are the best estimates available for calculating emissions savings from the use of reprocessed SUDs at this time. With time, and the input of more LCAs, AMDR anticipates data reliability will increase.



<u>Scope</u>

AMDR includes the greenhouse gas emission reductions (in terms of both weight (kgCO2e) and percent) reported in LCAs that compare the use of a reprocessed SUD to its original device counterpart. Because of the lack of FDA or other regulatory oversight, we exclude any studies that assess in-house (or hospital-based reprocessing, such as that done in Central Sterile Departments). AMDR requires that studies must be adherent to ISO 14040 standards and undergo an academic peer-review process to be included in the analysis.

AMDR divides the published studies, based on the type of SUD evaluated, into one of three categories: (1) cardiovascular (labelled EP), (2) surgical (labelled OR), or (3) non-invasive, or patient care.

Assumptions and Constraints

AMDR assumes that the peer-review process provides an adequate review to assure accuracy. Only LCAs that have gone through an academic peer-review process, or an ISO 14040 compliant expert review panel are included.

In 2023, the first year of this comparative analysis, AMDR examined eight known peer-reviewed LCAs of R-SUDs compared to original equipment. Thereafter, on an annual basis, AMDR will review any studies released in the time since our previous review. AMDR's evaluation of the literature and outputs should serve only as an estimation, as we know that the CO2 impact for different types of devices within each category (cardiovascular, surgical, non-invasive) will vary. However, as more LCAs are peer-reviewed and included in the calculator, the results will sharpen.

Tools and Resources

To identify LCAs for inclusion, AMDR relies on and reviews <u>https://healthcarelca.com/</u>, an opensource aggregator of published health sector LCAs. We also use Google alerts and standard literature searches. The specific LCAs used to power the calculator are listed at the end of this document.

Procedures and Techniques

After categorizing included LCAs into the aforementioned SUD types, AMDR reviews the product(s) assessed, the included or excluded components of their life cycles, and the reported kgCO2e and percent reduction from using R-SUDs. Each LCA study within each category is weighted evenly to calculate the average reduction attributable to the use of the R-SUDs in that category.

After determining the average reduction per category, we then calculate the weighted average emission reduction based on relative volume share and publish the overall reduction estimated for the use of R-SUDs compared to its virgin counterpart.



Categories of Devices for Determination of CO2 Reduction

AMDR provides the following guidance for determining which reprocessed products should be applied in which categories of the calculator. This also reflects the categorization AMDR uses to determine its annual total carbon emission reduction data.

I) EP/Cardiovascular

- Diagnostic electrophysiology (EP) catheters
- Ultrasound catheters
- Intra-cardiac echocardiography catheters
- Intravascular catheters
- Mapping catheters
- Coronary sinus catheters
- EP cables
- Introducer sheaths
- Ablation catheter
- Transseptal needles
- Radiofrequency catheter

2) OR/Surgery

- Clamps and dissectors
- Infusion pressure bags
- Reamers
- Suture passers
- Soft tissue ablators
- Scissor tips
- Balloon inflation devices
- Endoscopic accessories
- Sealers and dividers

- Ultrasonic scalpels
- Trocars
- Laparoscopic instruments (includes babcocks, dissectors, graspers and scissors)
- Arthroscopic shavers
- Arthroscopic wands
- Bits, burs, and blades
- Shavers
- External fixation devices and components

3) Patient Care Devices

- Blood pressure cuffs and tourniquet cuffs
- Patient fall alarms
- Air transfer mattresses/Hovermatts
- Pneumatic tourniquet cuffs
- Infusor bags
- Tourniquets
- EKG and ECG leads and cables
- Femoral compression devices
- Pulse oximeter sensors
- Sequential compression devices/DVT sleeves

Risks and Mitigation

AMDR acknowledges that (1) LCAs include a large number of inputs, assumptions, and approaches for which slight changes (e.g. transportation, reprocessing methodology, cleaning agents used; inventory libraries used; etc.) would result in different output data; (2) only a small number of LCAs are currently available; (3) the majority of SUDs that have been cleared for reprocessing by regulatory authorities have not yet been studied.



Over time, as more publications are published, our confidence level in the kgCO2e or percent reduction determined becomes higher.

The need to measure greenhouse gas emissions is urgent and no other methods that compares R-SUDs to virgin SUDs are available. AMDR believes we can't afford to "let the perfect get in the way of the good." Given that every LCA comparing R-SUDs to virgin SUDs indicates a 30% to 65% reductions in kgCO2e thus far, we are confident that we have devised a conservative but fair formula for estimated reductions. Those using the data should be careful to explain these calculations create rough estimates only.

Roles and Responsibilities

AMDR's communications lead reviews the peer-reviewed LCAs annually and creates a spreadsheet for input and initial calculations. AMDR's research lead then reviews and edits the content as necessary. AMDR's president and CEO reviews, edits, and signs off on the calculations. The information is presented to AMDR's Member Data Committee, consisting of two or more member representatives. After input is accepted, the president and CEO authorizes final approval.

<u>Timeline</u>

On an annual basis, AMDR issues member data from the previous year announced by news release. The approved emission reduction calculations will be included in this annual publication.

ⁱ MJ Eckelman, et. al, <u>Health Care Pollution And Public Health Damage In The United States: An Update</u>, *Health Affairs* 2020 39:12, 2071-2079



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LCAs used to power AMDR CO2 Calculator April 22, 2024

Year	Category	Title	Authors	Journal	SUD GHG (kgCO2e)	rSUD GHG (kgCO2e)	% savings from rSUD	Device Type
2021	ep Catheters	Combining Life Cycle Assessment and Circularity Assessment to Analyze Environmental Impacts of the Medical Remanufacturing of Electrophysiology Catheters	Anna Schulte *, Daniel Maga and Nils Thonemann	<u>Sustainability</u>	1.75	0.87	-50%	EP Catheter
2022	EP CATHETERS	Assessing Long-Term Medical Remanufacturing Emissions with Life Cycle Analysis	Julia A. Meister , Jack Sharp, Yan Wang * and Khuong An Nguyen	<u>Processes</u> (MDPI)	1.53	0.61	-60%	EP Catheter
2023	EP CATHETERS	Comparative Carbon Footprint of Reprocessed Single Use Medical Devices	Anthesis	<u>Whitepaper</u>	8.49	4.32	-49%	ICE Catheter
2023	OR DEVICES	Comparative Carbon Footprint of Reprocessed Single Use Medical Devices	Anthesis	<u>Whitepaper</u>	3.75	2.01	-46%	Ultrasonic shears
2023	OR DEVICES	Comparative Carbon Footprint of Reprocessed Single Use Medical Devices	Anthesis	<u>Whitepaper</u>	1.51	1.01	-33%	Bipolar elecrosurg
2023	OR DEVICES	Comparative Carbon Footprint of Reprocessed Single Use Medical Devices	Anthesis	<u>Whitepaper</u>	5.34	4.11	-23%	Tissue removal
2023	PATIENT CARE	Comparative Life Cycle Assessment Between Single-Use and Reprocessed IPC Sleeves	Sabrina Lichtnegger, Markus Meissner, Francesca Paolini, Alex Veloz, Rhodri Saunders	<u>Risk</u> <u>Management</u> <u>and</u> <u>Healthcare</u> <u>Policy</u> (Dovepress)	7	4.2	-40%	Compression Sleeve
2023	PATIENT CARE	Comparative Carbon Footprint of Reprocessed Single Use Medical Devices	Anthesis	Whitepaper	0.15	0.07	-53%	Pulse oximeter