Experiences from remanufacturing of medical devices in NHS England

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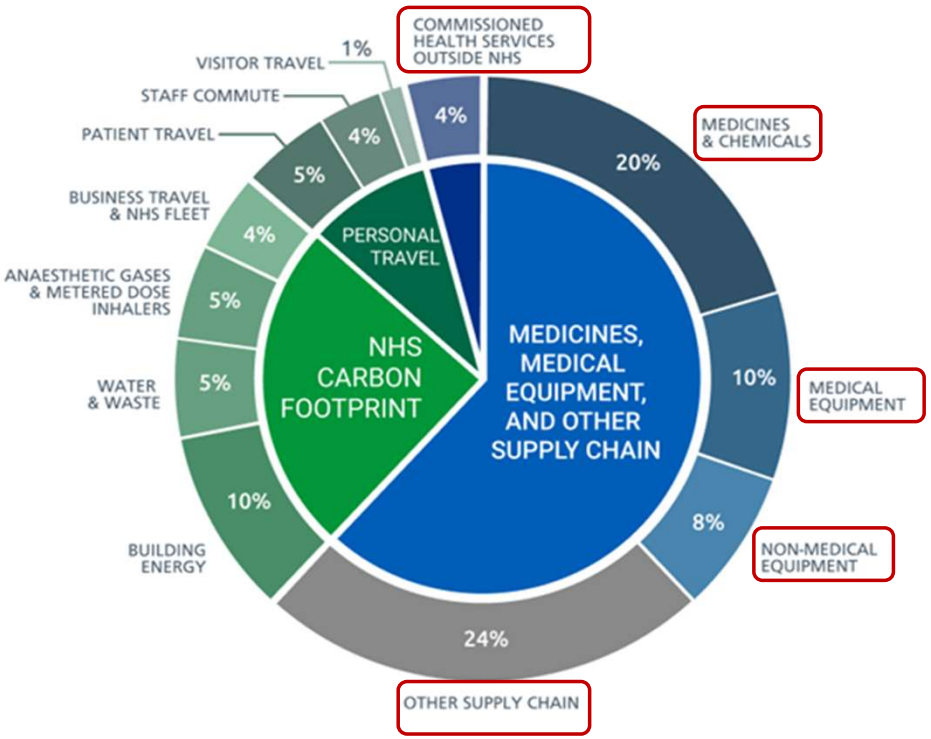
Plastics in Healthcare, Friday 5th May 2023

Background - NHS targets and emissions

62% of NHS carbon emissions occur in the supply chain

The NHS Carbon Footprint



The NHS is committed to net zero

100%

By 2040 for the emissions we control directly (the NHS Carbon Footprint)

*with an ambition to reach an **80% reduction**, compared with a 1990 baseline, **by 2028 to 2032***

100%

By 2045 for all emissions, including those embedded in the supply chain (the NHS Carbon Footprint Plus)

*with an ambition for an **80% reduction**, compared with a 1990 baseline, **by 2036 to 2039***

NHS Net Zero Supplier Roadmap

2022

From April 2022, all NHS procurements will include a minimum 10% net zero and social value weighting. The net zero and social value guidance for NHS procurement teams will help unlock health-specific outcomes (building on PPN 06/20).

2023/24

From April 2023, for all contracts above £5 million per annum, the NHS will require suppliers to publish a carbon reduction plan for their UK Scope 1 and 2 emissions and a subset of scope 3 emissions as a minimum (aligning with PPN 06/21).
From April 2024, the NHS will extend this requirement to cover all procurements.

2027

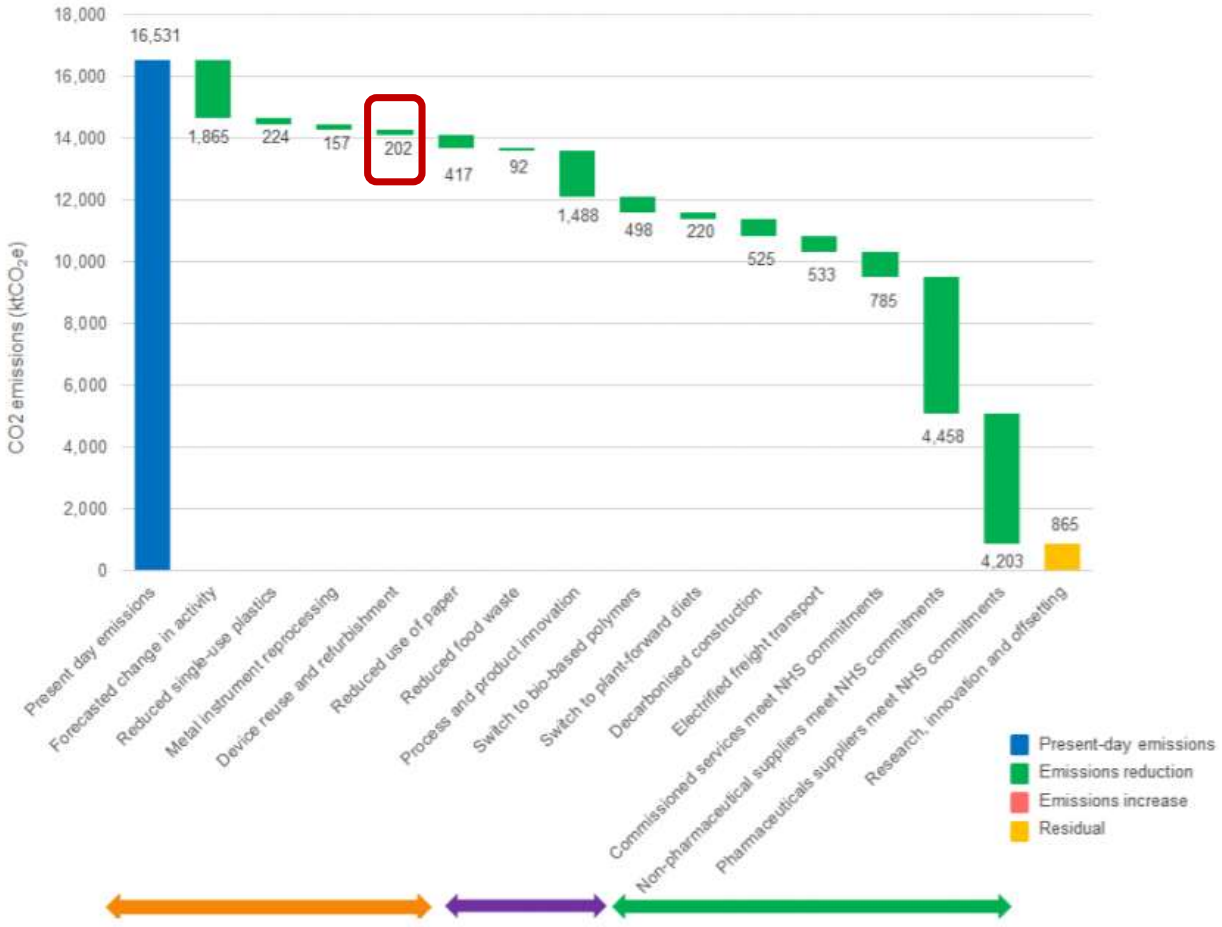
From April 2027, all suppliers will be required to publicly report targets, emissions and publish a carbon reduction plan for global emissions aligned to the NHS net zero target, for all of their Scope 1, 2 and 3 emissions.

2028

New requirements will be introduced overseeing the provision of carbon foot printing for individual products supplied to the NHS. The NHS will work with suppliers and regulators to determine the scope and methodology.

Interventions to reduce supply chain emissions

In the Net Zero report, there are 13 interventions that were identified within the Supply Chain workstream. Device reuse and refurbishment presents a sizeable opportunity to move away from single use.



Resource efficiency	Reduced single-use plastics
	Metal instrument reprocessing
	Device reuse and refurbishment
	Reduced use of paper
	Reduced food waste
	Process innovation
Low carbon products	Product innovation
	Switch to bio based polymers
	Switch to plant forward diets
Decarbonise suppliers	Decarbonised construction
	Electrified freight transport
	Commissioned healthcare
	Supplier partnerships to meet NHS commitments

The Business Case

Many medical devices (e.g. catheters and surgical instruments) are durable and expensive products that can be remanufactured to quality assured standards, extending their useful life, offering carbon and cost savings.

Revenue and savings

Generate income through collection of used devices.

Remanufactured products cost up to 50% less than their virgin manufactured equivalents.

Quality assured

Remanufactured devices are regulated in line with MHRA guidelines and must be CE marked to be on the market.

All products are checked for safety, performance and conformity assessment. A unique identifier ensures traceability.

Greener NHS ambition

Remanufactured devices generate 50% less CO_2 emissions, avoiding extraction and consumption of new material.

Device reuse contributes to the NHS Net Zero Plus target and trusts Green Plan delivery actions.

Ease of implementation

Setting up a collection scheme is simple, and remanufactured devices can be purchased through NHS Supply Chain.

'The use of remanufactured circular mapping catheters is safe, efficient and reliable. Widespread use of remanufactured single use devices offers the possibility of significant economic benefit'

Leung et al. Journal of Interventional Cardiac Electrophysiology

Case study example

Leeds General Infirmary Cath Labs diverted over 102 kg of waste, generated over £13k in revenue, and a further 50% savings of some £12k to the NHS for remanufactured devices used in 2020 alone.

NHS
The Leeds Teaching Hospitals
NHS Trust

Where's the best place to start?

MHRA classes are risk-based, considering the duration of contact, degree of invasiveness and body part affected by use of the device

Class I – non-invasive or transiently used surgically invasive devices that are designed for reuse via standard decontamination protocols. Not eligible for remanufacture

Class II and above *eligible* for remanufacture according to MHRA guidance

Categories of SUDs currently available as part of a remanufacturing programme in the UK (typically Class IIb and above):


Article

Assessing Long-Term Medical Remanufacturing Emissions with Life Cycle Analysis

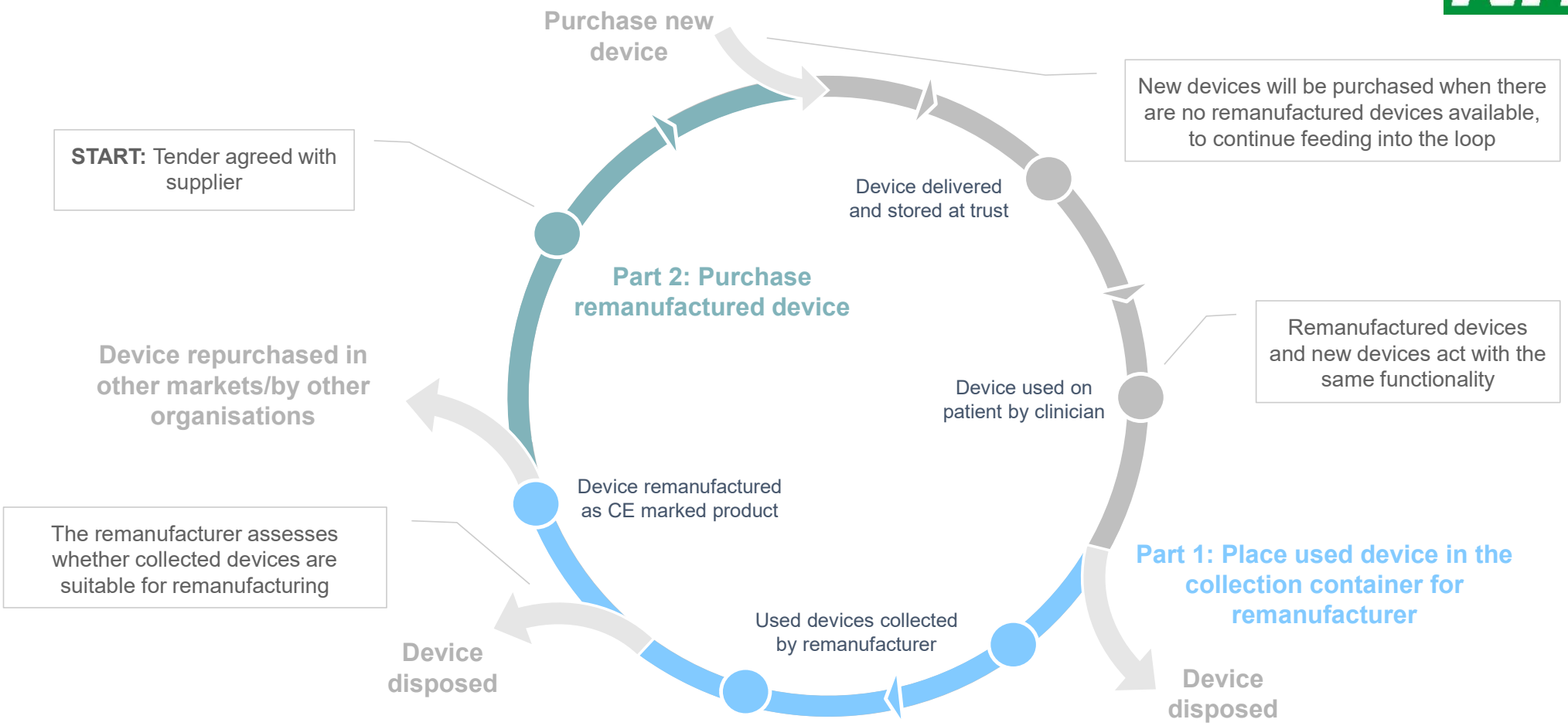
Julia A. Meister, Jack Sharp, Yan Wang * and Khuong An Nguyen

Combining Life Cycle Assessment and Circularity Assessment to Analyze Environmental Impacts of the Medical Remanufacturing of Electrophysiology Catheters

by Anna Schulte *, Daniel Maga and Nils Thonemann

- Diagnostic Catheters
- Ablation Catheters
- 3D Mapping Catheters
- Surgical and Orthopaedic Instruments
- Endoscopic and Further Medical Devices

Remanufactured medical device lifecycle



Key considerations

Safety & liability

- Awareness of evidence base to alleviate IPC concerns
- Liability transfers to remanufacturer

Existing commitments & practices

- Establish new contracts while existing contractual commitments run out & instigate pilots for small % of supply
- Instigate collections as a first step

Awareness

- Understanding of the difference between re-processing of reusables & remanufacturing
- Exposure to active suppliers or available devices
- Awareness of key business case numbers for switching (cost & carbon savings)

Market maturity

- Portfolio of available devices
- Variety of models to accommodate surgeon model preferences

What about safety & functionality?

All remanufactured devices have the CE, or UKCA, certification mark…

A CE Mark is a symbol that must be affixed to class II & III medical devices to be sold on the European market. The mark indicates that a product:

- Fulfils the requirements of relevant European device directives
- Meets the relevant performance and safety standards for full functionality and application, including associated accessory devices
- Is fit for its purpose and will not endanger lives or property
- Is EN ISO 13485 EU MDD 93/42/EWG compliant

CE mark

… what this means for healthcare providers:

- Remanufactured medical devices share a *similar risk profile* to a new single-use medical device
- Preparation and handling processes for used devices must be followed to ensure any infection risk is minimised
- All medical devices used *must show the CE mark*, to confirm *product liability is provided by the remanufacturer*
- Implement and follow an effective quality and safety assurance programme (i.e. protective regulations), to include procedures to safely handle and transfer devices from locality to remanufacturer

UKCA mark

Infection Risk

Following the device preparation and handling process mitigates the risk of used medical devices causing an infection:

High Risk Exposure

Devices that are, or have the potential to have been, exposed to high risk infectious diseases are treated in the same way as any other medical device: destroyed, with no exceptions

What about safety & functionality?

J Interv Card Electrophysiol. 2019; 56(2): 205–211.
Published online 2018 Dec 26. doi: 10.1007/s10840-018-0497-x
PMCID: PMC6848800
PMID: 30588568

Remanufactured circular mapping catheters: safety, effectiveness and cost

Lisa WM Leung,[✉] Banu Evranos, Alexander Grimster, Anthony Li, Mark Norman, Abhay Bajpai, Zia Zuberi, Manav Sohal, and Mark M. Gallagher

January 2008

REPROCESSED SINGLE-USE MEDICAL DEVICES

FDA Oversight Has Increased, and Available Information Does Not Indicate That Use Presents an Elevated Health Risk

Engagement & awareness

Encouraging the right behaviours

Staff	Responsibilities	Tools
Any staff member responsible for the preparation, handling, and cleaning of devices	*Encourage and reinforce the right behaviours at each step in the preparation and handling process and effective contract management*	*Visual aids and procedural documentation detailing step-by-step guidance for appropriate preparation and handling of device*
Clinical leads- theatre/cath lab managers, lead EP Physiologists	Clinical and theatre staff are typically involved with the preparation and handling process and should understand correct procedure for each of the following steps: 1. Preparation & testing 2. Cleaning & drying 3. Packaging 4. Storage & collection 5. Disposal	**Procedural documents** **Posters/ Signage** **Training sessions** **Labels**
Theatre or Cath Lab staff i.e. scrub team, nurses, runners, ODPs		
Administrative staff i.e. material/stock managers, procurement	Administrative staff typically responsible for: 1. Contract management 2. Inventory management i.e. supply 3. Performance reporting i.e. commercials	**Procedural documents** **Commercial reporting**

Additional support & resources

Support tools and events co-developed with 12 NHS trusts

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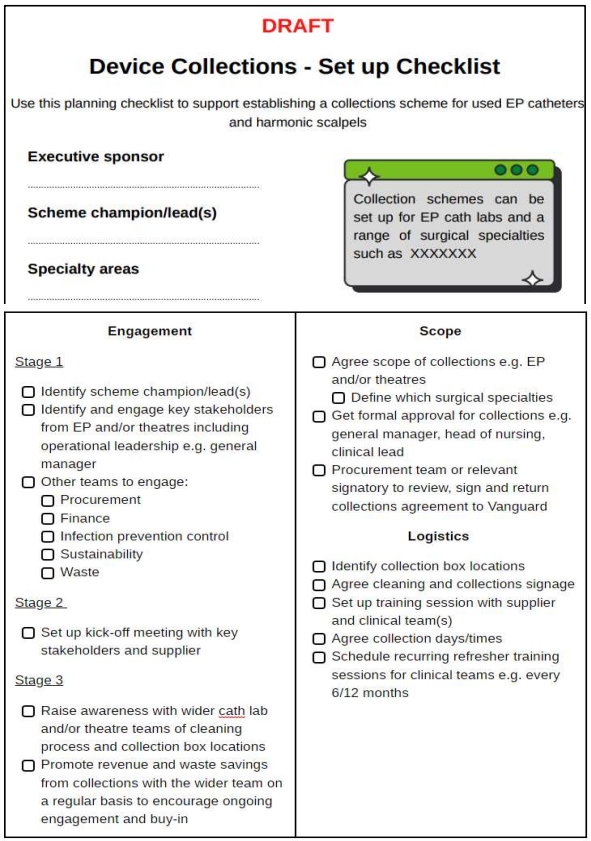
Support tools and events co-developed with 12 NHS trusts



DRAFT

Device Collections - Set up Checklist

Use this planning checklist to support establishing a collections scheme for used EP catheters and harmonic scalpels

Executive sponsor

.....

Scheme champion/lead(s)

.....

Specialty areas

.....

Collection schemes can be set up for EP cath labs and a range of surgical specialties such as XXXXXXX

Engagement

Stage 1

- ☐ Identify scheme champion/lead(s)
- ☐ Identify and engage key stakeholders from EP and/or theatres including operational leadership e.g. general manager
- ☐ Other teams to engage:
  - ☐ Procurement
  - ☐ Finance
  - ☐ Infection prevention control
  - ☐ Sustainability
  - ☐ Waste

Stage 2

- ☐ Set up kick-off meeting with key stakeholders and supplier

Stage 3

- ☐ Raise awareness with wider cath lab and/or theatre teams of cleaning process and collection box locations
- ☐ Promote revenue and waste savings from collections with the wider team on a regular basis to encourage ongoing engagement and buy-in

Scope

- ☐ Agree scope of collections e.g. EP and/or theatres
  - ☐ Define which surgical specialties
- ☐ Get formal approval for collections e.g. general manager, head of nursing, clinical lead
- ☐ Procurement team or relevant signatory to review, sign and return collections agreement to Vanguard

Logistics

- ☐ Identify collection box locations
- ☐ Agree cleaning and collections signage
- ☐ Set up training session with supplier and clinical team(s)
- ☐ Agree collection days/times
- ☐ Schedule recurring refresher training sessions for clinical teams e.g. every 6/12 months

10 REASONS WHY

to start or expand a device remanufacturing scheme

Building on the NHSE Device Remanufacture How-to Guide, here are **10** reasons why NHS trusts should consider remanufactured harmonic scalpels (energy devices) and electrophysiology (EP) catheters

1 Remanufactured devices are safe, sterile and tested with the same guarantees, warranties and assurances as a new devices

There is no difference in the expected clinical performance and safety between a new and remanufactured device. They are fully regulated by the MHRA and must meet the same requirements as a new device. Each remanufactured device is CE/UKCA trademarked and individually tested, including fully traceable laser marking, providing quality assurance.

2 No specialist training, new equipment or changes to existing policy are required

Remanufactured harmonic scalpels and EP catheters are the same product as new devices. Clinicians will not notice the difference between a new and remanufactured device, and no additional training is required. After use, they go through additional functionality testing, enhanced cleaning and replacement of component parts as required. The MHRA advises remanufactured devices can be expected to work with the same ancillary equipment as new devices and should be used in line with the remanufacturer's instructions and local medical device management policies to ensure optimal performance and assure patient safety.

3 Remanufactured medical devices have been tried and tested in the UK and used widely internationally for years

As of October 2022, 34 trusts in England use remanufactured devices. Their use is commonplace in the US, Europe, Canada, Israel and Japan with 300 device types approved by the U.S. Food and Drug Administration (FDA), (ADMR). In Germany, 1,000 different remanufactured products are used in 27 university hospitals. In 2020, over 34 million remanufactured devices were used across 10,000 hospitals globally. Between April - September 2022, an NHS supplier reported 1,356 EP catheter and harmonic scalpel devices had been remanufactured and reused in the UK.

4 Using remanufactured devices delivers substantial carbon savings

Life Cycle Assessments have identified remanufactured devices can generate up to 50% less carbon (How-to guide), by avoiding extraction and consumption of new material and shorter transport distances. With many medical devices, including new surgical scalpels and EP catheters produced in the US, carbon emissions from transport and distribution costs are greater than for devices remanufactured in Europe.

5 Device collections are a quick-win net zero initiative for clinical staff

Setting up collections for used devices is an easy approach to starting a sustainability initiative and does not require a commitment to use a remanufactured device. The collections process is a sustainable alternative to disposing of a used device as a waste item, with basic training in after-use packaging provided. Your trust will then benefit from carbon and waste savings, collection payments, and data reports.

Understanding the business case

Product Opportunity Dashboard - Remanufactured Devices (RMD)

This tab provides the estimated opportunity for annual carbon (CO2e) and cost saving associated with the collection of devices for remanufacture and the use of remanufactured devices. Opportunity is presented at Trust level

Org Name [redacted] | Intervention Group: EP Catheters | % Remanufactured: 80% | Reset All Filters

Latest Date: January 2023
(refreshed on 31st August 2022) Published

This dashboard is updated yearly.

Current opportunity - Used eligible device collection

saves

3 kgCO2e

&

£200

RMD device scheme status

Using RMDs | Trialling RMDs | Collection Only

Hospital [redacted]

Regional RMD scheme status

LONDON

Hospital [redacted]

Current opportunity - Devices eligible for RMD switch

3%

saves

6 kgCO2e

&

£2,600

RMD Alternatives

OEM Product Name	RMD Product Name
Celsius C-Type 7F 115	Vanguard Ablation Catheter uni BWA
Celsius D-Type 7F 115	Vanguard Ablation Catheter uni BWA
Celsius DS D-Type 7F 115	Vanguard Ablation Catheter uni DS B..
Celsius E-Type 7F 115	Vanguard Ablation Catheter uni BWA
FlexAbility	Vanguard Irrigated Ablation Catheter u..

Future opportunity - Increased % eligible devices

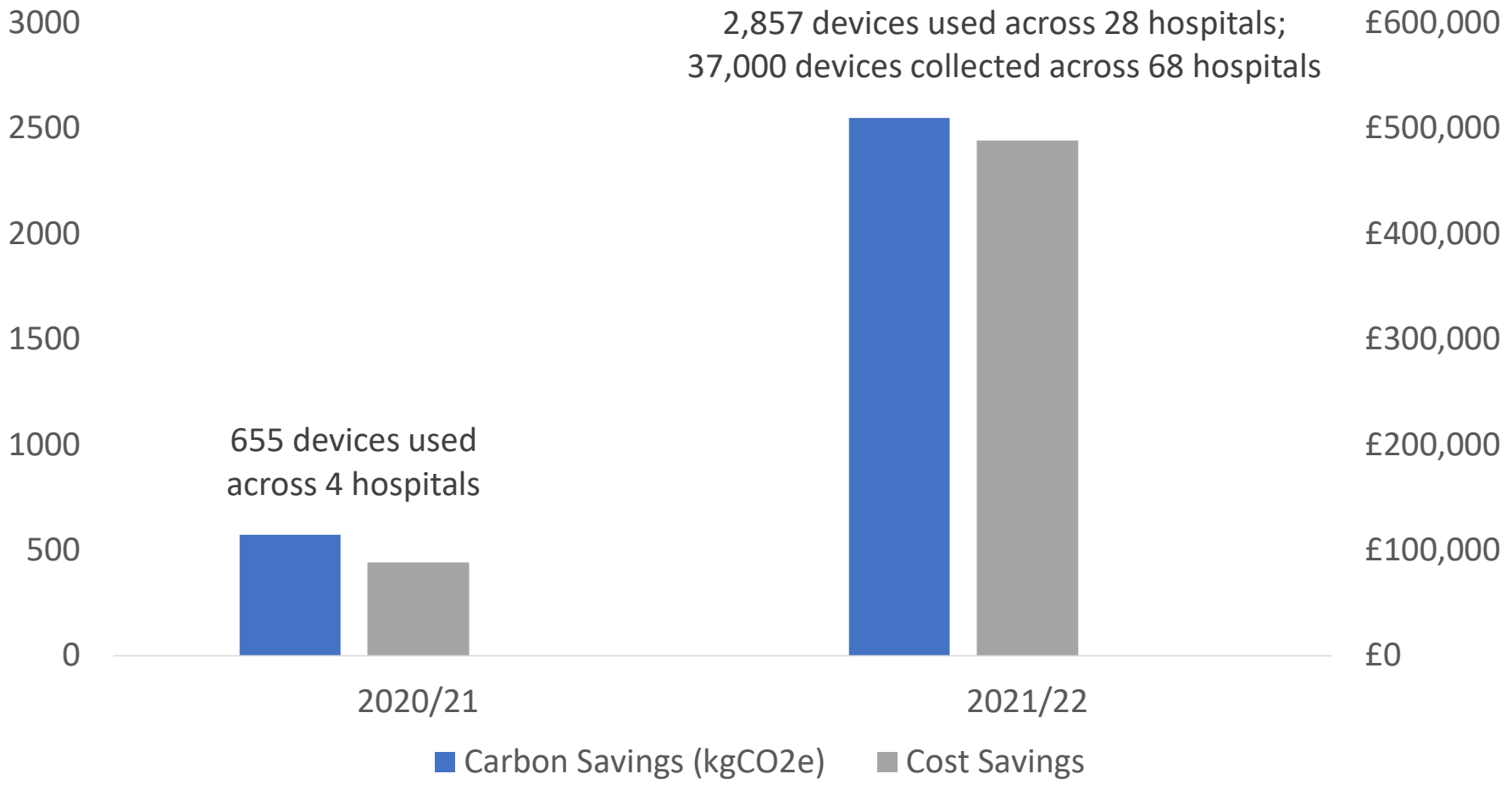
= 186 kgCO2e

= £72,800

% Portfolio Eligible for RM: 100%

For queries please contact: england.ccf-sustainability@nhs.net

A year on…


3000
2500
2000
1500
1000
500
0
£600,000
£500,000
£400,000
£300,000
£200,000
£100,000
£0
655 devices used across 4 hospitals
2,857 devices used across 28 hospitals; 37,000 devices collected across 68 hospitals
2020/21
2021/22
Carbon Savings (kgCO2e)
Cost Savings

Future areas of priority

Establishing larger evidence-base on functionality & safety; sharing lessons learned through case studies

Highlight best practice in handling & processing

Bringing OEMs on the journey

Focus on single-use products for which there are no reusable alternatives and with higher potential “turn-rates”

Promote domestic closed-loop remanufacturing contracts