Health Innovation Wessex

Independent evaluation of PlasmaTYPHOON+

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Disclaimer

This report presents the findings of an independent evaluation of PlasmaTYPHOON+ endoscope drying and storage system. The findings of this independent evaluation are those of the authors and do not necessarily represent the views of PENTAX Medical or other key stakeholders.

Declaration of Interest Statement

Health Innovation Wessex supports innovators to bring their innovations to the NHS as well as provide an evaluation service more broadly to our members and others. On occasion, we evaluate innovations that we have also supported. Whilst these evaluations are independent, for transparency we disclose our dual role where applicable. In this case, HIW only had a role in the evaluation of PlasmaTYPHOON+. PENTAX Medical were awarded this evaluation following a competition run by Health Innovation Wessex and funded by the Office for Life Sciences in June 2023.

Acknowledgements

We would like to thank the staff from the decontamination unit, authorised engineers for decontamination, and PENTAX Medical who contributed to the evaluation. The decontamination unit and all participating staff have been anonymised for this report.

Health Innovation Wessex

Table of Contents

Executive Summary

This report describes an independent real world evaluation of an innovation in use in the NHS, the PlasmaTYPHOON+ system developed by PENTAX Medical, undertaken by the Health Innovation Wessex Insight Team.[1]

Drying cabinets have been the standard method, based on guidelines (Health Technical Memorandum [HTM] 01-06), for the management of flexible endoscopes after they have been reprocessed through a washer. In 2017, PlasmaBiotics introduced a newer and faster technique for drying and storage of flexible endoscopes, the PlasmaTYPHOON+ and PlasmaBAG system.

Health Innovation Wessex conducted the evaluation of PlasmaTYPHOON+ and PlasmaBAG system between November 2023 and May 2024 in a decontamination unit in the south of England.

In May 2023, two PlasmaTYPHOON+ and PlasmaBAG systems were implemented at the decontamination unit. These were under consideration to replace the SURESTORE™ Storage & Endoscope Transport System, based on a business case that anticipated resultant cost savings and improved efficiency in the drying and storing of flexible endoscopes. Several large storage cabinets are also present at the decontamination unit and their value is also under consideration.

A mixed methods design explored three broad areas of interest for PENTAX Medical and the decontamination unit: (1) energy consumption and plastic waste of PlasmaTYPHOON+ and related devices, (2) stakeholders' perceptions of acceptability and impact of the PlasmaTYPHOON+ and PlasmaBAG system, and (3) an assessment of PlasmaTYPHOON+ related workflow.

Three systems were compared in this evaluation. The PlasmaTYPHOON+ system was compared against two existing drying and storage systems at the decontamination unit, those being SURESTORE™ and a large drying cabinet.

On energy consumption, in a direct comparison, PlasmaTYPHOON+ used 22 times less electricity than the existing storage cabinet. Due to the unit context, the PlasmaTYPHOON+ required an air compressor and combined used eight times less electricity than the storage cabinet. Comparisons with SURESTORE™ indicate PlasmaTYPHOON+ used less electricity in a direct comparison, but more when requiring an air compressor. The storage cabinet, using electricity but rarely used for storage, was a very large user of energy. It was estimated to use 4,505 kWh yearly, which is equivalent to 1.9 metric tons or 1,878 kilograms of carbon dioxide. This is equivalent to 37.1% of an average home's electricity use for one year, the energy needed to charge 123,989 smartphones, and greenhouse gas emissions from 4,803 miles driven by an average petrol-powered car.

[1] PENTAX Medical were awarded this evaluation following a competition run by Health Innovation Wessex and funded by the Office for Life Sciences in June 2023.

Findings on plastic waste, by using the PlasmaBAG and not the SURESTORE™ system, estimated a reduction in single-use plastic waste of 2,623.31kg between May 2023 and March 2024. This was 50% higher than the projected reduction in the hospital business case made prior to the implementation of PlasmaTYPHOON+.

The use of PlasmaTYPHOON+ supports the 'green endoscopy' position statements on sustainable decontamination units from the British Society of Gastroenterology (BSG), Joint Accreditation Group (JAG) and Centre for Sustainable Health (CSH). However, each unit must ensure any potential benefits are not lost. The absence of medical air (ultra-clean, dry, purified, colourless, odourless, non-flammable gas) and the required use of air compressors increased electricity use. Using both the fully implemented PlasmaTYPHOON+ system and partially de-implemented SURESTORE™ and storage cabinet systems, at the same time, results in unnecessary energy consumption.

On acceptability, the PlasmaTYPHOON+ system was perceived as highly acceptable by unit staff. It was viewed by unit staff as an excellent replacement for SURESTORE™ and the storage cabinet systems, had minimal burden for training and use, was faster, and staff were confident to use it. Unit staff also reported colleagues in the endoscopy and theatre departments preferred PlasmaTYPHOON+ compared to previous systems.

Authorised Engineers for Decontamination (AED) had mixed views on PlasmaTYPHOON+ and were concerned about its validation within a regulatory environment that only provided guidance for drying cabinets. AEDs were uncertain about how and who should validate PlasmaTYPHOON+, perceived different AEDs having different methods and priorities, and called for an urgent update to the HTM 01-06 guidance for drying endoscopes.

On impacts on the decontamination unit, the implementation of PlasmaTYPHOON+ led to £107,856.59 in financial savings in FY23-24 for the decontamination unit. The savings were due to a large reduction in use of the SURESTORE™ system and implementing two PlasmaTYPHOON+ systems. The pay-per-use cost of SURESTORE™ was higher than the PlasmaTYPHOON+ system.

On the speed of drying endoscopes, when considering the drying and storing process alone our analysis indicates PlasmaTYPHOON+ saved 2 minutes and 11 seconds per scope compared to SURESTORE™ and saved 2 hours, 55 minutes, 31 seconds per scope compared to the storage cabinet.

When considering the full scope turnaround time – using the time 'returned to wash area' and time 'despatched' as a proxy for processing time in the unit – there appeared to be little difference between PlasmaTYPHOON+ and SURESTORE™ systems. However, it was not possible to measure factors beyond the PlasmaTYPHOON+ drying steps accurately to provide a whole-system scope turnaround analysis.

Whilst there was no meaningful change in the total number of scopes processed by the decontamination unit in the year before and the period after the implementation

of PlasmaTYPHOON+, the mean number of scopes processed per day slightly increased after the implementation of PlasmaTYPHOON+. After the introduction of PlasmaTYPHOON+, there was an 8% decrease in scopes being sent for servicing or repair, and a 4% decrease in processing failure rates compared to the year prior.

The contributing factors to an increase in speed and efficiency from using PlasmaTYPHOON+ was the system being easier and safer to operate. Furthermore, fewer failures in the drying process were reported in the operational data and unit staff interviews, which avoids reprocessing endoscopes.

On unit staff wellbeing, unit staff reported PlasmaTYPHOON+ was a faster and less stressful drying and storage method. It has helped relieve the pressure of dealing with priority requests for endoscopes from endoscopy and theatre departments, which occur daily. Unit staff also reported fewer cases of repetitive strain injury compared to when using the previous SURESTORE™ system, which involved a difficult process to seal the bag. They also reported less risk of chemical-related injury from bottled chemicals needed for the SURESTORE™ system.

By implementing PlasmaTYPHOON+, decontamination unit staff have benefited from improved relationships with other hospital departments. The latter were part of the driver for change to PlasmaTYPHOON+ and the decontamination unit has been viewed as responsive to the wider needs of the hospital.

On the implementation of PlasmaTYPHOON+, the pre-implementation activities and decisions between decontamination units and AEDs are influenced by several factors. AEDs appear to have differing views on the evidential requirements for new devices. This is in part driven by:
(a) the current mismatch between key regulatory guidance (HTM 01-06) which is focused on processes and maintenance of drying cabinets
(b) some level of tension within the AED community around appropriate AED professional backgrounds/skillsets to effectively validate a device outside of current guidance
(c) some level of tension within the AED community about the influence of individual AED commercial interests
(d) AEDs demonstrating differing levels of risk toward new devices, and
(e) an apparent absence of AED collaboration and opportunities to share and learn from one another.

Once the decision to implement PlasmaTYPHOON+ was taken by the decontamination unit and relevant AED, the practical setup by unit staff – with PENTAX Medical training support – was perceived as easy and straightforward.

A range of suggested recommendations for the decontamination unit, PENTAX Medical, and the AED community are provided. Importantly, there is an urgent need to review and amend the HTM 01-06 guidance to standardise the validation of drying cabinet replacement devices, such as PlasmaTYPHOON+.

1. Background

1.1. The PlasmaTYPHOON+ and PlasmaBAG system

Drying cabinets have been the standard method, based on the Health Technical Memorandum (HTM) 01-06[2] guidelines, for the management of flexible endoscopes after they have been reprocessed through a washer. A drying cabinet contains a forced air source and circulation which is connected directly to the flexible endoscopes to inject high-quality air into the channels. Drying can take many hours and the subsequent storage time varies depending on the cabinet type (e.g. 7 to 31 days before being reused).

In 2017, PlasmaBiotics manufactured a newly patented technique for drying and storage of flexible endoscopes, the PlasmaTYPHOON+ and PlasmaBAG system. This system has been distributed by PENTAX Medical. The PlasmaTYPHOON+ is a small desktop device (see Figure 1) that creates a special airflow to completely dry the narrow flexible endoscope channels in approximately one and a half to five minutes depending on the endoscope type.

In terms of efficacy to dry to an acceptable level of microbiological safety, the PlasmaTYPHOON+ and PlasmaBAG system have been tested by Eurofins Biotech Germande Laboratory, that have COFRAC accreditation. The system is certified to comply with the NFEN16442 standard[3] for drying and storage of flexible endoscopes, contributing to improved hygiene and patient safety. The PlasmaTYPHOON+ and PlasmaBAG system, is proven to be more effective and more efficient than conventional drying and storage systems, even when compared with a horizontal vacuum drying and storage system[4] and is a validated process[5][6].

[2] https://www.england.nhs.uk/publication/management-and-decontamination-of-flexible-endoscopes-htm-01-06/
[3] EN 16442. (2015) Controlled environment storage cabinet for processed thermolabile endoscopes
[4] Hamel C, Bourhis M, Pain JB. (2019) Comparison of two storage techniques for heat-sensitive flexible endoscopes. Hygienes; XXVII:4
[5] Biotech Germande. (2015) Evaluation of the efficacy of a drying unit for internal channels of endoscopes according to NF S98-030 (clauses 4.3.3 and 6.2.3)
[6] Biotech Germande. (2017) Evaluation of the ability of a storage system (Plasmabiotics) to maintain the microbiological quality of heat sensitive endoscopes. Tests performed according to a test method based upon NF EN 16442

Figure 1. PlasmaTYPHOON+ system

1.2. Real world evaluation rationale

The microbiological efficacy of PlasmaTYPHOON+ and PlasmaBAG system has been tested in several studies. However, it is currently unknown how the system is perceived in a working decontamination unit and to what level the operational efficiencies are accurate under real world conditions. Furthermore, it is unknown if the anticipated benefits from reduced energy consumption and plastic waste savings are seen under real world conditions.

A real world evaluation of PlasmaTYPHOON+ and PlasmaBAG system, within a decontamination unit in an acute hospital in the south of England, was undertaken by the Insight team at HIW. The decontamination unit has been anonymised in this report at their request due to protecting staff identities and commercial sensitivities.

Due to the context of the decontamination unit under study, the PlasmaTYPHOON+ and PlasmaBAG system were compared against existing drying and storing systems SURESTORE™ Storage & Endoscope Transport System and a large storage cabinet. Comparisons were made on electricity use, plastic use, and time taken to use each device in real world settings.

PENTAX Medical were awarded this evaluation following a competition run by Health Innovation Wessex and funded by the Office for Life Sciences in June 2023.

1.3. Context of the Decontamination Unit

The unit operates Monday to Friday 8am to 11pm and Saturday to Sunday 9am to 5pm.

In May 2023, two PlasmaTYPHOON+ and PlasmaBAG systems were implemented at the decontamination unit. These were designed to replace the SURESTORE™ system,

based on a business case that anticipated resultant cost savings and improved efficiency. Several large storage cabinets are also present at the unit with no current plans for decommissioning.

Devices involved in this evaluation:

1. PlasmaTYPHOON+ and PlasmaBAG system (two currently in use)
2. Standalone air compressor (required to support PlasmaTYPHOON+ use in the unit)
3. Existing storage cabinet (facilitating the older drying process)
4. SURESTORE™ storage system (provides a patient-ready packaged flexible endoscope with a long shelf life).

Importantly, the large storage cabinet under study was not compliant with current regulations for drying and storage. It remains at the unit as a backup device and its usage is under review. Several other large storage cabinets are in use at the hospital the unit serves, but their energy usage was outside the scope of the evaluation.

2. Evaluation Methods and Questions

Between November 2023 and January 2024, the Insight team scoped and co-designed a real world evaluation on three broad areas of interest for PENTAX Medical and the decontamination unit:

1. energy consumption of PlasmaTYPHOON+ and related devices
2. stakeholders' perceptions of acceptability and impact of the PlasmaTYPHOON+ and PlasmaBAG system
3. assessment of PlasmaTYPHOON+ related workflow.

A fourth area of interest, the impact of PlasmaTYPHOON+ on the hospital trust's endoscopy services, was planned but could not be operationalised within the evaluation timeframe. This is a limitation of the current evaluation.

2.1. Evaluation Design

Based on scoping meetings and an assessment of evaluation options, this evaluation used convergent mixed methods[7] adopting a partially mixed equal status design[8] to address the evaluation questions. A range of quantitative and qualitative data collection tools were used between January and May 2024 to understand the impact and value of the PlasmaTYPHOON+ and PlasmaBAG system in one decontamination unit in the south of England.

[7] Creswell JWPC, Vikki L. Designing and conducting mixed methods research. 3rd ed. LA: SAGE Publications Ltd; 2018.
[8] Teddlie CT, Abbas. Mixed methods in social and behavioral research. 2nd ed. LA: SAGE Publications Ltd; 2010.

A range of data sources and stakeholder perspectives were included in this evaluation:

1. Decontamination unit operational/scope use data. For anonymisation reasons, the data system will be referred to as an Electronic Endoscope Tracking Application (EETA).
2. Decontamination unit financial data.
3. Observational assessment of time taken to process scopes with PlasmaTYPHOON+.
4. Interviews with senior and operational staff at the decontamination unit.
5. Interviews with authorised engineers for decontamination. This small group of professionals (15 in England, 35 across the UK) provide independent auditing and technical advice on decontamination procedures, maintenance, testing and management of the decontamination equipment.

Results from these data sources were synthesised to address the evaluation questions.

2.2. Evaluation area 1: Energy consumption and single-use plastic waste of PlasmaTYPHOON+ and PlasmaBAG

The PlasmaTYPHOON+ and PlasmaBAG innovations are designed to be faster and more efficient than previous methods of drying and storing endoscopes. Related to these efficiencies is the amount of energy and plastic waste used and potentially saved by their use.

As part of the ambition for 'greener endoscopy', it has been recognised that the evidence base of the actual carbon footprint of clinical activity and various elements of endoscopic procedures is presently lacking. The British Society of Gastroenterology (BSG), Joint Accreditation Group (JAG) and the Centre for Sustainable Health (CSH)[9] have called for the design of decontamination units to include sustainability as an explicit criterion for procurement of hardware and consumables (Position Statement 2.3). Furthermore, they have recommended all equipment, including computers and machines, should be turned off when not in use (Position Statement 3.6).

2.2.1. Energy consumption

The level of electricity used in kilowatt hours (kWh) was measured across five key devices in the decontamination unit:

1. PlasmaTYPHOON+ device 1
2. PlasmaTYPHOON+ device 2
3. air compressor device required in the unit for PlasmaTYPHOON+
4. large storage cabinet
5. SURESTORE™ storage device.

Comparisons between these devices and with relevant position statements were made to highlight the real world situation.

[9] Sebastian S, Dhar A, Baddeley R, et al. (2023) Gut;72:12-26.

2.2.2. Single-use plastic waste

The single-use plastic waste generated by PlasmaBAG and SURESTORE™ processes was measured and compared. For PlasmaTYPHOON+, the single-use plastic waste generated included the PlasmaBAG ECO and tracking label. For SURESTORE™, the single-used plastic waste generated included the SURESTORE™ outer pouch, CLEANASCOPE™ ADVANTAGE Transport and Short-term Storage System tray liners and tracking label. These elements of the two systems were weighed by the evaluators ten times, and the mean of the ten weights used to enable the estimated change in single plastic waste of SURESTORE™ (used between 01 May 2022 and 30 April 2023) and PlasmaBAG (used between 01 May 2023 and 22 March 2024) within the single-use plastic analysis.

Operational scope usage data exported from the EETA by the decontamination unit provided the total number of uses of the two systems to make the comparison.

2.3. Evaluation area 2: Acceptability of PlasmaTYPHOON+ and PlasmaBAG

To understand the acceptability of PlasmaTYPHOON+ and PlasmaBAG, implemented in May 2023, interviews were conducted with two senior and three operational staff at the decontamination unit. This data was supplemented by three interviews with Authorised Engineers for Decontamination, who provided a broader understanding of the regulatory environment.

All semi-structured interview schedules were informed by the Sekhon et al. (2017)[10] definition of acceptability as a multi-faceted construct that reflects the extent to which people delivering or receiving a healthcare intervention consider it to be appropriate, based on anticipated or experienced cognitive and emotional responses to the intervention. The different facets that lead an individual to judge an innovation 'acceptable' include affective attitude, burden, perceived effectiveness, ethicality, intervention coherence, and self-efficacy.

All qualitative interviews were analysed using a framework approach[11] and themes presented in appendix table 1.

[10] Sekhon, M., Cartwright, M. & Francis, J.J. (2017) Acceptability of healthcare interventions: an overview of reviews and development of a theoretical framework. BMC Health Services Research, 17: 88.
[11] Ritchie J, Lewis J. (2003) Qualitative research practice: a guide for social science students and researchers. London: Sage

2.4. Evaluation area 3: Assessment of PlasmaTYPHOON+ and PlasmaBAG workflow

Whilst the flow of PlasmaTYPHOON+ related activities has been described to be beneficial by the developer of PlasmaTYPHOON+[12], this evaluation has investigated several activities to understand use within real world settings. Specifically, this evaluation examined:

1. Speed of individual devices during the drying process
2. Speed of scope turnaround
3. Efficiency of unit operations.

To examine speed of individual devices, all the relevant drying steps/processes were mapped and confirmed with unit staff. For PlasmaTYPHOON+ scope drying during the observational visits, the time taken for each step was measured and recorded by the evaluators. As SURESTORE™ and the large storage cabinet were not in regular use, a baseline position[13] was obtained from the unit staff based on their years of experience. They were asked to estimate the time taken for each step using SURESTORE™ and the cabinet. A comparison was made between PlasmaTYPHOON+, SURESTORE™, and the large storage cabinet.

To examine scope turnaround time, unit operational data was used to make a high-level comparison of scope turnaround before (01 May 2022 – 30 April 2023) and after (01 May 2023 to 22 March 2024) the implementation of PlasmaTYPHOON+. This used the time an individual scope was 'returned to wash area' at the decontamination unit and time 'despatched' from the unit as a proxy measure for the overall processing time within the decontamination unit.

For efficiency of unit operations, a pre- and post-comparison was made using the proxy measure for overall processing time for scopes. To assess repairs and servicing, a pre- and post-comparison was made using the number of scopes recorded as 'away for repair' or 'away for servicing'. Failure rates were compared using the number of scopes recorded as 'reprocessor failure' or 'vacuum packing failed' pre- or post-PlasmaTYPHOON+ implementation.

2.5. Evaluation Questions

1. What is the energy consumption (kWh) of PlasmaTYPHOON+ under real world conditions in a decontamination unit?

2. How does the energy consumption (kWh) and single-use plastic waste of PlasmaTYPHOON+ compare with SURESTORE™ and the large storage cabinet under real world conditions?

[12] Caesar PJ & Vinteler, D. (2022) White Paper: Endoscope Drying and Storage. Safe drying and storage of flexible endoscopes through a new innovative technology. PENTAX Medical.
[13] https://www.frontiersin.org/articles/10.3389/fenvs.2021.724095/full

3. What is the acceptability of PlasmaTYPHOON+ within real world settings?

4. To what extent has PlasmaTYPHOON+ altered the speed of the endoscopy drying process?

5. What are the contributing factors for PlasmaTYPHOON+ altering the speed of the endoscopy drying process?

6. Has the wellbeing of decontamination unit staff changed since the introduction of PlasmaTYPHOON+?

7. How has PlasmaTYPHOON+ been implemented and what lessons have been learned to support future adoption in other units?

3. Results

3.1. PlasmaTYPHOON+, PlasmaBAG, and 'Sustainable Endoscopy'

3.1.1. Energy consumption analysis

The unit staff interviews indicated a perceived sense of reduced electrical power usage for PlasmaTYPHOON+, as stated by the staff member below. However, a quantitative assessment of real world power usage had yet to be done by the unit.

"I'm sure it [PlasmaTYPHOON+] must use less energy." (Unit staff 4)

Five energy monitors were connected to five devices at the decontamination unit for six weeks between mid-March and the end of April 2024. The evaluator observational visits and unit staff interviews indicated all five devices were routinely left on, including overnight and at the weekend, despite the ability to place three of the five devices (PlasmaTYPHOON+ 1 and 2, and SURESTORE™) into standby mode or turn off completely. Therefore, the kWh readings obtained could be reduced further with power management procedures.

The large storage cabinet was a considerably greater user of electricity, as seen in Table 1 and Figure 2.

As a standalone device, at week six, the cumulative kWh for the PlasmaTYPHOON+ 1 was **22 times lower** than the large storage cabinet. When combining the kWh for PlasmaTYPHOON+ 1 and the required air compressor, their combined kWh were **eight times lower** than the large storage cabinet.

Using a greenhouse gas equivalencies calculator[14], the 579 kWh used by the large storage cabinet in six weeks is equivalent to 0.241 metric tons or 241 kilograms of

[14] https://www.epa.gov/energy/greenhouse-gas-equivalencies-calculator

carbon dioxide. This is equivalent to 4.8% of an average home's electricity use for one year, the energy needed to charge 15,936 smartphones, and greenhouse gas emissions from 617 miles driven by an average petrol-powered car.

The SURESTORE™ system was very rarely used during the evaluation timeframe, so the readings should be understood in that context. Whilst largely unused, by week 6 the **SURESTORE™ cumulative kWh was 5.8 kWh higher** than PlasmaTYPHOON+ 1 when comparing devices directly. However, due to the need for an air compressor at the unit, the **SURESTORE™ cumulative kWh was 45.4 kWh lower** by week six than the combined PlasmaTYPHOON+ 1 and air compressor kWh. Assuming SURESTORE™ was in use to the same degree as other devices in the unit prior to the introduction of PlasmaTYPHOON+, it is not unreasonable to conclude that SURESTORE™ use would be comparable with combined PlasmaTYPHOON+ and air compressor use.

Table 1. Weekly energy consumption by device and relevant device combinations

Device	**kWh (cumulative)**						
	Week 1**	**Week 2**	**Week 3**	**Week 4**	**Week 5**	**Week 6**	**Estimated yearly kWh*****
PlasmaTYPHOON+ 1	5.42	8.268	10.66	13.6	16.57	19.5	146.8
PlasmaTYPHOON+ 2	5.195	8.062	10.34	13.35	16.42	19.2	146.1
Air compressor*	13.6	20.65	26.05	34.27	43.41	51.1	390.4
PlasmaTYPHOON+ 1 + air compressor*	19.0	28.9	36.7	47.9	60.0	70.7	537.3
PlasmaTYPHOON+ 2 + air compressor*	18.8	28.7	36.4	47.6	59.8	70.4	536.5
SURESTORE™	6.36	10.61	13.79	17.51	21.39	25.3	197.3
Large storage cabinet	145.8	241.7	315.8	401.1	490.1	579.0	4,505.3

*Required for PlasmaTYPHOON+ use in the deployment context
**Monitoring started 1.5 weeks before first reading taken
***Estimated yearly kWh based on average difference between each measured week, multiplied by 52 weeks

Using the greenhouse gas equivalencies calculator, the yearly 4,505 kWh used by the large storage cabinet is equivalent to 1.9 metric tons or 1,878 kilograms of carbon dioxide. This is equivalent to 37.1% of an average home's electricity use for one year, the energy needed to charge 123,989 smartphones, and greenhouse gas emissions from 4,803 miles driven by an average petrol-powered car.

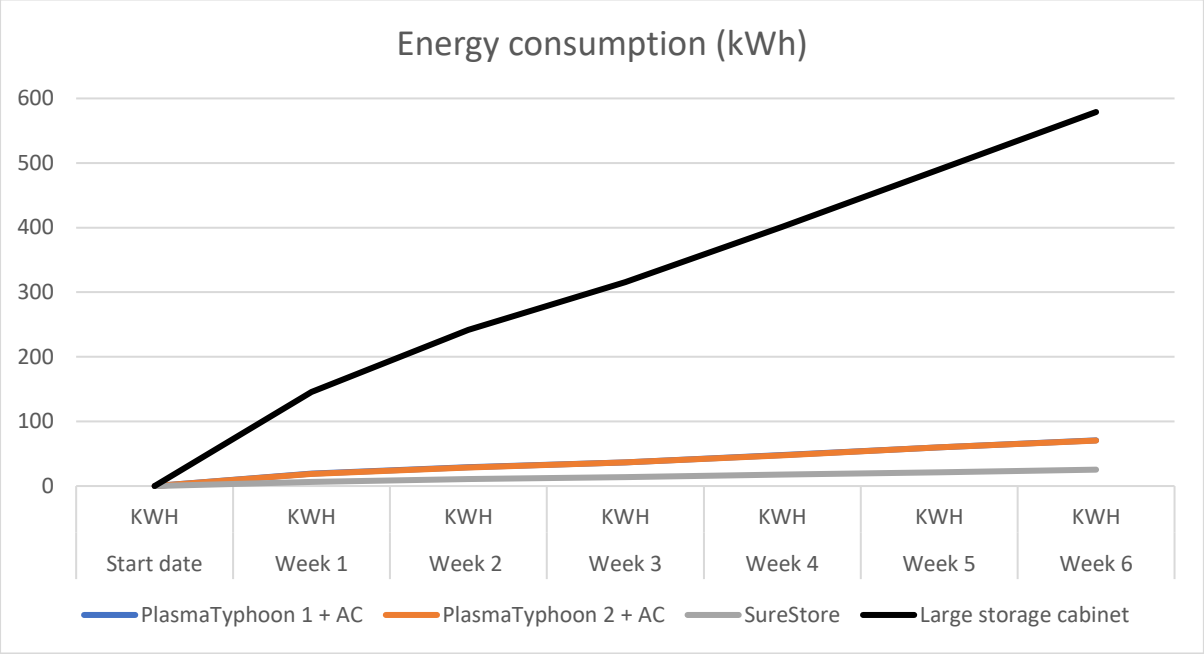

Figure 2. Energy consumption (cumulative) by device and device combinations (kWh). Please note the PlasmaTyphoon 1 + air compressor blue line is hidden behind the PlasmaTyphoon 2 + air compressor line.

Our observations and interviews indicated the SURESTORE™ system and large storage cabinet were not in regular use and could be switched off or removed. Senior unit staff were aware of this but also cited concerns about their ability to fully de-implement the previous systems.

The unit is currently operating the previous (SURESTORE™ and large cabinet) and new drying and storing techniques. The full de-implementation of the previous systems would permit further energy savings.

3.1.2. Single-use plastic waste analysis

'Reprocessor' report data exported from EETA was filtered by scope code to identify the number of scopes processed by the decontamination unit that were previously dried and stored using SURESTORE™ but which could have been dried and stored using PlasmaTYPHOON+ and PlasmaBAG prior to the implementation of PlasmaTYPHOON+ (between 01 May 2022 and 30 April 2023). The number of scopes processed by PlasmaTYPHOON+ and PlasmaBAG in the period following implementation of PlasmaTYPHOON+ (01 May 2023 to 22 March 2024) were also identified. This data was subsequently used to undertake the single-use plastic waste analysis below. To note, on any given day approximately 10-15% of scopes are requested as priorities and only washed; they are not dried or stored using PlasmaTYPHOON+ or PlasmaBAG, and not recorded on the EETA system. The plastic waste analysis could only use data on scopes actually processed through PlasmaTYPHOON+, so the plastic waste analysis has a minor limitation of some missing data.

Identification of scope drying and storing process using scope codes

The scope inventory report was analysed with support of a Decontamination Unit Officer to accurately determine the process by which the different scopes were dried and stored. The total number of scopes recorded in the decontamination unit scope inventory report was 288 scopes.

285 of the 288 scopes were recorded to have been dried and stored using SURESTORE™ before the implementation of PlasmaTYPHOON+. Three scopes recorded in the decontamination unit scope inventory report were not dried and stored (Figure 3).

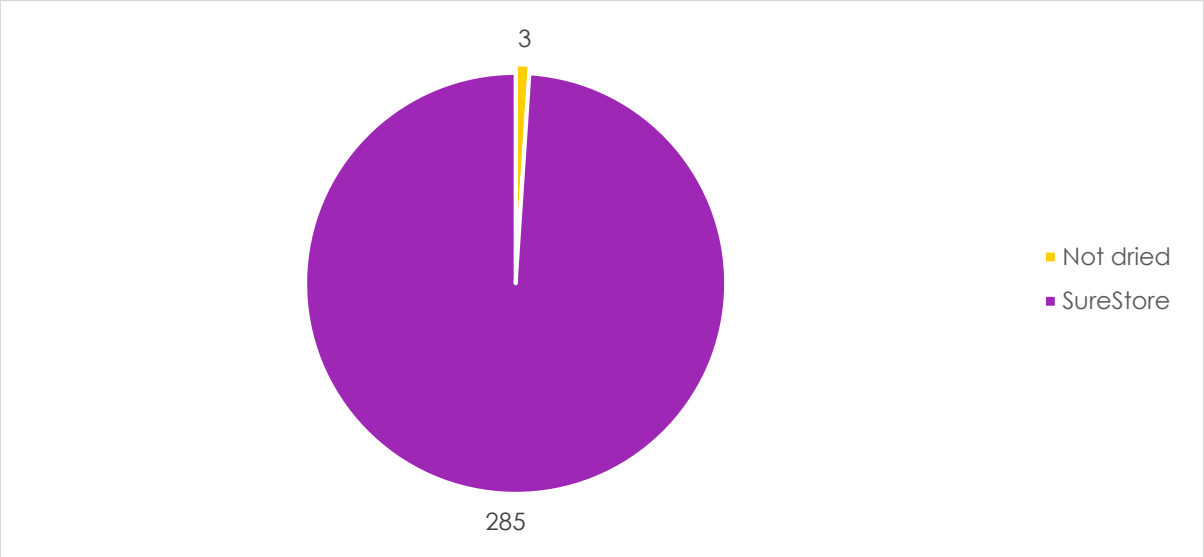

Figure 3. Scope drying and storage process prior to the implementation of PlasmaTYPHOON+.

278 of the 288 scopes included in the scope inventory report recorded on EETA were changed from being dried and stored to PlasmaTYPHOON+ in May 2023 (Figure 4).

Seven of the 288 scopes continued to be dried and stored using SURESTORE™ following the introduction of PlasmaTYPHOON+ within the decontamination unit in May 2023 (Figure 4).

Three of the 288 scopes were identified to be scopes not dried and stored by the decontamination service at all prior to the introduction of PlasmaTYPHOON+, and this process remained the same after the introduction of PlasmaTYPHOON+ (Figure 4).

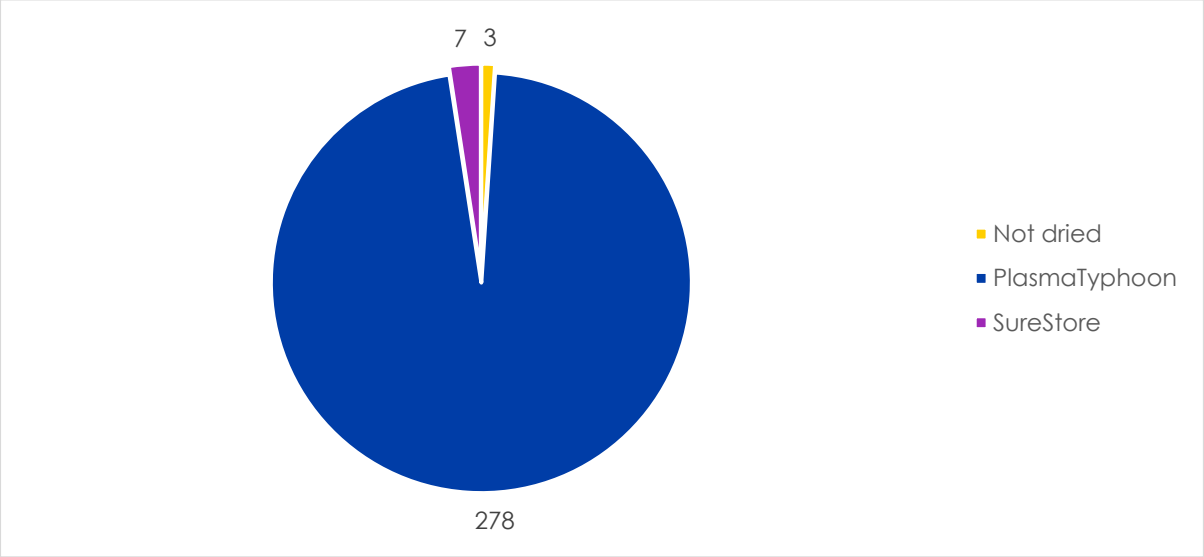

Figure 4. Scope drying and storage process following the implementation of PlasmaTYPHOON+.

Single-use plastic waste generated for each drying and storage process

For PlasmaTYPHOON+, the single-use plastic waste generated included the PlasmaBAG ECO and tracking label (63.8g). For SURESTORE™, the single-use plastic waste generated included the SURESTORE™ outer pouch, CLEANASCOPE™ ADVANTAGE tray liners, and tracking label (177.2g).

The difference in the weight of single-use plastic waste generated between the PlasmaTYPHOON+ and SURESTORE™ drying and storage methods is 113.4g (Table 2). Therefore, every time PlasmaTYPHOON+ was used to dry and store instead of SURESTORE™, 64% less single-use plastic waste was generated.

Table 2. Mean weight of single-use plastic according to each method

Method	**Mean weight of single-use plastic**
PlasmaTYPHOON+	63.8g*
SURESTORE™	177.2g

** PlasmaBAG ECO, the latest generation of PlasmaBAG, is produced with 80% recycled polyethylene.*
To note: the weight of the single-use plastic for CLEANASCOPE™ ADVANTAGE tray lining for scope storage and transport is 48.1g. There will have been a proportion of scopes which were required as priority each day that it is not possible to quantify which did not use either the PlasmaBAG ECO or the SURESTORE™ single-use plastics for storage or transport.

Single-use plastic waste generated pre- and post- implementation of PlasmaTYPHOON+

Of the 23,176 scopes reprocessed in the year between 01 May 2022 and the introduction of PlasmaTYPHOON+ on 01 May 2023, 23,173 scopes were dried and stored using SURESTORE™.

Three of the 23,176 scopes processed between 01 May 2022 and the introduction of PlasmaTYPHOON+ on 1 May 2023 were not dried and stored using SURESTORE™ (Figure 5).

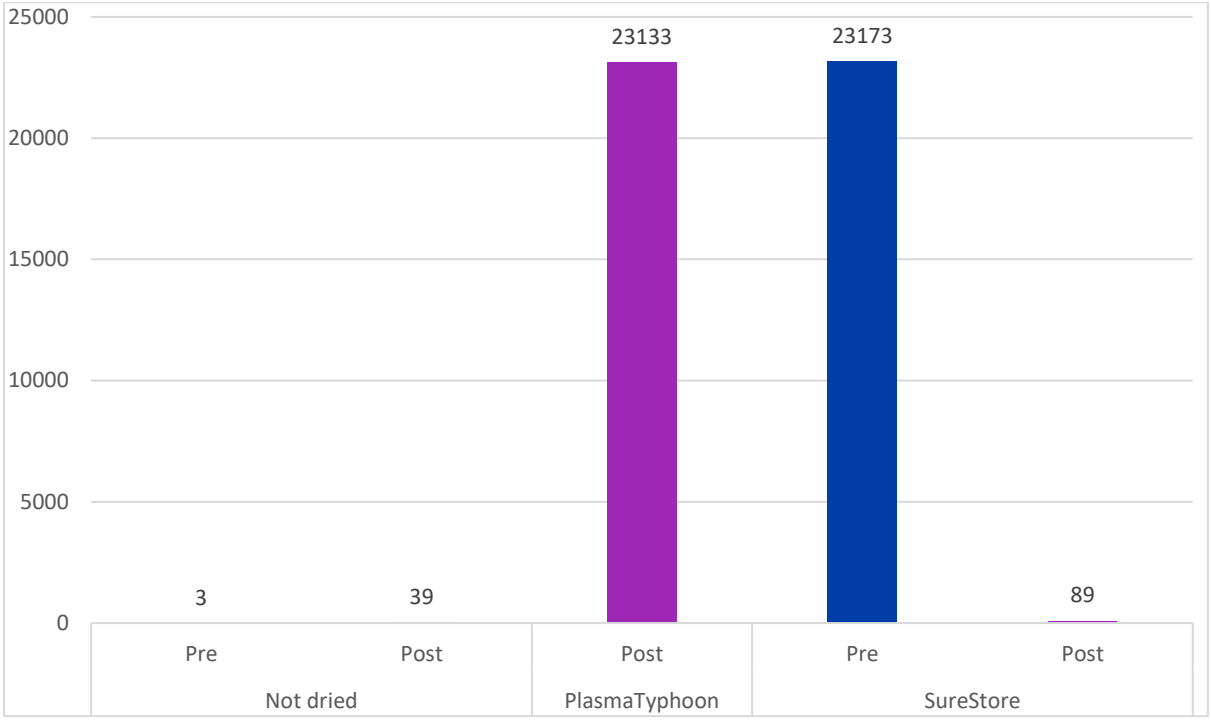

Figure 5. Drying and storage method for the scopes processed between 1 May 2022 (pre-implementation) and 30 April 2023, and 01 May 2023 and 22 March 2024 (post-implementation) of PlasmaTYPHOON+.

The 23,173 scopes reprocessed using SURESTORE™ between 1 May 2022 and the implementation of PlasmaTYPHOON+ on 1 May 2023 generated approximately 4,106.26kg of single plastic waste. Had PlasmaTYPHOON+ been available, this would have generated approximately 1,478.44kg of single-use plastic waste. Therefore, use of PlasmaTYPHOON+ could have reduced the single-use plastic waste generated by approximately 2,627.82kg.

Table 3. Estimated reduction in single-use plastic waste between SURESTORE™ and PlasmaTYPHOON+ between 01 May 2022 and 30 April 2023 and between 01 May 2023 and 22 March 2024.

01 May 2022 to 30 April 2023 (n=23,173)		
Total single plastic waste with SURESTORE™ method (kg)	**Total single plastic waste for the PlasmaTYPHOON+ method (kg)**	**Estimated potential reduction in single-use plastic waste generated had PlasmaTYPHOON+ been available (kg)**
4,106.26	1,478.44	2,627.82
01 May 2023 to 22 March 2024 (n=23,133)		
Total single plastic waste if SURESTORE™ method had been used (kg)	**Total single plastic waste for the new PlasmaTYPHOON+ method used (kg)**	**Reduction in single plastic waste generated (kg)**
4,099.17	1,475.86	2,623.31

As stated previously, after the implementation of PlasmaTYPHOON+ on 1 May 2023, 278 scopes were changed from being dried and stored using SURESTORE™ to PlasmaTYPHOON+. Therefore, the majority of the 23,261 dried and stored completed between 01 May 2023 and 22 March 2024 was using PlasmaTYPHOON+ as opposed to SURESTORE™ (Figure 5).

The drying and storage of the 23,133 scopes using PlasmaTYPHOON+ between 01 May 2023 and 22 March 2024 resulted in 1,475.86kg of single-use plastic being generated, compared to 4,099.17kg that would have been generated had SURESTORE™ been used. Therefore, there was an estimated reduction in single-use plastic waste generated of 2,623.31kg (Table 3).

Comparison of the weight of single-use plastic waste generated between the actual weight and the proposed weight

In the hospital business case introducing PlasmaTYPHOON+, it was proposed that there would be a reduction of 50g of single-use plastic waste per scope by using PlasmaTYPHOON+ compared to SURESTORE™. This demonstrates that the actual weight of single-use plastic waste saved when PlasmaTYPHOON+ is used is over 50% higher than projected in the business case.

Table 4. Difference in single-use plastic waste generated between the proposed single-use plastic waste reduction in business case and actual single-use plastic waste reduction.

Number of scopes processed with method changed from SURESTORE™ to PlasmaTYPHOON+	Total single-use plastic waste reduced based on 50g per scope as proposed in business case (kg)*	Total single-use plastic waste reduced based on actual weight of single plastic waste generated per scope (kg)	Difference in single-use plastic waste weight between proposed amount per scope in business case based on actual weight per scope (kg)
23,133	2,924.51	1,475.86	1,448.65

*Calculated by removing 50g from 177.2g to give the single-use plastic waste generated if the reduction was 50g as estimated in the business case.

The unit staff perspectives in relation to the reduction in single-use plastic corroborate the quantitative findings reported above. The carbon footprint theme from the interviews (see Appendix Table 1) indicated perceived benefits:

"It's more saving plastic more than anything." (Unit staff1)

"We used to use the tray liners with the SURESTORE™. So with the plasma we're not using the tray liners… no other plastic is going in with the plasma" (Unit staff 4)

Findings also highlighted another area of wastage which is reduced by PlasmaTYPHOON+ compared to the previous process that has not been captured in the quantitative findings.

"On the plasma, it's a small ticket with all the details on, with the SURESTORE™, it [the label] was a lot bigger, a lot bigger…and obviously if it was a fail, it would still print out a ticket fail. So that was extra wastage" (Unit staff 4)

Alongside the reduction in single-use plastic, the interviewees highlighted the lack of chemicals required in the PlasmaTYPHOON+ drying and storing process, which was felt to be another important environmental consideration as well as having patient benefits in relation to removing the risk of staining or injuring patients.

"Another thing we don't use the chemical on the Plasma where we do on the SURESTORE™" (Unit staff 4)

Therefore, the quantitative and qualitative findings demonstrate reduced single plastic waste generated by PlasmaTYPHOON+ compared to SURESTORE™ in this decontamination unit.

3.1.3. Comparison with 2022 green endoscopy position statements

The BSG, JAG and CSH[15] have jointly called for sustainable endoscopy. **Position statement 2.3** calls for sustainable decontamination units, to include a reduction in energy consumption and plastic waste.

Findings from this evaluation indicate that PlasmaTYPHOON+, in a direct comparison with SURESTORE™ and storage cabinets, greatly reduces electricity consumption. However, the context of the unit is important and two characteristics limit the potential gains. Firstly, the unit does not have a built-in medical air system so requires portable air compressors, which themselves require electricity. Secondly, the unit is currently operating the previous (cabinets) and the new drying techniques, thus using more total electricity than if they were using PlasmaTYPHOON+ only.

Findings on plastic waste indicate PlasmaTYPHOON+, specifically the PlasmaBAG, is achieving position statement 2.3. An estimated reduction of 2,623.31kg in single-use plastic waste generated was calculated from the use of PlasmaTYPHOON+ rather than SURESTORE™, between May 2023 and March 2024.

Position Statement 3.6 calls for all equipment, including drying machines, to be turned off when not in use. The evaluators' observational visits and unit staff interviews indicated all five devices were routinely left on, including overnight and at the weekend. Power management procedures at the unit would support reduced energy consumption and better achieve position statement 3.6.

3.2. Acceptability of PlasmaTYPHOON+

Interviews with unit staff and AEDs were analysed using a framework approach and the themes/sub-themes synthesised and presented in appendix table 1.

Overall, the PlasmaTYPHOON+ system was perceived as highly acceptable. However, some disagreement and complexity in views was apparent depending on participants' roles.

Three key themes influenced the level of acceptability and are described below.

3.2.1. Attitudes toward PlasmaTYPHOON+

Unit staff were unanimous in agreeing that PlasmaTYPHOON+ was **an excellent replacement system** for the SURESTORE™ system:

> *"I felt great about PlasmaTYPHOON+ [when it] was introduced. Our SURESTORE™ system was failing a lot, with multiple problems…like the wrong pressure and air bubbles in tubes, and bag sealing problems…this meant we were repeating the process a lot." (Unit staff 2)*

[15] Sebastian S, Dhar A, Baddeley R, et al. (2023) Gut;72:12-26.

Furthermore, the unit staff all agreed that using PlasmaTYPHOON+ was of **minimal burden** to them.

"We only needed one or two-days training and that was straightforward." (Unit staff 1)

"PlasmaTYPHOON+ is just such a straightforward process…where the SURESTORE™ was so fiddly." (Unit staff 4)

In contrast to the unit staff, the AEDs interviewed had considerable **concerns about the regulatory position** of PlasmaTYPHOON+ and other devices like it. Importantly, these were general concerns and not specifically directed at PlasmaTYPHOON+. At present, there are no clear guidelines for the regulation of devices that do not fit within the HTM 01-06 guidelines for drying cabinets; an AED must consider the available evidence provided by an innovator, any evidence in the research literature, and plan for a validation process that is tailored to a specific decontamination unit. The AED interviews give a strong indication that the absence of regulatory guidelines is challenging for the implementation of an innovation such as PlasmaTYPHOON+. It creates activity for AEDs as they attempt to work around the situation.

"It's another piece of kit that's found its way onto the market. There are no standards for it. You could probably cherry pick bits from a number of different standards, but when you actually come to the actual microbiology and the actual validation of the equipment then it opens a whole new ball game and it really does. I suppose, in a way it [PlasmaTYPHOON+] does work. It's very difficult to say that because if I was going to say, does it work, yes or no, then I would want to see an awful lot of work done in the laboratory and then out in the field." (AED 1)

"I'm afraid I'm old school, I've been doing this job a long time, and I've had a lot of people come to me with things [innovations] sort of saying they're the best thing since sliced bread and I found out that a lot of times the item is the sort of flavour of the month and then it disappears off the market because it wasn't worth it." (AED 2)

It was clear from the AEDs and unit staff that there is **a clear need to update the HTM guidelines** for drying endoscopes, particularly due to the absence of guidelines as a barrier for implementation of new methods and the increasing number of new methods for washing and drying endoscopes.

"It really could do with updating. That's the problem with the guidance that is out there. The HTMs [guidelines] were supposed to be a live document that were consistently to be evaluated and updated, but that's not the case." (Unit staff 5)

"I've had a lot of experience in the decontamination field and I feel that where we are now going backwards. The HTMs used to tell you what you needed to achieve…but now that the HTM tends to refer back to a standard, it goes back to the 15883 and 16442 standards…and they're very difficult to understand for somebody that's not reading them all the time. They can be very difficult to interpret." (AED 2)

3.2.2. Confidence in PlasmaTYPHOON+ related activity

Prior to the full implementation of PlasmaTYPHOON+, AEDs expressed **concerns about their confidence in the validation process**. It is usual practice to use a third-party (not the unit, hospital, or AED) to test the drying process against agreed standards. Also, the backgrounds of AEDs have been questioned, particularly about their level of understanding about the microbiology of drying endoscopes using new innovations.

"It's important to have a competent person capable of doing all the necessary testing to do with this equipment. I found a couple had falsified certificates and one that wasn't even qualified." (AED 3)

"When considering the installation qualification, operational qualification and performance qualification [the validation process]…equipment like this includes a lot of microbiology…it's one of the problems you have with ageing engineers or engineers that have never done biology at school and then all of a sudden they're trying to understand microbiology." (AED 2)

Furthermore, AEDs were **uncertain on the evidence requirements** to agree to a decision to implement PlasmaTYPHOON+. Importantly, AED agreement is not necessarily required, a hospital could decide to accept the risk themselves, but AEDs are an important part of the decontamination professional community.

"As it's new and the HTMs don't help us to completely assess it, I believe it needs to be tested to a higher level and really assessed rigorously…you know, because we only have the company's data or report to go on." (AED 1)

Often, the burden of evidence-seeking would fall to the decontamination unit or hospital. In the case of PlasmaTYPHOON+ use in the report, the unit undertook its own investigations.

"We went to one clinical site to see PlasmaTYPHOON+ in use before we adopted it and were given the validation data. Those two things combined and made us happy that we weren't taking on a risk." (Unit staff 5)

In contrast, once the decision to implement PlasmaTYPHOON+ was made and in use in a unit, **high staff confidence** to use PlasmaTYPHOON+ within the unit was apparent and was supported by good training to use the device.

"I'm very confident to use PlasmaTYPHOON+, it's very easy, I can use it with my eyes closed." (Unit staff 1)

"The training from [unit trainer] was really good, we knew what to do with PlasmaTYPHOON+ within a few days." (Unit staff 3)

3.2.3. Perceived effectiveness

An important influence on whether stakeholders accepted PlasmaTYPHOON+ was its perceived effectiveness. A range of factors were discussed during the interviews. PlasmaTYPHOON+ was considered by unit staff as **a faster drying process** than the previous system.

"SURESTORE™ had a longer process" (Unit staff 4)

"The system seems to be far simpler and a faster turnaround of scopes…there is a time-saving per scope compared to the SURESTORE™ system and large storage cabinets." (Unit staff 5)

Furthermore, PlasmaTYPHOON+ was considered an easier and safer method, and a better way to manage priority requests for scopes.

"We don't use the chemicals with PlasmaTYPHOON+ and this has increased the safety for unit staff and patients. There have been some cases of chemical bleaching [staining or injuring], so not using chemicals [required for SURESTORE™] is a good thing." (Unit staff 2)

Also, unit staff reported the PlasmaBAG system was **effective and preferred** by endoscopy staff.

"When we implemented PlasmaTYPHOON+, especially the tray and bag, we got no negative feedback from the main endoscopy department." (Unit staff 5)

In summary, prior to the implementation of PlasmaTYPHOON+, AEDs had mixed views on the acceptability of the PlasmaTYPHOON+ system. This is driven by their general attitude toward new innovations and the regulatory challenge of attempting to use current HTM 01-06 guidelines, focused on drying endoscopes in cabinets, with new drying solutions. It is also influenced by their limited confidence in the work-around validation process undertaken by third parties and AEDs without adequate microbiology knowledge. In contrast, once the decision to implement has been taken, unit staff were unanimous that the PlasmaTYPHOON+ system is easy to use and effective.

It appears the greatest challenge for the adoption of PlasmaTYPHOON+ is during the pre-implementation phase, during which several factors – both specific to the innovation and more broadly – can influence the decision to implement.

3.3. Impact on the Decontamination Service

3.3.1. Financial impact of PlasmaTYPHOON+

A range of scope usage, contractual and financial data was provided for the evaluation by the decontamination unit. Table 5 below presents a comparison of costs between financial years 2022-23 and 2023-24.

The data presented below has been adjusted to account for the following factors:

- Two PlasmaTYPHOON+ units were implemented in May 2023 (part way into FY23-24)
- The SURESTORE™ remained in the unit but its use was proactively reduced.
- The use of large storage cabinets did not change across the FY22-23 and FY23-24 timeframe
- The cost of purchasing PlasmaTYPHOON+ devices (two) and leasing air compressors to facilitate PlasmaTYPHOON+ use in the decontamination unit, and related maintenance costs were included in the PENTAX Medical Pay Per Use contract
- The costs of purchasing and maintaining SURESTORE™ were included in the Cantel Medical Pay Per Use contract

Actual savings to the decontamination unit from the partial de-implementation of one SURESTORE™ system and implementation of two PlasmaTYPHOON+ systems in FY23-24 was £107,856.59.

Table 5. Cost comparison of de-implementing SURESTORE™ and implementing PlasmaTYPHOON+ within the decontamination unit

Cost to decontamination unit	**FY22-23**	**FY23-24**	**Notes**
PENTAX Medical PlasmaTYPHOON+ Pay Per Use contract agreement	£0	£91,317.20	20,660 scopes were processed in PlasmaTYPHOON+, at £4.42 PPU cost.
SURESTORE™ Pay Per Use contract agreement	£200,160.18	£982.08	19,566 scopes were processed in SURESTORE™ in FY22-23 and 96 in FY23-24, both at £10.23 PPU cost.
Staff time to train to use systems	£81.94	£86.25	15 unit staff were trained to use both systems, taking 7.5 hours total. Costs were based on combined staff hourly rates.
Total costs	£200,242.12	£92,385.53	
Total savings in FY23-24		£107,856.59	

3.3.2. Speed of individual devices

Evaluators' observational visits audited the PlasmaTYPHOON+ drying time of 88 scopes of various types. A comparison of process speed was made between PlasmaTYPHOON+, SURESTORE™ and the large storage cabinet (see Table 6).

On average, the relevant PlasmaTYPHOON+ steps – from an endoscope being released from the cleaning process to awaiting transfer to its destination – took 6 minutes and 29 seconds. By comparison, the relevant processes with SURESTORE™ took longer, at an average 8 minutes 40 seconds. The process of taking an endoscope to the large storage cabinet was understandably faster (average 2 minutes); however, this was then followed by a three-hour wait before the scope was useable.

Table 6. Comparison of drying process speed

Comparison device	**Key steps**	**Total time of process**
PlasmaTYPHOON+	Endoscope released from Automated Endoscope Reprocessor (AER) cleaning process with 100% complete (no errors in cleaning) and carried to tray/drying area, login to EETA to confirm cycle number is the same with EETA, quality assurance process check ticket information, remove excess water from scope outer controls by hand using sterile absorbent pad, activate PlasmaTYPHOON+ screen, select correct connector tubes for specific scope, connect connector tubes to scope. Unit user scans bar code of staff member and scope, follow on-screen instructions, select 'Dry&Store' (99% of the time), press ok, then while waiting for the drying cycle to finish, use air gun to manually dry the external parts of scope. Complete paperwork, after cycle disconnect tubes, place scope into PlasmaBAG and seal, use green connector cone to pierce bag, press ok, add plasma air to bag, remove cone, cover hole in bag with green circular sticker, and add all relevant information to the outer bag. Place scope, sealed in its bag, on grey tray and await transfer to relevant department.	6 mins 29 secs (+ unknown time to transfer to relevant dept)
SURESTORE™	Endoscope released from AER cleaning process with 100% complete (no errors in cleaning), login to EETA to confirm cycle number is the same with EETA, quality assurance process, place the scope on a vacuum tray with a sterile white liner. Remove excess water from scope outer controls by hand using sterile absorbent pad. Connect tubes to scope, input key information on SURESTORE™, enter unit staff code, press start and wait for hydrogen peroxide to be flushed through the scope's channels, manage any fail reports; if cycle fails, start the cycle again. After cycle, disconnect all the connections. Insert red bag inside green bag with tray for use by receiving department, enclose tray with green liner, place all above into large vacuum bag and seal, proceed with the	8 mins 40 secs (+ unknown time to transfer to relevant dept)

Comparison device	Key steps	Total time of process
	vacuum phase, enter all the relevant information on the EETA then await transfer to relevant department.	
Large storage cabinet	Login to EETA to compare cycle number is the same with EETA, quality assurance process check ticket information, take scope to cabinet, connect tubes within cabinet to scope, scan the staff barcode, the scope barcode, and the barcode of the shelf where the scope is being stored, input the scope number onto the EETA.	2 mins (+ 3 hours storage before scope is useable)

The speed of device use was considered an Important driver in the hospital business case to adopt PlasmaTYPHOON+, claiming there would be a staff labour saving of 2 minutes and 53 seconds per scope compared with SURESTORE™. Our analysis indicates that to be broadly accurate, with PlasmaTYPHOON+ saving 2 minutes and 11 seconds per scope compared to SURESTORE™.

Using PlasmaTYPHOON+ saved 2 hours, 55 minutes, 31 seconds per scope compared to the large storage cabinet.

Interestingly, one of the themes from the staff interviews highlighted that staff wellbeing was improved from the faster individual device drying and storing process. It helped to create important space and time within the unit to deal with priority scope requests from endoscopy and theatre departments, which are a daily challenge. Based on discussions with staff, the number of priority scope requests can average 15 to 20 per day, which is approximately 10 to15% of all scopes processed daily.

"We have the challenge of managing the priority scopes...theatres can call us and say they need ten scopes urgently this morning and we need to make that happen. That can be stressful when we are waiting for the reprocessor and need to dry scopes...it was worse before...having to tell them the scopes are being dried in the cabinet." (Unit staff 3)

3.3.3. Speed of scope turnaround

Although the drying process using PlasmaTYPHOON+ is only part of the whole scope turnaround journey, unit operational data was used to make a high-level comparison of scope turnaround before and after the implementation of PlasmaTYPHOON+.

Reprocessor report data exported from EETA was used to compare the year before (01 May 2022 – 30 April 2023) and period after PlasmaTYPHOON+ implementation (01 May 2023 to 22 March 2024) to determine whether there was a change in scope turnaround time, from time 'returned to wash area' and time 'despatched' as a proxy for time in department being processed.

When cleaning this data and from the observations undertaken as part of this evaluation, the evaluators identified the real world complexity in measuring this outcome.

Therefore, there are three caveats to this data to acknowledge that significantly affect this data and the reported findings:

1. This data has been used as the best available proxy measure for scope turnaround time, as this data is not just for the drying and storage time but for the entire decontamination process.
2. From the observation visits to the decontamination unit, some staff recorded 'despatch' on EETA once the scope had been released from AER cleaning process at the same time as logging to T-Doc to confirm cycle number with EETA. Therefore, this data may not accurately capture the 'drying and storage' time despite 'despatch' being the final time stamp recorded in EETA.
3. It is not clear whether the additional drying time in the large storage cabinets is accounted for within the EETA data, which would considerably change the results below if it is not.

The data reported below is calculated from the scopes with a recorded date and time for 'returned to wash area' on EETA that also had a recorded 'despatch' date and time on EETA as a representation of the speed of unit processes.

Table 7. Mean time taken to process scopes pre- and post-PlasmaTYPHOON+ implementation.

	Pre-PlasmaTYPHOON+ between 1 May 2022 and 30 April 2023 (n=20,109)	**Post-PlasmaTYPHOON+ between 1 May 2023 and 22 March 2024 (n=22,341)**	**Change**
Time (average: mean) (hh:mm:ss)	02:05:58	02:09:13	+00:03:15

Based on the data and caveats above, although it would appear no significant change in the total scope turnaround time has been observed from the introduction of PlasmaTYPHOON+, it is also important to recognise that the findings are currently indicative.

3.3.4. Efficiency of unit operations

The evaluators used reprocessor report data exported from EETA to compare the year before (01 May 2022 – 30 April 2023) and period after PlasmaTYPHOON+ implementation (01 May 2023 to 22 March 2024) to determine whether there is a change in the total number of scopes processed.

46,437 scopes were processed by the decontamination unit between 01 May 2022 and 22 March 2024 according to the number of scopes scanned as 'returned to wash area' on EETA.

23,176 (49.9%) of the 46,437 scopes were processed in the year prior to the implementation of PlasmaTYPHOON+ in May 2023 (Figure 6). 23,261 (50.1%) of the 46,437 scopes were processed in the period following the implementation of PlasmaTYPHOON+ in May 2023 (figure 6 below).

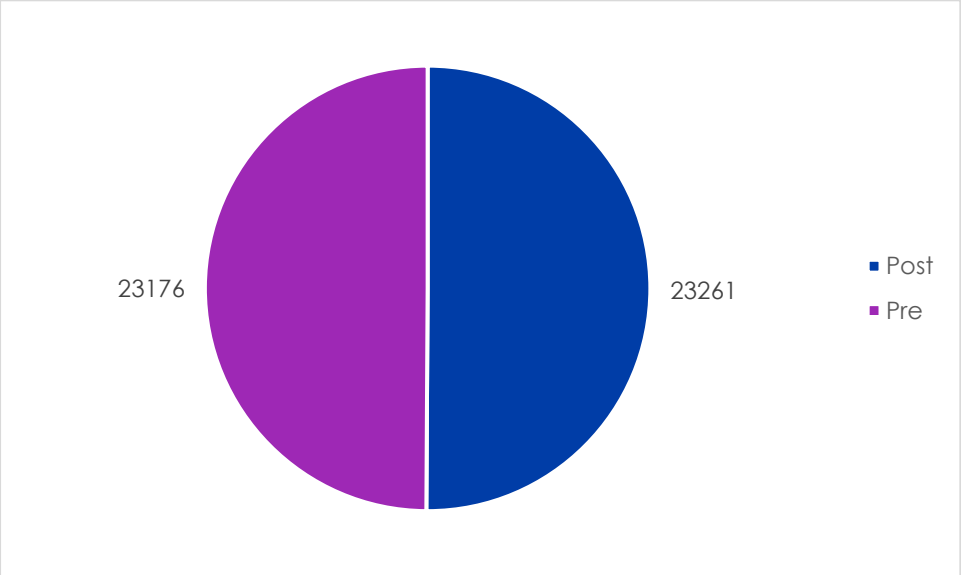

Figure 6. Number of scopes processed in the year before (01 May 2022 – 30 April 2023) and period after (01 May 2023 to 22 March 2024) the implementation of PlasmaTYPHOON+.

Table 8 and Figure 7 present the number of scopes processed according to each month between 01 May 2022 and 22 March 2024.

Table 8. Number of scopes processed according to each month between 01 May 2022 and 22 March 2024.

Month and Year	Number of scopes processed	% of total number of scopes processed
05/2022	2,068	4.5
06/2022	2,136	4.6
07/2022	2,054	4.4
08/2022	2,069	4.5
09/2022	2,120	4.6
10/2022	2,026	4.4
11/2022	1,969	4.2
12/2022	1,604	3.5
01/2023	1,753	3.8
02/2023	1,762	3.8

Month and Year	Number of scopes processed	% of total number of scopes processed
03/2023	1,909	4.1
04/2023	1,706	3.7
05/2023	2,042	4.4
06/2023	1,986	4.3
07/2023	2,148	4.6
08/2023	2,006	4.3
09/2023	2,111	4.5
10/2023	2,219	4.8
11/2023	2,375	5.1
12/2023	2,083	4.5
01/2024	2,300	5.0
02/2024	2,245	4.8
03/2024	1,746	3.8
TOTAL	**46,437**	**100**

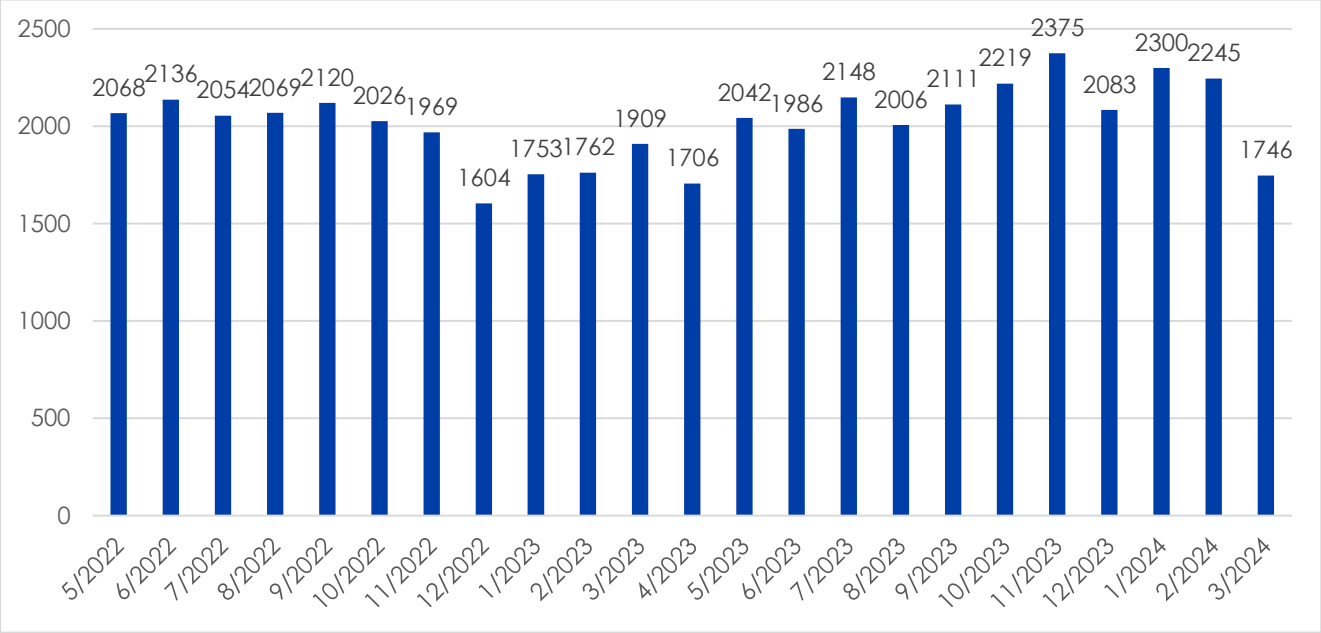

Figure 7. Number of scopes processed per month between 01 May 2022 and 22 March 2024.

There appears to be little to no change in the number of scopes processed by the decontamination unit in the year before and the period after the implementation of PlasmaTYPHOON+ or per month.

Of note, however, the mean number of scopes processed per day from 01 May 2022 to 22 March 2024 was 67. The average number of scopes processed per day in the

year prior to and period after the implementation of PlasmaTYPHOON+ was 63 and 71 respectively.

3.3.5. Repairs and servicing

The evaluators used data exported from EETA to compare the repair and servicing of scopes in the year before (01 May 2022 – 30 April 2023) and period after PlasmaTYPHOON+ implementation after (01 May 2023 to 22 March 2024) to determine whether there was a change in the number of scopes requiring repair or servicing.

1,014 scopes were sent for either servicing or repair between 01 May 2022 and 22 March 2024. 60 (6%) scopes were sent for servicing, and 954 (94%) scopes were sent for repair (Figure 8).

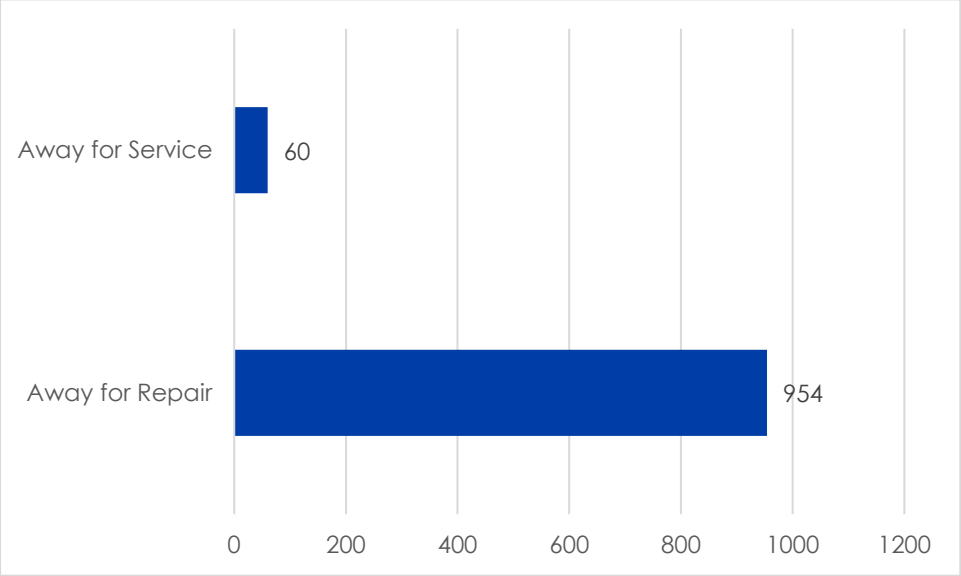

Figure 8. Number of scopes sent for either servicing or repair between 01 May 2022 and 22 March 2024.

548 (54%) of 1,014 scopes sent for servicing or repair occurred in the year prior to the implementation of PlasmaTYPHOON+ in May 2023. 532 of these were scopes which required repairing, with 16 requiring servicing (Figure 9).

466 (46%) of the 1,014 scopes sent for servicing or repair occurred in the period following the implementation of PlasmaTYPHOON+ in May 2023. 422 of these were scopes which required repairing, with 44 requiring servicing (Figure 9).

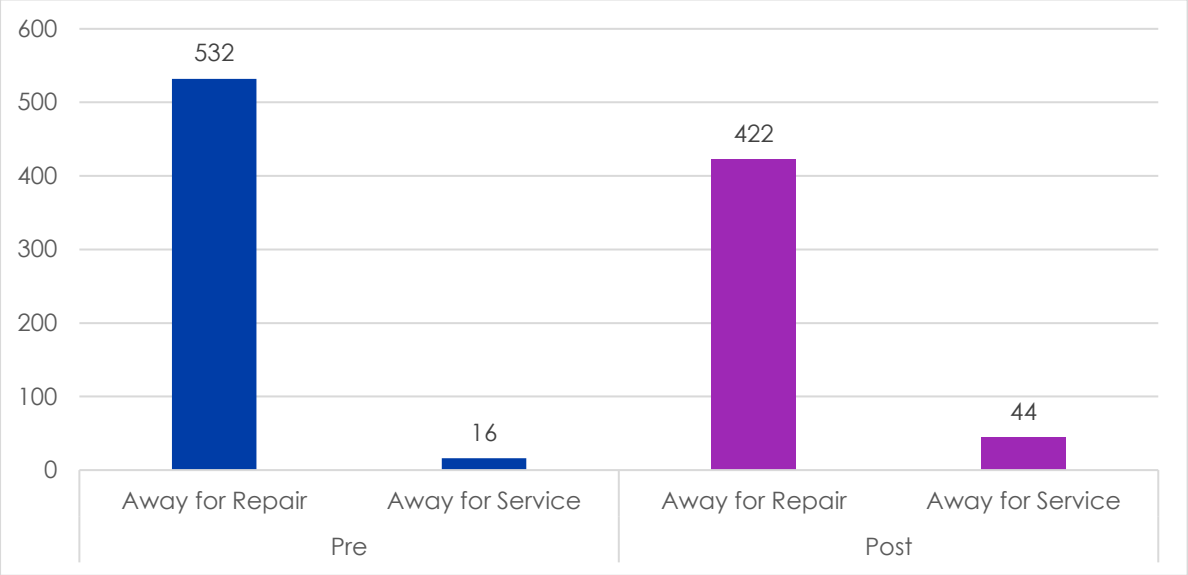

Figure 9. Number of scopes sent for either servicing or repair recorded between 01 May 2022 and 30 April 2023 (pre-implementation) and 01 May 2023 and 22 March 2024 (post-implementation) of PlasmaTYPHOON+.

There was a decrease of 8% in the number of scopes sent for servicing or repair in the period following the implementation of PlasmaTYPHOON+ compared to the year prior to the implementation of PlasmaTYPHOON+.

Of note, 44 (73%) of the 60 scopes sent for servicing occurred in the period following the implementation of PlasmaTYPHOON+.

Table 9 presents the number of scopes sent for service or repair per month between 01 May 2022 and 22 March 2024.

Table 9. The number of scopes sent for service or repair per month between 01 May 2022 and 22 March 2024.

Month and year	Number of scopes sent for service and repair	Number of scopes sent for repair	Number of scopes sent for service
05/2022	43	41	2
06/2022	45	45	0
07/2022	58	56	2
08/2022	59	59	0
09/2022	55	52	3
10/2022	41	36	5
11/2022	44	44	0
12/2022	28	28	0
01/2023	50	49	1
02/2023	35	33	2
03/2023	44	43	1

Month and year	Number of scopes sent for service and repair	Number of scopes sent for repair	Number of scopes sent for service
04/2023	46	46	0
05/2023	50	47	3
06/2023	38	35	3
07/2023	31	31	0
08/2023	45	38	7
09/2023	39	35	4
10/2023	46	38	8
11/2023	51	49	2
12/2023	46	39	7
01/2024	50	48	2
02/2024	45	41	4
03/2024	25	21	4

The graphs below show the number of scopes sent for either (i) servicing and repair (Figure 10), (ii) repair only (Figure 11), and (iii) servicing only (Figure 12) per month between 01 May 2022 and 22 March 2024.

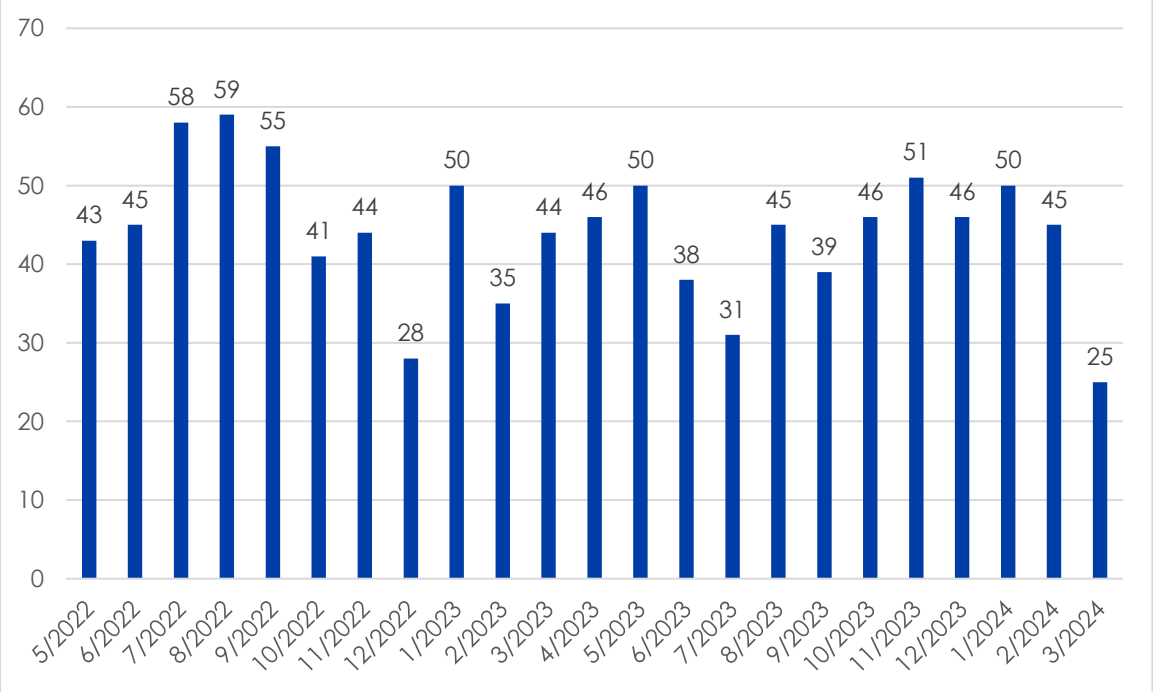

Figure 10. Number of scopes sent for either servicing and repair per month between 01 May 2022 and 22 March 2024.

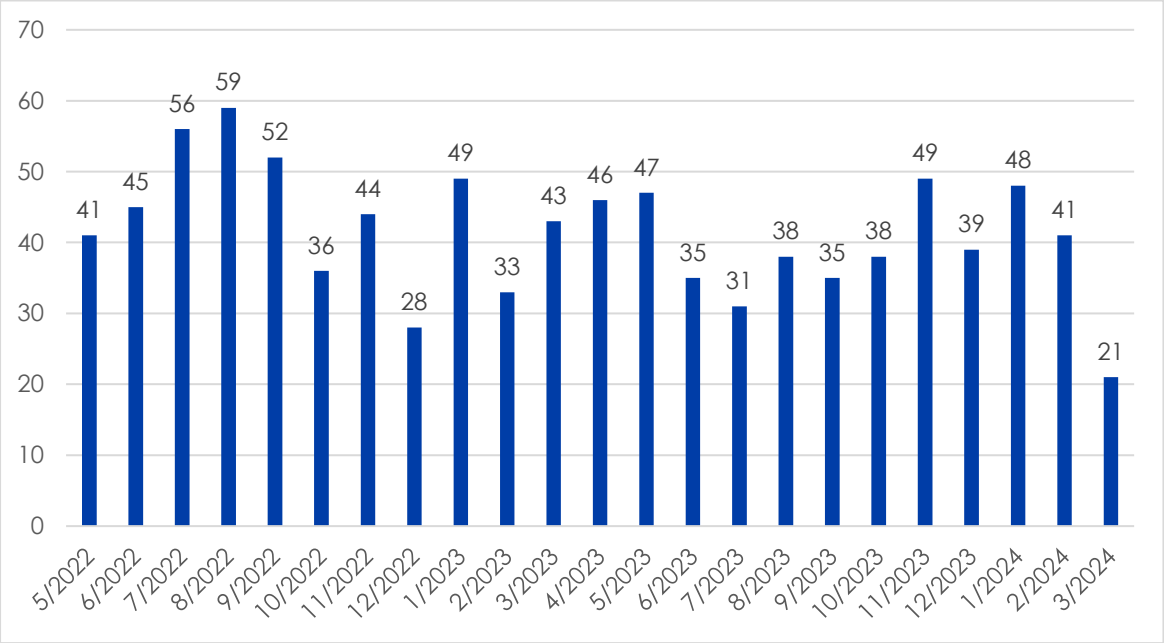

Figure 11. Number of scopes sent for repair per month between 01 May 2022 and 22 March 2024.

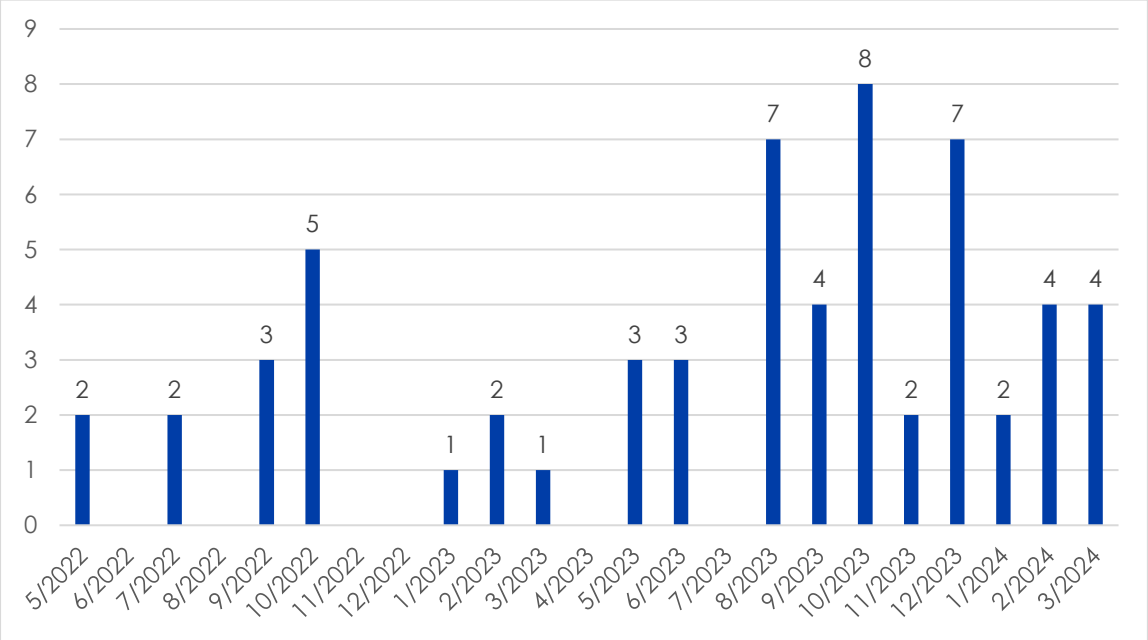

Figure 12. Number of scopes sent for servicing per month between 01 May 2022 and 22 March 2024.

Although there are no obvious trends in the repair data per month, the same pattern of increasing numbers of scopes being sent for servicing in the period following implementation of PlasmaTYPHOON+ can also be observed in the monthly data.

3.3.6. Failure rates

The evaluators used reprocessor report data exported from EETA to compare the year before (01 May 2022 – 30 April 2023) and period after PlasmaTYPHOON+ implementation (01 May 2023 to 22 March 2024) to determine whether there is a change in failures during the cleaning or drying process. This data was themed into washing or drying fails.

9,037 failures during the decontamination process were recorded between 01 May 2022 and 22 March 2024. 23 (0.26%) were due to vacuum packing failures (in essence, occurring during the drying and storage process), and 9,014 (99.74%) were due to reprocessor failures (in essence, occurring during the washing process). (Figure 13).

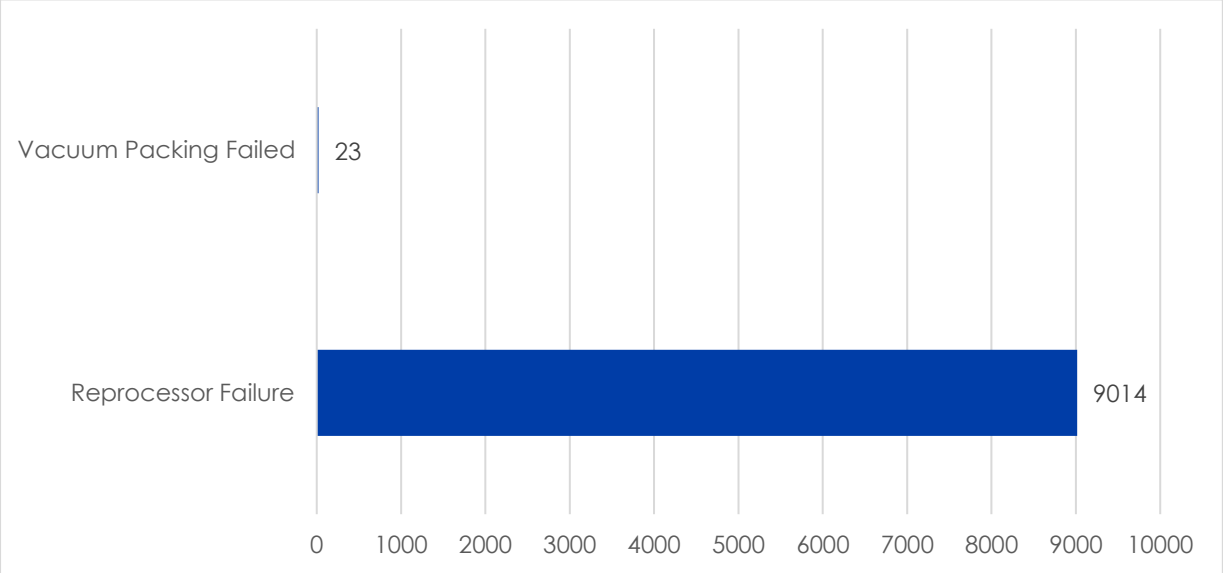

Figure 13. Number of failures during the decontamination process recorded between 01 May 2022 and 22 March 2024.

4,659 (52%) of 9,037 failures occurred in the year prior to the implementation of PlasmaTYPHOON+ in May 2023. 16 (0.34%) of these were vacuum packing failures, with 4,643 (99.66%) being reprocessor failures (Figure 14).

4,378 (48%) of the 9,037 failures occurred in the period following the implementation of PlasmaTYPHOON+ in May 2023. 7 (0.16%) of these were vacuum packing failures, with 4,371 (99.84%) being reprocessor failures (Figure 14).

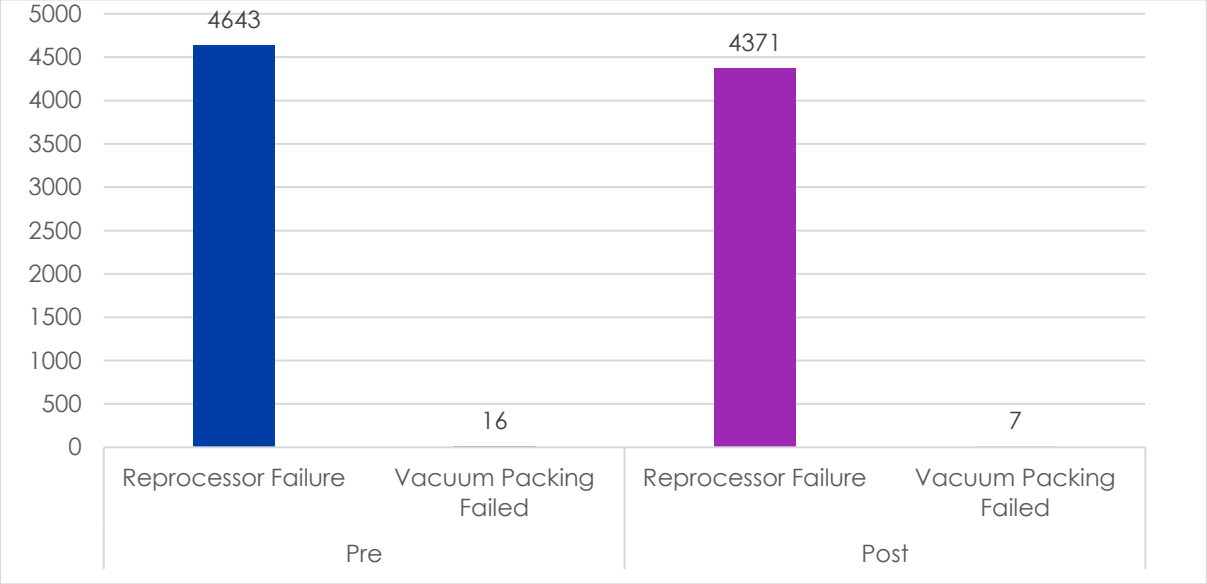

Figure 14. Number of failures during the decontamination process recorded between 01 May 2022 and 30 April 2023 (pre-implementation) and 01 May 2023 and 22 March 2024 (post-implementation) of PlasmaTYPHOON+.

This indicates a 4% reduction in the failure rates in the period following the implementation of PlasmaTYPHOON+ in May 2023 compared to the year prior to the implementation of PlasmaTYPHOON+.

Table 10. The number of scopes which failed reprocessing or vacuum packaging according to each month between 01 May 2022 and 22 March 2024.

Month and year	Number of scopes failing reprocessing or vacuum packaging	Number of scopes failing reprocessing	Number of scopes failing vacuum packaging
05/2022	426	426	0
06/2022	258	257	1
07/2022	285	285	0
08/2022	440	440	0
09/2022	375	372	3
10/2022	457	454	3
11/2022	443	442	1
12/2022	412	412	0
01/2023	458	457	1
02/2023	404	403	1
03/2023	403	400	3
04/2023	298	295	3
05/2023	335	328	7
06/2023	305	305	0

Month and year	Number of scopes failing reprocessing or vacuum packaging	Number of scopes failing reprocessing	Number of scopes failing vacuum packaging
07/2023	313	313	0
08/2023	445	445	0
09/2023	448	448	0
10/2023	447	447	0
11/2023	465	465	0
12/2023	412	412	0
01/2024	497	497	0
02/2024	441	441	0
03/2024	270	270	0

The graphs below show the number of scopes failing either (i) reprocessing or vacuum packaging (Figure 15), (ii) reprocessing (Figure 16), and (iii) vacuum packaging (Figure 17) per month between 01 May 2022 and 22 March 2024.

Of note here, there were no recorded scopes to have failed vacuum packaging since the month of PlasmaTYPHOON+ implementation.

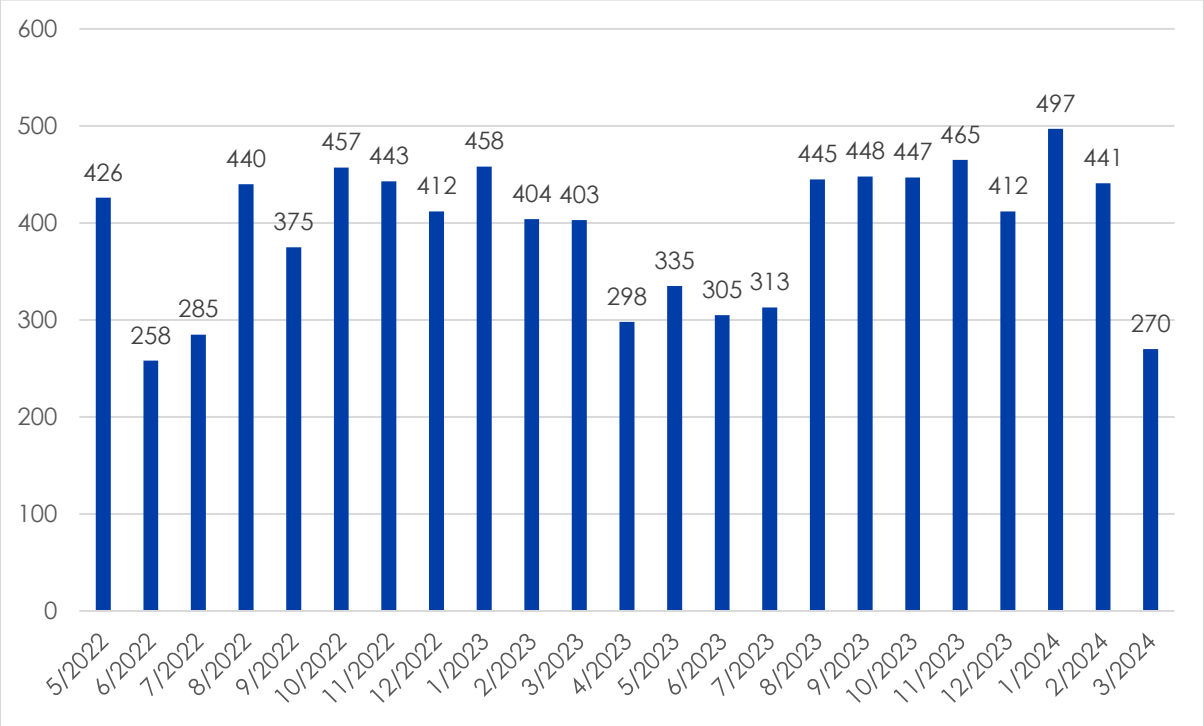

Figure 15. Number of scopes failing either reprocessing or vacuum packaging per month between 01 May 2022 and 22 March 2024.

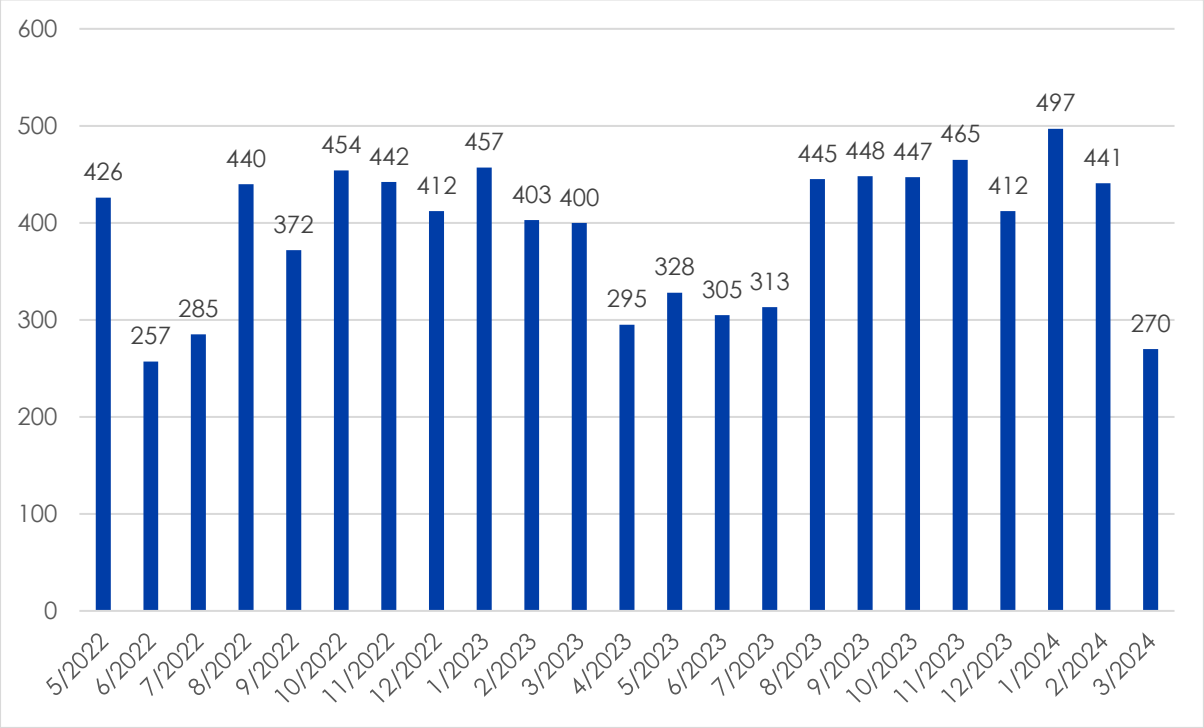

Figure 16. Number of scopes failing reprocessing per month between 01 May 2022 and 22 March 2024.

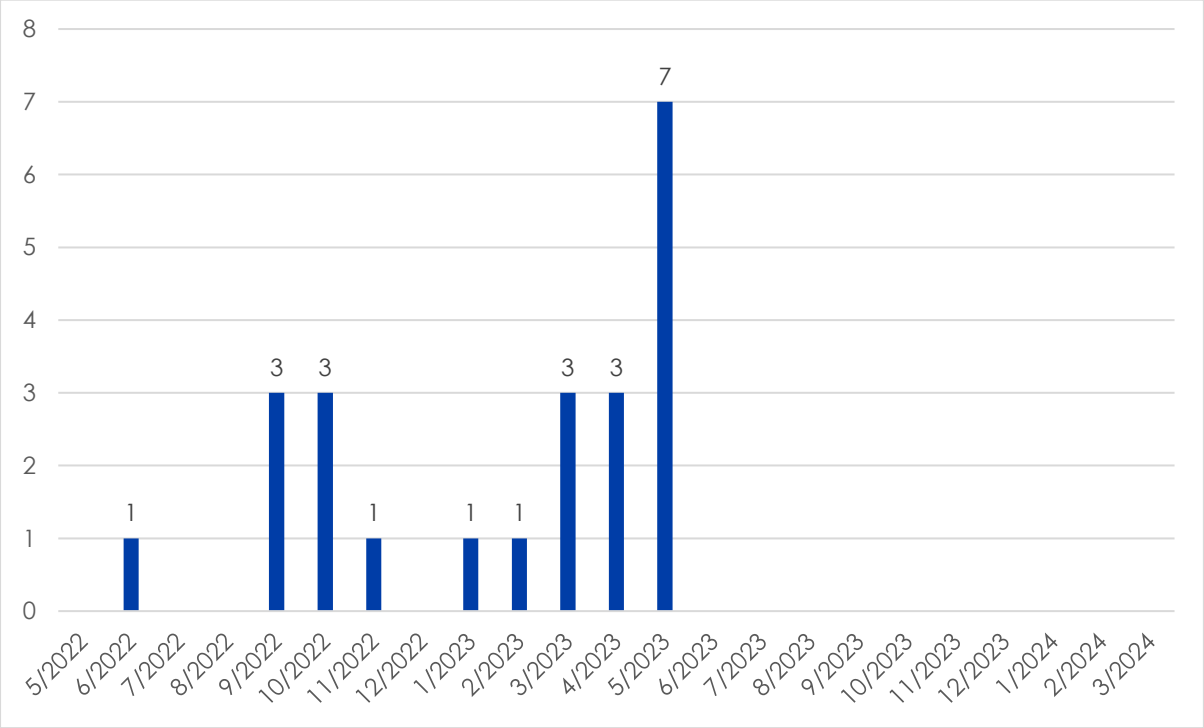

Figure 17. Number of scopes failing vacuum packaging per month between 01 May 2022 and 22 March 2024.

In summary, the implementation of PlasmaTYPHOON+ has impacted the decontamination unit in several important ways. Most notably, the unit has realised £107,856.59 in actual savings in FY23-24.

In addition, some operational benefits have been realised, including a faster drying and storage process compared to previous systems when focused solely on the drying and storing phase. It was clear the faster drying and storage time released time for unit staff to process more endoscopes or provide them with more space to rest as they undertake a busy and stressful role.

There were some minor benefits seen, with a decrease of 8% of scopes being sent for servicing or repair in the period following the implementation of PlasmaTYPHOON+. Importantly, the evaluators were not able to fully study the total scope turnaround time from entry to exit of the decontamination unit; therefore, limited change was seen on this factor. Nonetheless, the average number of scopes processed per day after the implementation of PlasmaTYPHOON+ increased from 63 to 71.

There are undoubtedly onward benefits for endoscopy and theatre departments at the hospital, but unfortunately it was not possible to study those impacts within the scope of this evaluation.

3.4. Impact on Decontamination Unit staff

The implementation of **PlasmaTYPHOON+ had a positive impact** on decontamination unit staff and wider stakeholder relationships at the hospital.

The unit staff interviews highlighted three ways in which the unit staff benefited. Firstly, from experiencing a **faster and less stressful drying and storage method**.

"With the guys that have been here for a long time, yeah, they are happy. They're happy with the plasma… it's just a lot quicker." (Unit staff 4)

"The work was hard when I started but it's easier now with PlasmaTYPHOON+. With SURESTORE™ it takes longer, and that's especially a problem and stressful when we need to provide scopes for a priority situation…I would like to keep PlasmaTYPHOON+ here to be honest." (Unit staff 1)

"There's more room in the decontamination unit, we're not squashed in as much…we were using drying cabinets all the time and they're quite large…the trays in the rack system are very space-saving compared to the footprint of a storage cabinet." (Unit staff 5)

Secondly, from **not using chemicals** (SURESTORE™ requirement) during the drying and storing process.

"There's no chemicals with PlasmaTYPHOON+ so we're not changing bottles and risking any problems for chemical skin irritations." (Unit staff 3)

Thirdly, from **avoiding repetitive strain** injuries.

"With SURESTORE™ you had to seal the bag and that started a lot of repetitive strain because it was quite hard with the sealer." (Unit staff 4)

"How scopes were packaged previously did result in some repetitive strain injuries in the unit. The system [PlasmaTYPHOON+] they're using now doesn't present a risk with regards to any type of repetitive strain because you're not using a tool or anything like that, which is what they were doing before...so that risk is lower." (Unit staff 5)

These benefits have improved the workplace wellbeing of unit staff and created space for rest periods and/or to manage unpredictable daily requests for priority scopes by endoscopy and theatre departments.

Another theme from the staff interviews highlighted **improved wider stakeholder relationships**.

"The main endoscopy department was the key driver because they were the ones giving us the most feedback about the problems with the SURESTORE™ system. I think they appreciated the fact that we [decontamination unit] took on board their concerns...we were seen to be responsive and that was a positive. There's been good endoscopy unit acceptance of PlasmaTYPHOON+." (Unit staff 5)

"The [hospital] departments are happy we're using PlasmaTYPHOON+ and not SURESTORE™ because there was a lot of complaints about SURESTORE™ as it was such a wet process a lot of scopes went away for repair." (Unit staff 4)

3.5. Implementation of PlasmaTYPHOON+

The implementation of PlasmaTYPHOON+ can be viewed from two key perspectives. Firstly, how it is viewed prior to implementation, and secondly, after it has been implemented. The former views are largely linked to AEDs and decontamination unit leaders and the latter views are largely linked to unit staff using PlasmaTYPHOON+ daily.

Several themes and sub-themes contribute to an understanding of the implementation journey of PlasmaTYPHOON+ (see Appendix Table 1).

3.5.1. Implementation challenges - decision to implement

It was clear across all the interviews that taking the decision to implement PlasmaTYPHOON+, and other similar devices, requires considerable discussion, coordination of available evidence, and device validation. Central to this process were AEDs, who operate as private consultants registered with the Institute of Healthcare Engineering and Estate Management (IHEEM) to regulate and oversee decontamination equipment and processes in England. This small group of consultants (15 in England, 35 across the UK) have a strong influence on decisions made in decontamination services.

It was apparent that **AEDs had differing views on evidential requirements for new devices.** This is in part driven by the current mismatch between key regulatory guidance (HTM 01-06) which is focused on processes and maintenance of drying cabinets.

"The trouble is that different AEDs have different views of what's needed to validate PlasmaTYPHOON+...there are no standards and you can pick bits off a number of different standards...but it depends on who is looking at it, they have to satisfy themselves that the testing is being carried out." (AED 1)

AEDs also demonstrated **differing levels of risk** (to them) toward new devices, such as PlasmaTYPHOON+.

"I know there are some AEDs that don't like PlasmaTYPHOON+ and won't sign-off the reports...so in those hospitals the hospital senior staff take on the risk to use it and carry on." (AED 3)

The above issues can be explained in part by the apparent **tension within the AED community, particularly around AED professional backgrounds**.

"AED professional backgrounds is an area that needs looking at…it is predominantly engineers and microbiologists but 90% of the validation process is microbiological…this is where a lot of AEDs struggle…I think they just leave it to the consultant microbiologist within the hospital." (AED 1)

Furthermore, ways in which AEDs operate, particularly around their **commercial interests**, have added to the tension uncovered within the interviews.

"Our understanding with IHEEM is that we [AEDs] have no affiliation with a private company, but if an AED happens to be working for a chemical company or manufacturer, how can they really be totally independent? This has happened and it does make me question the decision-making by certain AEDs." (AED 3)

In addition, an apparent **absence of AED collaboration** further affects the ability of the AED community to share and learn from one another. It is possible the above challenges have been ongoing for many years and are yet to be adequately resolved to the satisfaction of the AED community. The follow-on effect of these issues is the absence of any changes to the HTM 01-06 guidance on drying endoscopes to account for new devices.

"I don't speak to any other AEDs and as far as I know they don't speak to anybody else either…we are basically operating independently of each other…we don't share information with each other…we used to have a meeting, that was the AED Group which met regularly every six months and you had to go…but it doesn't happen now." (AED 2)

The above themes present a challenging picture of the regulatory environment for decontamination services and its relationship with innovative technologies. The implementation of PlasmaTYPHOON+ and similar devices may rely on having an open-to-innovation AED in the region, and adaptive bespoke validation process for units. Importantly, there is an urgent need to re-examine the guidance documents used by AEDs to validate and regulate new decontamination innovations.

3.5.2. Implementation process

In contrast to views shared by AEDs about implementation decision-making, the views of unit staff were far more positive.

Unit staff reported that **a validation process was enacted** to satisfy the evidential needs of their AED and senior hospital colleagues. This was perceived as particularly important for units considered early adopters, whereby limited information was available on real world impact.

"It was a case of looking at the validation behind this particular system, which our AED looked at and was happy with, and I was aware of other AEDs in the industry who were happy with the system…and therefore we could be confident that we weren't introducing an unknown element." (Unit staff 5)

Unit staff unanimously reported **PlasmaTYPHOON+ was easy to implement** within the unit once the decision to implement was taken. It was easily installed, training was available, and maintenance processes explained. PENTAX Medical supported the implementation and as result the decontamination unit only needed a short amount of time to set up the equipment and train staff.

"I asked them [Pentax] questions or got the feedback. It was pretty straightforward." (Unit staff 4)

"It's just everyone getting used to the change…they all spoke to Pentax about the process…they were all trained" (Unit staff 4)

Several **minor issues** were reported by unit staff and these could be considered by PENTAX Medical for improvement.

Tray options: "In the case of urethrascopes, they are a lot more delicate than the gastroscopes and colonoscopes…we had concerns from our theatres about the scope moving around too much in the tray…so we talked to Pentax and they let us know there was validation to use moulded trays in the plasma bags…so we switched presentation to the moulded trays in the plasma bags which our theatres are now happy with." (Unit staff 5)

Bag size/handling for larger scopes: "The bagging and sealing part after the scope is dried can be hard one-handed. Sometimes with the larger scopes it's a two-person job." (Unit staff 1)

4. Conclusions

4.1. Energy consumption (evaluation questions 1 and 2)

1. In a direct comparison, PlasmaTYPHOON+ used 22 times less electricity than the storage cabinet. Due to the unit context, the PlasmaTYPHOON+ and air compressor combined used eight times less electricity than the storage cabinet. Comparisons with SURESTORE™ indicate PlasmaTYPHOON+ used less electricity in a direct comparison, but more when requiring an air compressor.

2. The storage cabinet, using electricity but not routinely storing endoscopes, was a very large user of energy. It was estimated to use 4,505 kWh yearly, which is equivalent to 1.9 metric tons or 1,878 kilograms of carbon dioxide. This is equivalent to 37.1% of an average home's electricity use for one year, the energy needed to charge 123,989 smartphones, and greenhouse gas emissions from 4,803 miles driven by an average petrol-powered car.

3. The previous (SURESTORE™ and cabinet) and PlasmaTYPHOON+ drying and storing systems were all connected to the electrical supply and permanently switched on. Therefore, the potential energy savings of PlasmaTYPHOON+ operating on its own were not achieved by the unit.

4. Findings on plastic waste, by using the PlasmaBAG and not the SURESTORE™ system, estimated a reduction in single-use plastic waste of 2,623.31kg between May 2023 and March 2024. This was 50% higher than the projected reduction in the hospital business case made prior to the implementation of PlasmaTYPHOON+.

5. The use of PlasmaTYPHOON+ supports the BSG, JAG, and CSH 'green endoscopy' position statements on sustainable decontamination units. The absence of medical air and use of air compressors increased electricity use and operating PlasmaTYPHOON+, having not fully de-implemented SURESTORE™ and storage cabinets, results in unnecessary energy consumption.

4.2. Acceptability (evaluation question 3)

6. The PlasmaTYPHOON+ system was perceived as highly acceptable by decontamination unit staff. It was viewed as an excellent replacement for SURESTORE™ and the storage cabinet systems, had minimal burden for training and use, was faster, and staff were confident to use it. Unit staff also reported colleagues in the endoscopy and theatre departments preferred PlasmaTYPHOON+ compared to previous systems.

7. AEDs had mixed views on PlasmaTYPHOON+ and were concerned about its validation within a regulatory environment that only provided guidance for

drying cabinets. AEDs were uncertain about how and who should validate PlasmaTYPHOON+, perceived different AEDs having different methods and priorities, and called for an urgent update to the HTM 01-06 guidance for drying endoscopes.

4.3. Speed of drying processes (evaluation questions 4 and 5)

8. When considering the drying and storing process alone, our analysis indicates PlasmaTYPHOON+ saved 2 minutes and 11 seconds per scope compared to SURESTORE™ and saved 2 hours, 55 minutes, 31 seconds per scope compared to the storage cabinet.

9. When considering the full scope turnaround time – using the time 'returned to wash area' and time 'despatched' as a proxy for time in department being processed – there appeared to be little difference between PlasmaTYPHOON+ and SURESTORE™ systems. However, it was not possible to measure factors beyond the PlasmaTYPHOON+ drying steps accurately and a whole-system scope turnaround analysis is needed.

10. Whilst there was no meaningful change in the total number of scopes processed by the decontamination unit in the year before and the period after the implementation of PlasmaTYPHOON+, the mean number of scopes processed per day slightly increased after the implementation of PlasmaTYPHOON+.

11. After the introduction of PlasmaTYPHOON+, there was an 8% decrease in scopes being sent for servicing or repair, and a 4% decrease in processing failure rates compared to the year prior.

12. An additional impact from using the faster and more efficient PlasmaTYPHOON+ system was £107,856.59 in financial savings in FY23-24 for the decontamination unit. The savings were due to hugely reduced use of the SURESTORE™ system and implementing two PlasmaTYPHOON+ systems. The pay-per-use cost of SURESTORE™ was higher than the PlasmaTYPHOON+ system.

13. The contributing factors to an increase in speed and efficiency from using PlasmaTYPHOON+ was the system being an easier and safer system to operate. Furthermore, fewer failures in the drying process were reported in the operational data and unit staff interviews, which avoids reprocessing endoscopes.

4.4. Unit staff wellbeing (evaluation question 6)

14. Unit staff reported PlasmaTYPHOON+ was a faster and less stressful drying and storage method. It has helped relieve the pressure of dealing with priority

requests for endoscopes from endoscopy and theatre departments, which occur daily.

15. Unit staff also reported fewer cases of repetitive strain injury compared to when using the previous SURESTORE™ system, which involved a difficult process to seal the bag. They also reported less risk of chemical-related injury from bottled chemicals needed for the SURESTORE™ system.

16. By implementing PlasmaTYPHOON+, decontamination unit staff have benefited from improved relationships with other hospital departments. The latter were part of the driver for change to PlasmaTYPHOON+ and the decontamination unit have been viewed as responsive to the wider needs of the hospital.

4.5. Implementation (evaluation question 7)

17. The pre-implementation activities and decisions between decontamination units and AEDs are an important and decisive phase, and may determine whether innovation is adopted. This phase is influenced by several factors, including the context of the decontamination unit, AED views on evidential requirements of new innovation, AED views on risk related to the new innovation, and the need for updated guidance.

18. Both unit staff and AEDs highlighted the urgent need for a review of current HTM 01-06 guidance on drying cabinets. This evaluation highlights how the absence of regulatory guidance for drying cabinet replacement innovation, such as PlasmaTYPHOON+, creates tensions and challenges that impact upon the adoption of innovation.

19. AEDs appear to have differing views on the evidential requirements for new devices. This is in part driven by:

    a. The current key regulatory guidance (HTM 01-06) which is focused on processes and maintenance of drying cabinets and not cabinet replacement devices like PlasmaTYPHOON+.
    b. Apparent tension within the AED community around appropriate AED professional backgrounds/skillsets to effectively validate a device outside of current guidance.
    c. Apparent tension within the AED community about the perceived influence of individual AED commercial interests.
    d. AEDs demonstrating differing levels of risk toward new devices.
    e. Apparent absence of AED collaboration and opportunities to share and learn from one another. These tensions helped to explain the entrenched positions of individual AEDs and could lead to some regions of the country adopting innovation less often than others.

20. Once the decision to implement PlasmaTYPHOON+ was taken by the decontamination unit and relevant AED, the practical setup by unit staff – with PENTAX Medical training support – was perceived as easy and straightforward.

21. This evaluation highlights the energy consumption costs of running multiple drying and storage systems at the same time. Consideration should be given to the process of de-implementing previous systems to maximise the benefits offered by new systems. Not fully de-implementing older systems could cancel out the value of the newer systems.

5. Considerations

5.1. Considerations for Decontamination Units

1. PlasmaTYPHOON+ has some benefits in speed and efficiency, and clear benefits in energy consumption and reduced plastic waste compared to previously used drying and storage systems. However, these benefits are being reduced by the partial continuation of the use of previous systems. This is particularly the case for electricity consumption and its associated costs.

2. In relation to the requirement for medical air in the decontamination unit, the reliance on air compressors adds to the energy consumption and dilutes the potential carbon footprint benefits of using PlasmaTYPHOON+.

3. Our analysis indicated PlasmaTYPHOON+ saved time processing each scope, when just considering the drying and storing process. However, it was not possible to fully investigate the scope turnaround time to appreciate the whole process. It is recommended that scope turnaround time is investigated to fully appreciate the value of PlasmaTYPHOON+ in a wider sequence of activities incorporating washing, drying, storing, using, and reprocessing.

4. Some of the analyses in this evaluation were limited due to the available operational data. Decontamination units may want to ensure staff are consistent and systematic in the way activity is being tracked in EETA. This would include ensuring each step of activity is recorded on the EETA in the same order as the unit processes required to be undertaken. In addition, data being recorded at a time which accurately reflects when the activity being tracked happened. For example, it would be useful to ensure each scope has a 'despatch' time and date tracked within EETA, and that the 'despatch' time accurately reflects the time the scope was despatched from the unit. Also, not all scopes were tracked as 'returned to wash area'; some missed this tracking step and were first tracked on EETA with the tracking step, 'recorded used on patient'. Improvements would aid the development of business cases in future as well as ensure the data quality is high and the decontamination unit managers can be confident in the interpretations being made from the tracking data available.

5.2. Considerations for PENTAX Medical

5. The value of PlasmaTYPHOON+ can be reduced by the implementation context and operational arrangements within decontamination units. It is therefore recommended that local 'value and impact cases' are developed to reflect the real world use of the PlasmaTYPHOON+ and PlasmaBAG system. These cases can include factors examined in this evaluation, e.g. real world energy consumption, plastic waste, speed and efficiency, and cost savings. Developing cases will identify situations where the system can be most effective and may provide a method for PENTAX Medical to support decontamination units' development of business cases for PlasmaTYPHOON+ adoption.

5.3. Considerations for wider stakeholders

6. There is a need for a coordinating force to drive and manage the various stakeholders required to update / create guidance for drying cabinet replacement systems like PlasmaTYPHOON+. Stakeholders include the Department of Health, NHS England, IHEEM, and the AED community. A coordinating force could potentially help to manage some tensions within the AED community about the appropriate validation methods for drying cabinet replacement devices.

7. The is a need to standardise guidance and validation processes for new drying cabinet replacement devices.

8. The AED community are key stakeholders in the adoption of innovations such as PlasmaTYPHOON+. Opportunities for collaboration within this community, including pooling shared experiences and knowledge, could provide learning to inform future adoption.

9. Whilst the adoption of PlasmaTYPHOON+ was not a difficult challenge in the unit under study, this evaluation highlights the different professional backgrounds of AEDs and some differences of opinion on the safety of innovations that can affect adoption. This was a signal to consider professional backgrounds and differences as they may hinder innovation adoption. A review of qualifications and competencies could be undertaken to enhance professional collaboration.

10. When adopting innovation, it is important to consider the de-implementation of previous or concurrent ways of working. The simultaneous operation of multiple systems potentially limits the benefits of the innovation being introduced. In this case, the energy consumption benefits of PlasmaTYPHOON+ were reduced by maintaining the previous systems.

Appendix

Appendix Table 1: Synthesised interview themes

	Theme	Sub-theme
1	Attitudes toward PlasmaTYPHOON+	An excellent replacement system
		Minimal burden to staff
		Regulatory concerns from AEDs
2	Confidence in PlasmaTYPHOON+ related activity	High unit staff confidence
		Uncertainty on evidence requirements for regulation
3	Perceived effectiveness	A faster drying process
		An easier and safer method
		An effective PlasmaBAG system
		A better way to manage priority requests for scopes
4	Impact on staff wellbeing	A less stressful drying method for staff
		Not using chemicals (SURESTORE™ requirement)
		Avoiding repetitive strain injuries
5	Impact on carbon footprint	-
6	Impact on stakeholder relationships	-
7	Implementation challenges - decision to implement	Complications from AED professional backgrounds
		Differing burden of proof from AEDs (for decision to implement)
		Differing levels of risk from AEDs
		AED community collaboration
		Influence of commercial interests
8	Implementation process	Validation process required, especially for early adopters
		Easy to implement within the unit
		Technical issues