Tiny Air
Pre-cleaning Efficacy Trials

Comprehensive Evidence Review with Supporting Documentation

Tiny Air

1. Cowlairs Rewash Study

Title	Maternity Sets Study – Summary Report
Dates	June 2023-Feb 2024
Report Date	30 June 2024
Study Lead	Shona Macwilliam (Quality Manager)
Tiny Air Version	V2

NHS Greater Glasgow and Clyde

Study Objective

This study addressed a persistent rewash issue associated with maternity instrument sets at Cowlairs CDU. These sets were historically problematic due to variable manual pre-cleaning effectiveness and backlog, leading to high level downstream washer-disinfector non compliance.

1. Cowlairs Rewash Study

Study Design and Data Capture

The study was designed and implemented by Shona MacWilliam, using the CDU's barcode-based instrument tracking system to enable:

- Set-level traceability
- Identification of pre-cleaning method (manual vs Tiny Air)
- Association with Washer Disinfector No. 5
- Objective capture of rewash outcomes

Each Tiny Air unit was assigned a unique barcode and scanned alongside the maternity set barcode.

Operational Controls

Set Type

Maternity sets only

Washer Disinfector

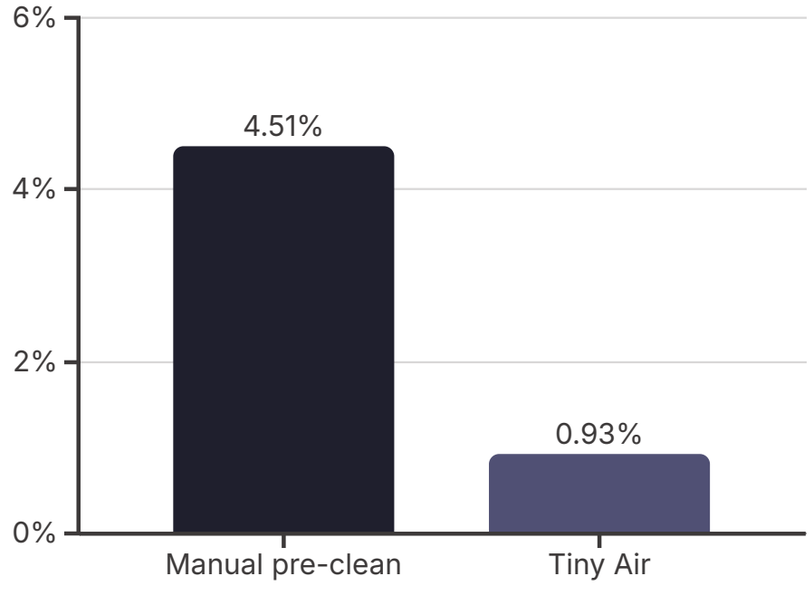
WD No. 5 (constant throughout)

Staff Instruction

- **Tiny Air installed:** all maternity sets pre-cleaned using Tiny Air
- **Tiny Air not installed:** all maternity sets manually pre-cleaned

1. Cowlairs Rewash Study

Results



Condition	Duration / Volume	Rewash Rate
Manual pre-clean (WD-level)	17 weeks	4.51%
Tiny Air maternity sets (set-level)	1,293 sets	0.93%

Data Sources

- Rewash data (2).xls
- Tiny air input (2).xlsx
- details wk5.6.23 -12.9.23 and 8.2.24 -17.2.24 (2).xls

1. Cowlairs Rewash Study

Technical Interpretation

~80% Reduction

Direct set-level comparison between manual and Tiny Air pre-cleaning of maternity sets demonstrates an approximately 80% reduction in rewash.

High-Risk Instrumentation

This result is notable given the high-risk nature of maternity instrumentation.

Large Dataset

Significant dataset size of 1,293 sets provides robust evidence.

Real-World Environment

Mixed-load production environment reflects actual operational conditions.

A direct set-level comparison between manual and Tiny Air pre-cleaning of maternity sets demonstrates an **~80% reduction in rewash**. This result is notable given:

- The high-risk nature of maternity instrumentation
- Large dataset size
- Mixed-load production environment

2. Lanarkshire Study (Private CSSD)

Title	Production/ Capacity and Efficacy Study – Summary Report
Dates	Nov 2023- Nov 2025
Report Date	6th Jan 2026
Study Lead	Chris King - Project manager
Tiny Air Version	V2.1

Study Objective

To evaluate department-wide efficacy, production and capacity performance with and without Tiny Air across all set types.

2. Lanarkshire Study (Private CSSD)

Study Design

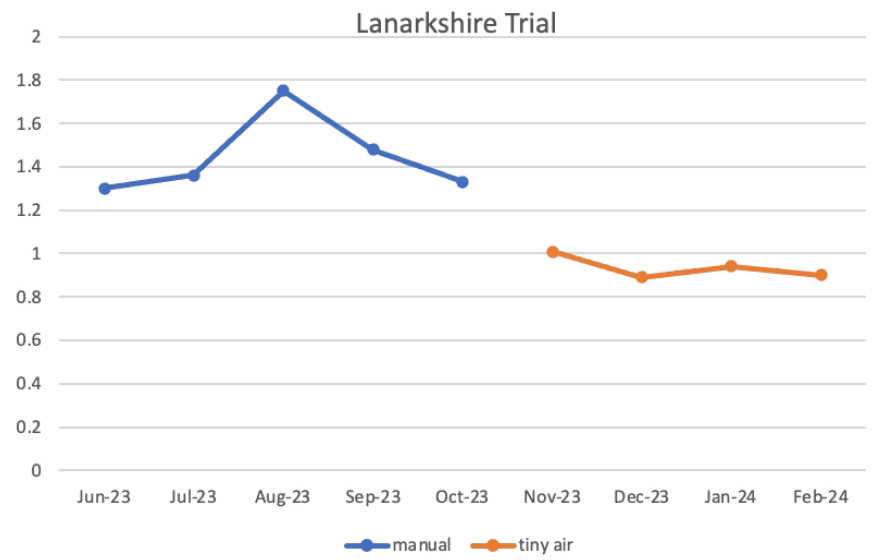
- Real-world production study
- Data Includes:
  - Sets requiring pre-cleaning
  - Sets not requiring pre-cleaning
- Comparison of operational periods with and without Tiny Air

Data Sources

Rewash data (2).xls

details wk5.6.23 -12.9.23 and 8.2.24 -17.2.24 (2).xls

Screenshot 2025-10-03 at 19.47.27.png



2. Lanarkshire Study (Private CSSD)

Results

1.44%	0.93%	31%
Baseline Rewash Rate	**Rewash Rate with Tiny Air**	**Relative Reduction**
Performance without Tiny Air	Performance with Tiny Air implementation	Overall improvement in rewash rates

- Baseline rewash rate: 1.44%
- Rewash rate with Tiny Air: 0.93%
- Relative reduction: 31%
- Capacity/ Production increase across unit 10%

Initial analysis covered 9 weeks; operational data has now exceeded 2 years, with performance remaining stable.

Technical Interpretation

> This study demonstrates sustained, scalable rewash reduction across a full production environment, independent of short-term behavioural change. Non-complicance review identified items outside of wash scope: rust and hard acrylic adhesives cement.

3. Raigmore CDU Trial (NHS Highland)

Title	Pre-clean Exeter Rasp Study – Summary Report
Dates	5- 16 Dec 2023
Report Date	30 March 2024
Study Lead	Anne Cosh - Head of Decontamination
Tiny Air Version	V2.1

Study Objective

To explore:

- The limits of Tiny Air performance on multiple diverse sets with challenging contamination
- CDU-based pre-cleaning workflows
- Inspection-led decision making

3. Raigmore CDU Trial (NHS Highland)

Study Design

3. Raigmore CDU Trial (NHS Highland)

Trial Protocol and Results

- Tiny Air applied only to sets defined as requiring pre-cleaning
- Protocol:

01

2-minute Tiny Air cycle

Initial automated pre-cleaning cycle

02

Visual inspection

Careful examination of instruments

03

Additional 2-minute cycle only if contamination remained

Targeted secondary cleaning when required

Data Source

- trial record CDU.pdf

Results

164

Sets processed

0.6%

Rewash rate

Interpretation

Demonstrates very low rewash rates when targeted pre-cleaning is combined with structured inspection and CDU governance. For context the 0.6% set rewash was due to 1 instrument non compliance in 5000 processed , a fragment of bone trapped in a a forcept distal end.

4. National Treatment Centre (NTC) Trial

Title	**Point-of-Use Pre-Cleaning, IFU Compliance, and Instrument Protection**
Dates	15–22 Feb 2025
Report Date	5 April 2025
Study Lead	James Bilbao - Instrument Manager
Tiny Air Version	V2.1

Study Purpose

The National Treatment Centre (NTC) trial aimed to assess the efficacy of **automated Point-of-Use (PoU) pre-cleaning** utilising Tiny Air, focusing particularly on:

- **Ensuring consistent compliance with manufacturer Instructions for Use (IFUs)** within operating theatre settings.
- **Minimizing dependence on manual PoU pre-cleaning performed by theatre staff** an approach known for its variability and lack of control.
- **Evaluating how promptly removing soil contributes to preventing corrosion and surface damage** resulting from blood and saline exposure.

This investigation aligns with established recommendations highlighting that **delays in pre-cleaning and saline contact are major factors in instrument degradation**, especially when residues are permitted to dry onto instrument surfaces.

4. National Treatment Centre (NTC) Trial

Methodology

- **Setting**: Operating Theatre (Point of Use)
- **Coverage**: Instrument sets identified by manufacturer IFUs as requiring pre-cleaning.
- **Operational framework**:
  - Tiny Air was positioned at the Point of Use.
  - **Pre-cleaning duties were carried out by trained CSSD personnel**, not theatre staff.
- **Pre-cleaning procedure**:
  - Automated **2-minute Tiny Air pre-clean applied immediately following procedures**.
  - Visual inspection performed, by experience independent instrument manager.
  - An additional 2-minute cycle was initiated only if visible contamination persisted.

This model was chosen to guarantee:

1. **Technical uniformity**
2. **Clear accountability for IFU adherence**
3. **Safeguarding instruments during their most vulnerable post-use phase**

4. National Treatment Centre (NTC) Trial

Inspection and Oversight

- Trial Coordinator: James Bilbao, Instrument Manager, Liverpool NHS University Trust.
- Inspection areas:
  - Residual blood and visible organic matter.
  - Hinges, joints, serrations, and other areas identified as high-risk by IFUs.
  - Early indicators of surface damage linked to retained blood or saline.

The inspection process was conducted independently of theatre staff to uphold impartiality and technical reliability.

4. National Treatment Centre (NTC) Trial

Results

200

Sets Evaluated

Number of instrument sets processed in the trial

0%

Rewash Frequency

No sets needed rewashing after disinfection

The 0% rewash rate demonstrates that:

- Unwavering IFU Adherence: CSSD-managed PoU pre-cleaning achieved consistent compliance with manufacturer Instructions for Use.
- Effective Contaminant Elimination: Blood and saline were effectively removed before drying or setting.
- Downstream Process Safeguarding: Cleaning operations were protected from preventable failure.

4. National Treatment Centre (NTC) Trial

Technical Interpretation – Corrosion and Instrument Damage

Both international standards and national guidelines consistently emphasize that blood and saline pose a direct threat to reusable surgical instruments:

- Saline is not a cleansing agent and should not be used for extended soaking due to its chloride content.
- Chloride ions accelerate pitting corrosion, discoloration, and degradation of passive layers on stainless steel.
- Dried blood and protein soils heighten the demand for aggressive mechanical or chemical cleaning, further increasing the potential for damage.

Prompt, controlled removal of contaminants at the Point of Use reduces:

- The duration of corrosive exposure.
- The likelihood of biofilm formation.
- Mechanical stress during subsequent processing.

The NTC findings confirm that automated PoU pre-cleaning directly supports these principles in practice.

4. National Treatment Centre (NTC) Trial

Operational Recommendation

Based on the trial outcomes and aligned directives:

> **Point-of-Use pre-cleaning should be performed by CSSD staff using Tiny Air rather than theatre staff.**

This approach:

Aligns accountability for IFU compliance with expert decontamination knowledge.

Minimizes variability caused by competing theatre priorities.

Enhances auditability and traceability.

Actively safeguards instruments from corrosion triggered by blood and saline exposure.

4. National Treatment Centre (NTC) Trial

Conclusions and Standards

The NTC trial substantiates that CSSD-led, automated Point-of-Use pre-cleaning was made possible by the use of the Tiny Air machine, that it:

- Ensures consistent IFU compliance.
- Eliminates rewashing within the assessed cohort.
- Reduces the risk of corrosion and premature instrument damage.
- Allows one person to operate Tiny Air pre-clean sets from 2 busy theatres, replacing 6 manually cleaning at sinks.

From both a standards-compliance and asset-protection standpoint, early CSSD intervention at the Point of Use represents optimal practice.

Standards and Guidance Alignment (Referenced)

ISO 17664: Mandates manufacturers to specify validated pre-cleaning steps and stresses the importance of early soil removal to facilitate effective reprocessing.

ISO 7153-1: Identifies the performance limitations of stainless steel and its vulnerability to chloride-induced corrosion.

HTM 01-01: Stipulates that instruments must be kept moist after use, must not be soaked in saline, and should be cleaned as soon as feasible to prevent damage and the fixation of soil.

5. Cowlairs Exeter Rasp Pre-clean Study

Study Metadata

Title	Pre-clean Exeter Rasp Study – Summary Report
Dates	6–11 March 2023
Report Date	30 March 2023
Study Lead	Andrew Birch (AED)
Tiny Air Version	V2

Study Objective

To evaluate the effectiveness of automated pre-cleaning technologies in removing impacted bone from Exeter Hip Rasps, and to understand:

- Comparative efficacy of Ultrasonics, Tiny Air, and Washer Disinfection
- The impact using Tiny Air of positioning and configuration of rasps
- The comparative efficacy of same-day pre-cleaning

5. Cowlairs Exeter Rasp Pre-clean Study

Context

Cowlairs CDU experiences significant backlog, with instruments often sitting ≥24 hours before reprocessing, allowing contamination to dry and compact—particularly within rasp teeth.

5. Cowlairs Exeter Rasp Pre-clean Study

Study Design

- Randomised comparative testing using live surgical instruments
- Sets split and tagged to ensure equivalent contamination challenge
- Each group processed through one of three workflows:

Automated Processes

- **Ultrasonic Washer Disinfector**
  - Medisafe MED531155NPR
  - 35 min cycle, 40 °C, Neodisher MediClean forte
- **Tiny Air V2**
  - 2 × 2-minute cycles
  - Cold mains water, no detergent
- **Washer Disinfector**
  - Steelco TW3000/2
  - 40–90 °C tunnel cycle

All instruments subsequently completed a WD drying cycle.

5. Cowlairs Exeter Rasp Pre-clean Study

Assessment Method

- Protein detection using Pro-Reveal
- Primary metric: number of rasp teeth containing impacted bone

Results – Headline Performance

Tiny Air (fixed, optimised positioning)	**0.26**
Tiny Air (loose in basket)	0.58
Ultrasonic cleaner	2.1
Washer Disinfector only	4.33
Tiny Air – same-day cleaning	**0** (limited sample)

5. Cowlairs Exeter Rasp Pre-clean Study

Conclusions and observations

Based on 51 contaminated rasps over 5 days:

- Tiny Air is up to 10× more effective than ultrasonics at removing impacted bone
- Tiny Air is up to 16× faster than ultrasonic processing
- Tiny Air 92% reduction in environmental impact when compared to ultrasonics

The report explicitly notes that larger sample sizes are required for statistical confidence, but the methodology was robust and AED-led.

Additional Observations

- Bone trapped in rasp teeth is a significant clinical and decontamination risk
- Same-day pre-cleaning markedly improves outcomes
- Damaged rasps are harder to clean
- Rigid positioning is useful for cleaning efficacy
- Ultrasonics outperform washer disinfectors alone
- Tiny Air outperforms both significantly
- Rasp tips remain challenging and require further development work

Overall Technical Conclusions

Across all documented studies in the dataset and Exeter Rasp report:

Reduces Rewash Rates

Tiny Air consistently reduces rewash rates across all study environments

Improves Pre-cleaning Consistency

Delivers reliable, repeatable pre-cleaning performance

Excels with Complex Instruments

Performs particularly well on high-risk, complex instruments

Benefits Scale From:

Specific Instrument Challenges

Rasps and complex surgical tools

High-Risk Set Categories

Maternity and specialist instrument sets

Whole-Department Workflows

Full production environment implementation

Conclusion

> Collectively, the independent data supports Tiny Air as both a rewash reduction technology and a high-efficacy automated pre-cleaning platform, with clear implications for quality, throughput, energy use, and sustainability.