Waste & Environmental Solutions

Albion Environmental

NHS Northumbria
Northumbria Specialist Emergency Care Hospital, Northumbria Way, Cramlington, NE23 6NZ

Site Management Plan
August 2023

PREPARED BY	Stella Consonni (Senior Consultant)	**DATE**	**07.06.2023**
REVIEWED BY	Jane Bond (Project & Business Development Director)	**DATE**	**01.08.2023**
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Albion Environmental Limited

Albion House,
1 Damside,
Ayr, KA8 8ER
Scotland, UK

www.albion-environmental.co.uk
T: 01292 610 428
E: info@albion-environmental.co.uk

Registered in Scotland No. SC254498. VAT Registration No. 806 4312 55.

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1.0 INTRODUCTION

1.1 Background

Peacocks Medical have developed Curo and have trialled an innovative system in hospitals and healthcare facilities over the past three years. Curo processes clinical waste on-site through sterilisation and creates inert floc that will be used by waste to energy facilities. The Northumbria Healthcare NHS Foundation Trust proposes to install this technology at Northumbria Specialist Emergency Care Hospital (NSECH) with the aim of minimising the impact on the environment by treating waste locally and to help the NHS return substantial cost savings that can be reinvested back into patient care.

This Site Management Plan accompanies the Bespoke Permit Application and details the proposed activities at the site Northumbria Specialist Emergency Care Hospital. The hospital proposes to carry out a thermal treatment (via autoclave) of its own healthcare wastes (wastes produced by the hospital only).

The autoclave (CISA WSD200) specifications are detailed in Appendix C. The Clinical Waste Process Validation is also attached in Appendix K.

1.2 Review and Updating

The Site Management Plan (SMP) shall be reviewed at least on an annual basis in line with EA requirements. When there is a change to the infrastructure of the site or a change in the site operations, this plan will be amended, and the EA will be consulted for approval prior to the change being implemented.

1.3 List of Revisions

Table 1 below is used to record information each time the SMP is revised. Revisions can only be carried out by authorised personnel.

Table 1. List of Revisions

Revision number	Revision authorised by	Date submitted to SEPA	Revision owner

1.4 Site Location

Northumbria Specialist Emergency Care Hospital
Northumbria Way
Cramlington
NE23 6NZ

National Grid reference number is NZ 27690 75603.

The treatment will occur within the designated Hospital building and the public are prevented from gaining access by signage and enforcement by hospital staff. See Location Plan Appendix A and site Layout Plan Appendix B.

1.5 Hours of Operation

The hospital proposes to carry out the treatment of waste via autoclave daily in 12 hours, Mondays to Fridays.

2.0 WASTE QUANTITIES, TYPES & STORAGE

2.1 Quantities & Types of Waste

The maximum amount of waste on site (pre and post treatment) at any one time will not exceed 10 tonnes.

The process capacity of the CISA-WSD200 autoclave is a maximum of 3.2t per day.

Types of wastes and quantities proposed to undergo onsite autoclave treatment are as follows:

- 18-01-03*infectiouswaste (orange bag)
- 18-01-03*infectiouswaste (orange and yellow lidded sharps – non pharmaceutically contaminated)
- 18-01-04Offensivewaste (tiger stripe bags)

Waste Description	EWC /LoW Code	Estimated tonnage /day	Estimated tonnage /year
Wastes whose collection and disposal is subject to special requirements in order to prevent infection	180103*	0.27	98.46
Wastes whose collection and disposal is not subject to special requirements in order to prevent infection (for example dressings, plaster casts, linen, disposable clothing, diapers)	180104	0.56	204.61
TOTAL (t)		**0.9**	**313.7**

2.2 Waste Storage

Wastes shall be stored on site for the maximum periods as per table below:

Waste Materials	Maximum Duration of Storage
Infectious clinical waste	5 days
Offensive waste	5 days
Floc (treated waste)	5 days

All waste (pre and post treatment) will be stored within the designated building. The building has an impermeable surface with a sealed drainage system (Appendix D Site Drainage Plan). This will ensure that in the event of a spillage there is no risk of emission to land or surface waters, and that emissions to foul sewer are controlled. In addition, waste will be stored in secure, fully enclosed, leak-proof containers. This will further minimise the risk of odour, litter and pest infestation and will also further reduce the risk of emissions arising from a spillage.

Clinical waste for treatment will be brought into the designated building within enclosed rigid yellow bins. These bins will be temporarily stored prior to treatment (Appendix B site layout plan).

The sterilised waste (floc) will be collected in bags within fully enclosed rigid green bins and stored temporarily prior to being removed for further treatment.

Wastes will be stored in a way that:

- Allows easy inspection
- Ensures that all labels and date markings are visible

During storage periods, each healthcare waste stream will not be mixed with:

- A different stream of healthcare waste
- Any other waste, substance, or material

Storage areas, containers and infrastructure will be inspected as part of a daily inspection/ housekeeping.

Issues identified will be dealt with immediately and records will be logged and kept on site.

3.0 SITE OPERATIONS

The site proposes to carry out an onsite thermal treatment of its own healthcare wastes (ancillary to hospital activities) via an autoclave process. The treatment process will occur at the designated building within the Hospital area on impermeable surface with sealed drainage system, see Appendix B for site layout.

3.1 Acceptance Procedure

Prior to treatment at the onsite autoclave, all wastes will be visually inspected by dedicated trained staff to ensure they are applicable for the treatment. Those wastes applicable for treatment via autoclave will be placed at the designated area to initiate the process.

In the event where waste is identified as not applicable for autoclave treatment, these will be dispatched off site for appropriate treatment (incineration) and or disposal at a permitted facility. Each bin will be labelled with the information required for onward transfer. Waste transfer and or consignment notes will be exchanged, completed, and recorded as required.

Details of the risk assessment for the process including acceptance procedure and Standard operating practices is provided in Appendix L

3.2 Thermal Treatment by Autoclave

The CISA WSD200 autoclave (Appendix C for specifications) uses a wet thermal method. The system comprises of a sterilizer chamber and a shredding device which is embedded in the same enclosed container beside the autoclave. The shredder is accessible through a hatch/ door, through which the waste is placed by the trained staff.

The shredding process is carried out after the sterilisation of the waste. The sterilising treatment process and the shredding process are detailed with photos in Appendix F.

No compaction will be carried out at any point during the process.

The autoclave is designed to minimise point source emissions to air, specifically the emission of bioaerosols, compounds with the potential to cause odour, and volatile organic compounds. It is fitted with HEPA filters to prevent the emissions of bio-aerosols during the process. Once used, the filters are then processed in the autoclave and treated as waste. Post process shredding of treated wastes minimises the potential for bio - aerosols emissions. Liquids from the waste and the process are sterilized internally before being discharged via the HEPA filter into the foul sewage drain (sealed drainage system).

3.3 Process Output (floc- treated material)

Typically, this process reduces the waste weight by 20% as the organics and liquids are removed. The autoclave WSD200 process capacity is 3.2t/day. The amount of floc produced from this would be 2.56t/day. The annual throughput is estimated at 660t.

The sterilised waste (floc) will be collected in bags within 240l fully enclosed rigid green bins and stored temporarily.

The floc will then be collected by Northumberland Council at first, then sent to a permitted facility (Teeside Energy from Waste facility) which will carry out further treatment on the floc (primarily for metal separation) then will utilise it as fuel at the energy from waste plant.

3.4 Container and Surfaces Disinfection

A bin washer is provided (**ref Site Layout Plan Appendix B**)

All bins discharging waste will be disinfected through the bin washer system prior to leaving the treatment facility (**ref Appendix J**).

The disinfection method will ensure that:

- It will physically remove contamination
- It will be capable of achieving disinfection across the broad spectrum of microorganisms with the parameters used (time, concentration, temperature, quantity)
- It will not produce emissions of pathogenic bioaerosols or chemical agents, or must make sure these emissions are contained and managed appropriately

The run-off from the disinfection will be directed to the hospital's sealed drainage system, discharged to foul sewer as required (see Appendix D for drainage plan).

3.5 Recording & Tracking System

The autoclaves are equipped with a traceability system which weighs and places a unique number in all batches via automatic labelling, (see Appendix G – Process flow chart for details).

The tracking system will operate as a waste inventory and will be able to record data including:

- The total quantity of waste treated on site at any one time.
- A breakdown by type of the waste quantities treated/ pending treatment.
- The quantity of waste on site compared with the limits authorised by your permit.
- The length of time the waste has been on site.
- The quantity of treated materials (floc) at any one time

The waste inventory and all other records for as long as the site has a permit.

3.6 Drainage

The storage and onsite treatment process of the hospital's healthcare wastes will be carried out within the building on impermeable surface in the designated 'recycling room' only. The Hospital has in place an appropriate sealed drainage system detailed in Appendix D Site Drainage Plan. The qualified water treatment facility, where foul sewer is discharge to, is Northumbrian Water.

3.7 Autoclave Contingency Plan

An Autoclave Contingency Plan (Appendix E) was developed as per EPR 5.07.

An Autoclave Monitoring Plan (Appendix H) and Start up and Shut down plan (Appendix I) are provided.

3.8 Pre-Operational Autoclave Treatment Procedures

The Applicant is aware that a commissioning validation report must be submitted to the EA for approval after the permit application is submitted and once requested by the EA, as required, that would cover as a minimum:

- The treatment efficacy of the autoclave, in accordance with the appropriate measures in Annex 1 of the sector guidance note EPR 5.07 on clinical wastes
- The proposals for routine monitoring of treatment efficacy comply with the appropriate measures in Annex 2 of the sector guidance note EPR 5.07 on clinical wastes
- The proposals for routine monitoring of emissions comply with the appropriate measures in Annex 3 of the sector guidance note EPR 5.07 on clinical wastes

The treatment process shall not be made operational until the Environment Agency has given prior written approval on the above. Appendix K provides a validation plan proposed for the equipment.

4.0 RECORDS

4.1 Records

All records shall:

- Be legible
- Be made as soon as reasonably practicable
- If amended, be amended in such a way that the original and any subsequent amendments remain legible, or are capable of retrieval
- Be retained, unless otherwise agreed in writing by the Environment Agency, for at least 6 years from the date when the records were made, or in the case of the following records until permit surrender:
    - off-site environmental effects; and
    - matters which affect the condition of the land and groundwater.

The operator shall keep on site all records, plans and the management system required, unless otherwise agreed in writing by the Environment Agency. The NHS Northumbria Healthcare NHS Foundation Trust has a waste management policy in place Doc Ref_waste-management-policy which provides details on the

5.0 ENVIRONMENTAL CONTROLS

A site risk assessment has been undertaken (Doc Ref_NSECH_Risk_Assessment)

5.1 Litter

All site operations will occur within the Hospital building at a specified area; therefore, litter is unlikely to be a significant issue. All healthcare waste will be received in the appropriate container which will significantly reduce the potential of litter building up at the site. Good housekeeping practices will be implemented by the Applicant to ensure the site is maintained in a clean and tidy condition. Daily site inspection/ walkovers will be undertaken by dedicated staff to prevent building up of litter and for cleaning purposes when any litter is identified.

5.2 Adequately Secured Waste

The waste will be stored and managed using bags and sealed bins.

5.3 Vermin Control

A pest control contract covering the premises will be in place, with regular inspections. Any infestation of rodents shall be reported by staff to the site management for immediate action to be taken.

5.4 Odour Control

The potential for significant odour emissions arising from the site operations were identified as very low by the Risk Assessment carried out on site. This is because the site operations will only occur within the designated building. In addition, the autoclave is fully enclosed (including the shredding process) in order to eliminate the potential for the release of pathogens from the untreated waste. The autoclave is equipped with an air extraction system with a HEPA air filter system. The HEPA filter will remove small particulates from the air and trap it, preventing their release to atmosphere and also providing odour and dust control.

An odour management plan is provided (Doc Ref_NSECH_Odour Management Plan)

5.5 Dust Control

The potential for significant dust emissions building up from the site operations were identified as very low by the Risk Assessment carried out on site. This is because the site operations (storage of wastes and treatment) will only occur within the designated building. In addition, the autoclave is fully enclosed (including the shredding process) in order to eliminate the potential for the release of pathogens from the untreated waste. The autoclave is equipped with an air extract system that will vent to atmosphere via a HEPA air filter system. The HEPA filter will remove small particulates from the air and trap it, preventing their release to

atmosphere and also providing dust control.

5.6 Noise Control

The potential for significant noise emissions arising from the site operations were identified as very low by the Risk Assessment carried out on site. This is because the site operations (storage of wastes and treatment) will only occur within the designated building. In addition, the autoclave is fully enclosed (it includes the shredding process). The equipment on site is maintained as per manufacturer guidelines and maintenance service is provided periodically and on demand by qualified staff (provided by the contractor Curo/Peacocks). See Appendix E for Contingency Plan.

5.7 Leak and Spillage Control

All waste pre and post treatment shall be stored within the designated building on an impermeable surface with the appropriate sealed drainage system.

Emergency spillage kits will be held on site in order to absorb any spillages of liquids. Where applicable, the spillage will be dealt with in accordance with appropriate Emergency Procedures as outlined below. Training in the use of the spillage kits will be given to nominated site staff.

Any spillages of solid and liquid waste will be cleaned up as soon as practicable and normally within a few hours of the spillage.

6.0 SITE STAFF AND MANAGEMENT

6.1 Senior Management

Senior management will provide sufficient support to ensure site activities comply with the Permit. The Site Manager will be Matthew Clements, Strategic Waste Manager.

The Site Manager will have sufficient control of the facility, including, but not be limited to the following:

- Have day-to-day control of the facility or activity, including the manner and rate of operation
- Make sure that permit conditions are complied with
- Decide who holds important staff positions and have incompetent staff removed, if required
- Make investment and financial decisions that affect the facility’s performance or how the activity is carried out
- Make sure activities are controlled in an emergency

The Site Manager shall ensure that all staff are aware of the conditions of the Permit and trained to a level pertinent to their position.

6.2 Fit & Proper Persons

Part II of the Environmental Protection Act 1990, introduced the concept of a "Fit and Proper Person", considered fit and proper in the operation of a waste management facility if:

- The person has not been convicted of any relevant offences.
- The person is considered to be technically competent.
- The person issued with the site licence has adequate financial arrangements to discharge his licence obligations.

The site operator complies with all criteria above.

6.3 Technical Competence

In accordance with the EA Guidance the operator must demonstrate that they have the technical competence to carry out the activity.

The technically competent person for the site will be provided by Albion Environmental through Craig Chandler (Appendix M WAMITAB Certificate). He will attend the site for a minimum of 20% of the operational hours per week to a maximum of 2 days per week. In addition, Daniel Kendall will be providing technical management for the site. Daniel is currently being registered to undertake the relevant WAMITAB/CIWM qualification, Level 4 High Risk Operator Competence for Managing Thermal Treatment of Hazardous Waste (HR0C5)

Appendix A – Site Location Plan and Proposed Permit Boundaries

KEY

PERMIT BOUNDARY

N

Rev	A	B	C	D	E	

Drawn by RB	Scale NTS	Original Size A3
Surveyed by JB	Date 25/07/2023	Drg File Name 2023-6333

NORTHUMBRIA HEALTHCARE TRUST
NORTHUMBRIA WY NE23 6NZ
CRAMLINGTON

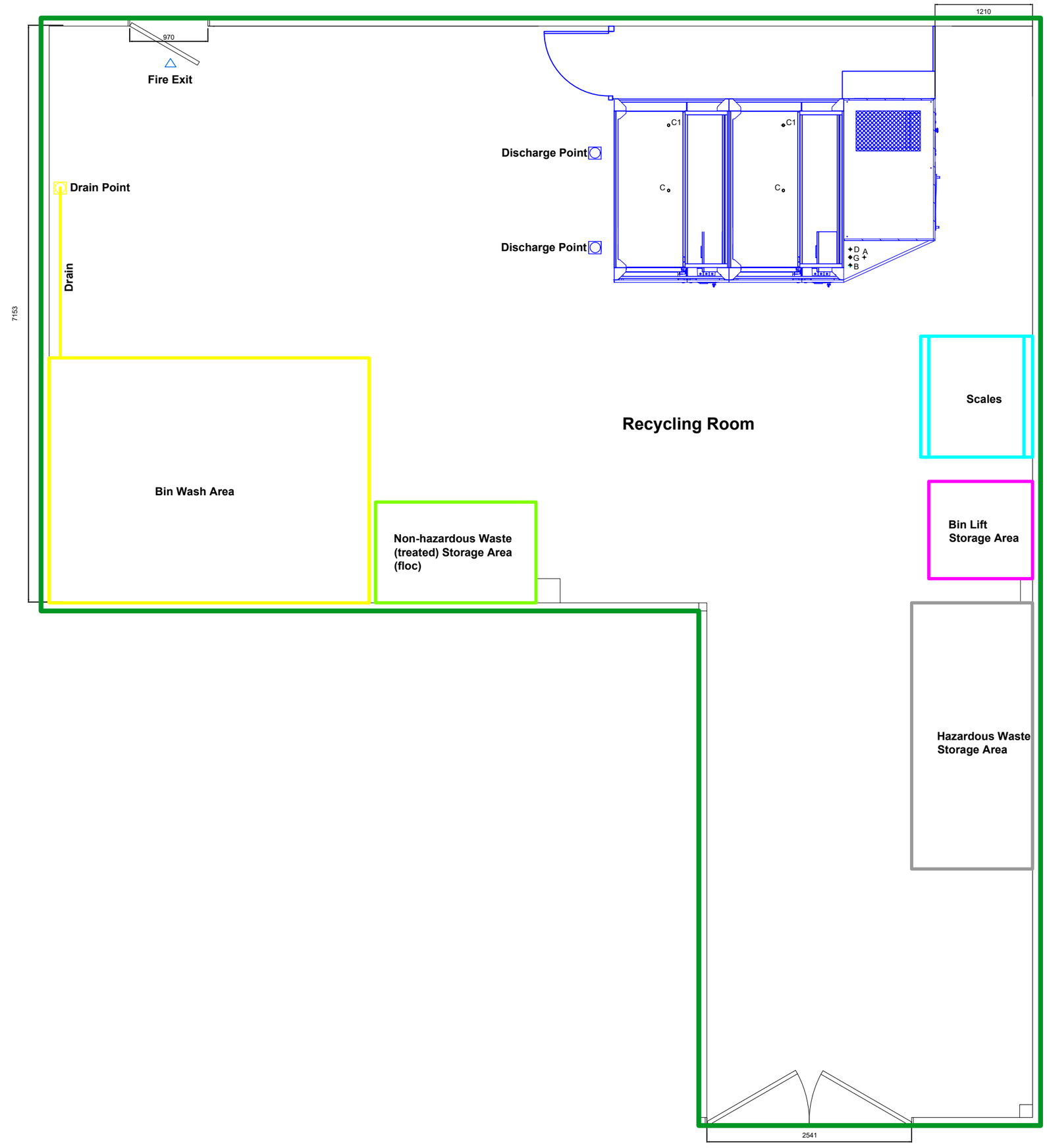
NORTHUMBRIA SPECIALIST EMERGENCY CARE HOSPITAL
SITE LOCATION PLAN

Albion Environmental

Albion House
1 Damside
KA8 8ER
AYR
01292 610428
info@albion-environmental.co.uk
www.albion-environmental.co.uk

DRAWING No.	REV.
2023-6333-002	REV

Appendix B – Site Layout Plan



KEY

- PERMIT BOUNDARY
- BIN WASH AREA
- BIN LIFT STORAGE AREA
- SCALES
- HAZARDOUS WASTE STORAGE AREA (MAXIMUM STORAGE OF 2 x 770 l BINS)
- NON HAZARDOUS WASTE (TREATED) STORAGE AREA (FLOC) (MAXIMUM STORAGE OF 2 x 240 l BINS)

A	POWER CONNECTION POINT
B	COMPRESSED AIR
C	MACHINE DRAIN
C1	VACUUM DRAIN
D	POTTABLE WATER
G	SOFTENED WATER

Rev						
Hazardous and Non-hazardous waste areas added						
A	B	C	D	E		

Drawn by: RB	Scale: NTS	Original Size A3
Surveyed by: JB	Date: 25/07/2023	Drg File Name: 2023-6333

NORTHUMBRIA HEALTHCARE TRUST
NORTHUMBRIA WY NE23 6NZ
CRAMLINGTON

NORTHUMBRIA SPECIALIST EMERGENCY CARE HOSPITAL
SITE LAYOUT
PLAN

Albion Environmental

Albion House
1 Damside
KA8 8ER
AYR
01292 610428
info@albion-environmental.co.uk
www.albion-environmental.co.uk

DRAWING No.	REV.
2023-6333-005	A

Appendix C – Autoclave Specifications Datasheet

WSD200 Technical Datasheet

WSD GENERAL DATAS

Overall dimension	
Width	3980 mm
Depth	2280 mm
Height	2260 mm

Performance	
Capacity of the sterilization system	Up to 200 kg/h*
Capacity of shredder system	Up to 200 kg/h
System compliance to rule:	4.3, 4.1.4 of UNI 10384-1

**based on bags density*

STEAM STERILIZER (x 2)

Chamber Dim. (each unit)	
Chamber volume	868 lt
Chamber depth	2000 mm
Chamber width	660 mm
Chamber height	660 mm

Load capacity (each unit)	
Autoclavable bag	12-25 units

Weights	Empty	Max Weight (test)
Total weight single door	1260 Kg	2365 Kg
Total weight double door	1480 Kg	2585 Kg
Loading on floor single door	388 Kg/m^2	730 Kg/m^2
Loading on floor double door	450 Kg/m^2	790 Kg/m^2

Door type	Automatic vertical sliding
Door/s motion	Pneumatic

Heating variants	
E : electric self-produced steam	☑
V : direct steam	☑
EV : electric self-production and direct steam	☑

General Characteristics

Operation	Fully automatic
Alarm Type	Audible and visible, printed on paper
Transportation	Possibility of shipment in 2 sections
Fluids control (steam/water)	Pneumatically operated valves
Noise	53dBA average value, 64dBA max value
Command service access	Openable panels, front access
Plant service access	Openable panels, front access

Construction Characteristics

Construction	
Chamber	8.0 mm thick, AISI 316L / W.Nr.1.4404
Jacket	5.0 mm thick, AISI 316L / W.Nr.1.4404
Doors	10.0 mm thick, AISI 316L / W.Nr.1.4404
Vessel internal finish	Mirror-like polishing, RA < 0.2 µm
Sustaining frame	2.0 mm thick, AISI 304L / W.Nr.1.4307
Outer panels	1.5 mm thick, AISI 304L / W.Nr.1.4307
Outer panels finish	Scotch-Brite® grade brushing finish

Pressure vessel	
Chamber test pressure	5.8 Bar
Jacket test pressure	6.8 Bar
Max Temperature	148°C
Max operative temperature	138°C
Max working pressure	3.5 Bar
Operative pressure	2.2 - 2.6 Bar
Certification	2014/68/EU

Insulation	
Vessel insulation	Fonitek melamine foam pads 30÷60 mm
Insulating factor	thermal conductivity < 0.035W/m°K
Insulation sheathing	1.0 mm, brushed aluminium
Tubes insulation	Silicone foam hoses with inner Kevlar mesh
Surface temperature	Not exceeding 45°C
Thermal dispersion at 23°C	3875W total, 2250W surface (fronts)

Validation connections	
Chamber temperature	DN15 male, with plug
Chamber pressure	DN25 male, with plug

Plant Characteristics

Hydraulic	
Hydraulic piping	gas-thread, AISI 316L / W.Nr.1.4404
Pneumatic Valves	Angle seat, 16 Bar, 180°C
Valves Material	AISI 316L / W.Nr.1.4404
Steam traps	
Steam trap chamber	Thermostatic-type
Steam trap jacket	Floating-type
Certified Safety valve	(1) 3.5 Bar, AISI 316L / W.Nr.1.4404
Air Filter	Emflon II, 0.02µm filtration
Analog pressure gauges	
Chamber gauge front	-1/0/5 Bar, ±5% class, 0.2 bar div.
Jacket/Generator gauge	-1/5 Bar, ±5% class, 0.2 bar div.
Chamber gauge rear (2P)	-1/0/5 Bar, ±5% class, 0.2 bar div.

Door Motion	
Pneumatic system	Double cylinder with lock Ø32 L732 mm
Motion pneumatic characteristics	max 150N push power

Electric	
Electric box access	Front access, extractable on rails
Electric box insulation	Insulation grade IP55 (water-proof)

Temperature control	
Sampling devices	Thermoresistance PT100 DIN Class A
Sensor position	Chamber (1)
Liquid cycle probe (option)	Chamber (1)
Sensor accuracy	In process accuracy ±0.1°C

Pressure control	
Sampling devices	4÷20 mA transducers -1/6 Bar
Sensor position	Chamber (1), Jacket (1)
Sensor accuracy	In process accuracy ±0.1KPa

Vacuum plant

Aquazero® vacuum system	
Type	Waterless mechanical dry system
Power	2.1 kW (50 Hz) / 3.0 kW (60 Hz)
Suction power	80 m^3/h
Service water consumption	0 lt/min
Drain cooling before pump	Not required

Supplies and Consumptions

Power requirements	
Standard voltage	400VAC ±10% 3L+N+PE
Other voltages (on request)	240VAC ±10% 3L+PE
Frequency	50Hz / 60Hz
Max power absorption	52 kW (E/EV/SV), 5 kW (V/SV)
With upgrade generator 72kW	79 kW

Supplies	Requirement
Service water (only for drain cooling)	
Service water	DN15, 1/2"F, 1.5÷3 Bar, 15 lt/min
Quality	Soft, ≤ 8°F, 10-20°C
Treated Water (generator)	
Treated water	DN15, 1/2"F, 1.5÷3 Bar, 20 lt/min
Quality	Demineralized, 5µs/cm^2, ph 5-7
Steam	
Steam, Clean (V/EV version)	DN15, 1/2"F, 3÷3.5 Bar, 80 Kg/h
Quality	Saturated steam 97%
Compressed air (valves)	
Compressed air	DN15, 6÷8 Bar, 15 Nlt/min
Quality	Dry, oil less, dew point -40°C
Drain	
Main drain	DN40, 1-1/2"F, 135°C
Condense recovery (if requested)	DN15, 1/2"F, 135°C

Consumption	
Power	
Power consumption (V/version)	3 kWh/cycle
Power consumption (E/EV/ version)	28 kWh/cycle
Treated Water	
Treated water (E/EV version)	40~50 lt/cycle
Steam	
Steam, Clean (V/EV version)	35 Kg/cycle
Compressed air	n.d.

WSD200 Technical Datasheet

Management system

Control System	Primary
Primary Control Device	Industrial-grade PLC
User interface and type of display	Colour, Touch-screen, 7" diagonal
Printer	Dot-matrix, 24 columns
Communication ports	RJ45 Ethernet, RS232, RS485
Capacity of internal storage	80 cycles + alarms
Data download	USB female port on panel
USB storage capacity	20000 cycles with 4Gb USB
F0 function	monitored, printed, programmable
Stand-by/Wake-up	Programmable, elapsed time/hour
Operator identification	Up to 70 users with password
Programmed maintenance	Automatic, on parts working time

Sterilization Cycles

Validated programmed cycles	Duration
Sterilization cycle 138°C for 10' (Waste)	45-50 min
Vacuum leak test cycle	25 min
Bowie&Dick cycle	30 min
Open cycles (from 01 up to 60)	variable
Liquids cycle 121°C for 20' natural cooling	variable

Specific Models Features

Steam filter characteristics (V/EV version)	
Steam filter element	Accuracy 5 µm
Steam filter housing	AISI 304 / W.Nr.1.4301
Vacuum filter characteristics	
Steam filter element	HEPA FILTER H14
Steam filter housing	AISI 304 / W.Nr.1.4301

Steam generator characteristics (E/EV version)	
Generator volume, dimensions	60 lt, ØXD 355X679 mm
Vessel material	4.0 mm, AISI 316L / W.Nr.1.4404
Vessel test pressure (relative)	11.1 Bar
Vessel insulation, thickness	Mineral wool, 15.0 mm
Insulating factor	thermal conductivity 0.033 W/m°K
Vessel weight	45 Kg (empty), 105 Kg (full)
Max working temperature	148°C
Max working pressure	3.5 Bar
Heating elements (E/EV/)	45 kW (5X9000 W)
Steam productivity	77 Kg/h
Heating elements material	Incoloy 800 A

Steam generator control characteristics (E/EV)	
Regulation pressure switch	0.5÷6 Bar, Switching Diff. 0.15 Bar
Safety Thermostat	0-300°C, accuracy ±1°C
Water level	Sensitivity 5÷100 KΩ, ±30% accuracy
Feeding pump	AISI 316 / W.Nr.1.4401
Pump power	0.55 kW (50 Hz) / 0.74 kW (60 Hz)

Safety features

Device against simultaneous opening of doors (interlock)
Device against opening of doors in case of chamber pressure
Device against closure of door in case of obstacles on its way
Device against injection of steam in chamber if door is open
Device against overpressure of the jacket
Device to prevent motor overloads due to missing supply water
Device to guarantee integrity of door sealing
Device to prevent over temperature during sterilization plateau
Device to prevent low temperature during sterilization plateau
Device to detect temperature and pressure sensors failure
Device to detect out of calibration of sensors
Device against heaters working without water in steam generator
Device to disconnect power in case of short circuits
Device to control door opening until product temperature <80°C

Options Available

TSP	Secondary touch-screen 7" on unloading side	☑
MRC	Mirror-reverse chamber version	☑
UPS	Backup UPS for control system	☑
RMS	Remote maintenance system	☑

SHREDDING SYSTEM (x 1)

Cutting Chamber	600 x 800 mm
Installed Power	15 kw (7.5 kw + 7,5 kw) – 20HP(10HP+ 10HP)
Drive	By gears
Number of cutting shafts	2
Number of knives	30
Number of conveyor shafts	2
Number of conveyor knives	30
Rotating speed (RPM)	18

TRACEABILITY

(configuration and qty. to be defined according customer request)

Hardware
Personal Computer
Weight scale stand-alone
Weight scale in a "totem" configuration
Barcode reader
Label printer

Software
TraceWaste license
Machine monitoring license

TRACEWASTE

Manufacturing Standards

Machinery Directive	2006/42/EC
Low Voltage Directive	2014/35/EU
Electromagnetic Compatibility	2014/30/EU
Electrical Equipment Safety	IEC 60204-1:2016
Pressure Equipment Directive	2014/68/EU
Quality Management System	UNI EN ISO 9001:2015
Equipment and processes tor sterilization of hospital waste	Italian UNI 10384:94

Appendix D – Site Drainage Plan


INSET
Permit boundary
MORTUARY ACCESS
ACCESS GATE FROM ADJACENT FIELD
FINAL CONSTRUCTION ISSUE
NORTHUMBRIA EMERGENCY CARE CENTRE
FOUL WATER DRAINAGE LAYOUT
7805/C/104
FC01

Appendix E – Autoclave Contingency Plan

Waste & Environmental Solutions

Albion Environmental

NHS Northumbria
Northumbria Specialist Emergency Care Hospital
Northumbria Way, Cramlington, NE23 6NZ

Autoclave Contingency Plan

August 2023

PREPARED BY	**Stella Consonni (Senior Consultant)**	**DATE**	**19.05.2023**
REVIEWED BY	**Jane Bond (Project & Business Development Director**	**DATE**	**01.08.2023**
SIGNATURES			
VERSION No.	1.0		

Albion Environmental Limited

Albion House,
1 Damside,
Ayr, KA8 8ER
Scotland, UK

www.albion-environmental.co.uk
T: 01292 610 428
E: info@albion-environmental.co.uk

Registered in Scotland No. SC254498. VAT Registration No. 806 4312 55.

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1.0 INTRODUCTION

1.1 Overview

As part of the Bespoke Permit Application, this Contingency Plan provides the required information including ceasing acceptance of waste, as per section 1.1 of the EPR 5.07 guidance, regarding the use of the CISA steriliser supplied by Peacocks Medical Group Limited.

2.0 CONTINGENCY PLAN

The Contingency Plan sets out the procedures to ensure appropriate response to incident occurring to the autoclave. This section provides a description of procedures to respond to incidents including target times for dealing with them when applicable.

2.1 Incidents – Typical Support

Overall, in the event of an incident with the autoclave, the first response support to the Northumbria Specialist Emergency Care Hospital (NSECH), that will be provided by the Autoclave supplier (Peacocks), includes the following procedures:

- Emergency response to assess level of damage, decide whether to invoke the Contingency Plan of the site and at what level, to notify staff etc.
    - Timescales: within 2 hours of the disaster

- Provision of an emergency level of service
    - Timescales: Within 4 hours of the disaster

- Support for restoration of key services
    - Timescales: Within 8 hours of the disaster

- Recovery to business as normal
    - Timescales: Within 8 hours of the disaster

As part of the supplier's (Peacocks) support, in the unlikely event of a major incident and their service cannot be resumed within 48 hours, they will provide appropriate cover, e.g., allocate another unit to the service located within the vicinity and/or replace the unit with a mobile support system. Any downtime will be recovered by making available additional personnel to work out of hours such as evenings and weekends.

2.2 Autoclave Breakdown

In the incident of malfunctioning/ breakdown of the Autoclave, while section 2 above is followed, the NSECH would have wastes collected by a qualified third party (Sharpsmart Limited) for treatment/ and or incineration. It is worth pointing out that, due to the low quantity of wastes proposed to be treated on site, the risk of accumulation of wastes exceeding the allowed tonnage is considered exceptionally low.

2.3 Maintenance/ Servicing of Autoclave

Maintenance of autoclave will take place for testing and servicing periodically as required. These intervals will occur as follows:

- 1 day per month visit

- 2 days every 6 months visit

- 2 days annual visit

The site's autoclave can treat wastes daily in 12 hours, Mondays to Fridays. So, in such maintenance/ servicing events, the site would run for extended hours to catch up the surplus wastes, for example run for 24 hours to

catch up 3 days surplus. Where systems are more than 1 module e.g WSD200, 50% capacity will be available during the service and routine monitoring visit.

2.4 Emergency Contacts

The Emergency contacts are established between Peacocks and the NSECH for the following:

- Assessing the extent of the problem and its impact on the service
- Establishing facilities for an emergency level of service – off site
- Restoring key services within agreed timeframes
- Report, advise and liaise with the NSECH on the emergency and preventative measures for the future

Contact List:

- On Call Engineer – 7 engineers on rota (service manager Danny Kendall)
  - Mobile no - 07967308163 / 07790578002 / 07968038950
  - Availability – 24 hours
- Admin Support – email sme-service@peacocks.net (technical and service or sme-orders@peacocks.net for account and consumables)
  - Office no – 0191 2769618
  - Office hours 07:00 – 17:00
- Operations Manager – Andrew Hough
  - Mobile no - 07968038950
  - 8am – 8pm
- Operations Director – Gary Cooper
  - Mobile no -- 07790578002
  - Office hours – 07:00 – 17:00
- Facilities Manager – Matthew Clements – Strategic Waste Manager
  - Mobile no – 07766026959

Appendix F – Autoclave Waste System User Manual v0.1

curo

By Peacocks

WASTE SYSTEM USER & SETUP MANUAL
V0.1

In partnership with

NHS
Northumbria Healthcare
NHS Foundation Trust

PEACOCKS EST. 1903

cisa
We care about life

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Curo

Contacts

Company Address

CURO
Peacocks Medical Group
Benfield Business Park
Benfield Rd
Newcastle-Upon-Tyne
United Kingdom
NE6 4NQ

Tel: 0191 276 9633

Web: www.curowaste.co.uk
Web: www.peacocks.net

Sales

Tel:
Email:

Engineering / breakdowns

Tel: 0191 276 9618
Email: sme-service@peacocks.net

Parts & Consumables

Tel: 0191 276 9633
Email: sme-orders@peacocks.net

Personal Protection and Hygiene

Purpose

These instructions provide guidance on the use of Personal Protective Equipment (PPE) and Hygiene Requirements within the waste treatment area and includes visitors to the waste treatment area.

Instruction

General

By complying with the following instructions, waste system operators will be:

- Protected from possible exposure to infection / contamination.
- containing possible infection / contamination to a specific area.
- Protecting fellow staff from possible exposure to infection / contamination.
- Protected from burns from hot surfaces.

Waste Operators

- At the beginning of each shift, change from your personal clothing into the provided uniform, In the changing rooms.
- Leave all cosmetics, hand cream, food and drink in the appropriate areas.
- Cover any cuts, abrasions or other skin lesions.
- Long sleeve clothing and gloves provided to be worn when working around hot surfaces.

Personal Hygiene within the Waste Treatment Area

To ensure a high standard of personal hygiene for all staff within the waste treatment Area.

- Put on gloves.
- Put on Needlestick Resistant gloves when handling Waste Bags (ANSI/ISEA 105 Standard)
- After handling waste or chemicals, remove gloves and dispose.
- After removal of gloves – Wash hands.
- Do not touch face or hair before washing hands – You may have chemicals or contaminants on your hands.
- DO NOT EAT IN THIS AREA – Chemicals or contamination may be transferred to your “food”.
- Always wash hands in hand wash sink prior to leaving the waste area.

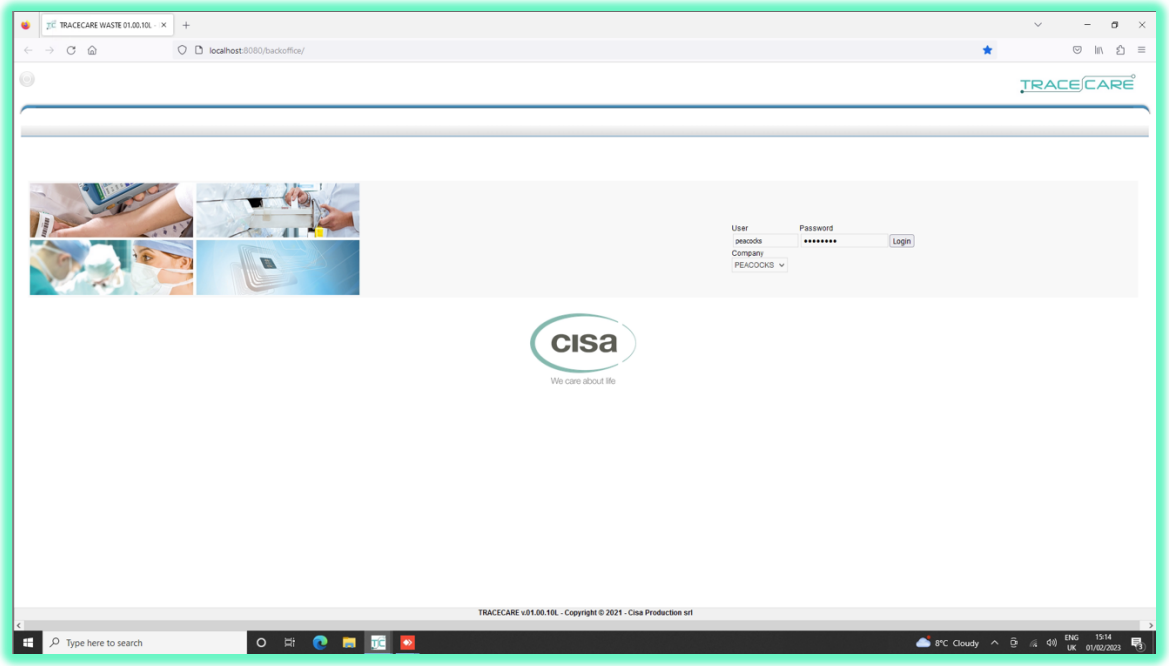
TraceWaste

Logging in

Once the pc is turned on and logged in, follow the procedure Below: -

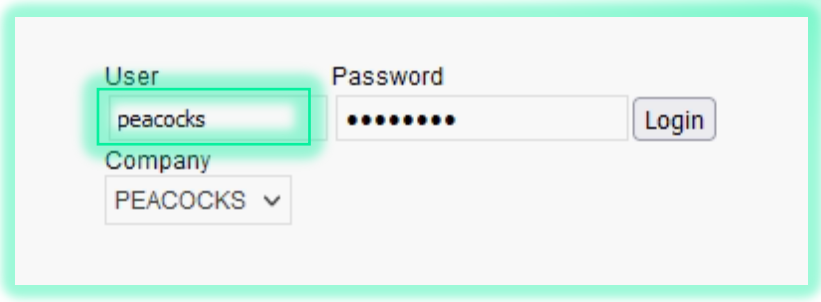
- Click on the icon for Tracewaste / Tracecare

- Once the software opens the screen will look like the following: -

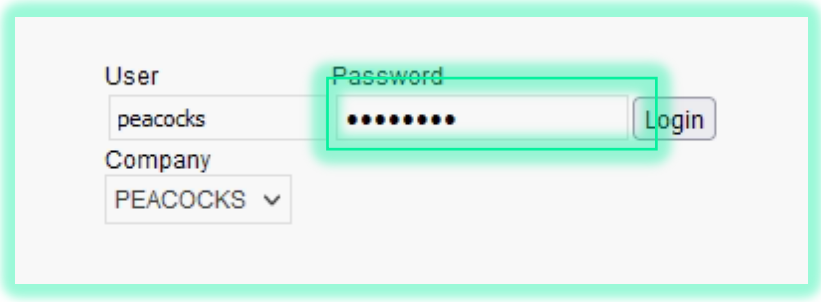


- Each user and supervisor will be issued with there own individual log on details and should be entered as follows.

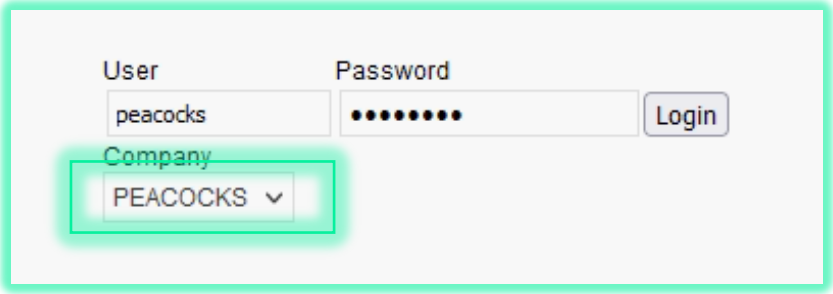
- Enter Your Username/Id under the heading “User”



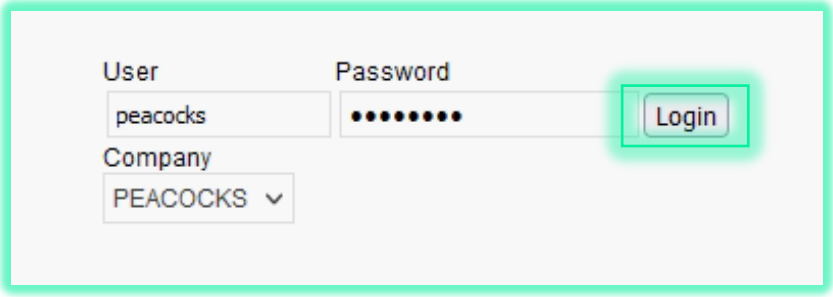
- Enter your password under the heading “Password”



- From the “Company” selection box choose the site you are operating under



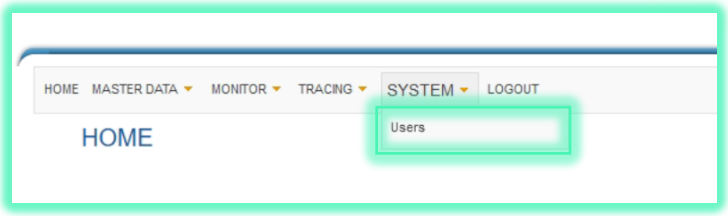
- Click on the “Login” button



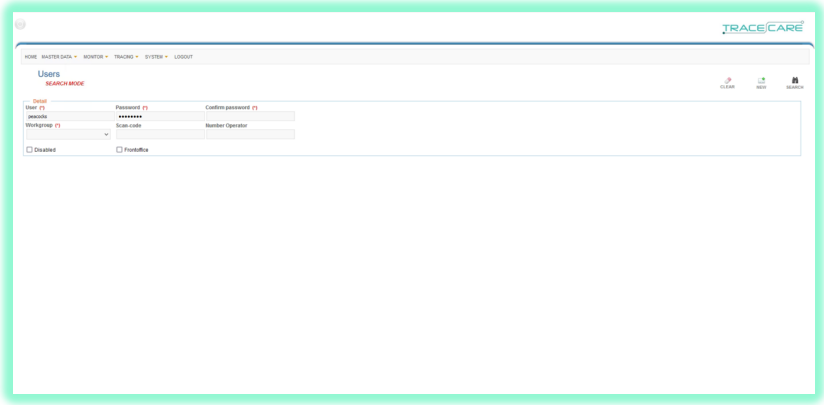
Setting Up Users

To set up users you must have admin rights.

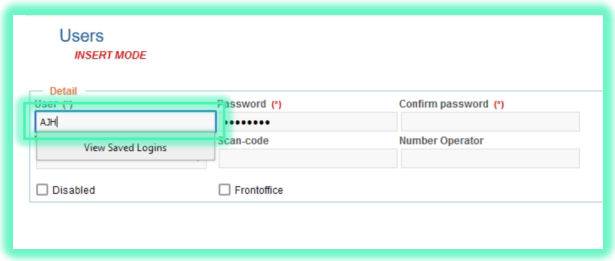
- From the main page locate the “system” tab and click on the user’s menu.



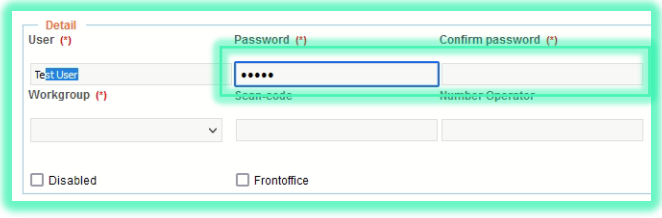
- Once clicked a user’s menu will appear.



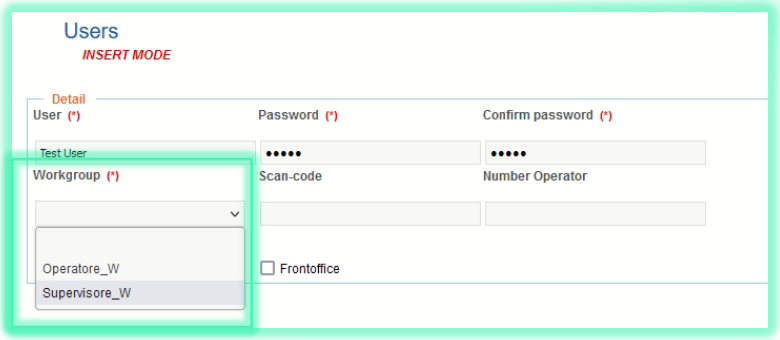
- Click on “New” in the top right-hand corner.
- Enter the new users name in the user box



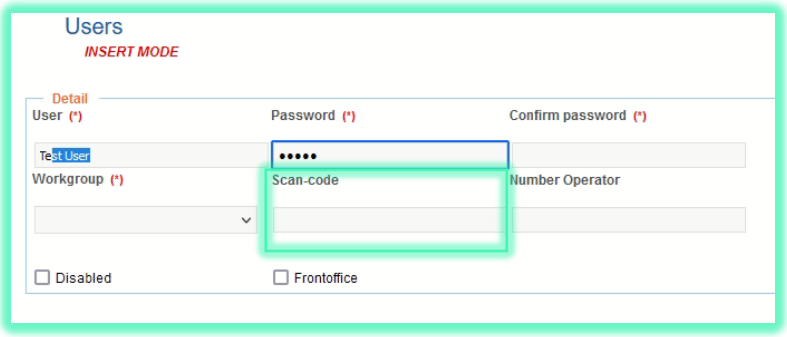
- Enter a password in the password box and repeat the same password in the “confirm Password” box.



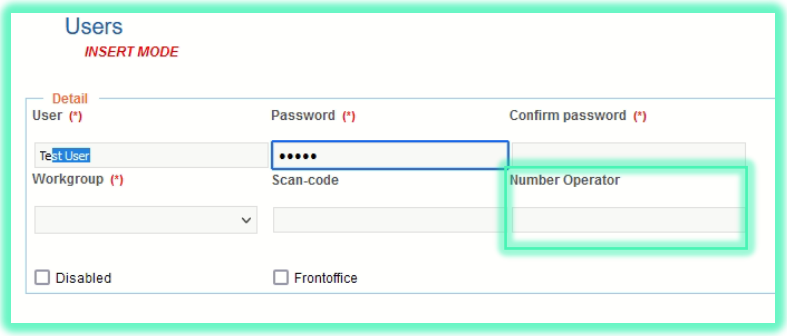
- For the Workgroup choose either “Operatore_W’ or “Supervisore_W” for the user profile that you are setting up.



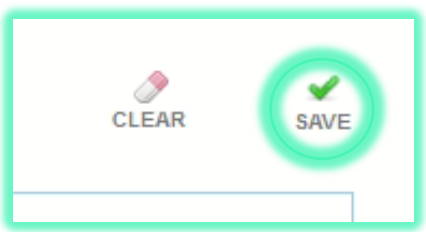
- For the Scan-Code, this is a code for creating the Unique barcode for this user enter a 4 digit number here



- In the “Number Operator” box enter the operator number e.g., 0001, 0002 etc.



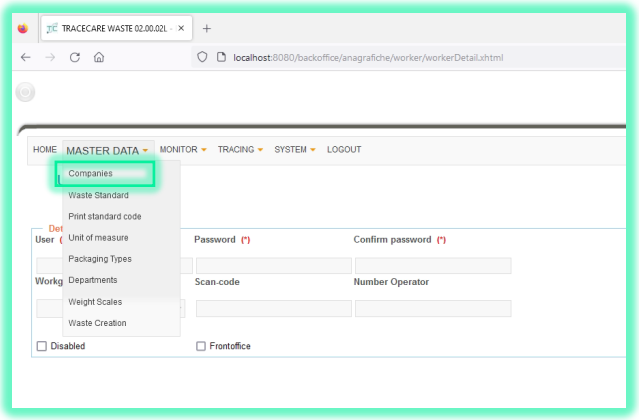
- Once the user details are filled in with the correct details click on “Save” in the top right-hand corner.



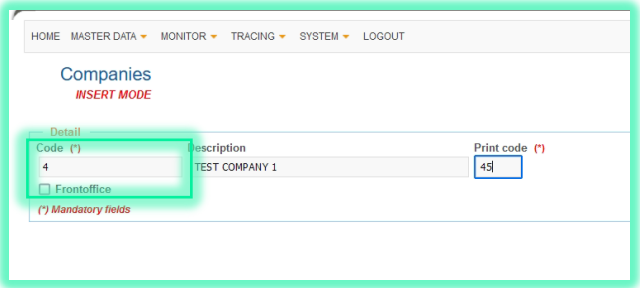
Setting up Customer/Company

To set up company names you must have admin Rights.

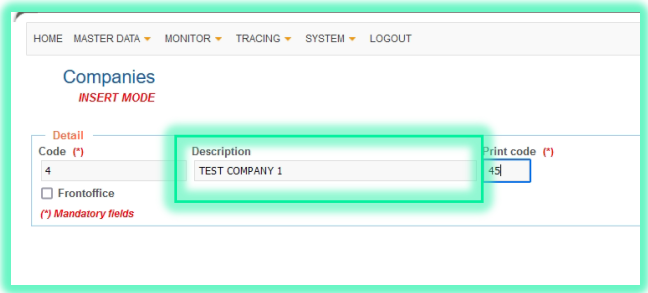
- From the main page locate the “MASTER DATA” tab and click on the Companies menu.



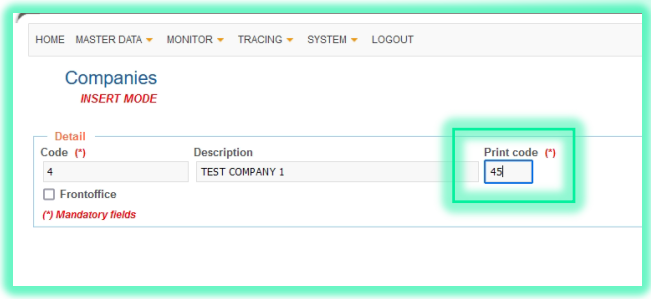
- On the detail part input a company Code Number



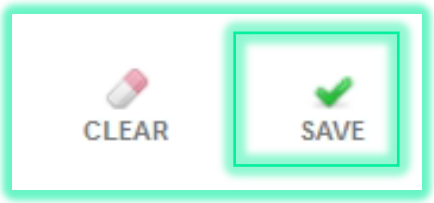
- In the “Description” box enter the name of the Company / Hospital



- In The “Print Code” box enter a unique identification code for your Hospital / Company

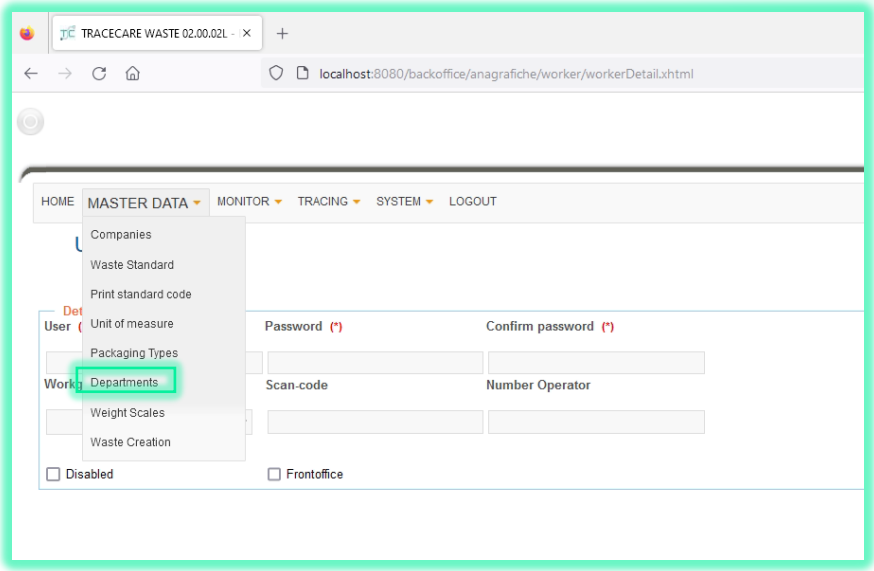


- To save the new Customer / Hospital, click on the save Icon to the top right of the screen

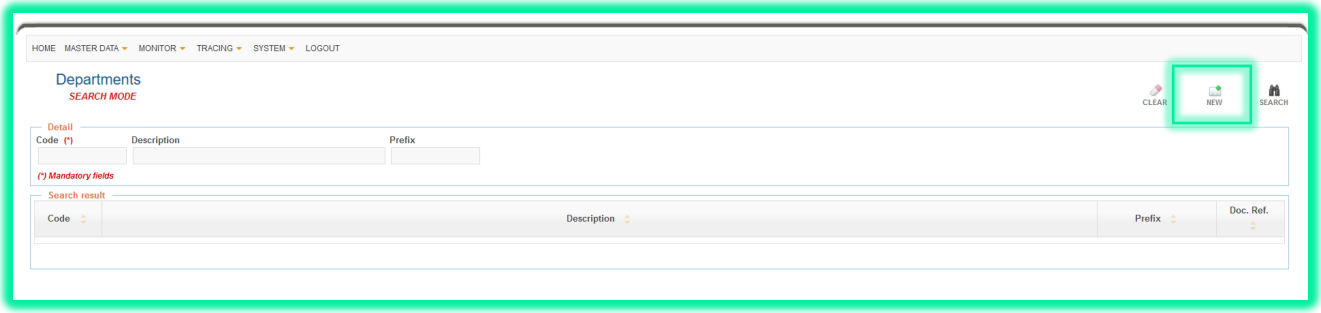


Setting up Departments

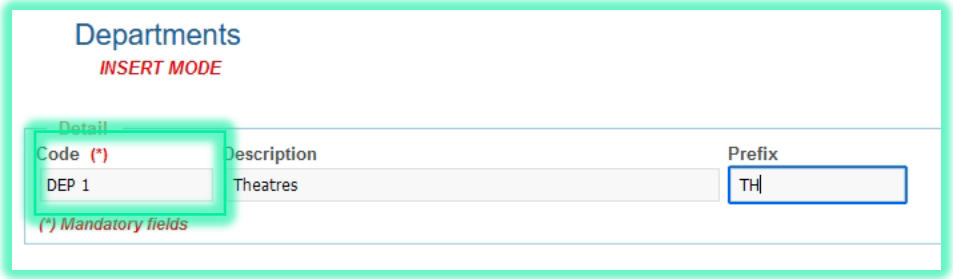
- From the main page locate the “MASTER DATA” tab and click on the “Departments” menu.



- At the top right-hand side of the Departments Tab click on the “New” icon.

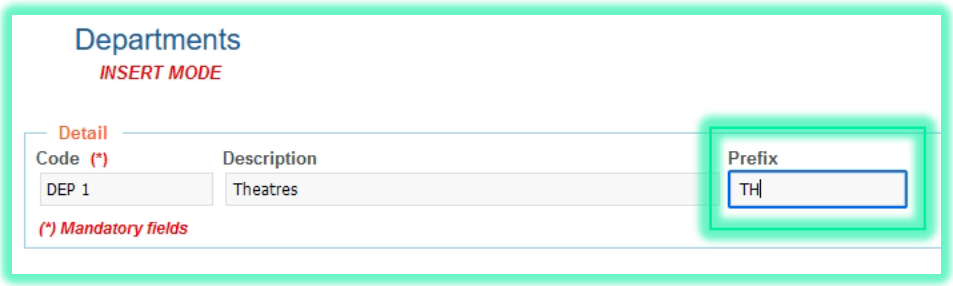


- In the “Code” box enter a code to identify the department.

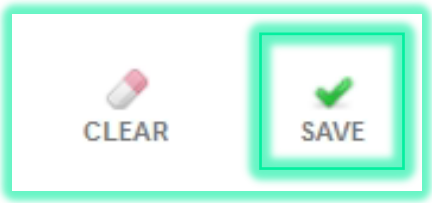


- In the “Description” box enter the name of the department

- In the “Prefix” box enter a unique prefix for the area

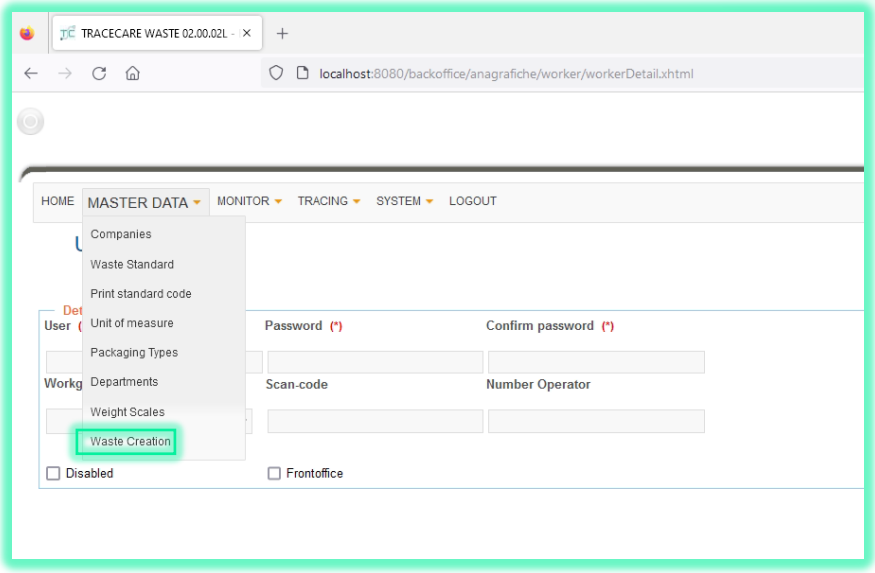


- Once all the boxes are filled click the “Save” icon

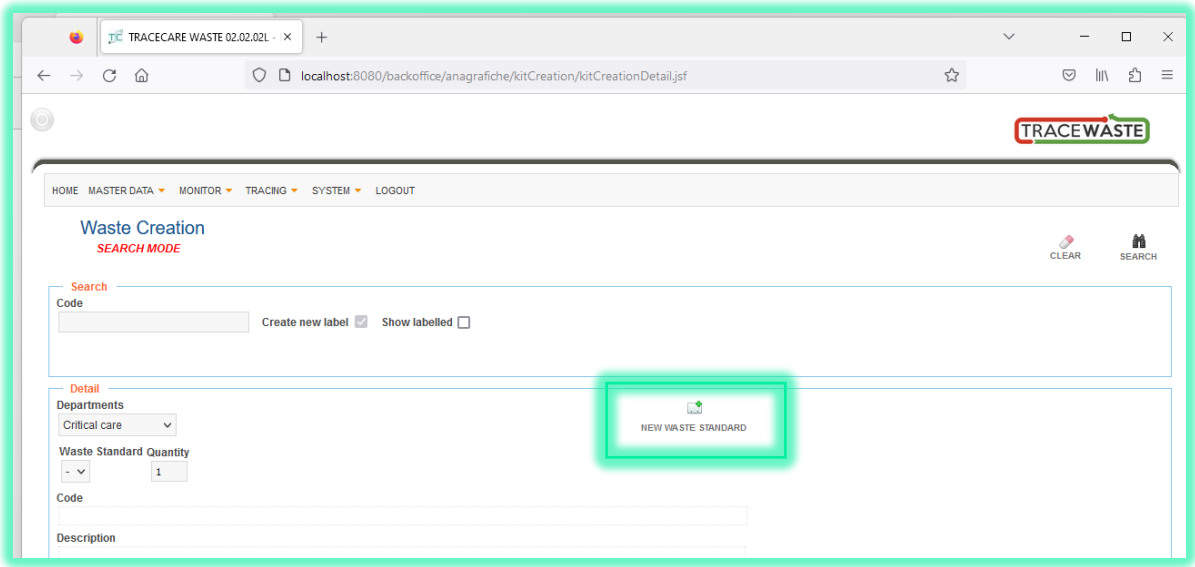


Waste Types & Setup

- From the main page locate the “MASTER DATA” tab and click on the “Waste Creation” menu.



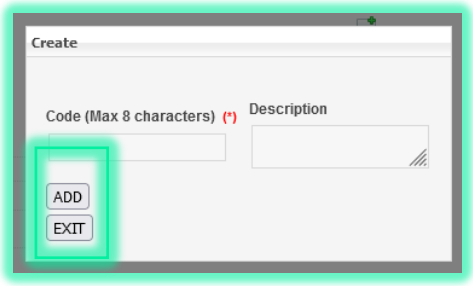
- Select the department in which you require the new waste type.



- Enter an eight digit code for the waste type e.g. Yellow01.

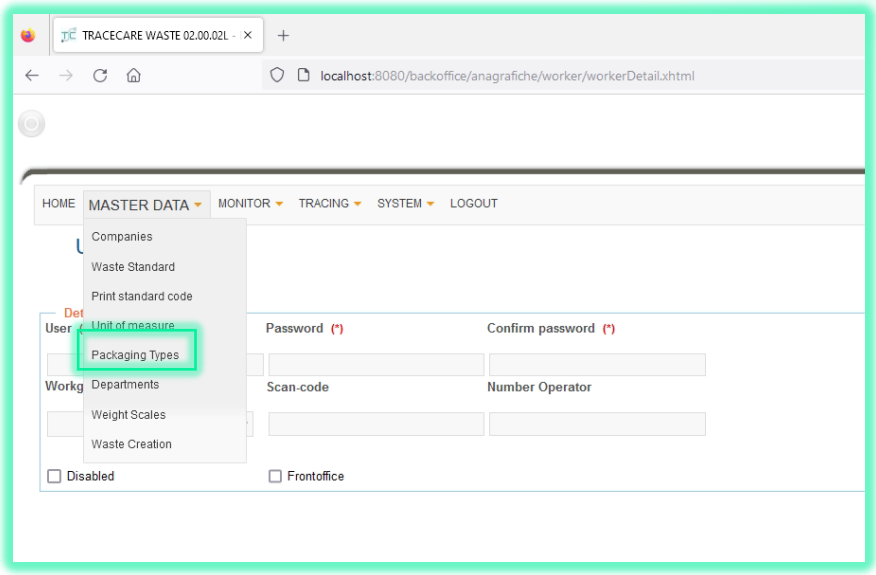
- Enter a description for the waste type e.g. Yellow Bag.

- Click on the ADD button followed By Exit

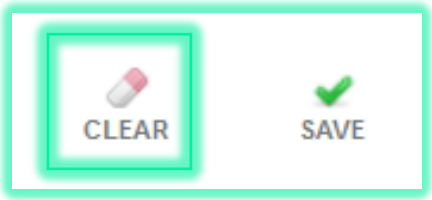


Packaging Types & Setup

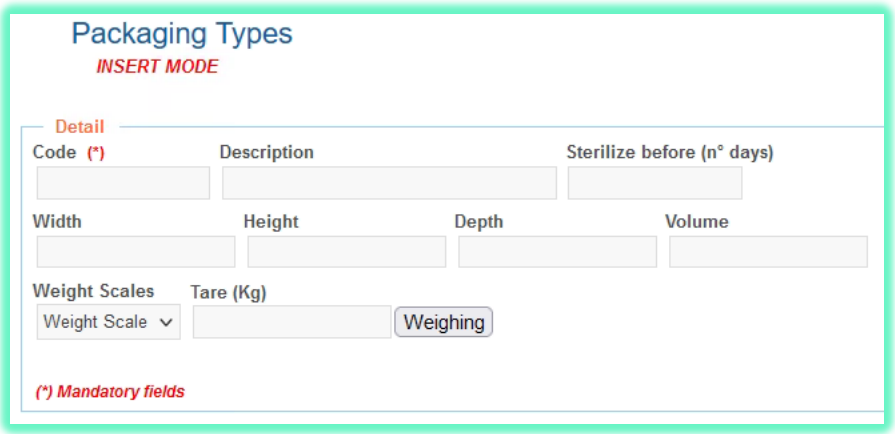
- From the main page locate the “MASTER DATA” tab and click on the “Packaging Types” menu.



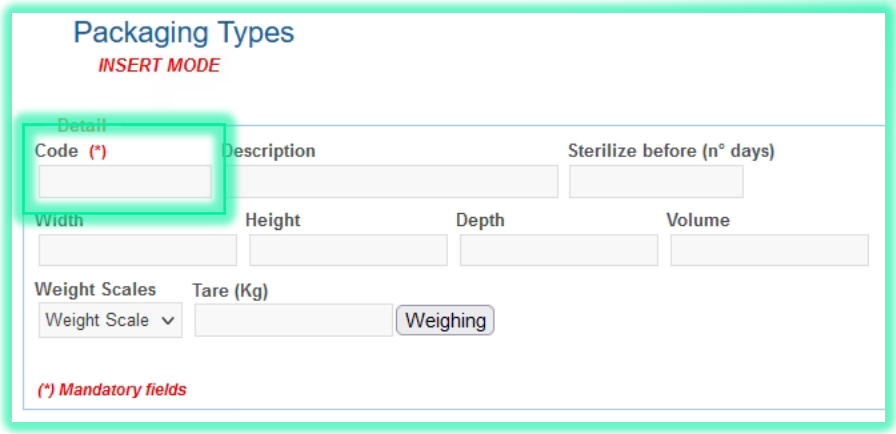
- When the packaging Types page loads firstly click on the clear Icon to the top right of the screen.



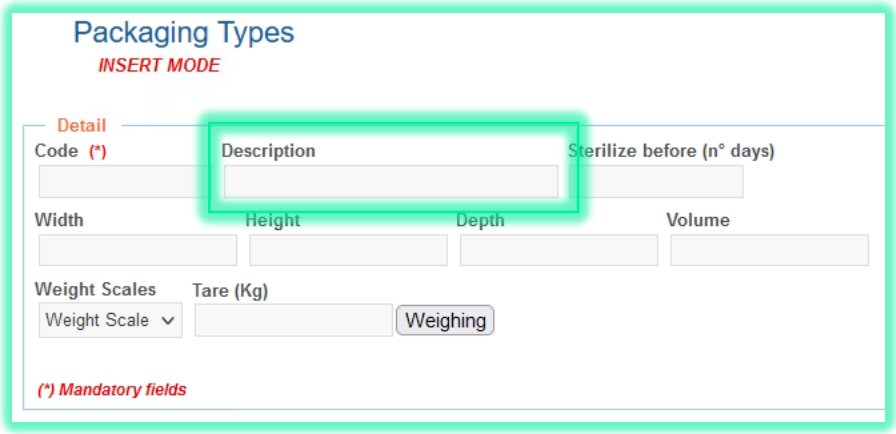
- You should now have an empty form to be filled in as below.



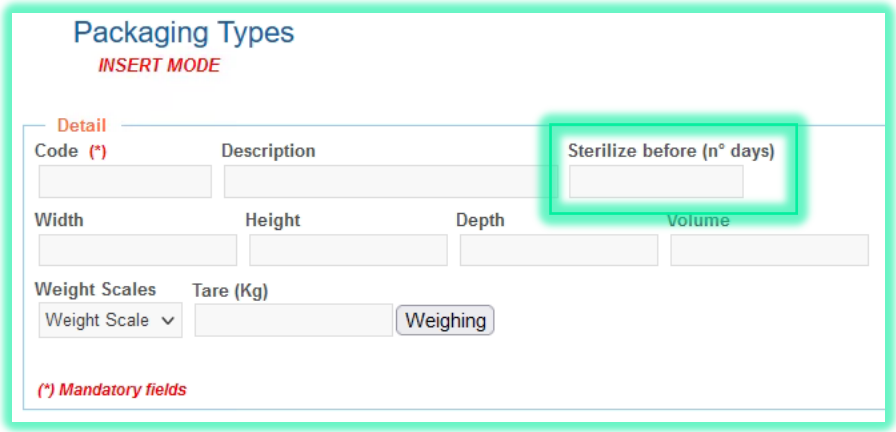
- In the “Code” box enter a unique code for the type of packaging, e.g., Bin 1, YellowBin660.



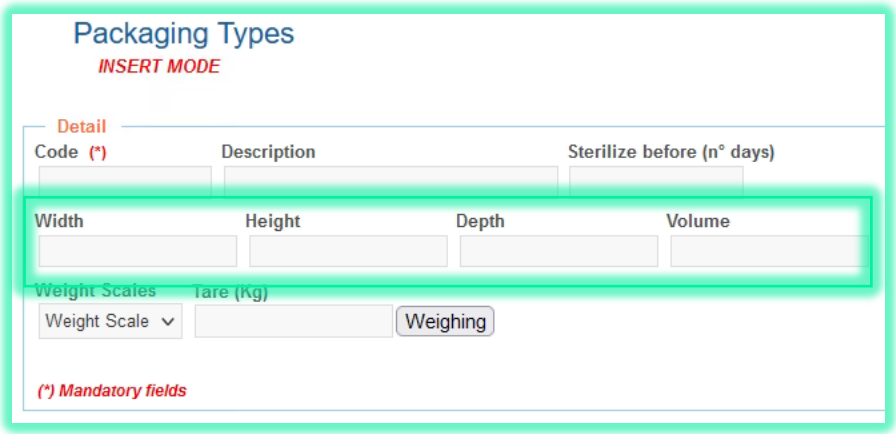
- In the “Description” box add a brief description of the packaging type e.g., yellow 660ltr Bin.



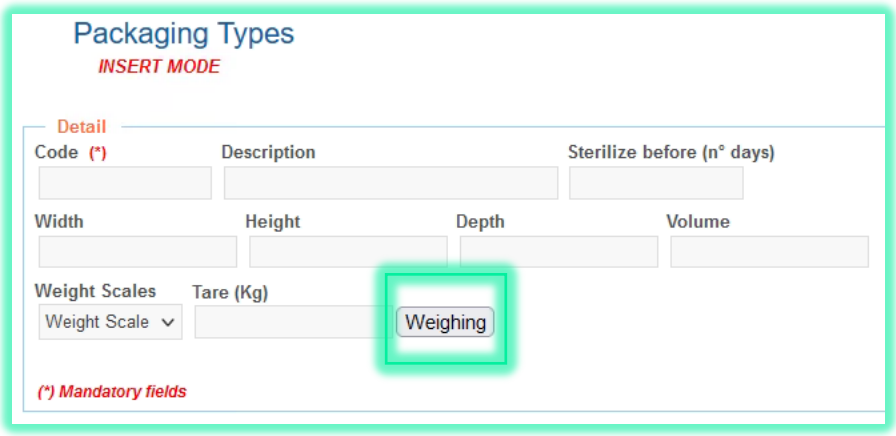
- In the “Sterilize before (n° days)” box enter the number of days that the waste can be stored prior to Sterilisation, if the waste packaging type does not require sterilising, then enter “0”.



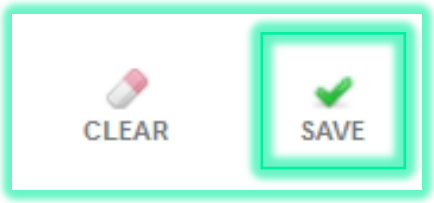
- In the next 4 boxes (Width, Height, Depth & Volume) enter the dimensions and loading volume of the item.



- Place The empty packaging onto the scales and click on the Weighing Button, once pressed a weight will appear in the “Tare” box.

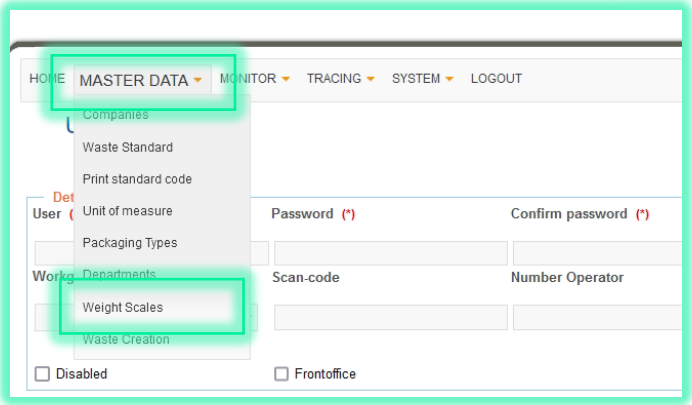


- Once finished click on the “Save” button.

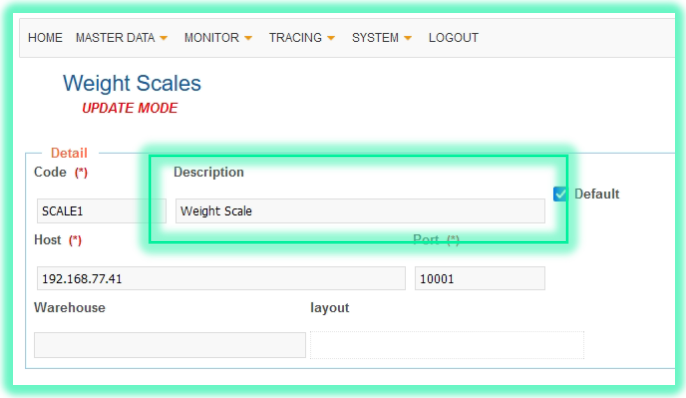


Setting Up Scales & unit of Measure

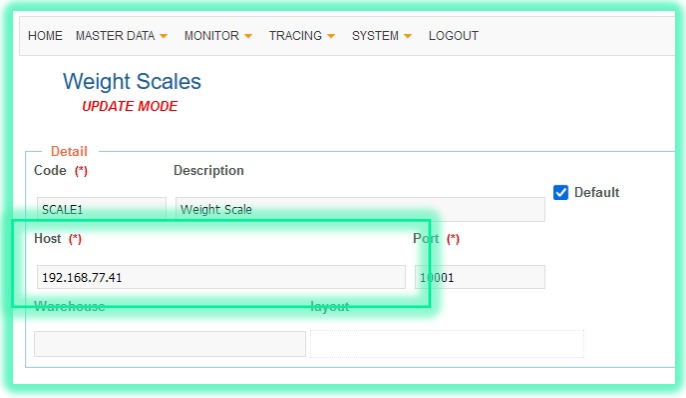
- On the “MASTER DATA” menu select “Weight Scales”



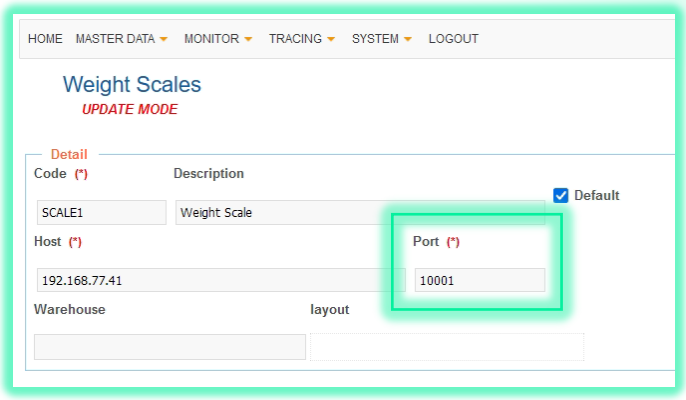
- In the “description” box enter the type of scale e.g., Large Platform, Small Weigh Bridge etc.



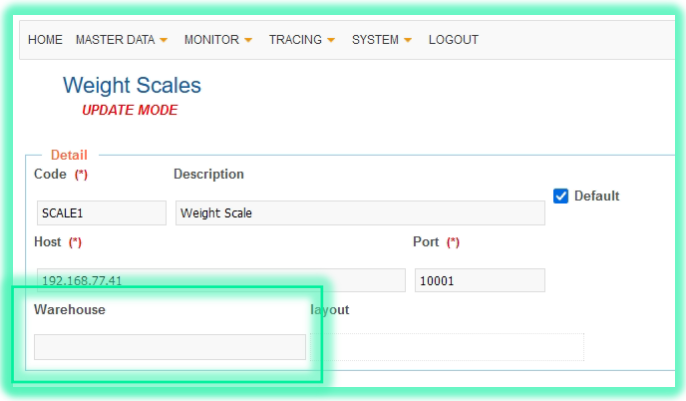
- In the “Host” Box enter the IP Address Of The Weighing transmitter (Laumas TLB4), This is usually set to 192.168.77.41, but may be different if set up on hospital network (Please see laumas TLB4 Set up).



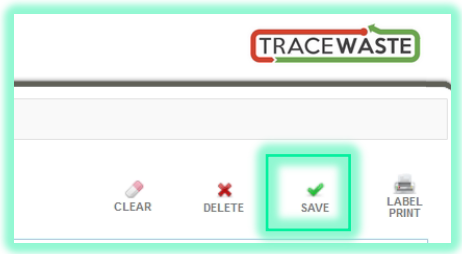
- In the “Port” box enter the number 10001, this is standard for all the scales connected to Tracewaste.



- In the “Warehouse” box enter the Location of the weighing Scale.



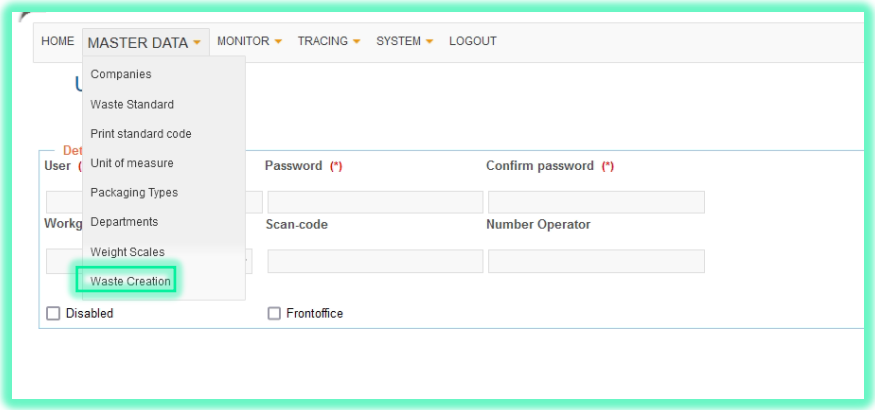
- Once all settings have been entered press the save Icon to the top right of the screen.



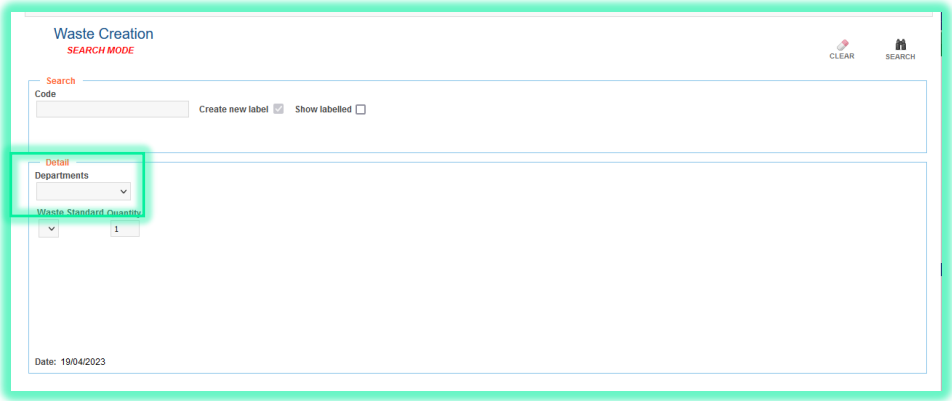
Step By Step Guide on Using Tracecare to Track Waste

Waste Creation

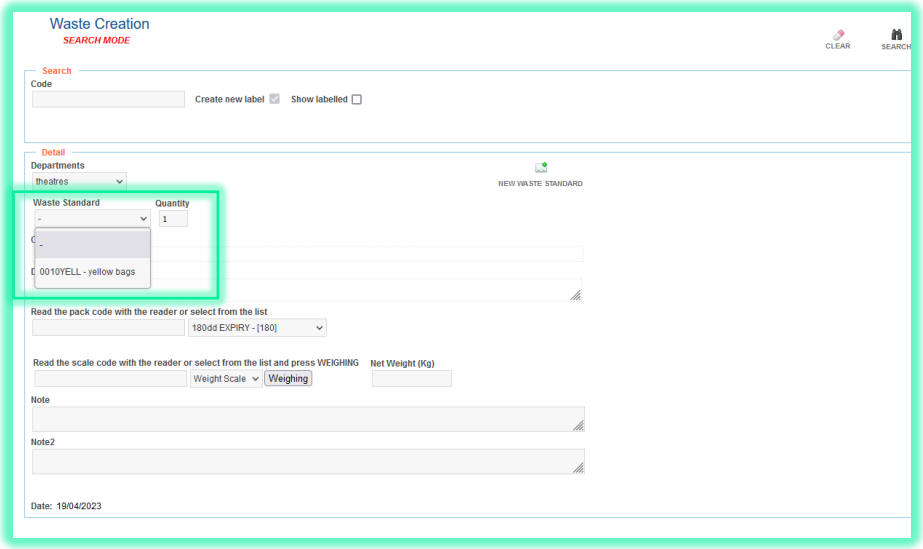
- Log Into TraceWaste with your User ID and Password.
- From the main page locate the “MASTER DATA” tab and click on the “Waste Creation” menu.



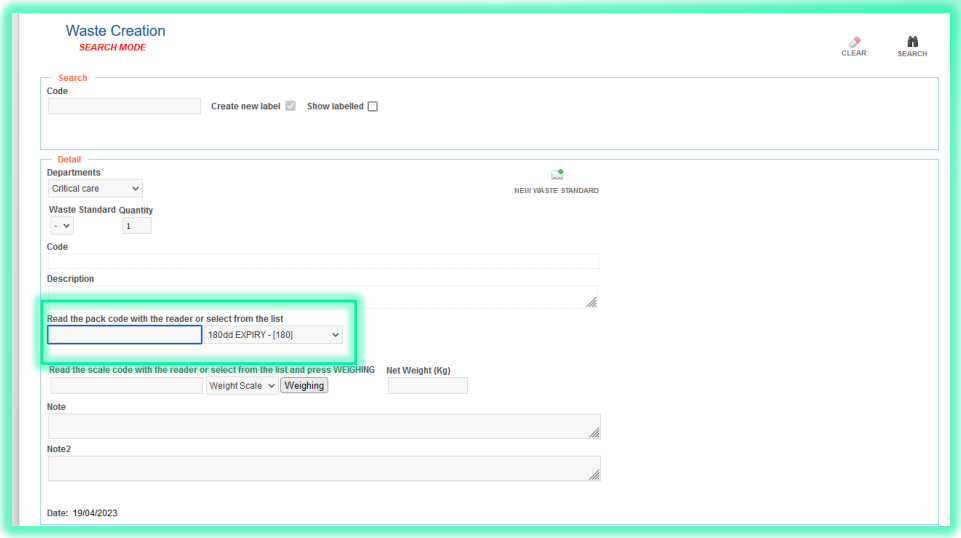
- Select the department where the waste was transported from



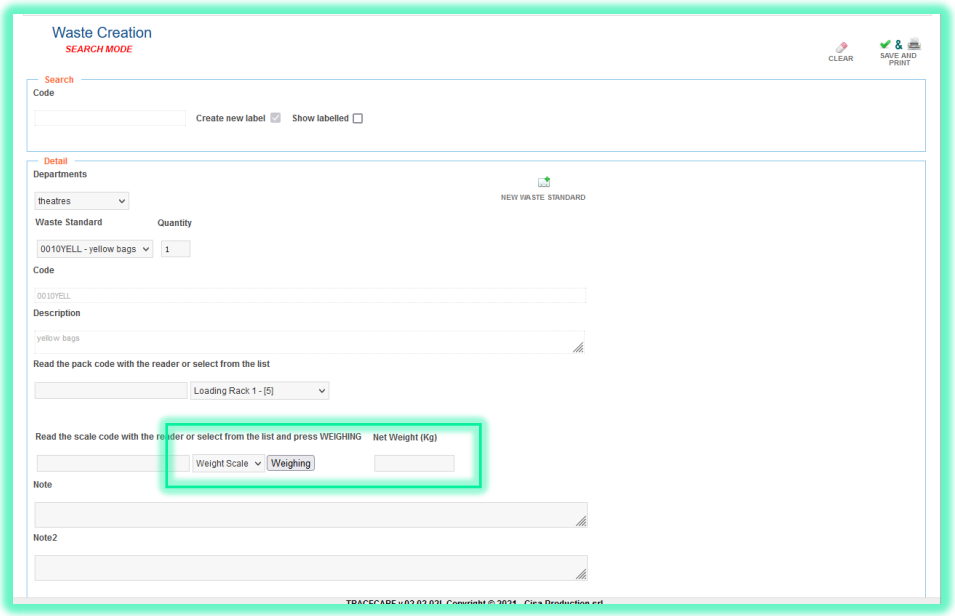
- Select the waste standard E.G. Yellow Bag, Orange Bag etc.



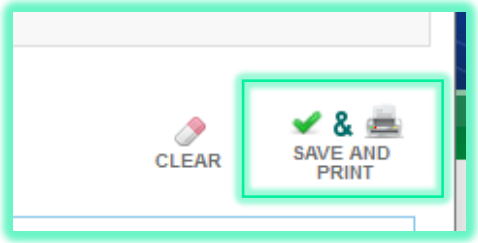
- Select the packaging type or using the barcode reader scan the rack or bin used.



- Ensure the waste is located correctly on the scales then press the “Weighing” icon.



- Click On the Save & Print icon to the top right of the screen.

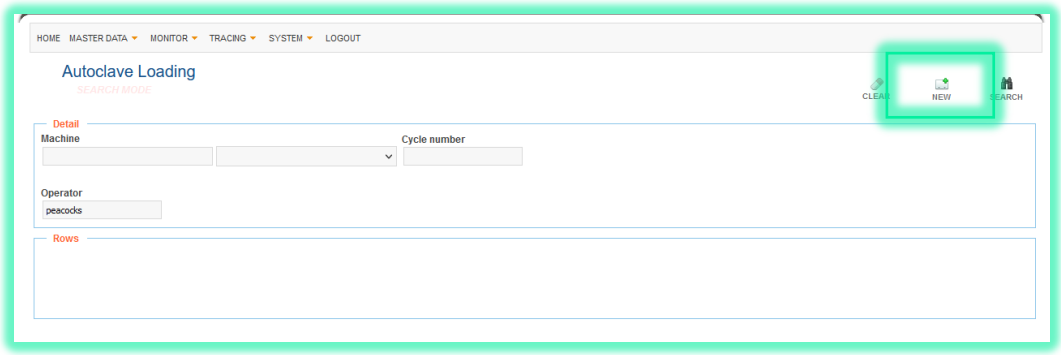


- Remove the large, printed label and affix to the top of the waste located in the rack.

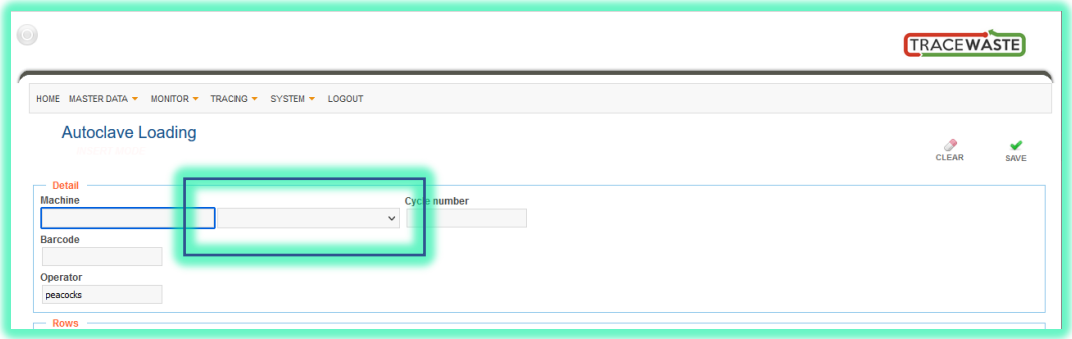
Waste Treatment

- From the main page locate the “TRACING” tab and click on the “Autoclave Loading” menu.

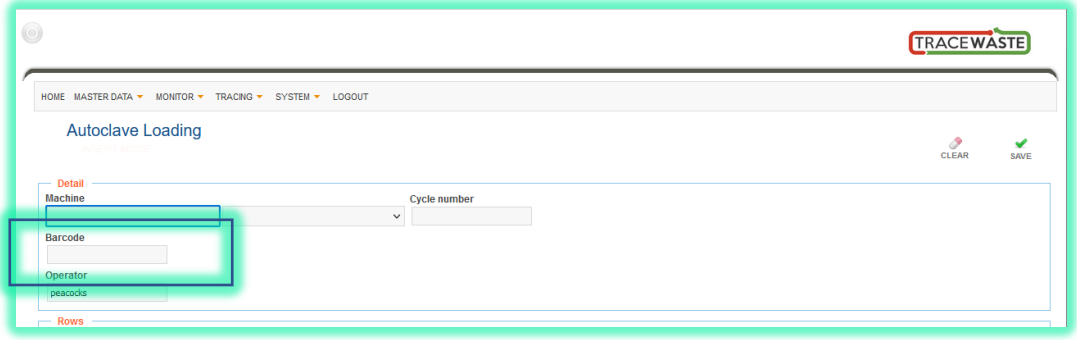
- Click on the NEW icon on the top right of the screen.



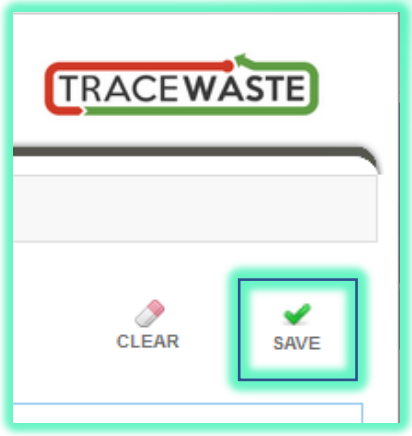
- Select the autoclave that is to be loaded with waste.



- Click the barcode box and using the barcode reader, scan the barcode on top of the waste.



- Press Save on the top right of the screen

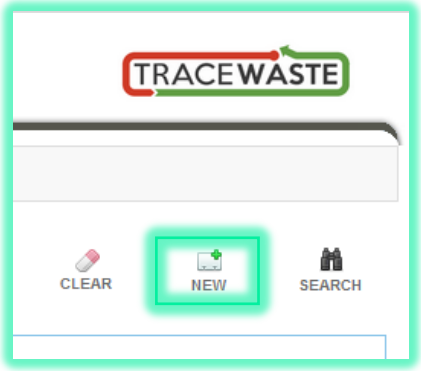


- Repeat above if a second load rack is used
- Load the steriliser with the waste and start the cycle.

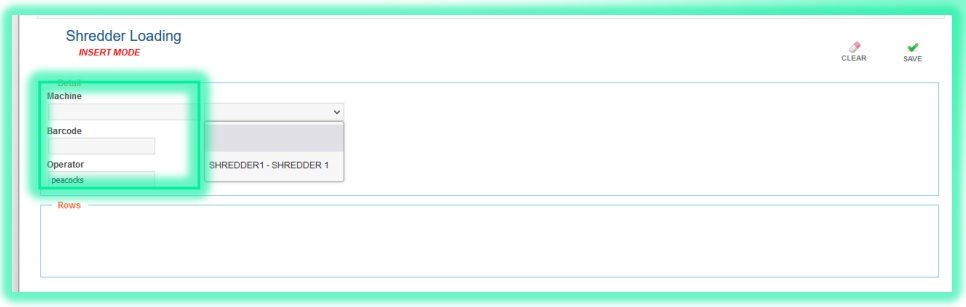
Waste Destruction

- Once the waste has been removed from the autoclave goto the main page locate the “TRACING” tab and click on the “Shredder Loading” menu.

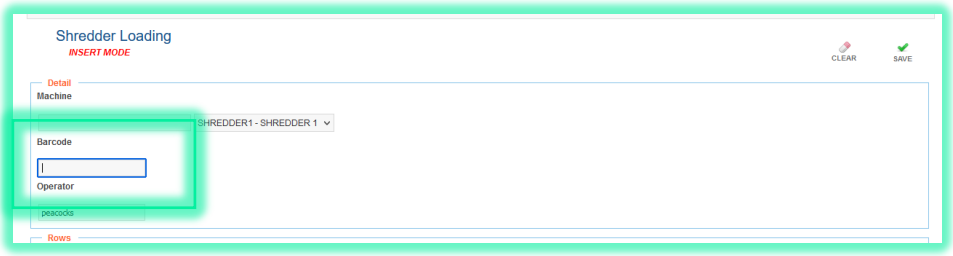
- On the shredder loading page select the “New” Icon to the top right of the screen



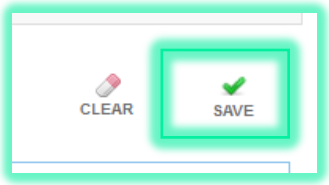
- Select the shredder to be used.



- Click on the barcode box then using the barcode scanner, scan the barcode on top of the waste.



- Click on the Save Button in the top right of the screen.



- Load the waste into the shredder and start the shredder.

Steriliser

Loading Carriages

Manual Loading

TBC – waiting on real loads

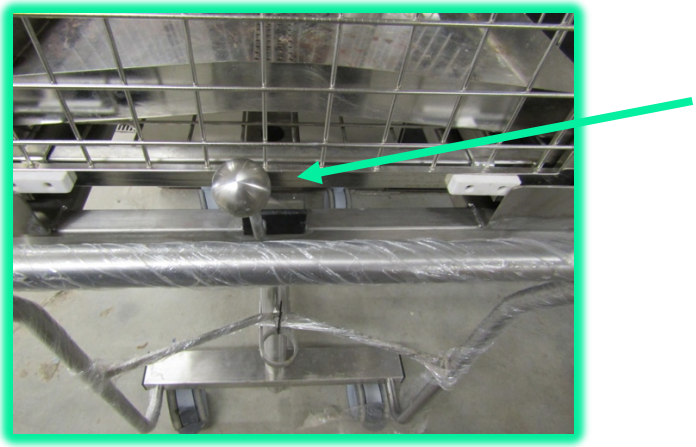
Automated Loading

TBC – waiting on real loads

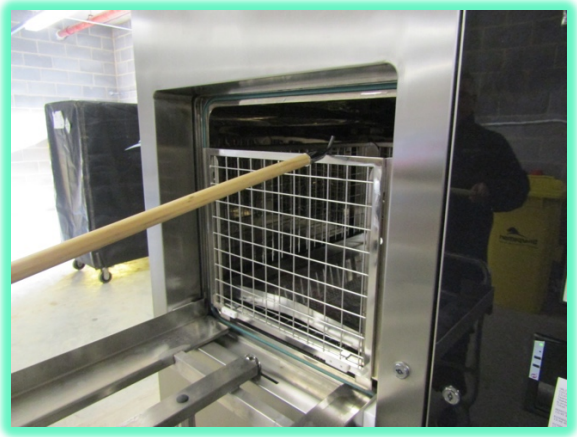
Loading Carriage into Steriliser

- Open the loading door to the steriliser by pressing the “Open Door” icon on the display.
- Align the trolley to the front of the steriliser.

- Lock the rear wheels of the trolley
- Engage the trolley lock located to the rear of the trolley, ensuring that it securely locks onto the machine.



- Using either heat protective gloves or the pushing rod, push the rack towards the steriliser until fully inserted into the chamber.



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Starting a Cycle

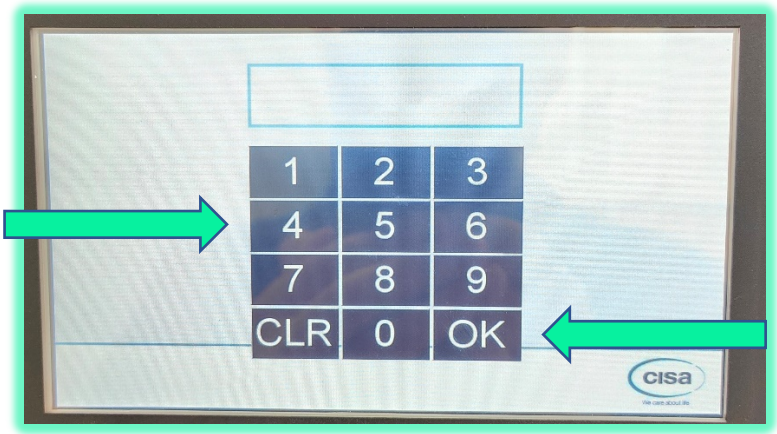
- Close door by pressing the “CLOSE DOOR” icon on the display, and the red up button at the same time (Ensure the rack is fully inserted into the chamber)

- On the display select “START CYCLE”

- Select the cycle type to be run, this should always be “Waste 138°C”, the icon will highlight in blue if successful.

- Press “OK” To Progress to the next screen.

- Enter your operator code using the keypad on the display then confirm by pressing “OK”.



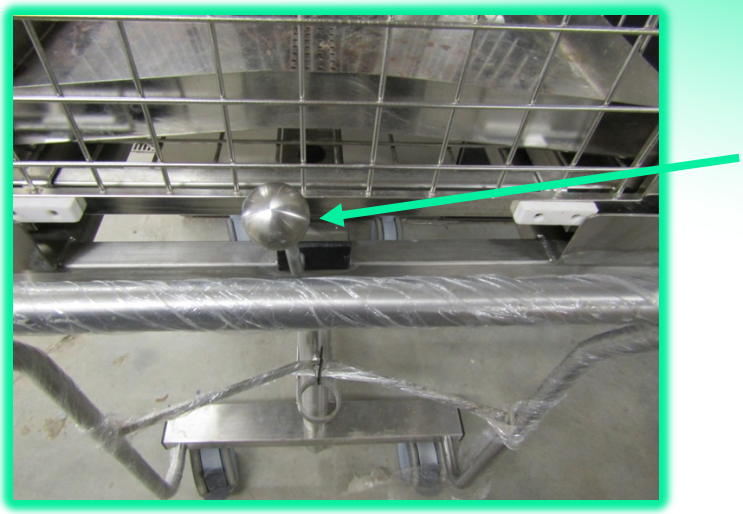
- Confirm the selected cycle is the correct one, and press “YES” on the display to confirm. The cycle will now start.

Unloading Carriage from Steriliser

- Once the cycle has finished and the door is open, take care not to touch the Carriage without Heat Proof Gloves.

- Align the trolley to the front of the steriliser

- Lock the rear wheels of the trolley
- Engage the trolley lock located to the rear of the trolley, ensuring that it securely locks onto the machine.



- Using the rack removal tool, pull the rack towards the trolley until fully loaded on the top of the trolley.

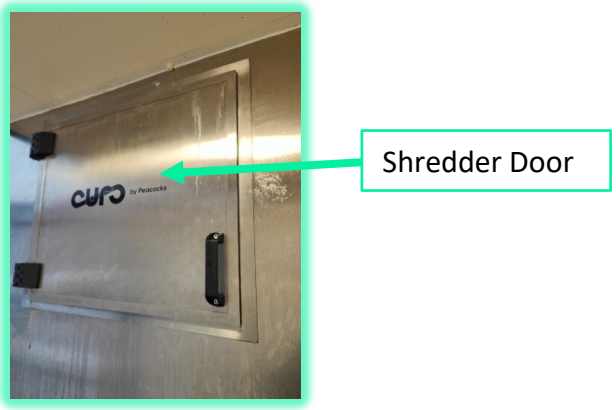
- Unlock the trolley from the machine.
- Disengage the brakes on the trolley and move the trolley away using the handle to the rear of the trolley.

Shredder

Loading the Shredder

1. Ensure that the shredder is in standby before continuing

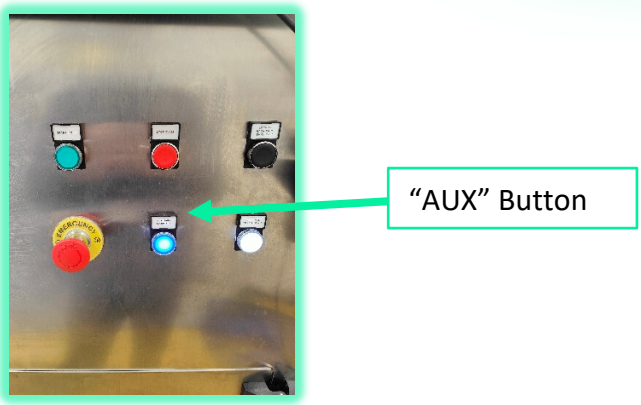
2. Open the shredder hopper door.



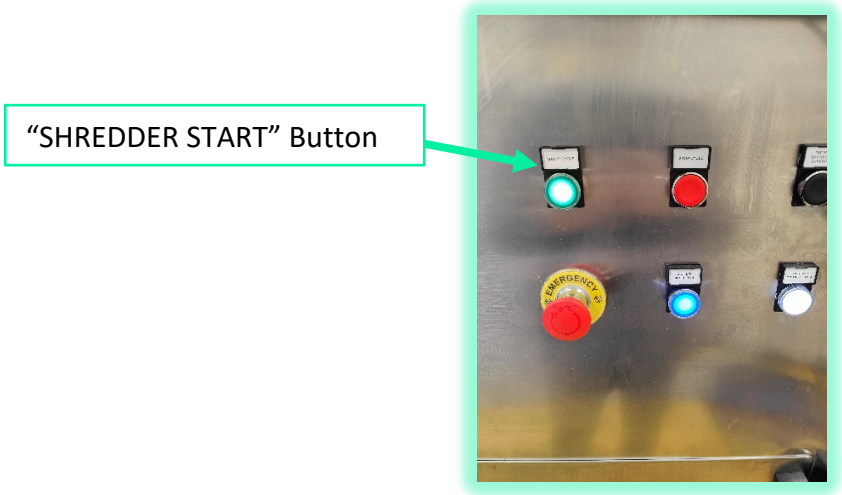
3. Wearing hand protection (gauntlets) or a grabber, carefully load the hopper with the waste bags and securely close the door.

Operating the Shredder

1. On the shredder control panel press the “AUX” Blue button (This should illuminate if all doors are closed, and the stop button is not engaged).



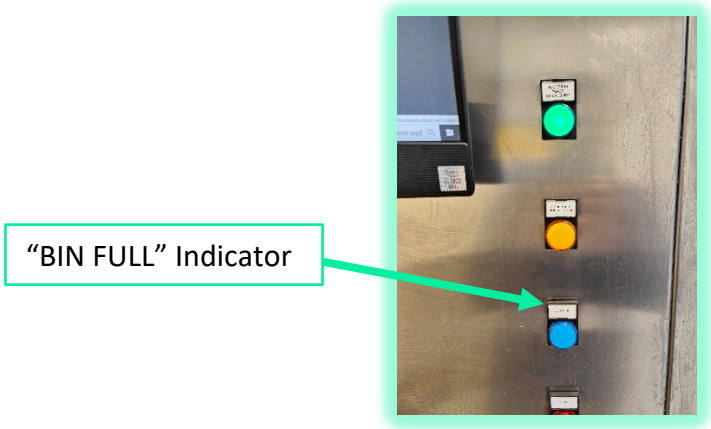
2. Press the “SHREDDER START” button. (Shredder will run for about 2 Mins)



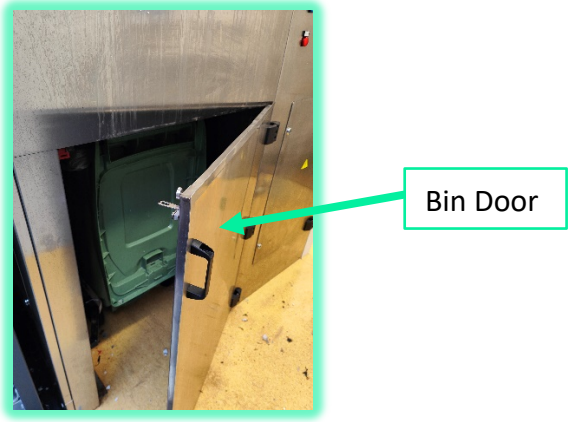
3. The shredder will automatically stop after 5 minutes. (If shredder continues press the stop button)

Unloading the Shredder Bin

1. When the “BIN FULL” indicator is illuminated, it is then time to unload the bin



2. Ensure that the shredder is not operational.
3. Press the emergency stop button in.
4. Open the bin door. (if the door does not release then the unit is possibly still running)



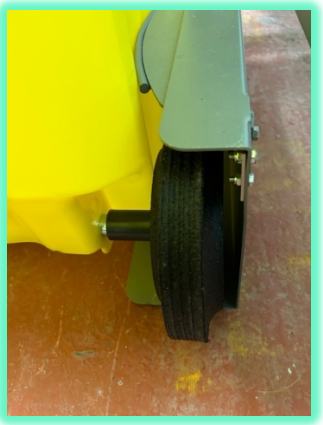
5. Remove the bin from the shredder and remove the bag.
6. Tie the top of bag and insert new empty bag into the bin.
7. Replace bin back into the shredder bin storage and close the door.

Bin Tipping Station

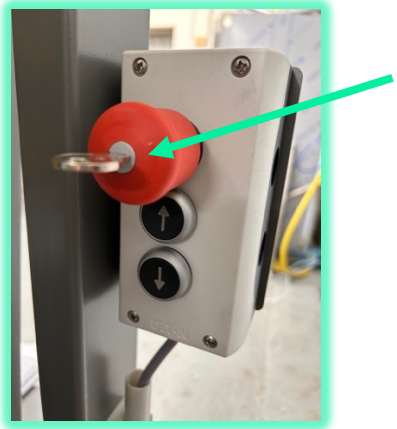
Operation

1. Observe the manufacturers Operating Manual
2. Release the parking brakes on the two swivel castors.

3. Take hold of the waste bin tipping station by the handles and move it to the place of use.
4. Apply both parking brakes on the swivel castors.
5. Push the waste bin between the two swivel castors into the entry shaft of the swivel Device.



6. Insert the key in the emergency stop key switch and turn it.



7. Press the up button to raise the tipping device with the waste bin until it is clear of the ground.

8. Release the locks on the two swivel castors.
9. Move the waste bin tipping station to the emptying point.
10. Apply both parking brakes on the swivel castors
11. Press the UP button to raise the tipper until the waste has ejected from the bin.

12. Press the DOWN button to move the tipper device back to the starting position.
13. Remove the bin from the tipper shaft.

Parking

1. Release the parking brakes on the two swivel castors.
2. Take hold of the handles on the bin tipping station and push to the bin tipping parking space.
3. Apply both parking brakes of the swivel castors.
4. Press the stop button on the device and remove the key.

Weighing Scales

Weight Scale Settings

Buttons on the TLB4 Weight Transmitter

	To Enter a menu/Confirm the data entry.
	To modify the displayed value of menu item.
	To select a new value or modify the displayed menu item
	To cancel and return to the previous menu

Accessing the parameters settings menu

- From the Weight display, Press Simultaneously Keys

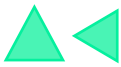
- The Display should be displaying “CALIb”.

Setting units of Measure

- From the Parameters settings menu Press 
- The Display should Read “FS-tEO”
- Press the  until the display Reads “unit” then press 
- Press the  Buttons until the display reads “Hi LOG” then press 
- This will set the unit of Measurement to Kilograms

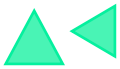
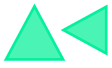
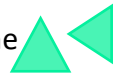
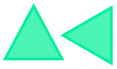
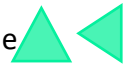
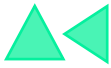
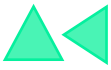
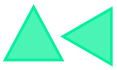
Weight Scale Calibration

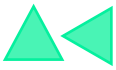
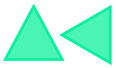
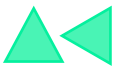
- From the Weight display, Press Simultaneously Keys

- The Display should be displaying “CALIb”.
- From the Parameters settings menu press 
- The Display should Read “FS-tEO”
- Press the  until the display Reads “weight” then press 
- The current weight will now be displayed
- Place the weights (70kg) onto the load platform.
- Check that the display reads the same as the weight on the load platform.
- To adjust the value to match the calibration weight Press the  until the display is reading the correct value.
- Press the Enter Button  to confirm the new value.
- Remove the weights so that there is on 35kg’s left on the platform and check that this is correct.
- Press the X Button repeatedly until the weight is now displayed in the working display.

Weight Scale Transmitter Communication Settings

IP Address – 192.168.77.41
Subnet – 255.255.255.0
Gateway – 192.168.77.24

- From the Weight display, Press Simultaneously Keys 
- The Display should be displaying “CALIb”.
- Press the  until the display Reads “EtHnET” then press 
- The Display should be displaying “IPAddr”.
- Press  then enter the first 3 digits of the IP Address using the  Buttons.
- Press  then enter the second 3 digits of the IP Address using the  Buttons.
- Press  then enter the Third 3 digits of the IP Address using the  Buttons.
- Press  then enter the Fourth 3 digits of the IP Address using the  Buttons.
- Press  then 
- The Display should be displaying “IPAddr”.
- Press the  until the display Reads “SUbnET”
- Press  then enter the first 3 digits of the Subnet Address using the  Buttons.
- Press  then enter the Second 3 digits of the Subnet Address using the  Buttons.
- Press  then enter the Third 3 digits of the Subnet Address using the  Buttons.
- Press  then enter the fourth 3 digits of the IP Address using the  Buttons.
- Press  then 
- The Display should be displaying “SUbnET”.
- Press the  until the display Reads “GATUAY”

- Press  then enter the first 3 digits of the gateway Address using the  Buttons.
- Press  then enter the Second 3 digits of the Gateway Address using the  Buttons.
- Press  then enter the Third 3 digits of the Gateway Address using the  Buttons.
- Press  then enter the fourth 3 digits of the Gateway Address using the  Buttons.
- Press  then 
- The Display should be displaying “SUbnET”.
- Press the  until the display Reads “NODE” then press 
- The Display should be displaying “nOnE”.
- Press the  until the display Reads “ASCII” then press 
- Press the  until the display Reads “NOdU60” then press 
- Press the  until the display Reads “100” then press 
- Press  Repeatedly until the display returns to the operating screen.

Housekeeping

Tracewaste

Steriliser

Shredder

Plant Area

Consumables

Steriliser

- Printer Paper (Autoclave) – Part No. 0334709
- Printer Ink Ribbon – Part No. 0333247
- Deodoriser Pearls – Part No. Deodoriser pearl DE0D1

Water Softener

- Salt Tablets

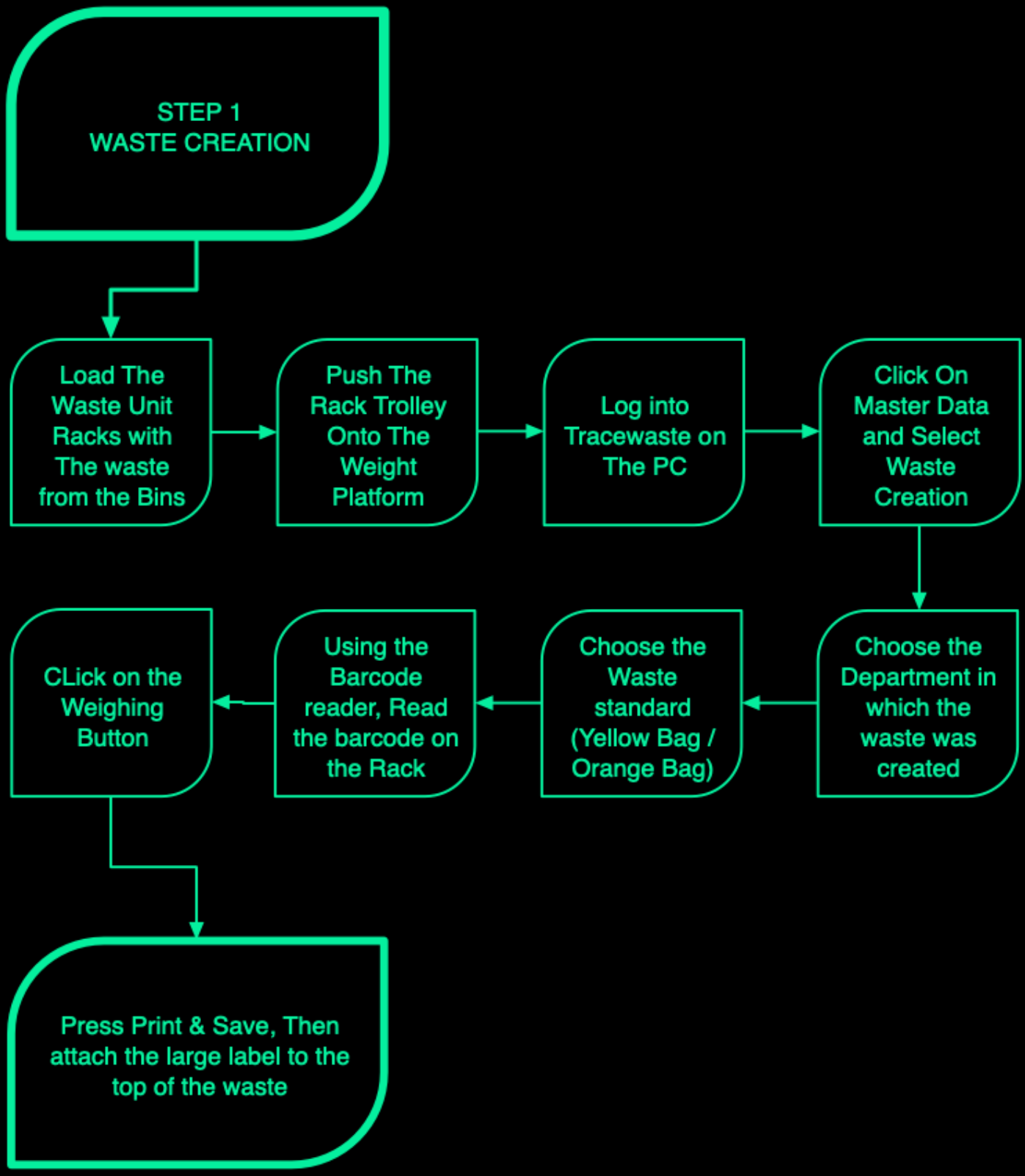
Label Printer

- Label Printer Ink Ribbon GK420T – Part No. 0347203
- Labels for Printer – Part No. 0346659

Process Flow Charts

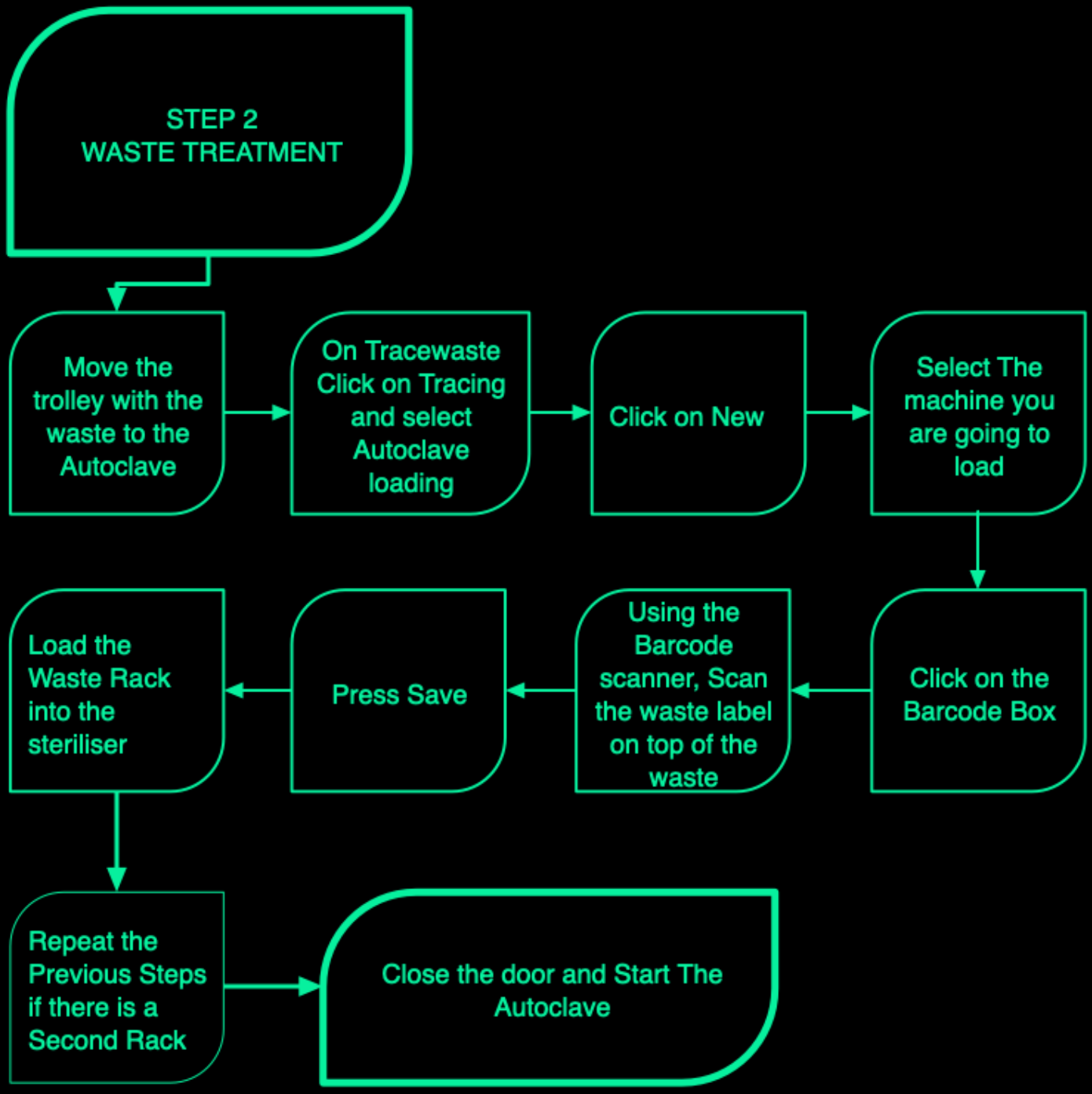
curo
By Peacocks

WASTE CREATION



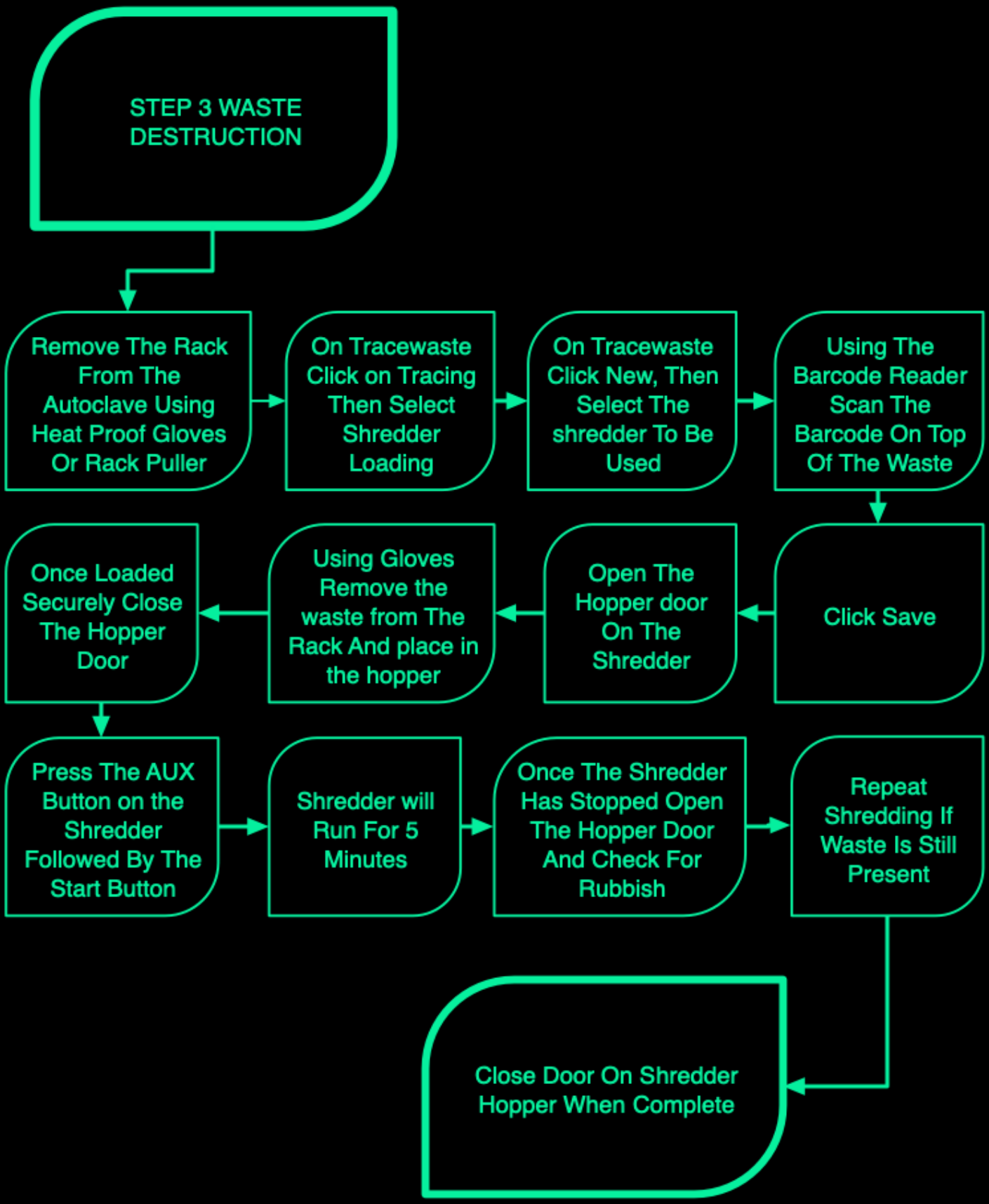
curo
By Peacocks

WASTE TREATMENT



curo
By Peacocks

WASTE DESTRUCTION



Appendix G – Process Flow Chart

WSD

PROCESS FLOW CHART

START

OPERATING THEATRE

TEMPORARY WASTE STORAGE

1 step

BATCH IDENTIFICATION

The scale is connected to the Tracecare® system. Once the container has been weighed, Tracecare® automatically prints the label with:

- BATCH IDENTIFIER (LABEL) + WEIGHING IF AVAILABLE
- DEPARTMENT
- WASTE TYPE (e.g. Italian UNI 10384, 4.1.2)

WSD Tracecare®
Tracecare® Printer and
Tracecare® Barcode reader

TRACECARE

With Tracecare® it is possible to trace the flow of the waste (for example, to trace the operator and the logistic time from the OT or from the temporary storage to WSD).

1step

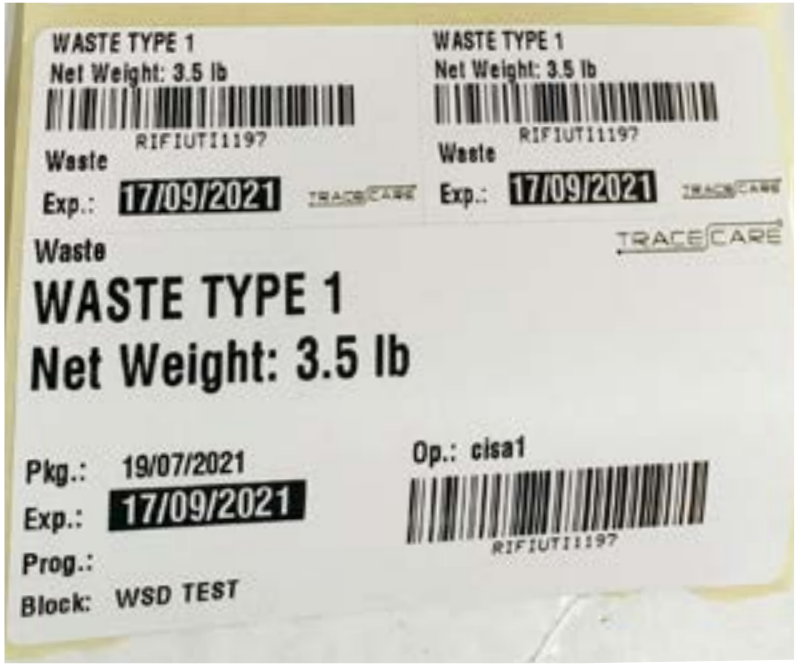
WEIGHING

- BATCH IDENTIFIER (LABEL)
- DEPARTMENT
- WASTE TYPE*
- (e.g. Italian UNI 10384, 4.1.2)

*WASTE TYPE
(e.g Italian UNI 10384 Table 4.1.2.):

0 = Liquids
1 = Solids
2 = Glasses
3 = Unsorted

TRACECARE® LABEL



APPLICATION ON OUSIDE SURFACE OF THE PLASTIC CONTAINER

LABEL TO BE APPLIED ON THE BAG

LABEL FOR USE BY THE FACILITY

Barcode reader gun for traceability:
- waste
- Container
- Operator
- Check point / location

2step

LOT ACCEPTANCE
IN THE WSD

cisa
We care about life

SOFTWARE TRACECARE®

The label outside the container is used to track all logistics activities

The label on the autoclavable bag is used to track the load/unload of the autoclave and the load of the shredder with a pre-defined and non-modifiable sequence

Tracecare® Barcode reader

Tracecare® Station

3step

WASTE TREATMENT
PROCESS

cisa
We care about life

3A

PATH A
TYPE 0

containers with high quantity of residual liquids
e.g. dialysis filter bags

BAGS FULL

3B

PATH B
TYPE 1,2,3

Mixed bags with a low percentage of liquid.
e.g. residual liquid in vials and syringes

AUTOCLAVABLE PLASTIC BAGS

3step

WASTE TREATMENT
PROCESS

3A
LIQUIDS CYCLE
BAGS FULL

WSD Autoclave
Solid/Liquids cycle

Bag emptier
machine

SHREDDED EMPTY BAGS

LIQUIDS

The shredders can be more than one and / or with dedicated shredder to the relative type of waste.

WSD Shredder

DISPOSAL UNSORTED MUNICIPAL WASTE

WATERS REFLUE

FINISH

3step

WASTE TREATMENT
PROCESS

cisa
We care about life

3B
SOLIDS CYCLE AUTOCLAVABLE

PLASTIC BAGS

WSD Shredder

WSD Autoclave
Solid/Liquids cycle

The shredders can be more than one and / or with dedicated shredder to the relative type of waste.

DISPOSAL
UNSORTED
MUNICIPAL WASTE

FINISH

4step

PATH container

CONTAINER TRACEABILITY

Full traceability of each container using a different plastic label

n.|||||||

4A

4B

Washing Tunnel

4 Container Washer

OPERATING THEATRE

TEMPORARY WASTE STORAGE

H

FINISH

Appendix H – Autoclave Monitoring Plan

Waste & Environmental Solutions

Albion Environmental

NHS Northumbria
Northumbria Specialist Emergency Care Hospital, Northumbria Way, Cramlington, NE23 6NZ

Autoclave Monitoring Plan
August 2023

PREPARED BY	**Stella Consonni (Senior Consultant)**	**DATE**	**01.06.2023**
REVIEWED BY	**Jane Bond (Project & Business Development Director)**	**DATE**	**01.08.2023**
SIGNATURES			
VERSION No.	1.0		

Albion Environmental Limited
Albion House,
1 Damside,
Ayr, KA8 8ER
Scotland, UK
www.albion-environmental.co.uk
T: 01292 610 428
E: info@albion-environmental.co.uk
Registered in Scotland No. SC254498. VAT Registration No. 806 4312 55.

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3.0 PROPOSED ROUTINE MONITORING 3

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3.2 Monthly Monitoring Tasks 3

3.3 Quarterly Tasks (after first 6 months) 3

3.4 Six Monthly Monitoring Tasks 4

3.5 Annual Monitoring Tasks 4

4.0 LABORATORY SPORE INACTIVATION QUALIFICATION 5

5.0 TREATMENT PROCESS EFFICACY 5

1.0 INTRODUCTION

1.1 Overview

As part of the EA Bespoke Permit application, this Plan includes details on the proposed monitoring of ambient air and surfaces for bio-aerosols, treatment efficacy and HEPA filters regarding the use of the on-site CISA WSD200 steriliser supplied by Curo/Peacocks Medical Group Limited.

2.0 PROPOSED MONITORING PLAN

An autoclave monitoring plan is part of the service package provided by Peacocks. This proposed Autoclave Monitoring Plan details the emissions monitoring frequency and parameters schedule that is proposed to be carried out on the Autoclave, in accordance with relevant guidelines. Additional monitoring will be conducted if issues are identified during servicing and or maintenance, and or if required by the EA.

Monitoring frequency of bioaerosol emissions will be conducted for the first six months according to the EPR 5.07 guidelines and the EA Health Technical Memorandum 07-01 – Safe Management of Healthcare Waste. Subsequently, rather than carry out tests for other devices every four years (as per EPR 5.07), the supplier will carry out those tests annually to ensure autoclave's efficiency.

3.0 PROPOSED ROUTINE MONITORING

This list provides the proposed routine monitoring of emissions and treatment efficacy that will be carried out by the supplier/ Peacocks and or designated trained staff in order to prevent air emissions, leaks, parts functioning and ensure efficiency of the sterilization and shredder processes. It includes monitoring of HEPA filters.

3.1 Weekly Monitoring Tasks

- Vent moisture from compressor
- Check softener salt levels and top up if required

3.2 Monthly Monitoring Tasks

- Check door seals on autoclave
- Check for leaks
- Change discharge HEPA filter
- 3x spore strips tests (every quarter after first 6 months)
- 3x biological indicators tests (every quarter after first 6 months)
- 1x thermometric test (every quarter after first 6 months)
- Record results and control biological indicator in software package provided on PC.
- Export waste processed figures for compliance to ERIC reporting

3.3 Quarterly Tasks (after first 6 months)

- 3x spore strips tests

- 3x biological indicators tests
- 1 x thermometric test

3.4 Six Monthly Monitoring Tasks

- Change discharge HEPA filter
- Change service parts
- Change vacuum filter
- 3x spore strips tests
- 3x biological indicators tests
- 1 x thermometric test
- Record results and control biological indicator in software package provided on PC.
- Carry out thermometric monitoring test at the same time as biological test
- Provide report for results

3.5 Annual Monitoring Tasks

- Check door seals on autoclave
- Check for leaks
- Clean area
- Clean out shredder
- Mop floors and surfaces with disinfectant
- Change discharge HEPA filter
- Change service parts
- Change vacuum filter
- Run 3 cycles with 3 biological indicators (spent consumables in load) as part of the revalidation
- Record results and control biological indicator in software package provided on PC.
- Carry out revalidation (repeat of initial commissioning with spore strips)
- Provide report for results
- Perform maintenance on PC database and complete full backup of data

4.0 LABORATORY SPORE INACTIVATION QUALIFICATION

Once allowed by the EA, as part of the commissioning plan, a spore inactivation qualification using the CISA WSD200 sterilizer will be carried out assuming a worst-case challenge load of relevant clinical wastes, as per EPR 5.07 guidelines Annex 1. The procedure, cycles and parameters analysed will be described in the Laboratory Spore Inactivation Analysis report. The results in both documents will aim to demonstrate that the sterilizer achieved the ISTAATT Level III treatment standards.

5.0 TREATMENT PROCESS EFFICACY

The Autoclave Commissioning-Validation Plan and Validation Reports-Lab Results will aim to demonstrate that the autoclave treatment process will meet ISTAATT Level III treatment standards and that all waste will be rendered safe, as required by the EPR 5.07 guidelines.

Appendix I – Start up and Shut Down Plan

Waste & Environmental Solutions

Albion Environmental

NHS Northumbria
Northumbria Specialist Emergency Care Hospital
Northumbria Way, Cramlington, NE23 6NZ

Start Up and Shut Down Plan

August 2023

PREPARED BY	**Stella Consonni (Senior Consultant)**	**DATE**	**01.06.2023**
REVIEWED BY	**Jane Bond (Project & Business Development Director)**	**DATE**	**01.08.2023**
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Albion Environmental Limited

Albion House,
1 Damside,
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www.albion-environmental.co.uk
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3.2 Weekly Tasks 4

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3.4 Six monthly Tasks 5

3.5 Annual Tasks 6

1.0 INTRODUCTION

1.1 Overview

As part of the Bespoke Permit application on behalf of the NHS, this Plan sets out the steps to be taken before start-up or shut down of the on-site CISA WSD200 steriliser supplied by Peacocks Medical Group Limited. It includes preventative measures to prevent environmental harm.

2.0 START UP AND SHUT DOWN PROCEDURES

2.1 Start Up Procedure

Start Up procedure occurs as follows:

1. Turn on water supply (external isolation)
2. Turn on power supply (external isolator)
3. Turn on power supply (internal isolator)
4. Press power switch on load side of autoclave

Unit will start to heat up to working temperature, this will take up to 1 hour to complete.

2.2 Shut Down Procedure

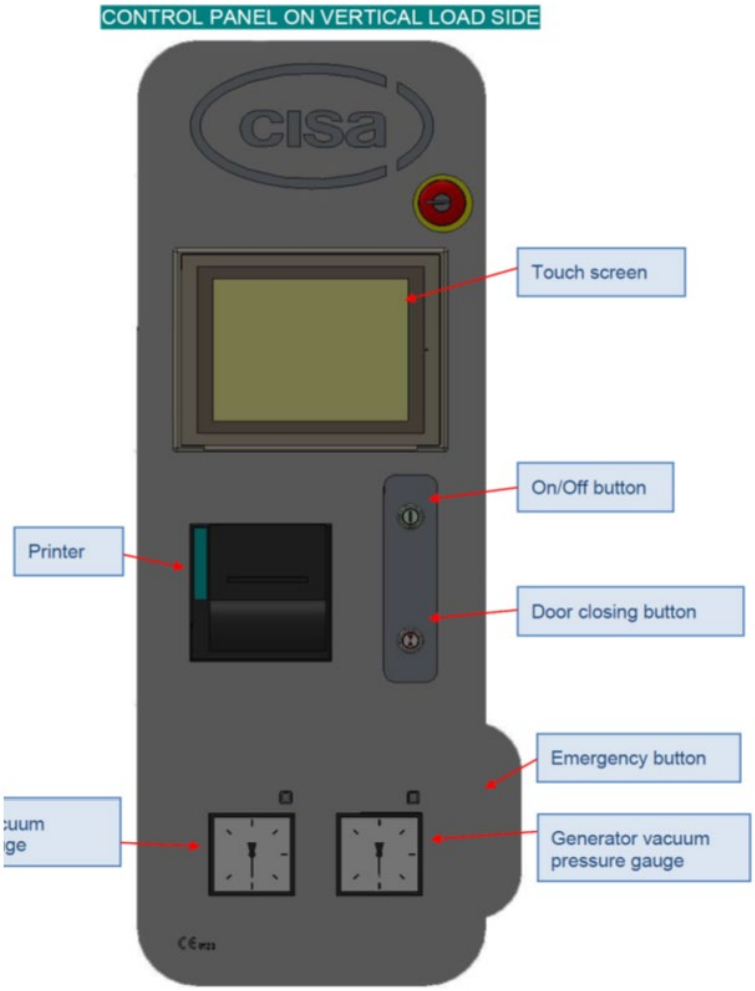
Start Up procedure occurs as follows:

1. Press power switch onload side of autoclave
2. Turn off power supply (internal isolation)
3. Turn off power supply (external isolation)
4. Turn off water supply (external isolation)

The unit is now isolated and shut down. It will take 2-3 hours to cool down.

All water from the jacket and chamber will be held inside the chamber and only discharged once the unit is started up again after reaching working temperature.

Control panel schematic is below.



3.0 PREVENTATIVE AND MAINTENANCE MEASURES

Preventative measures in order to prevent environmental harm will include daily, weekly, 6 monthly and annual tasks/ actions regarding maintenance and monitoring efficiency of the autoclave. These are as follows:

3.1 Daily Tasks

1. Check door seals on autoclave
2. Check for leaks
3. Clean area
4. Clean out shredder
5. Mop floors and surfaces with disinfectant

3.2 Weekly Tasks

1. Check door seals on autoclave

2. Check for leaks
3. Clean area
4. Clean out shredder
5. Mop floors and surfaces with disinfectant
6. Vent moisture from compressor
7. Check softener salt levels and top up if required

3.3 Monthly Tasks

1. Check door seals on autoclave
2. Check for leaks
3. Clean area
4. Clean out shredder
5. Mop floors and surfaces with disinfectant
6. Change discharge HEPA filter
7. Run 1 cycle with 3 biological indicators (spent filter in load)
8. Record results and control biological indicator in software package provided on PC.
9. Export waste processed figures for compliance to ERIC reporting

3.4 Six monthly Tasks

1. Check door seals on autoclave
2. Check for leaks
3. Clean area
4. Clean out shredder
5. Mop floors and surfaces with disinfectant
6. Change discharge HEPA filter
7. Change service parts
8. Change vacuum filter
9. Run 1 cycle with 3 biological indicators (spent filter in load)

10. Record results and control biological indicator in software package provided on PC.
11. Carry out thermometric monitoring test at the same time as biological test
12. Provide report for results

3.5 Annual Tasks

1. Check door seals on autoclave
2. Check for leaks
3. Clean area
4. Clean out shredder
5. Mop floors and surfaces with disinfectant
6. Change discharge HEPA filter
7. Change service parts
8. Change vacuum filter
9. Run 3 cycles with 3 biological indicators (spent consumables in load) as part of the revalidation
10. Record results and control biological indicator in software package provided on PC.
11. Carry out revalidation (repeat of initial commissioning with spore strips)
12. Provide report for results
13. Perform maintenance on PC database and complete full backup of data

Doc Ref_Site Management Plan appendices include specification details of the steriliser.

Appendix J – Morclean Bin Wash Guide

BIN WASH GUIDE & OPERATING INSTRUCTIONS

Bin Wash AUTO LITE Series V1 *(electrically operated, single head)*

AUTO LITE

Morclean Ltd. Speedwell Ind Est, Staveley, Chesterfield. S43 3JN

T| (01246) 471147

E| info@morclean.com

MORCLEAN
Let's Innovate

AUTO
LITE

Please read this entire manual before using this machine. The Morclean AUTO LITE Bin Wash machine is designed to clean empty bins that have previously had debris or litter removed from them.

The device is intended to clean the residue that the debris has left behind after fully emptying. After regular washing on a fixed term contract or round, typically 2-4 weeks, the bins should only contain smaller levels of residue resulting from the general dirtiness of the bin during that period.

When washing a bin for the first time, or after a long period of time the bin should be first scraped out, emptied, and the contents bagged up and disposed of, as per the Hints and Tips in the section of this manual. The machine and its filtration system is not designed to collect litter and debris, or to empty partially full bins into.

This machine produces high-pressure water that can be dangerous if misused. Never directthe nozzle or lance towards any part of the body or face.

We recommend use of protective clothing (PPE) including but not limited to water proof jackets, ear defenders, gloves, glasses and/or goggles when operating this machinery. You should carry out your own risk assessment and take professional advice in regards to PPE and/or health and safety of the operator or passers by

This machine must be stationary while in use, never run this machine with any covers removed or open, always close and fasten the catchment tray and lift mechanism etc at all times.

Please refer to the safety instruction in the later Section

THANK YOU

Thank you for purchasing a Morclean AUTO LITE bin wash Machine. In addition to any training you have received, this guide will provide you with instructions of how to set up and operate the machine.

This bin wash guide and operator's manual can be used for all LITE models including:

AUTO	LITE
AUTO	LITE V1

Bin Wash AUTO LITE Series V1. Specific images for the V1 series may vary

STOP!

Please read this manual carefully, if you have any questions or doubts then you can call Morclean

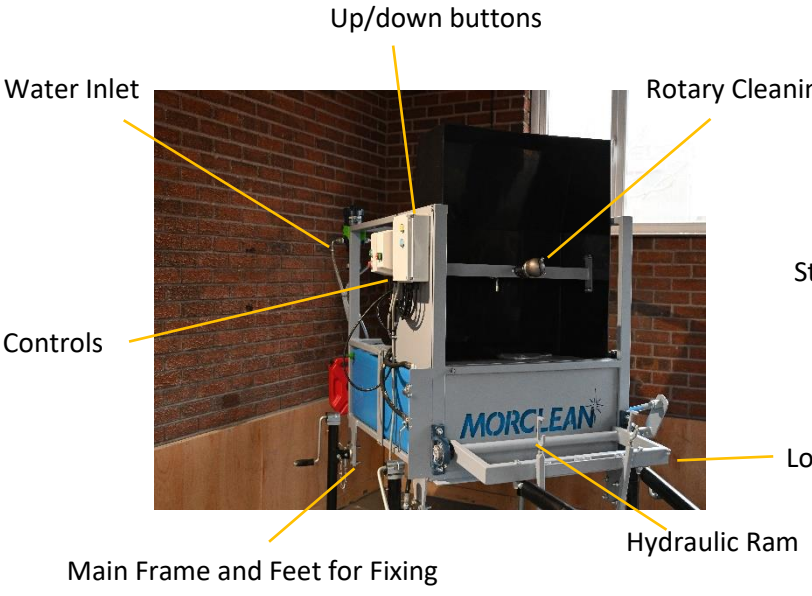
(01246) 471147

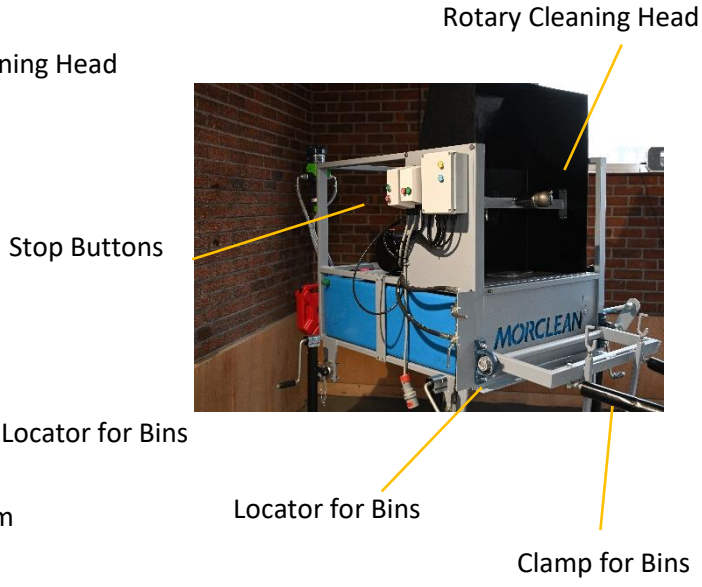
Or email info@morclean.com

Do not use this machine unless you are trained and familiar with the equipment, and have read these instructions in full

THE MACHINE

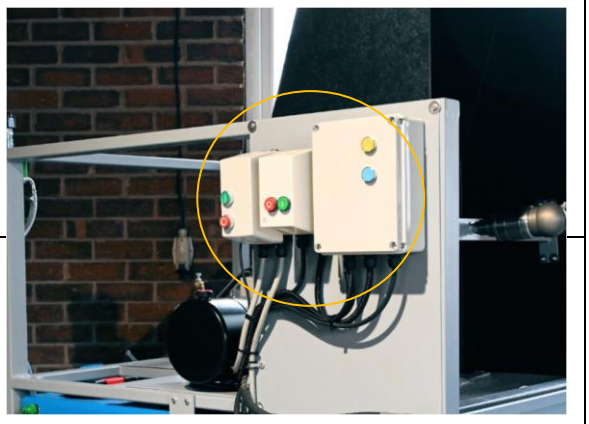
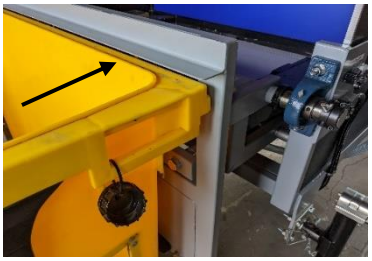

Control Panel
Anti-splash hood
Rotary Cleaning Head
Dosing System
Catchment Tray & Filters
Chemical Dispenser
Lift Mechanism
Locator for Bins
Water Tank

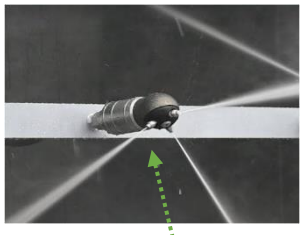

Up/down buttons
Water Inlet
Rotary Cleaning Head
Controls
Locator for Bins
Hydraulic Ram
Main Frame and Feet for Fixing


Rotary Cleaning Head
Stop Buttons
Locator for Bins
Clamp for Bins

QUICK START

Bin Wash AUTO LITE Series V1

Connect to a power supply	
Connect to the water supply	
Turn the hydraulics ON Refer to labels on the machine	
Turn the pump ON Refer to labels on the machine	Main Control Panel
Bring a bin to the lift and line up with the lift mechanism Images for the V1 series machine may vary	

Operate with the clamp when required	
Use the control panel to raise the bin vertically Refer to labels on the machine	
Operate ‘bin up’ Refer to labels on the machine	 
The lift mechanism will raise the bin inwards	
Water ON (rotary jets) and wash the bin (green) **DO NOT OPERATE WITHOUT A BIN IN PLACE** Refer to labels on the machine	 
The rotary head will start, clean the bin as required	 
Operate water OFF (red) to stop the rotary heads after the bin has been cleaned Refer to labels on the machine	 

Operate bin down Refer to labels on the machine	
The bin will rotate outwards	
Lower the bin	
The bin will lower vertically	
Remove the bin from the mechanism, remove the clamp if used Images for the V1 series machine may vary	 

IMPORTANT

Always carry out visual checks of the machine for damage & check all cables, hoses & fittings for general wear. Check all high pressure hoses for damage wear, & visually inspect push buttons & switches.

Water Fresher

The AUTO machine utilises a dosing system to freshen the water. When the cleaning lance or cleaning head is OFF, but the engine and pump is still running, then we call this ‘by-pass’ (because water is bypassing the cleaning devices and recirculating around the system). During this time you can add the water fresher

First, ensure that the dosing container is full and that it contains the freshening product

The dosing system is pre-set but the % can be changed if required

While the machine is in ‘by-pass’ you can open the dosing valve for a few seconds

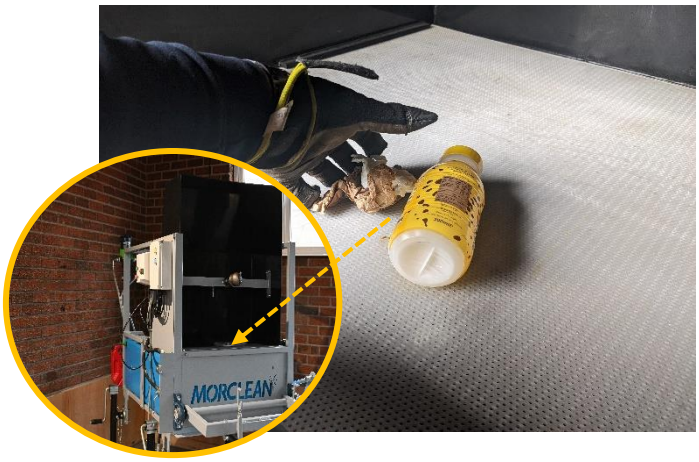
You will see and smell the water fresher, you can introduce the product during the day

Depending on the water quality, we’d normally expect the fresher to be used for 5-10 seconds every 20-40 bins. You can increase or decrease the dosing time

MAINTENANCE GUIDE & OTHER IMPORTANT INFORMATION

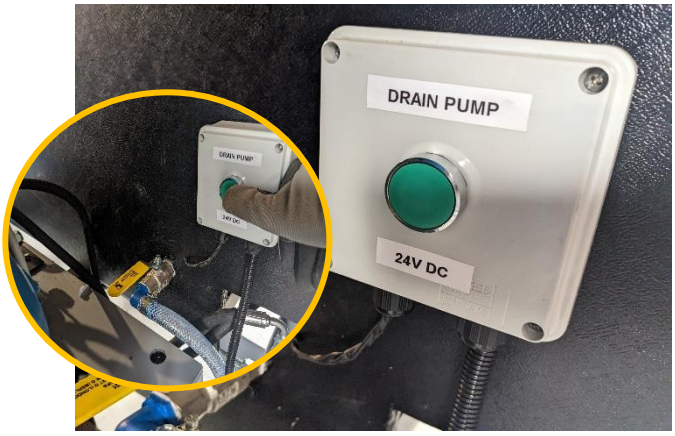
Please read carefully & refer to the separate instructions for individual items (such as the pumps). Ensure the machine is cleaned & checked regularly. Failure to do this can affect performance or void warranty

Always remove debris from the catchment tray during the day and bag up any items. Remove and clean the catchment tray



Empty the main catchment tank using the drain pump (by pressing the button)

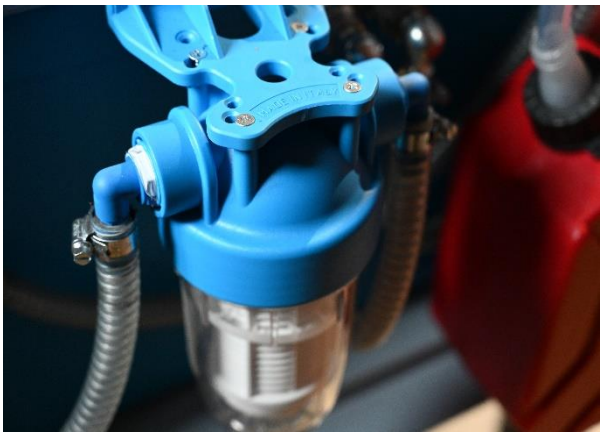
Optional drain pump fitted to some models



Remove the filters, remove any debris and clean under the tap or with a hose pipe.

To be completed after every fill/empty (daily)

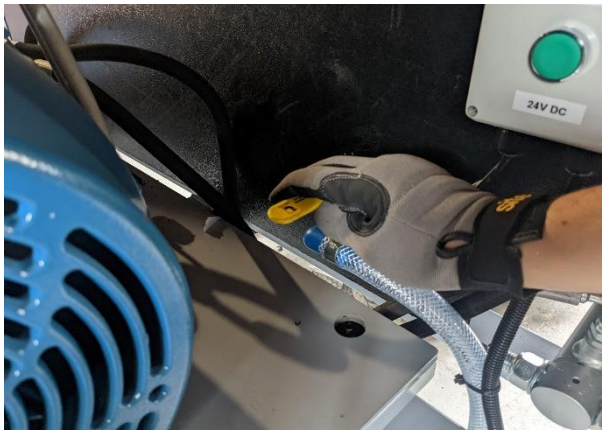
Images for the V1 series machine may vary



DAY TO DAY CLEANING Cont….

The catchment drain can be isolated if required during maintenance

Optional drain pump fitted to some models



The spanner (provided) is used to unscrew and clean the blue filter and clean under the tap or with a hose pipe. Ensure that the seal is inserted and that the filter is tightened so as not to leak water

To be completed after every fill/empty (daily)

Using the drain valve, you can completely empty both water tanks.

Optional drain pump fitted to some models

It is important that you keep ALL the filters clean and refill the main tank with clean water. Failure to do this can affect performance or void your warranty

MAINTENANCE GUIDE – CHECKS & FLUID LEVELS

Always refer to the separate instructions for the specification of lubricants to be used in the engine, hydraulic pump and high pressure pump.

Images for the LITE V1 series may vary

Check the fluid level in the hydraulic pump

Check the fluid level in the high pressure pumps

USING THE HAND LANCE

THE MACHINE CAN BE OPERATED USING THE HAND LANCE.

Never point the lance in the direction of the machine or another person

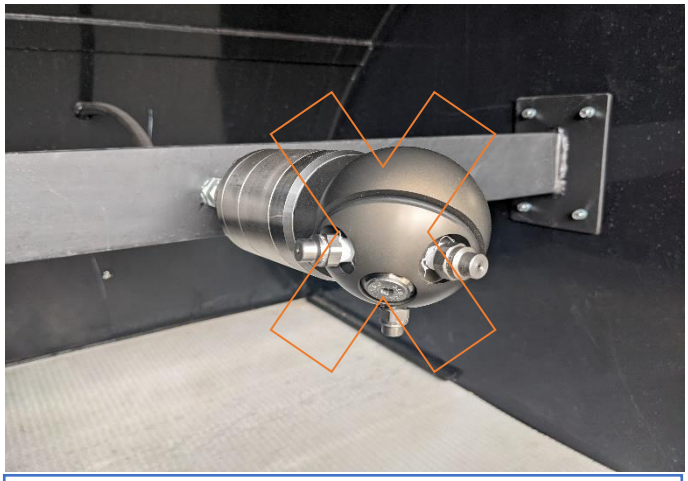
Turn on the high pressure pump Images for the V1 series machine may vary	
Operate the hand lance Optional hand lance fitted to some models only	

MAINTENANCE GUIDE – IMPORTANT INFO

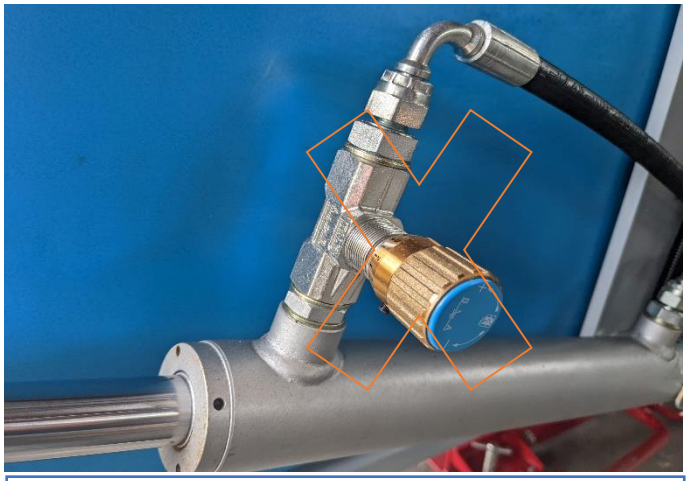
Do not adapt or make changes to the machine, parts, pumps or components. Unauthorised repair can affect performance or void your warranty

Images of the LITE Series V1 may vary

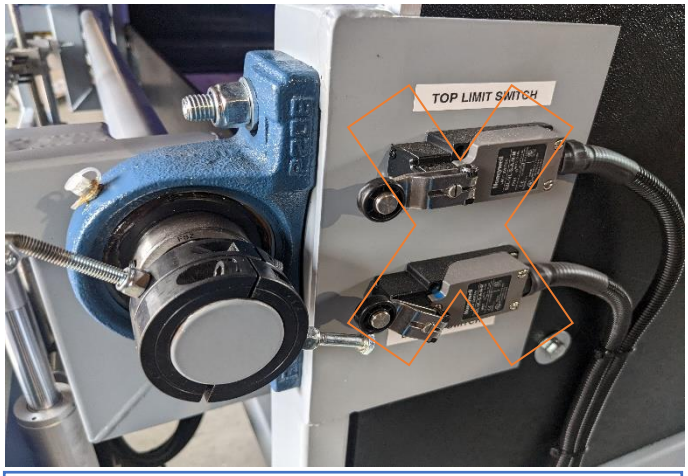
Keep clear of all mechanisms and the lifting device



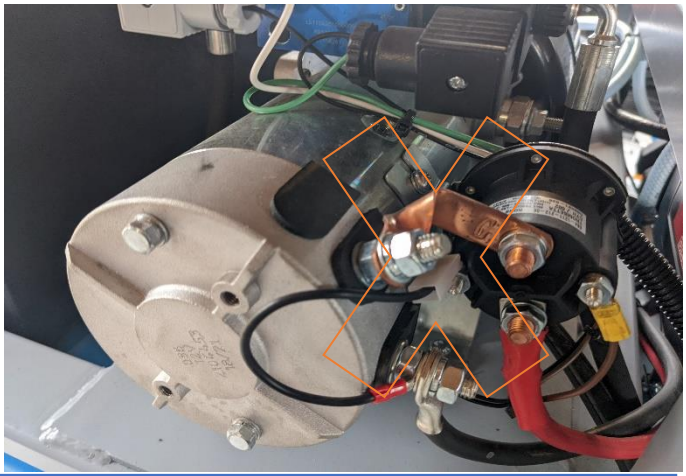
DO NOT tamper with, change or adapt the nozzles



DO NOT change settings or hydraulic valves



DO NOT spray high pressure water onto the switches



DO NOT tamper with cables or components

Always lubricate via the grease nipples

HINTS AND TIPS

IMPORTANT

Always carry out a visual check of the machine for damage and check all cables, hoses and fittings for general wear. Check all high pressure hoses for damage or excess wear, and visually inspect push buttons and switches.

Fill the main tank with clean water via the tank inlet and ensure all filters are clear and free from debris. Check and clean all water filters regularly and stop operating the machine if filters become blocked.

When the machine is not in use switch off as per operator'sinstructions (unless to add fresher)

When washing bins for the first time you may need to pre-scrape and remove heavy debris

Using the main remote switch - elevate the bins until they reach the tip positionand always release the switch when the bin is at the uppermost point.

Operate the lance to wash externally or with an accessory

Once the bin is clean you can spray in additional sanitiser to leave the bins smelling fresh, if you haven't used the water fresher device

Once lowered to the ground the bins can be lifted off the bin mechanism. Always release the switch once the bins are lowered.

Periodically you should clean any debris from the main catchment tray and bag it up to keep the main filter clean from plastic bags or larger debris that willprevent the escape of water.

The water within the tank will be recycled during the day

At the end of the day the main tank should be emptied into a suitable disposal point which is usually a mains foul drain as per the Environment Agencies PPG13 or GPP13 guidelines. Always check with your local water or sewer provider to ensure you are disposing of waste water legally and safely.

GENERAL

To wash the main filters you can connect the pump to a domestic hose pipewater supply using the inlet valve. This means fresh water will be used through the pump. Wash the filters from the front and behind if they are particularly dirty

This process should be carried out each day after use.
You should also clean the filter bowl and you can refill the main tank ready for the next day.

SAFETY

Always think safety for yourself, work colleagues and the public - & put safety first.

Always wear goggles, ear defenders & a face mask when using the machinery.

The machine produces high pressure water which can be dangerous if misused

Never point the lance in the direction of the machine or another person.

Never use the lance during an electrical storm.

Never allow the lance to come into contact with electrical cables.

Always secure the lance or hoses after use

Clear any loose debris from the collection tray regularly

Ensure the collection tray/lid is in its correct position

Always ensure that the bin lift is clear before operating.

Never lift a bin unless it is secured to the lifting device

Service the machine in accordance with recommendations (normally every 4 months).

GENERAL

• Regularly check the oil levels on the gearbox and pump and service in accordance with the manufacturer's recommendations (normally service every 4 months).

• All operators must be trained to use the pressure washer in accordance with the manual.

• All risk assessments should be carried out for each water jetting operation before commencement of works.

• We recommend that all operators should maintain a log book of use of the jetting unit. The information can be relatively simple and completed on a daily basis and of sufficient information to provide useful operating data.

• All maintenance must only be carried out by authorised Morclean repair personnel or Dealers

• The pressure washer must not be used when there is a clear fault or damage to it.

• Do not use the pressure washer while tired or under the influence of alcohol or drugs.

• Always ensure you safely route all hoses to the mains cable to minimise trip hazards and keep them away from the jetting area.

• All cleaning products used must be in accordance with your MSDS sheet (Material Safety Data Sheet).

• Never attempt to start the pump if there is a possibility that there is apparent freezing/frozen water in any part of the system,

• Never start the pump if any filtration devices have been removed.

• You may experience a kick back from the gun. Hold the gun and lance with both hands at all times during cleaning operation.

• The pressure washer must never be run with the covers open, lids removed, or filters taken off

DETERGENTS AND SANITISERS

While most are of low pH values and suitable for use, you should check that any chemicals used with this machine are suitable and will not damage the pump etc.

If in doubt please contact Morclean on (01246) 471147

WARRANTY

Warranty Terms

12 (twelve) months manufacturing parts warranty covering faulty components and materials from date of purchase.

Hose, gun & lance are only covered for initial 7 days.

Warranty does not cover damage caused by frost, fair wear and tear, chemicals, other than those recommended by Morclean, misuse or modification not authorised by Morclean.

Misuse including repairs or modification or any service activity carried out other than by Morclean registered engineers.

Warranty only valid if signed by both the manufacturer (Morclean) or authorized dealer, company stamp dated and all details are complete.

Customer copy must be produced to make a warranty claim

Customer must complete and return dealers copy within 7 days of purchase to ensure warranty cover.

Warranty cover is only applicable if machine is serviced by Morclean or an authorised and approved engineer.

TROUBLESHOOTING

Please refer to the troubleshooting guide for assistance, but if in doubt call Morclean. You should not attempt to carry out repairs or make changes to the machine which may affect the Warranty

Bin lift mechanism will not lift	Check battery power and charge and levels of hydraulic oil.
Bin mechanism will not lower	Check battery power and charge andlevels of hydraulic oil. DO NOT FORCE THE MECHANISM DOWN.
No pressure from lance	Check water tank is full. Check filters and filter bowl is clean (see diagnostic notes below).
Pulsating pressure from lance	Check filters are sealed and water tank is full, or check for debris in lance nozzle.
Uneven pressure for spray pattern	Check for debris in lance nozzle and clean if necessary.

DIAGNOSTIC GUIDE

If the machine has no pressure but the motor is running, you can check a few things first.

Disconnect the main high-pressure hose from the pump with the valve set to "CLEANING LANCE". If water flows from here then you know the pump is operating.

If the machine still does not operate then switch off and disconnect the lance from the trigger. If water flows from here then you know the pump is operating.

If the machine still does not operate when in the "CLEANING LANCE" position then it is likely the LANCE nozzle (tip) is blocked. DO NOT LOOK AT THE NOZZLE FROM THE FRONT TO CHECK.

MORCLEAN
Let's Innovate

Barclay-Phelps

Administration HQ
Hoi Yuen Road, Kwun Tong, Kowloon, Hong Kong
Technical File Centre
196 High Road, London, N22 8HH, United Kingdom

CERTIFICATE & DECLARATION OF CONFORMITY FOR CE MARKING

Company contact details:

Morclean Ltd
Stephenson Road Speedwell Industrial Estate, Staveley, Chesterfield S43 3JN
Registered in England. 04605133
Email. info@morclean.com www.morclean.com

Morclean Ltd. declares under their sole responsibility that their:

Morclean Wheelie Bin Washing Machines listed as the following models and variants
Swift. Custom. Custom Plus. Optima. Custom 40. Custom DAILY. SKID. Static. City. Cargo.
FLITE. AUTO & WR Variant. AUTO LITE. Custom TLX

comply with the Essential Requirements of the following EU Directives:
Machinery Directive 2006/42/EC
Low Voltage Directive 2014/35/EU
EMC Directive 2014/30/EU

and further conform with the following EU Harmonized Standards as applicable:
EN 60204-1:2006 + A1:2009
EN ISO 14120:2015
EN 809:1998+A1:2009
EN ISO 4413:2010
EN 61000-6-3:2007+A1:2011
EN 61000-6-1:2007

Dated: 16 August 2018
Position of signatory: Director
Name of Signatory: Peter Morley
Signed below:
on behalf of Morclean Ltd.

AUTO LITE

Appendix K – Validation Plan

1.0 This Agreement is between 20/30 Labs Ltd. (Provider) and Peacocks Medical (Customer):

1.1 Contact Details for 20/30 Labs Ltd. (Provider)

Address: Unit 6 Osyth Close
Brackmills Industrial Estate
Northampton
NN4 7DY

Telephone: 01604 660811
Fax: 01604 877866

E-mail: office@2030lab.com
orders@2030lab.com

1.2 Contact Details for Peacocks Medical (Customer):

Address: Benfield Business Park
Benfield Rd
Newcastle Upon tyne
NE6 4NQ

Telephone: 0191 276 9618
E-mail: Gary.cooper@peacocks.net

1.3 Protocol Approvals

PREPARED BY:	 Joseph Fitzsimons, Research Scientist 20/30 Labs Ltd.	DATE:	17TH OCTOBER 2021
APPROVED BY:	 Sue Stoppel, Head of Quality and Compliance 20/30 Labs Ltd.	DATE:	17TH OCTOBER 2021
APPROVED BY:	 Gary Cooper, Operations Director Peacocks SME LTD.	DATE:	17TH OCTOBER 2021

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2.0 PURPOSE

2.1 The purpose of this protocol is to qualify *CISA WASTE STERILISER P-6412LS* provided by Peacocks Medical; utilising Geobacillus stearothermophilus 10^6 spore strips. Study testing, and procedures are to demonstrate compliance to STAATT III (2005) methodology, while confirming a high degree of process efficacy. This validation will provide documented evidence that these processing procedures deactivate spores to acceptable pre-established international limits. The protocol presents necessary methods for clinical waste processing from the Environment Agency in parallel with the STAATT III and applies these techniques to *CISA WASTE STERILISER P-6412LS* provided by Peacocks Medical.

3.0 SCOPE AND BACKGROUND DESCRIPTION

3.1 This validation applies to the *CISA WASTE STERILISER P-6412LS* in use and being tested at Peacocks Medical Group Ltd, *Benfield Business Park, Benfield Rd, Newcastle-upon-tyne, NE6 4NQ*. Samples tested by and processed at 20/30 Labs Ltd, a UKAS ISO 17025 accredited facility at Osyth Close - Unit 6, Brackmills Industrial Estate, Northampton NN4 7DY. This protocol (*****) will be used in determination of qualification methods and acts as a service level agreement.

3.2 Recognized laboratory methods include those of the Department of Health and Social Care (UK Gov.), British (BS), European (EN), and International (ISO) Standards.

3.3 The Environment Agency document Clinical Waste EPR 5.07., STAATT III (2005)) were used to determine the test selection and where given the method. All other methods, not specifically stated were undertaken following National and International published standards.

3.5 Refer to Table A. below for Autoclave traceability for *CISA WASTE STERILISER P-6412LS* utilised for the study.

Table A. – Machine Utilised for Qualification Process

Machine Name [Description]	Model	Serial Number	Manufacture Date	Software Version
CISA WASTE STERILISER	P-6412 LS/2P/E/TS/SV	27874	04/2021	SW 1.1

4.0 Definition of Terms and Standards Applied to this Report

ISO 13485: 2016: 20/30 Labs Ltd hold this accreditation for the following scope; 'The provision of microbiological testing and consultancy for the medical device industry. Research, microbiological evaluation and decontamination validation of medical devices. The design and manufacture of cleansing and disinfecting solutions and testing consumables for the medical device industry'. This scope of accreditation covers the work undertaken on behalf of Peacocks Medical in this study, even though the autoclave is not a Medical Device it gives serves as added value.

ISO 17025: 2015: Under ISO 17025 (UKAS accreditation), specific laboratory tests are accredited not the actual test facility. The UKAS accredited tests that apply in the instance of this report are;
Sterility title and Bioburden title

Clinical Waste EPR 5.07 – This Sector Guidance Note is one of a series of additional guidance Notes pertaining to the Environmental Permitting Regulations. It sets out the standards and measures for the management of clinical wastes. It is essential to meet this standard to fulfil the requirements of both the Waste Framework Directive (WFD, 2018) and Best Available Techniques (BAT, BREF, 2018). This guidance sets out the requirement of how to comply with the Environmental Permit issued to process clinical waste. This document specifies that methods published by STAATT III should be followed

STAATT III – Treatment of infectious clinical waste must meet the State and Territorial Association on Alternative Treatment Technologies (STAATT) level III criteria demonstrating this either through validation and efficacy testing as specified in Environment Agency Guidance EPR5.07. This document provides the methods for use and recovery of *Geobacillus stearothermophilus* to provide calculations of microbial inactivation.

11737-2:2020, USP 71, ISO 11737-1:2018 – These standards are for the methods deployed to undertake bioburden and sterility of Medical Devices; 20/30 UKAS accredited methods. These principles shall be applied to the collection and recovery of the *Geobacillus stearothermophilus* spores

[NB] 20/30 Labs Ltd joint (ISO 17025 and ISO 13485) accreditation scope covers all the testing described in this report. Therefore, it is not necessary for the following documents to be in Appendices as they are audited by our notified bodies; method validations, staff training and competency records, supplier certifications, SOP's (testing protocols in full). This list is not exhaustive.

5.0 INTERNAL LABORATORY REFERENCES

Document	Title	Source
SOP L001	Laboratory Accommodation	2030Labs
SOP L002	Staff Training	2030Labs
SOP L003	Lab Cleaning	2030Labs
SOP L004	Microbiological Bench Techniques	2030Labs
SOP L006	Operational use of Autoclaves	2030Labs
SOP L007	Disposal of Waste Material	2030Labs
SOP L031	Goods receipt and Testing	2030Labs
SOP L044	LIMS and Reporting	2030Labs
SOP L053	Bioburden Testing of Medical Devices	2030Labs
V0036	Bioburden Validation UKAS	2030Labs

SOP ****	Sterility Testing of Medical Devices	2030Labs
V00**	Sterility Validation UKAS	2030Labs
SOP L054	Cleaning Monitoring and Working in the Clean Room	2030Labs
SOP Q002	Quality Systems Databases and Document Control	2030Labs
SOP Q003	Uncertainty of Measurement	2030Labs
SOP Q004	Proficiency Testing	2030Labs
SOP Q005	Validation Procedure	2030Labs
SOP Q006	Non-Conformance	2030Labs
SOP Q008	Customer Service	2030Labs
SOP Q013	Calibration of Temperature monitoring equipment	2030Labs
SOP Q015	Equipment maintenance and overview	2030Labs
SOP Q020	Calibration of Autoclaves	2030Labs
SOP Q038	External Audit	2030Labs

6.0 TEST METHODS

The following methods validate the use of the levels of testing protocols being listed:

6.1 Level 1: Basic Laboratory Technique.
6.1.1 Use:Limited to sample assessment pre-testing
6.1.2 Methods: Visual examination (per internal SOP/WI)
Microscope or other viewing system (i.e. Optical comparator, etc.)
Spectrophotometer (i.e. McFarland Standards)
IR Temperature Probes

6.2 Level 2: Standard Laboratory Technique.
6.2.1 Use:Limited to sample processing
6.2.2 Methods:
Class 5 Cleanroom
BI Recovery

6.3 Level 3: Standard Laboratory Technique.
6.3.1 Use:Limited to sample Investigation
6.3.2 Methods: Microscopy (EDIC, Standard)
MALDI Tof

7.0 EQUIPMENT AND MATERIALS

7.1 Steriliser

Manufacturer:	CISA
Model Number:	P-6412 LS/2P/E/TS/SV
Serial Number:	27874
Parameters:	10 minutes at 138°C. 1 Negative Pulse, 5 mins Drying

7.2 Test Organism: *G.stearothermophilus* (ATCC #7953)

8.0 NON-CONFORMANCE/DEVIATION/DISCREPANCY EVENTS

8.1 Any alteration of the following procedural steps, which has the potential contribution of variance to test results will be recorded upon the corresponding section of the document record of results for this protocol and will be discussed and resolved during the final report development and published information to remediate the occurrence.

8.2 The categorization of the alteration in procedure shall identify the occurrence as being an allowance due to documentation conflict, an unallowable occurrence, or an occurrence that will need further discussion prior being addressed.

9.0 PROCEDURE

Agreed course of action following Environment Agency, 'How to comply with your environmental permit', Clinical Waste (EPR 5.07); Annex 1 – Site Commissioning validation for clinical waste treatment

9.1 Deactivation of Spores

Agreed course of action following Environment Agency, 'How to comply with your environmental permit', Clinical Waste (EPR 5.07); Annex 1 – Site Commissioning validation for clinical waste treatment.

9.1.1 Spore strips containing >10^6 *Geobacillus stearothermophilus* are to be placed into surrogate carrier devices representing the most challenging load.

9.1.2 The Steriliser shall be full (to its agreed capacity), with a representative load with the spore strips distributed evenly within.

9.1.3 A 'normal cycle' shall be performed and the spore strips/carriers aseptically removed at the end of the cycle and returned to the laboratory for immediate processing.

9.1.4 Principles of Bioburden (SOP ****) and Sterility (SOP****) shall be followed where appropriate to transfer the Spore Strips from carrier to Media for incubation.

9.1.4.1 Once processed, recovery from the instruments shall be undertaken using a validated, UKAS-accredited method, according to ISO 11737-1, internal method SOP L053 "Bioburden Testing of Medical Devices": Instruments are aseptically handled and visually examined for any residual soil.

9.1.4.2 Instruments are placed into 500ml of sterile recovery diluent, containing a surfactant, and sonicated for five minutes, to recover any residual test soil into solution.

9.1.4.3 The diluent tested for the presence of *any* organisms by carrying out membrane filtration onto Kanamycin Agar and incubated for 24 hours ± 4 at 35°C ± 2.

9.1.5 Growth recovered shall be identified with MaldiTof to ensure that it is the target organism

9.1.6 The results to be compared to acceptance levels [11.0] and a conclusion made pertaining to the deactivation of spores using the steriliser under evaluation.

9.1.7 Results

Appropriate measures for Microbial Disinfection Efficacy – Spore Strips

Control Data

For the control data calculate and record the following:

9.1.7.1 The number of spores (cfu) recovered from each individual control spore strip;

9.1.7.2 The mean number (XC_C) of spores recovered from the control strips;

9.1.7.3 The $\log_{10}$ of (X_C);

9.1.7.4 Subtract 4 from the $\log_{10}$ of (X_C) to generate the **pass criteria**.

The subtraction of 4 is the 4 $\log_{10}$ reduction for STAATT Level III criteria.

Test Data

For the <u>combined</u> test runs calculate the following:

9.1.7.5 The number of spores recovered from each individual test strip;

9.1.7.6 The mean (X_T) number of spores recovered;

9.1.7.7 The standard deviation (σ) of spores recovered;

9.1.7.8 The Upper 95% (Lu) confidence interval of (X_T) (this will be approximated byX_T + 1.96σ);

9.1.7.9 The $\log_{10}$ of the Upper 95% (Lu) confidence interval of X_T. ($\log_{10}$Lu)(note if Lu = 0, then use '0' for $\log_{10}$Lu)

*This must include **<u>all</u>** the recovered test strips. If contamination is suspected either retest the sample or, if that is not possible, include the results in the data analysis.*

9.1.8 *Method Compliance*

Method SOP: sterility title	SOP ****
Validation Document: sterility title	V00**
External QC Scheme undertaken quarterly	N/A

10.0 Sample Size and Justification

10.1 The manufacturer of the steriliser states in The White Paper Document (Type Tests in accordance to uni 10384)(version .02, 06/08/21), that a maximum of 50kg of clinical waste can be processed within the chamber during a cycle. This waste is limited to 18.01.03*1 & 18.02.02*1 (ref: doc -MWT- Materials list for processing)

10.2 The distributor (Peacocks Medical) is validating the load for a maximum of 35kg to be used for the sole purpose of clinical waste of 18.01.03*1 & 18.02.02*1

10.3 Requirements for the minimum number of spore strips or samples recovered, required for microbial validation of Alternative Treatment Plants as detailed in Clinical Waste (EPR 5.07)

Single Load Capacity(Kg) Continuous throughput (Kg per Hour)	**recovered percycle or collection.**	**recovered for each cycle format**	**retained as controls**
0-10 kg	3	9	6
11-50 kg	4	12	6
51-250 kg	6	18	6
251-500kg	8	24	6
501-750kg	10	30	6
>750 kg.	12	36	6

Table 1 EPR 5.07, Annex 1, page 56, sample size justification

11.0 ACCEPTANCE CRITERIA (specified by customer)

The following criteria represent the minimum standard that must be achieved:

11.1 The $\log_{10}$Lu for each run must be less than or equal to the pass criteria

11.2 $\log_{10}(X_C)$ must be ≥5.

11.3 For thermal processes all thermal indicator strips must indicate that the required temperature time parameters have been achieved.

Where these criteria are passed then it is >97.5% probable that the worst-case items present in any clinical waste will be treated to the minimum standard.

12.0 RESULTS PRESENTATION

12.1 The corresponding qualification test report to this qualification protocol will be issued upon completion of the incubation and microbiological analysis, approximately 30 days following final laboratory analysis.

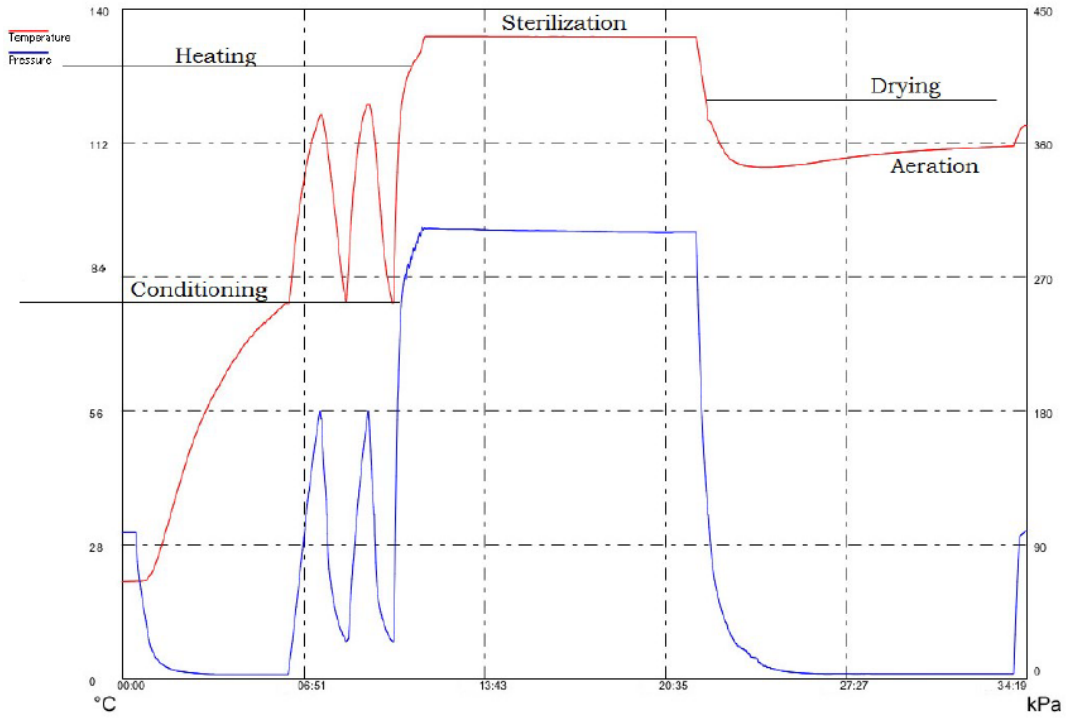
13.0 APPENDIX

13.1 Cycle Parameters; Steriliser (UK)

Inactivation pathogenic refuses HP

The waste is treated with high-pressure saturated steam and with a cycle temperature of 134°C or 138 °C. Both cycles are pre-programmed with pressure at 3 - 3,5 bar (absolute pressure) and sterilization time from 10 - 20 minutes.

MWT cycle:
-Conditioning
-Heating
-Sterilization
-Drying
-Aeration



13.2 ISO 13485 BSI Certificate

bsi.

By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

20/30 Labs Ltd.
Unit 6, Osyth Close
Brackmills Industrial Estate
Northampton
NN4 7DY
United Kingdom

Holds Certificate Number: **MD 631896**

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

The provision of microbiological testing and consultancy for the medical device industry. Research, microbiological evaluation and decontamination validation of medical devices. The design and manufacture of cleansing and chemical disinfecting solutions and testing consumables for the medical devices industry.

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2015-09-07
Latest Revision Date: 2021-09-03

Effective Date: 2021-09-07
Expiry Date: 2024-09-06

Page: 1 of 1

...making excellence a habit.™

This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract.
An electronic certificate can be authenticated online.
Printed copies can be validated at www.bsigroup.com/ClientDirectory

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.
A Member of the BSI Group of Companies.

13.3 UKAS Accreditation

Certificate of Accreditation

UKAS UNITED KINGDOM ACCREDITATION SERVICE

20/30 Labs Ltd

Testing Laboratory No. 4236

Is accredited in accordance with International Standard ISO/IEC 17025:2017 – General Requirements for the competence of testing and calibration laboratories.

This accreditation demonstrates technical competence for a defined scope specified in the schedule to this certificate, and the operation of a management system (refer joint ISO-ILAC-IAF Communiqué dated April 2017). The schedule to this certificate is an essential accreditation document and from time to time may be revised and reissued.

The most recent issue of the schedule of accreditation, which bears the same accreditation number as this certificate, is available from www.ukas.com.

This accreditation is subject to continuing conformity with United Kingdom Accreditation Service requirements.

Matt Gantley, *Chief Executive Officer*
United Kingdom Accreditation Service

Initial Accreditation: March 22, 2012
Certificate Issued: December 20, 2019

ilac-MRA UKAS

scan QR Code to verify

Appendix L – RAMS and SOPs for Autoclave Process

Northumbria Healthcare Facilities Management Ltd

NHS Northumbria Healthcare NHS Foundation Trust

The Northumbria Specialist Emergency Care Hospital

Northumbria Way
Cramlington
Northumberland
NE23 6NZ

RISK ASSESSMENT

AND

METHOD STATEMENT

Project	**Waste Autoclave System**
Site	**NSECH**
Prepared on:	**03/05/2022**
Revision	**01**
Author	**Bryan Thompson**
Signature	

This Risk Assessment and Method Statement (RAMS) has been developed to provide a safe system of work and must be adhered to at all times, any significant deviation from this system must be authorised by Area Estates and Facilities Manager This RAMS must be read before any works commence and signed for in Section 12

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SECTION 1 PRELIMINARIES

Prior to commencing work on Waste Treatment Plant all operatives must attend an induction and training session.

Prior to commencing work all operatives must be issued with the RAMS, upon acceptance of the RAMS all operatives must sign and date in Section 12.

SECTION 2: PERSONNEL AND EMERGENCY CONTACT DETAILS

Designation	**Name**	**Contact**
Site Manager	Nicola Cartwright	01916072140
Head Porter	Karen Horan	01916072160
Health and Safety	Bryan Thompson	07715237832
Estates	Leon Slater/Gary Talbot	01916072141
Peacocks		
Switchboard		01912031200
Emergency	Police/Fire etc	9999

SECTION 3: DESCRIPTION OF WORKS

3.1. This Method Statement Describes the work process for the safe usage of the Waste Treatment Plant at Northumbria Specialist Care Hospital (NSECH)

3.2. Operatives will ensure that work carried out on the Waste Treatment Plant does not put any third party at risk. Third Party interactions will be Risk Assessed on each occasion.

SECTION 4: SEQUENCE OF WORKS

CISA WDS 100 Autoclave Waste Machine

PHASE 1

1) Carry out visual inspection of plant and surroundings prior to starting up and running plant. Report any defects or issues to Line manager or Estates Department.
2) Start up plant following manufactures procedure. Allow plant to reach correct pressures and temperature prior to commencing a treatment cycle.
3) TASK 1 – on screen select:
   - MASTER DATA,
   - WASTE CREATION,

- ENTER PASSWORD.
- WARD
- STANDARD WASTE
- SAVE AND PRINT.

4) Take one of the small printed barcodes and stick it on to daily data sheet.
5) TASK 2- Select
   - TRACING
   - AUTOCLAVE LOADING
   - EXIT
   - NEW
   - MACHINE
   - AUTOCLAVE
   - (Scan Barcode)
   - SAVE and CONFIRM
6) AUTOCLAVE, touch screen to light up, press and hold OPEN DOOR to open autoclave. (Door will only open once machine is up to pressure)
7) Manually load autoclave bags in to Autoclave to capacity (do not put any non-autoclave bags in to machine) (do not over load) Ensure correct PPE is use as per Risk Assessment, whilst loading.
8) Put 2 x deodoriser tablets in Autoclave per load.
9) Close Autoclave door – Deadman's switch, press RED BUTTON and CLOSE DOOR at the same time on screen.
10) Once door is closed and ready to start Cycle insert time onto daily data sheet next to small barcode
11) START CYCLE –
    - PRESS START
    - OK
    - CONFIRM

PHASE 2

12) Once cycle complete, Press OPEN DOOR
13) Wear correct PPE as per Risk Assessment before next step.
14) Wheel out tray from AUTOCLAVE
15) Insert bag in to bottom collection hopper on shredder, close hopper door
16) Open top hopper door on shredder
17) Load sterilised waste into shredder (do not over fill)
18) Close Autoclave door Deadman's switch, press RED BUTTON and CLOSE DOOR on screen

Once loaded carry out phase 1 again before commencing with shredding

19) Shredder touch screen –
    - SHREDDER LOADING
    - MACHINE
    - SHREDDER
    - NEW

- MACHINE
- SCAN BARCODE
- SAVE AND CONFIRM

20) Attach second small barcode on to daily data sheet
21) Press AUX CONTROL (shredder cycle will run until Stop button pressed)
22) Once stopped and green light shows open bottom hopper door to remove bag of shredded waste
23) Secure bag and place large barcode on to bag.
24) Weigh bag and insert weight on to daily data sheet
25) Place bag into yellow waste bin
    End of Cycle

END OF SHIFT

26) Ensure autoclave and shredder are empty and cleaned out
27) Brush floors around Plant
28) Ensure no bags are left on the floor (all bags of waste must be stored in bins)
29) Remove treated waste bins to designated area.
30) Leave shredder hopper door open
31) Press OFF switch on Autoclave

EMERGENCY AND STOPPAGES

32) In emergency press emergency stop button
33) If Autoclave not running check all stop buttons, go through manufactures start up procedure and follow step by step guide
34) If shredder not working check for blockages, check both hopper doors are closed with no blockage on micro switch
35) If mechanical breakdown- report to Estates or Peacocks

SECTION 5: HAZARDS AND PREVENTATIVE MEASURES

Risk Assessments associated with task (see appendix)

Risk assessment Name	Date produced	Written by	Reviewed by	Review Date
Waste Treatment – Moving Bins	03/05/2022	Bryan Thompson		02/05/2023
Waste Treatment – Use of Autoclave	03/05/2022	Bryan Thompson		02/05/2023

SECTION 6: TRAINING AND SUPERVISION

6.1. All Operatives will be suitably qualified to carry out waste sterilisation operations

6.2 All Operatives will attend plant induction training and plant operation training

6.3. The monitoring and compliance of all Health and Safety Matters will be the responsibility of the Trust and NHFM Health and Safety team.

6.4. Day to day supervision of all plant operations will be the responsibility of the Head Porter

6.5. Overall responsibility for all Waste Plant operations is the Area Estates and Facilities Manager

SECTION 7: PERSONAL PROTECTIVE EQUIPMENT (PPE)

7.1. All operatives will wear personal protective equipment (PPE). All Operatives have a duty of care to wear the correct PPE and that the PPE is fit for purpose and is worn correctly.

7.2. The PPE required, as a minimum, is:

- Safety footwear, **EN ISO 20345:2011 S3 FO**
- Anti-needle stick gloves, (for use when loading/unloading Autoclave) **BS EN 388:2016 4.X.4.4.E**
- Thermal Arm Gauntlets, (for use when loading/unloading Autoclave) **BS EN 388:2016 4.X.4.4.F**
- Eye Protectors/Full face shield when loading Autoclave **EN 166:2001 1F**
- Disposable suit (for use when dealing with contaminated bins or split bags) **EN ISO 13982-1: 2004 +A1:2010**
- gloves for general use when not loading/unloading Autoclave
- disposable gowns

SECTION 8: INCIDENT REPORTING/FIRST AID

8.1 In the event of an accident, near miss or dangerous occurrence the operative must inform the site lead/head porter as soon as possible. All incidents/near misses must be reported via the Trust DATIX system.

8.2 There are First Aid kits and eye wash stations are available around the Waste Plant, any deficiencies to these kits must be highlighted as soon as possible to the Head Porter/Site Lead. Information of First Aiders is attached to Autoclave.

8.3 Any major incidents/Emergencies call 999 from an external phone or 9999 from an internal phone. Use hand held radio to contact Estates/Porters in case of Emergency.

SECTION 9: ENVIRONMENT

A high standard of house keeping is required around the Waste Plant. All waste is to kept in correct bins and any spillages must be cleared immediately. The area in and around the shredder must be fully cleaned at the end of each shift.

All pre-treatment and post treatment must be kept separate to avoid cross contamination. Any bins with split/contaminated loads must be separated and reported to Head Porter/Site lead.

SECTION 10: SPLIT BAGS AND CONTAMINATED BINS

10.1 Any bins that contain split autoclave or non-autoclave bags (tiger or orange) must be put to one side and reported. Details of ward/department must be noted on contamination sheet and photographs taken.

10.2 If a bin has split bags in then this must be transferred to unsplit bags before being processed. No split bags are to be put through the sterilisation process. Whilst transferring loose waste in to new bags the correct PPE is to be worn. (Anti needle stick gloves, Arm protection, Safety Shoes/boots, eye protection/full face mask, disposable gown).

10.3 If bin has non-autoclave bags, these should be removed and inserted in to the correct waste stream. Correct PPE should be worn whilst transferring waste (Anti needle stick gloves, Arm protection, Safety Shoes/boots, eye protection/full face mask, disposable gown)

SECTION 11: WARDS/CLINICAL AREAS RESPONSIBILITIES

11.1 Wards/Clinical areas should ensure that **only** the correct classification of waste is deposited in to waste bins. All bins in wards/clinical areas are marked with correct waste streams.

11.2 Wards/Clinical areas to carry out regular documented inspections of all waste receptacles to ensure that correct waste is being deposited.

11.3 Regular waste audits will be carried out by the Trust Health and Safety Department.

NB Do not mix load either bags or via the process

SECTION 12: AMENDMENTS

DATE	AMENDMENT	AUTHOR

SECTION 13: SIGNATURE SHEET

NAME	SIGNATURE	INDUCTION/TRINING CARRIED OUT BY	DATE	COPY OF RAMS GIVEN

APPENDIX 1: RISK ASSESSMENTS

Business Unit/Site	Service / Department	Date of Assessment	Date of Re-Assessment	Assessment Conducted by – BRYAN THOMPSON
NHFM - NSECH	Porters and Estates	03/05/2022	02/05/2022	Signature 
	Name of Assessment / Task			**Assessment Reviewed by – Nicola Cartwright**
	Waste Treatment – Moving Bins			Signature -  Date – 19/5/21

Who may be harmed – Operator, Staff, Visitors, Patients

HAZARD	ASSOCIATED RISKS	Initial Risk Rating (use table below)	CONTROL MEASURES	Residual Rating (use table below)	FURTHER ACTIONS REQUIRED (with date)
Bio Hazard	Death, Infection from waste/discarded bandages etc. in bins	High	• Ensure correct PPE is worn, - Gloves - Safety Boots • Clean hands, equipment after task complete • Ensure any cuts/abrasions are covered • Visually check bins for any obvious signs of spilt waste contents before moving bin • Do not transfer waste from one bin to another to make up full loads • Do not remove waste from bins	Moderate	

			• Ensure no waste can fall from bin whilst moving through hospital • Any spillages must be reported straight away to Domestic services. Do not leave spillage unattended • Make sure drain plug is secure and not leaking		
Needle Stick Injury	Death, Infection, Hepatitis etc.	Very High	• Wear correct PPE – - Gloves - Safety Boots • Do not use hands to compress waste into bins • Do not transfer waste from bin to bin • Report any needles to line manager • Use litter pickers to pick up any needles and dispose of in correct receptacle.	Moderate	
Manual Handling	Back injury, Strains	Moderate	• Check weight of bin before attempting to move • If bin is too heavy request assistance from a colleague • Any faults to function of the bin must be reported to line manager (i.e. Faulty wheels, damaged lid, split in bin.)	Low	
Contact with Staff, Patients, Visitors whilst Moving around Hospital	Injury, Slips, Trips, Falls. Crush injury. Infection	Moderate	• Do not move more then one bin at a time around the hospital • Plan route to reduce risk to patients and staff • Do not leave bins open/unlocked and unattended in public areas • Use appropriate lifts, do not share lift with patients and visitors	Low	

Business Unit/Site	Service / Department	Date of Assessment	Date of Re-Assessment	Assessment Conducted by –
NHFM - NSECH	**Porters and Estates**	**03/05/2022**	**02/05/2023**	**BRYAN THOMPSON** **Signature** 
	Name of Assessment / Task Waste Treatment – Use of Autoclave			**Assessment Reviewed by – Nicola Cartwright** **Signature -**  **Date –** 19/5/22

Who may be harmed – Operatives, Staff

HAZARD	ASSOCIATED RISKS	Initial Risk Rating (use table below)	CONTROL MEASURES	Residual Rating (use table below)	FURTHER ACTIONS REQUIRED (with date)
Bio-Hazard	• Infection from waste/discarded bandages etc. in bins • Infection from waste whilst manually loading in to Autoclave • Prosecution from Environment agency, Jail time, Unlimited Fines.	Very High	• Ensure correct PPE is worn, - Anti-needle stick gloves BS EN 388:2016 - Arm Gauntlet: BS EN 388:2016 - Safety Boots: EN ISO 20345:2011 S3 FO - Anti-shatter face shield: EN 166:2001 1F - Disposable Gown • Clean hands and equipment after task complete • Ensure any cuts/abrasions are covered • Visually check bins for any obvious signs of spilt waste contents before loading into autoclave • Any split bags/loads should be rejected and removed • Correct waste licence in place	High	• Mechanical aids needed to load Autoclave • Remove physical contact and manual handling of waste completely • Regular documented clinical checks on wards to ensure correct waste is deposited in to bins. • Consult with Infection Control

	Detriment to reputation		• Certificate of Technical Competency holder in place. • Correct training for staff on wards to ensure correct waste is put in to bags.		
Needle Stick injury	Death, Infection, Hepatitis etc	Very High	• If any needles seen then stop emptying bin and reject load • Ensure correct PPE is worn, whilst handling waste - Anti-needle stick gloves BS EN 388:2016 - Arm Gauntlet: BS EN 388:2016 - Safety Boots: EN ISO 20345:2011 S3 FO - Anti-shatter face shield: EN 166:2001 1F - Disposable Gown	High	• Mechanical aids needed to load Autoclave • Remove manual handling of waste completely
Manual Handling	Back injury, Strains, Repetitive Strain Injury (RSI) from use of litter picker, Contact with Bio – Hazard waste.	Very High	• Check/test weight of bags before attempting to lift • Do not over reach in to bottom of bin to lift bags – As per **RMP 04 Moving and Handling Policy** (use of mechanical aids required) • Do not use litter pickers (Strain to wrist, RSI) • Ensure correct PPE is worn, - Anti-needle stick gloves BS EN 388:2016 - Arm Gauntlet: BS EN 388:2016 - Safety Boots: EN ISO 20345:2011 S3 FO - Anti-shatter face shield: EN 166:2001 1F - Disposable Gown • Clean hands and equipment after task complete • Ensure any cuts/abrasions are covered	High	• Use of mechanical aids to remove the need to reach in to bin • Remove litter pickers and implement other means to reach bags at the bottom of bins

			• Visually check bins for any obvious signs of spilt waste contents before loading into autoclave • Any split bags/loads should be rejected and removed		
Use of Autoclave	Burns, Personal Injury, Infection, Strains, Contact With Bio-Hazard waste	Very High	• Ensure correct PPE is worn, whilst handling waste - Anti-needle stick gloves BS EN 388:2016 - Arm Gauntlet: BS EN 388:2016 - Safety Boots: EN ISO 20345:2011 S3 FO - Anti-shatter face shield: EN 166:2001 1F - Disposable Gown • Autoclave only to be operated by fully trained competent person(s) • Operatives must follow operating instructions at all times: **WASTE STERILISATION RAMS V01** • Any defects/leaks to be reported as soon as possible • Do not climb in to Autoclave to retrieve trapped/loose material • Ensure doors to Autoclave are completely clear before opening/closing doors. Doors are fitted with automatic locks and deadman's switch. • Keep work area as clean and clear as possible, do not leave excess bags on the floor. Clean up spillages straight away • Ensure untrained/Unautorised person do not interfere with operation	High	• Consult with Infection Control • Mechanical aids needed to load Autoclave • Remove physical contact and manual handling of waste completely

Use of Shredder	• Personal Injury, Strains, Cuts and abrasions, Loss of limbs.	Very High	• Do not attempt to run shredder with doors open. Automatic cut off devices and locks are fitted to both doors. • Do not over load shredder with bags • Ensure shredder and collection bay are cleared after each load to prevent buildup of flock • Follow operating instructions at all times • Only to be operated by trained competent person(s) • Any defects should be reported as soon as possible, do not attempt to run shredder if not functioning correctly. • If shredder is blocked do not attempt to unblock with hands. (see further actions) Operatives must follow operating instructions at all times: **WASTE STERILISATION RAMS V01**	High	• Clear manufactures instruction needed for unblocking of shredder as current system of using broom handle is inadequate and dangerous
Split bags/ Contaminated bins	• Death, Infection, Hepatitis etc • Airborne spores • As Needle Stick Injury • As Manual Handling	Very High	• If any needles seen then use pickers to remove needle to correct sharps container • Ensure correct PPE is worn, whilst handling waste - Anti-needle stick gloves BS EN 388:2016 - Arm Gauntlet: BS EN 388:2016 - Safety Boots: EN ISO 20345:2011 S3 FO - Anti-shatter face shield: EN 166:2001 1F - Disposable suit EN ISO 13982-1: 2004 +A1:2010 • Do not over reach in to bottom of bin to lift bags – As per **RMP 04 Moving and Handling Policy** (use of mechanical aids required)	High	• Consult with infection control regarding potential contamination from Airborne particles, bio-hazards etc • Look at alternative options to remove the need to manually handle any clinical waste

			• Clean hands and equipment after task complete • Ensure any cuts/abrasions are covered		
Lone Working	• Personal injury, stress, isolation	Moderate	• Effective communications, i.e. two-way radios • Regular welfare checks by supervisor/line manager • Regular breaks away from working area • Refer to **RMP59 Lone working policy**	Low	
Access/ Regress	• Personal Injury, Stress, Slips Trips and falls, Trapped limbs/fingers	Moderate	• Ensure access/Regress routes are clear at all times • Effective housekeeping • Ensure enough space around equipment to carry out tasks safely without being enclosed/trapped	Moderate	• Move shredder from current location as access in to shredder is tight against the wall, this could cause escape issues in case of emergency.

APPENDIX 2: RISK ASSESSMENT TOOL

The tables below can be used to grade any risks identified during the assessment.

1 What might the outcome be if an incident were to occur? The severity table below can be used to decide what the consequences might be if an incident were to occur

Descriptor	**Potential impact on staff, patients, visitors, contractors etc.**	**OR Potential impact on organisation and resource implications**	**OR Number of persons affected at one time**
Catastrophic / Tragic	Death / Suicide / Homicide	Criminal prosecution; extended service closure; significant financial costs; national publicity	Many (>50) e.g. vaccination error; screening error; over irradiation; failure to recall
Major	Permanent injury or harm Long term staff sickness > 4 weeks	Temporary service closure; HSE investigation; serious complaint anticipated; loss of public confidence	Moderate numbers (16-50) e.g. lost specimens; outbreak of infection
Moderate	Semi-permanent injury or damage Staff sickness > 3 days	Local adverse publicity; MDA reportable; HSE reportable; complaint anticipated	Small numbers (3-15) e.g. violent incident in A&E
Minor	Short term injury or damage Staff sickness < 3 days	Minimal risk to organisation; minor complaint possible	1-2
Insignificant	No injury or adverse outcome	No risk to organisation	N/A

2 **What are the chances of the event occurring again?** In order to obtain a realistic assessment of the event you need to consider how likely it is that an event will occur. This can be done using the likelihood table below.

Descriptor	**Description**
Certain / Almost certain	Event likely to occur on many occasions
Likely	Event will probably occur but is not an everyday occurrence
Possible	Event may occur occasionally
Unlikely	Do not expect the event to occur but it is a possibility
Rare	Can't believe this event will ever happen

3 **What is the overall risk score for this event?** Take the answers you obtained in Steps 1 and 2 and plot them on the table below. The colour category assigned determines the priority for action of the risk identified (this is line with the RMP03 Incident reporting Policy).

	Consequence				
Likelihood	**Insignificant 1**	**Minor 2**	**Moderate 3**	**Major 4**	**Catastrophic/Tragic 5**
1 Rare	Very low risk (green)	Very low risk (green)	Low risk (yellow)	Moderate risk (orange)	Moderate risk (orange)
2 Unlikely	Very low risk (green)	Very low risk (green)	Low risk (yellow)	Moderate risk (orange)	Moderate risk (orange)
3 Possible	Very low risk (green)	Low risk (yellow)	Low risk (yellow)	Moderate risk (orange)	High risk (brown)
4 Likely	Very low risk (green)	Low risk (yellow)	Moderate risk (orange)	High risk (brown)	V High risk (red)
5 Certain/almost certain	Very low risk (green)	Low risk (yellow)	Moderate risk (orange)	V High risk (red)	V High risk (red)

Risk Result of your mapping:

Rating	**Very low risk (green)**	**Low risk (yellow)**	**Moderate risk (orange)**	**High risk (brown)**	**Very high risk (red)**

APPENDIX 3: WASTE DATA SHEET

WASTE DATA -NSECH

DATE **WARD**

BARCODE – waste in to Autoclave	Cycle No	Load Time	Shredded weight	BARCODE – Waste out of shredder

DATE **WARD**

BARCODE – waste in to Autoclave	Cycle No	Load Time	Shredded weight	BARCODE – Waste out of shredder

APPENDIX 4: WASTE CONTAMINATION SHEET

Waste Contamination Sheet – NSECH

Date	Ward	Contamination or bags split - details	Reported to	Photos taken

Project – Waste Sterilisation
Site – NSECH
Author – Bryan Thompson
Date – 03/05/2022

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AUTOCLAVE LOADING & UNLOADING- OPERATIONAL PROCEDURES

1. PURPOSE:

To ensure the correct loading and unloading of the Autoclave by the operative

2. SCOPE:

All Waste Autoclave that has removable racks on trolleys for Loading & Unloading

3. RESPONSIBILITIES:

All Personnel that are trained to operate the waste system

4. PROCEDURE:

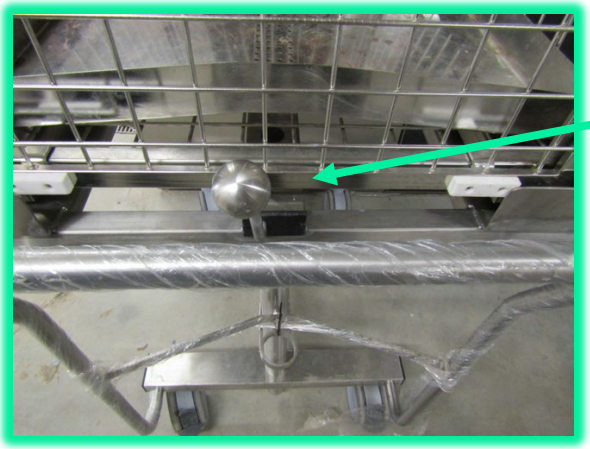
4.1. Personal Protective Equipment (PPE)

- Safety Shoes
- Heat proof gloves
- Hi-Vis Jacket / Waste coat
- Safety Glasses

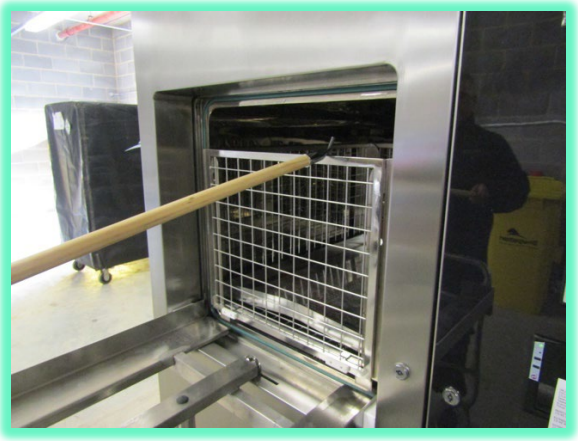
4.2. Loading Carriage into Autoclave

- Open The Loading Door to the autoclave by pressing the “Open Door” icon on the Display.
- Align the Trolley to the front of the autoclave.

- Lock the rear wheels of the trolley
- Engage the trolley lock located to the rear of the trolley, ensuring that it securely locks onto the Machine.



- Using Either Heat Protective Gloves or the Pushing Rod, Push the Rack towards the autoclave until fully inserted into the chamber.



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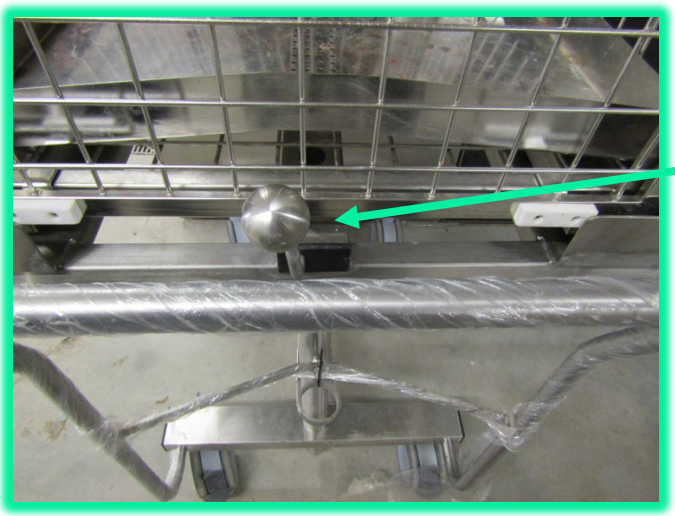
4.3. Unloading Carriage from Autoclave

- Once the cycle has finished and the door is open, take care not to touch the Carriage without Heat Proof Gloves or the unloading hook.
- Align the Trolley to the front of the autoclave

- Lock the rear wheels of the trolley
- Engage the trolley lock located to the rear of the trolley, ensuring that it securely locks onto the Machine.



- Using the rack removal tool, Pull the rack towards the trolley until fully loaded on the top of the trolley.

- Unlock the Trolley from the machine.
- Disengage The brakes on the trolley and move the trolley away using the handle to the rear of the trolley.

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WASTE SHREDDER OPERATION- OPERATIONAL PROCEDURES

1. PURPOSE:

To ensure the correct loading and use of a waste shredder by the operative

2. SCOPE:

All Waste shredders that have top loading doors with waste storage beneath

3. RESPONSIBILITIES:

All Personnel that are trained to operate the waste system

4. PROCEDURE:

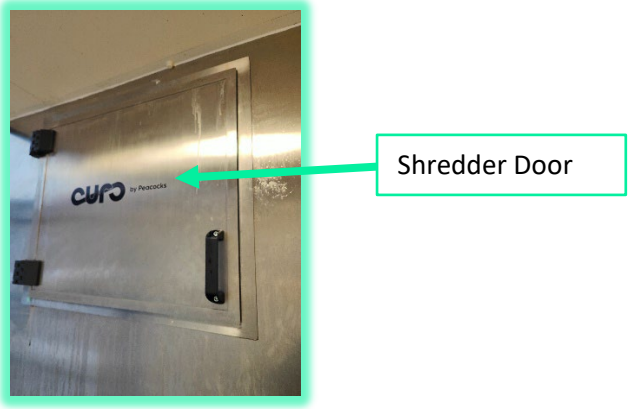
4.1. Personal Protective Equipment (PPE)

- Safety Shoes
- Heat proof gloves
- Hi-Vis Jacket / Waste coat
- Safety Glasses

4.2. Loading the Shredder

1. Ensure That the shredder is in standby before continuing

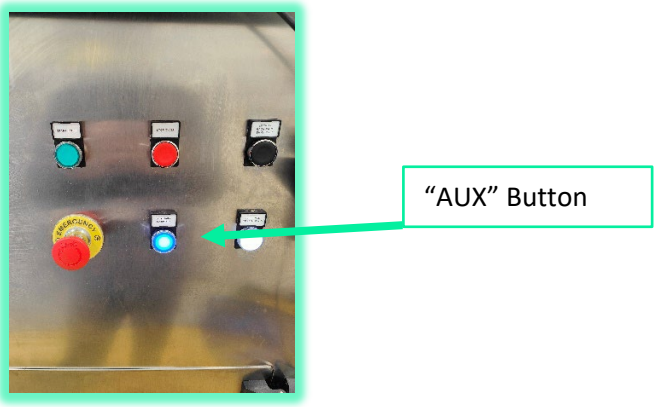
2. Open The shredder Hopper door.



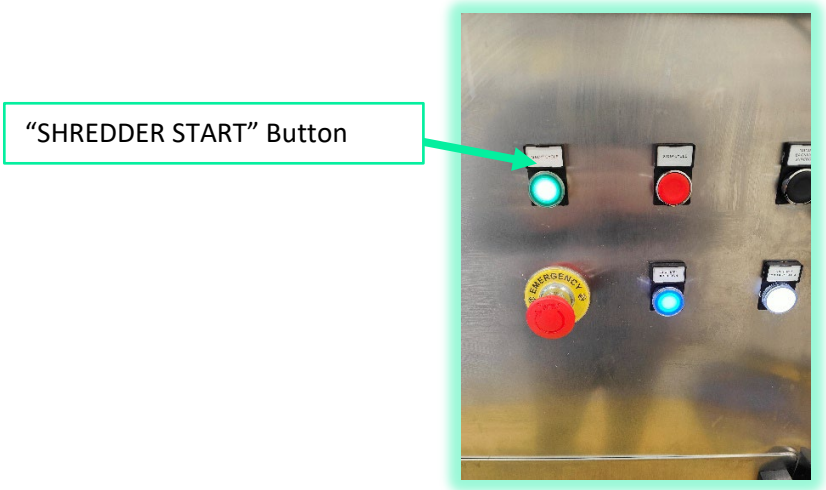
3. Wearing Hand Protection (Gauntlets) or a Grabber, Carefully Load the hopper With the Waste Bags and securely close the door.

4.3. Operating the Shredder

1. On the shredder control panel Press The “AUX” Blue button (This should illuminate if all doors are closed, and the stop button is not engaged).



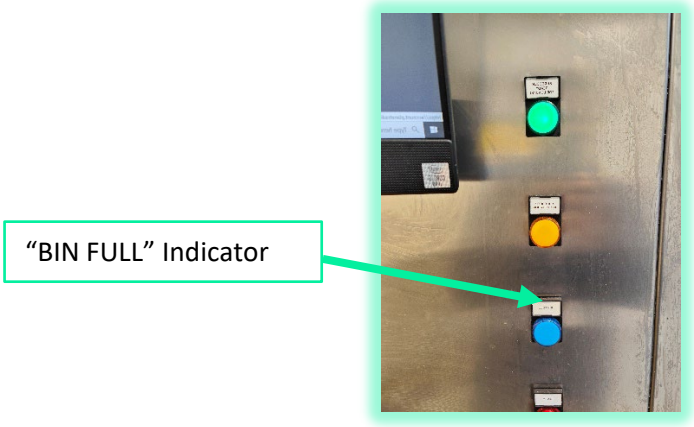
2. Press the “SHREDDER START” button. (Shredder will run for about 2 Mins)



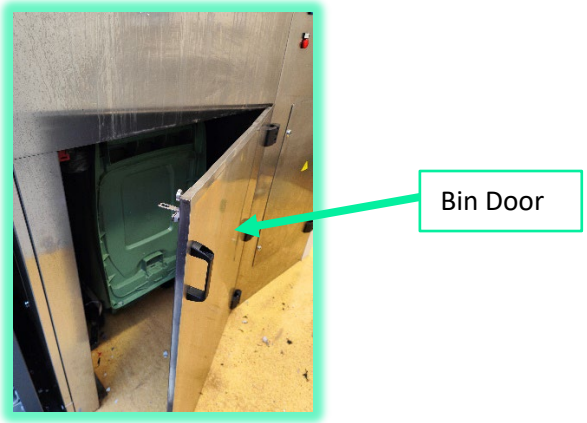
3. The Shredder will automatically stop after 5 Minutes. (If shredder continues press the stop button)

4.4. Unloading the Shredder Bin

1. When the “BIN FULL” Indicator is illuminated, it is then time to unload the Bin



2. Ensure that the shredder is not operational.
3. Press the emergency stop button in.
4. Open the bin door. (if the door does not release then the unit is possibly still running)



5. Remove the bin from the shredder and remove the bag.
6. Tie the top of bag and insert new Empty Bag into the Bin.
7. Replace Bin back into the shredder Bin storage and close the door.

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BIN TIPPER OPERATION- OPERATIONAL PROCEDURES

1. PURPOSE:

To ensure the correct loading and use of a waste shredder by the operative

2. SCOPE:

All Waste shredders that have top loading doors with waste storage beneath

3. RESPONSIBILITIES:

All Personnel that are trained to operate the waste system

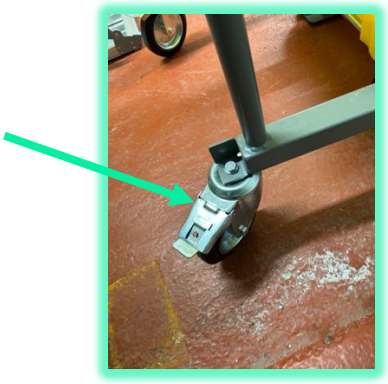
4. PROCEDURE:

4.1. Personal Protective Equipment (PPE)

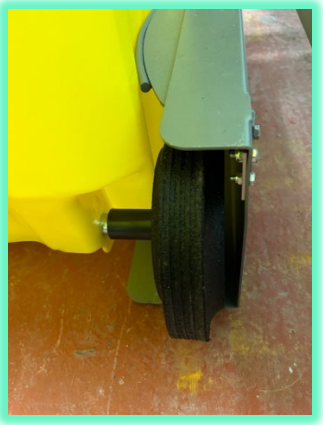
- Safety Shoes
- Hi-Vis Jacket / Waste coat

4.2. Operation

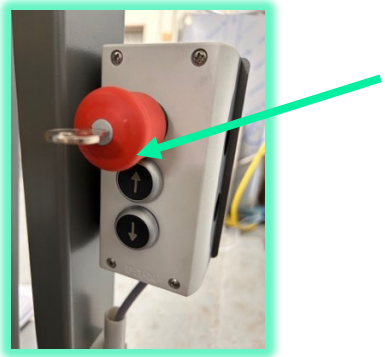
1. Observe the manufacturers Operating Manual
2. Release the Parking Brakes on the two swivel castors.



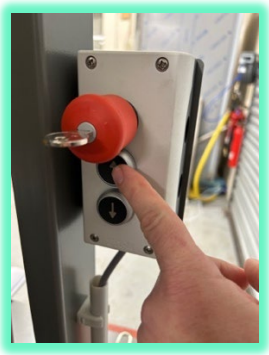
3. Take hold of the waste bin tipping station by the handles and move it to the place of use.
4. Apply both parking brakes on the swivel castors.
5. Push the waste bin between the two swivel castors into the entry shaft of the swivel Device.



6. Insert the key in the emergency stop key switch and turn it.



7. Press the up button to raise the tipping device with the waste bin until it is clear of the ground.



8. Release the locks on the two swivel castors.
9. Move the waste bin tipping station to the emptying point.
10. Apply both parking brakes on the swivel castors
11. Press the UP button to raise the tipper until the waste has ejected from the bin.

12. Press the DOWN button to move the tipper device back to the starting position.

13. Remove the bin from the tipper shaft.

Parking

1. Release the Parking Brakes on the two swivel castors.
2. Take hold of the handles on the Bin Tipping station and push to the Bin tipping Parking Space.
3. Apply Both Parking Brakes of the swivel castors.
4. Press the STOP button on the device and remove the key.

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Authorised by: Andrew Hough	

AUTOCLAVE CYCLE OPERATION - OPERATIONAL PROCEDURES

1. PURPOSE:

To ensure the correct starting and use of a waste Autoclave by the operative

2. SCOPE:

All Waste Autoclaves that are used for the Treatment of waste

3. RESPONSIBILITIES:

All Personnel that are trained to operate the waste system

4. PROCEDURE:

4.1. Personal Protective Equipment (PPE)

- Safety Glasses

4.2. Operation

4.2.2. Starting a Cycle

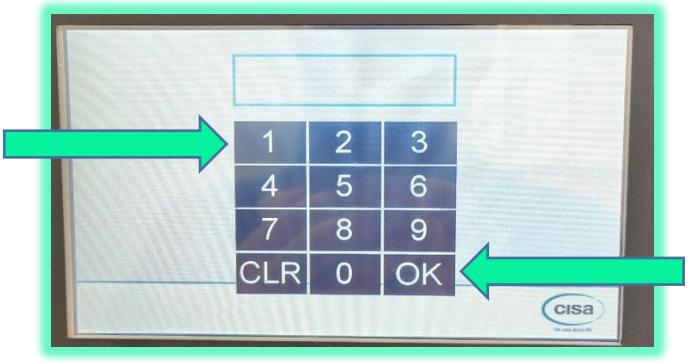
4.2.2.1. Close door by pressing the “CLOSE DOOR” icon on the display, and the red up button at the same time (Ensure the rack is fully inserted into the chamber)

4.2.2.2. On the display select “START CYCLE”

4.2.2.3. Select the cycle type to be run, this should always be “Waste 138°C”, the icon will highlight in blue if successful.

4.2.2.4. Press “OK” To Progress to the next screen.

4.2.2.5. Enter your operator code using the keypad on the display then confirm by pressing “OK”.



4.2.2.6. Confirm the selected cycle is the correct one, and press “YES” on the display to confirm. The cycle will now start.

Appendix M – WAMITAB Certificate for CoTC

CIWM

Continuing Competence Certificate

This certificate confirms that

Craig Chandler

Has met the relevant requirements of the Continuing Competence scheme for the following award(s) which will remain current for two years from 06/10/2022

LH	Landfill - Hazardous Waste
TSH	Transfer - Hazardous Waste
TMH	Treatment - Hazardous Waste

Expiry Date: 06/10/2024

Verification date: 04/10/2022

Authorised:

Professional Services Director

Learner ID: 11389

Certificate No.: 5208596

Date of Issue: 06/10/2022

CIWM Chief Executive Officer

The Chartered Institution of Wastes Management

Scan code on reverse to authenticate that this is a genuine paper