



Tiny Air

Surgical Automated Pre-Clean Machine

Instructions for Use

Tiny Air Pre-clean v2.1

Title: Instructions for use

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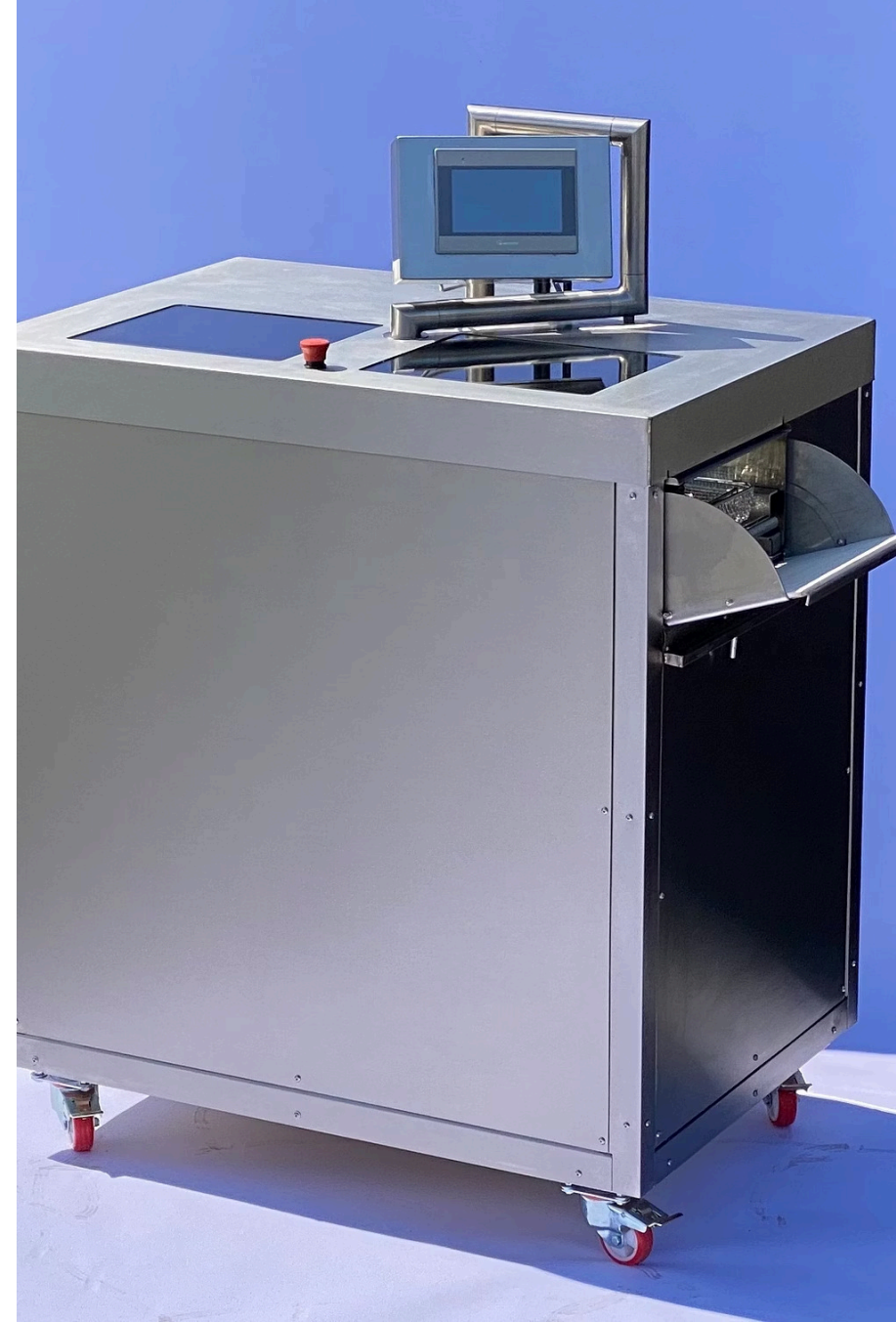
Overview

Tiny Air is a validated, fully automated pre-cleaning system for surgical instruments. The system's cold-water cycle removes contaminants prior to reprocessing in a washer disinfectant.

The Tiny Air system is intended to replace manual and/or ultrasonic pre-cleaning.

Regulatory Compliance

The V2.1 Tiny Air machine is a CE marked Class 1 Medical Device certified for pre-cleaning Surgical Instruments in a Sterile Services washroom or at point of use (Operating Theatre), prior to processing through a Washer/ Disinfectant.



Safe Working Procedure: Preparation

Standard Din Basket

The wash cabinet carriage is designed to hold a 480mm x 250mm x 50mm Standard DIN basket.

Carriage

The carriage can be used with other baskets including several bespoke graphics trays. The lip at each end of the carriage holds the basket in position.

Carriage Magnets

The carriage drive contains strong magnets, in normal use these are within the wash cabinet and pose no risk.

WARNING: Do not remove or handle the carriage if you have a pacemaker or ICD.

Instruments

The Tiny Air system is designed to pre-clean surgical instruments defined as suitable for pre-cleaning in the manufacturers IFU's, including surgical stainless steel (S5316), plastic instruments, and sets that are currently pre-cleaned manually e.g. Orthopaedic or Maternity sets.

The Tiny Air should not be used to pre-clean delicate instruments that would not normally be manually pre-cleaned, for example Ophthalmic devices.

The Tiny Air system is recommended for and compliant with installation at point of instrument use.

Basket and lid

A wire mesh lid or similar should be fitted to the basket during the cleaning cycle. Where devices are very small and could fall through the wire basket a jewellery type basket should be used and placed into the standard DIN basket for processing.

Loading the Machine

Doors

The doors open and close automatically. If the doors are obstructed, they will remain stationary and click loudly. If the doors are clicking remove the obstruction and the doors will reset automatically.

To remove a trapped obstruction, the doors can be physically pushed open or shut without damaging them.

The doors will be automatically open when the machine is ready to use. The doors should not be manually operated unless there is an issue.

If the machine is not in a ready state, use the following procedure:

1. press the emergency stop button.
2. turn the e-stop button clockwise to release it.
3. select 'reset e-stop' on the touch screen.

This procedure will reset the machine for use.

Basket Home

Press the "Basket Home" button to return the carriage to the input door.

The screenshot displays a control interface with the following elements:

- SYSTEM HEALTHY**: A green status indicator at the top center.
- START CLEANING**: A large green button in the center.
- STANDBY**: A green button below the start cleaning button.
- 12:00:00**: A yellow time display at the top right.
- SV1, SV2, SV3**: Three green status indicators on the right side.
- NO. RUNS: 0**: A text label below the status indicators.
- BASKET HOMING**: A large red button on the right side.
- LOGIN**: A light blue button below the basket homing button.
- ENGINEERING**: A light blue button at the bottom right.
- TIME REMAINING**: A text label on the left side.
- est. 0 : 00**: A yellow time display in the bottom center.
- TINYAIR-NAME**: A text label at the bottom center.
- DISINFECTION START**: A green button at the bottom left.

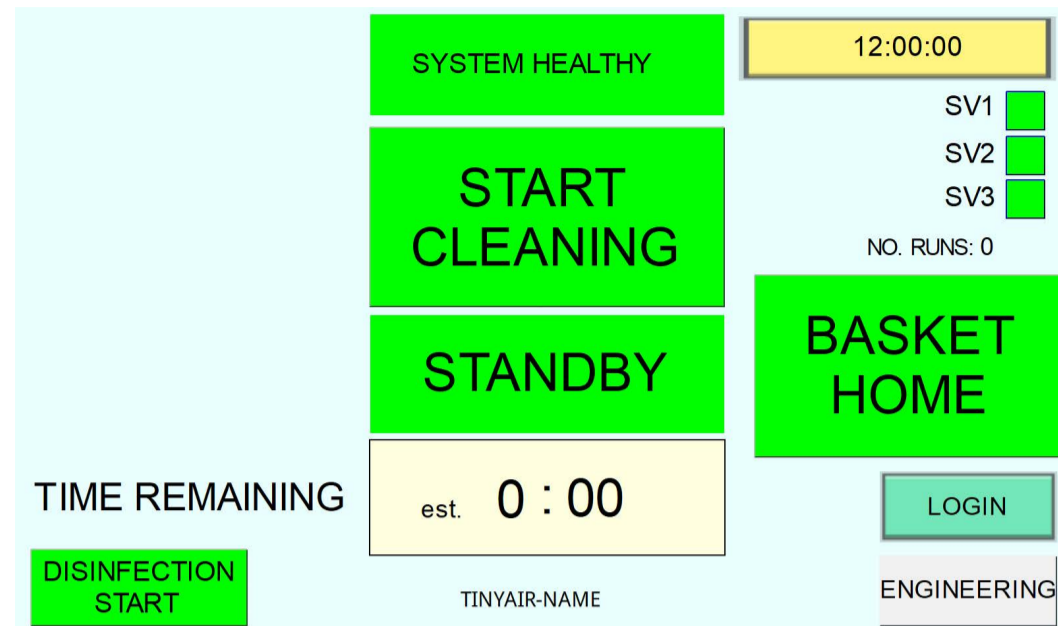
Insert Basket

Slide the loaded DIN basket into the carriage until you feel it drop slightly into the locating lip.

Starting the Cleaning Cycle

Touchscreen Interface

With the instruments loaded press the "Start Cleaning" button once on the touchscreen to begin the cycle.



The home screen of the touchscreen provides the user with key information

01

System State box

For the system to be used this box must show "System Healthy". If there is an issue this box will turn red and provide the information required to fix the issue e.g. wash cabinet high level, disinfection timeout etc. If you need to contact Tiny Air technical team please provide the system state information.

03

Mode box

The box directly above the timer provides the system operation information. e.g. Standby, cleaning, venting.

05

Disinfection Start button

This is a touch screen button to allow the user to start and stop a disinfection cycle.

07

Basket Home button

Moves the basket to the inlet door.

02

Start Cleaning button

The large central box is a touch button that allows the users to start and stop the cycle.

04

Timer

The timer starts as soon as the "Start Cleaning" button is pressed to provide the user a guide to time remaining.

06

Solenoid Value Indicators

SV1,2,3 provide information about which set of nozzles is cleaning.

08

Login button

Allows engineers to login to the maintenance interface.

Cycle Running

The cleaning cycle runs for 2 minutes, the information box will show "Cleaning". The red "Stop Cleaning" button will be visible throughout the cycle.

If there are any issues during the cycle press the "Stop Cleaning" button, the system will vent aerosols and the doors will open.

Post-Cycle Handling



Venting

Once the cycle ends, the doors will automatically crack slightly open for a few seconds while the machine extracts aerosols from the wash cabinet through an H13 HEPA filter. The doors will automatically open as the venting concludes.



Cycle complete

The cycle will be complete when the green "Start Cleaning" button shows on the touch screen and the doors are open.



Remove the instrument set

The basket will be at the opposite (exit) end of the machine ready to be unloaded. (Unless the machine is pre-configured to operate in a corner with a single door).

Unload Instruments

Carefully lift the end of the basket slightly to clear the lip, slide the basket out. Instruments should be visibly clean.

Repeat pre-clean if required

If any visible contamination remains, put the set back onto the carriage via exit door and select "Start Cleaning" to run a second 2-minute cycle (there is no need to select Basket Home).

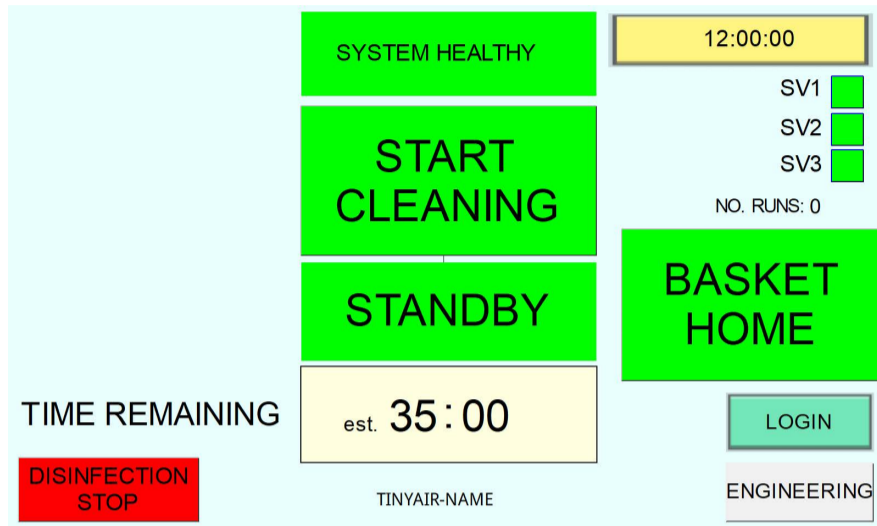
Check wash cabinet

Check inside wash cabinet for any instruments, if a lid has not been used it is possible that lighter instruments e.g. acetabular reamers can be dislodged from the basket.

Daily Maintenance

Auto Disinfection

Run the automatic disinfection cycle once a day. The disinfection uses hot water (80C+ for 10 minutes) to disinfect the inside of the wash chamber and drain. The cycle takes approx. 35 minutes contingent on the ambient temperature of the cabinet and water supply at the start of the cycle.



Drain Filter

Before removing the drain filter run the auto disinfection cycle.

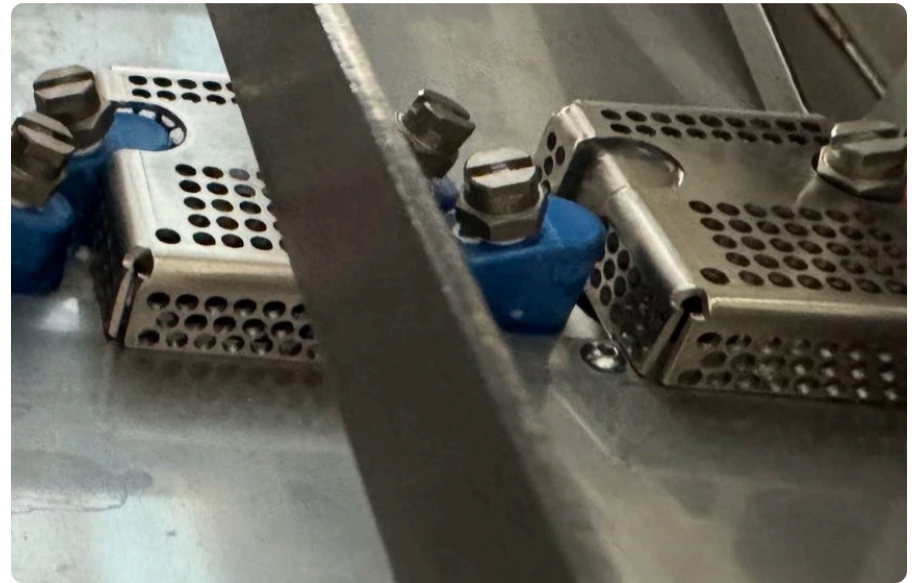
Please place a bowl under the drain filter at the right-hand end of the machine to catch any drips. Remove the circular clamp that holds the drain filter in place and remove.

Remove and clean the drain filter manually. The filter can be unscrewed allowing full disassembly for complete cleaning.



Wash Cabinet Strainers

Remove and manually clean the wash cabinet strainers.

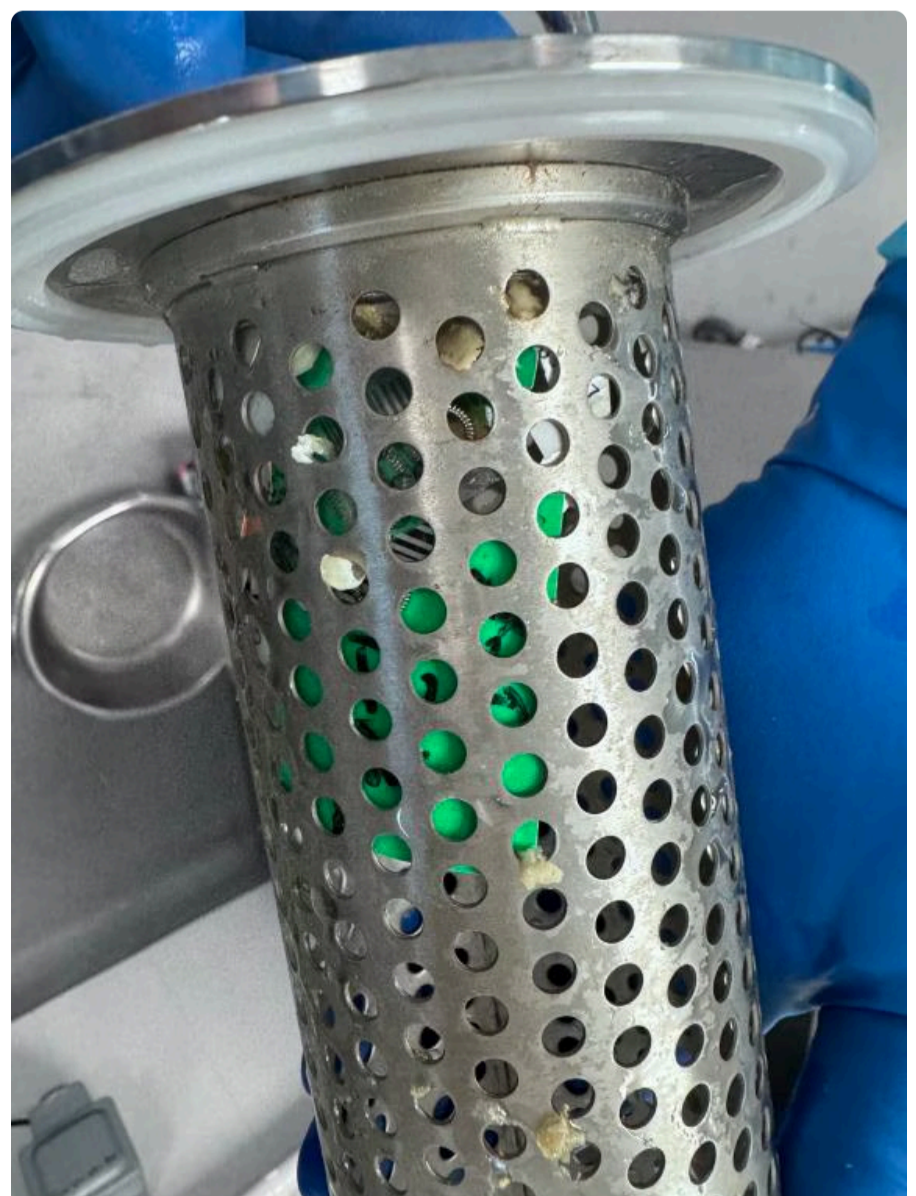


Door drip trays and bottles

Wipe clean the drip trays below the doors, empty and clean the drip tray bottles.



Drain Filter Disassemble



Safety Features

Emergency Stop:

Emergency Stop Button

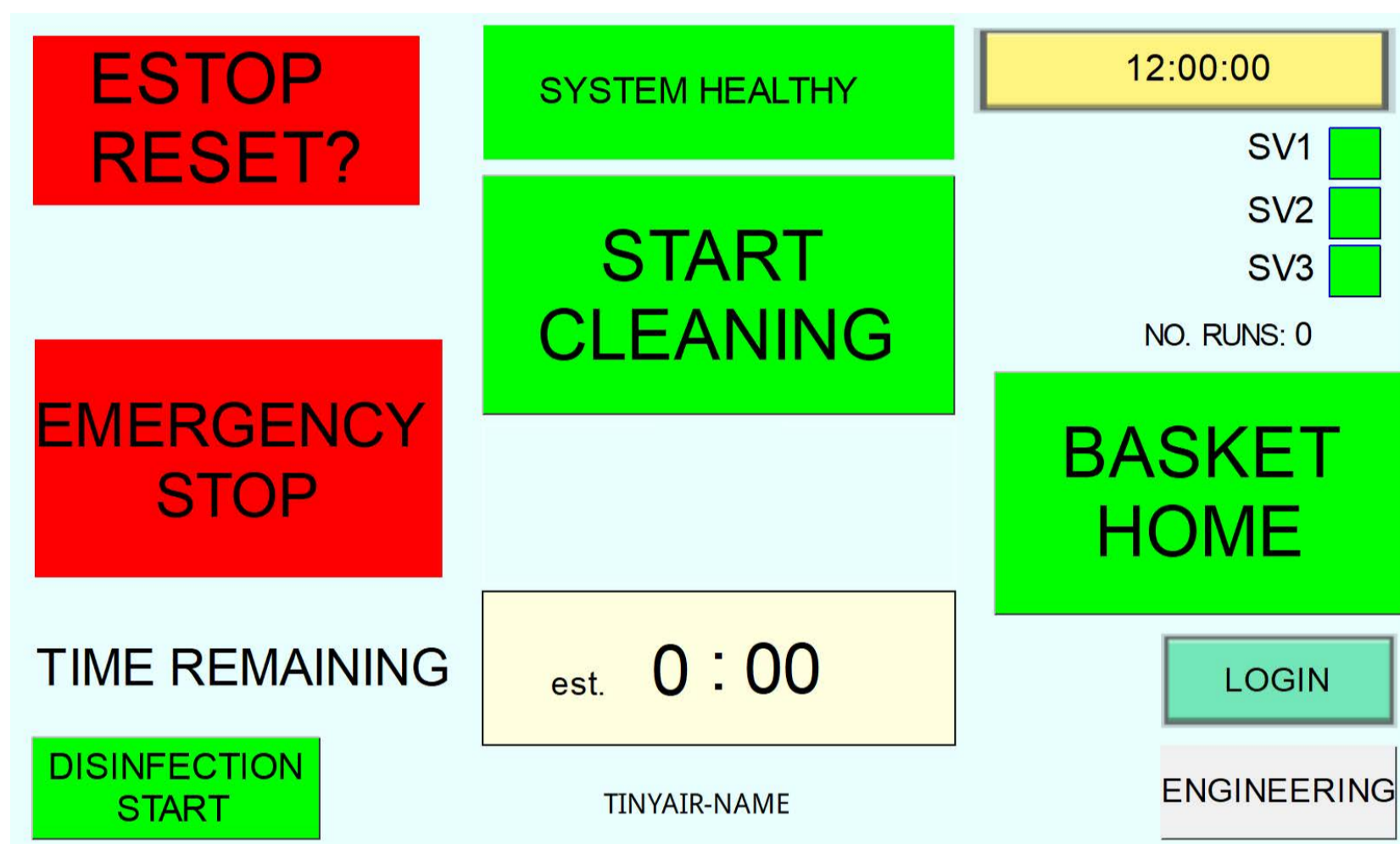
A physical red e-stop button is positioned front and centre of the machine and can be manually activated if any issue arises. This button can be reset by turning it clockwise until it pops up.

ESTOP faults

The system is set up to automatically e-stop the machine should any safety sensors be out of range. The cause of the e-stop will be shown in the system state box at the top of the touch screen.

ESTOP RESET

The touch screen offers an ESTOP RESET button. The reset will only work once the issue indicated has been resolved.



Doors

The motors that open and close the doors use low torque to prevent injury. The torque is increased only when the doors are closed to seal them firmly shut. The cycle will not run if the doors are not shut.

Anti-Flood

There are float switches in the base of the machine which, if activated due to a leak, will ESTOP the machine and cut the inlet water supply. In the event of a leak, turn off the power and water supply immediately, and contact the supplier.

Carriage Coupling

The magnetic carriage coupling is designed to release should any devices or the basket get stuck as it moves. This prevents damage to devices and the machine. If the carriage becomes uncoupled from the magnets, move in along rails until you feel it reconnects.

If the carriage is removed from the wash cabinet ensure that the magnetic coupling is facing towards the rear of the machine when it is replaced and reconnected with the magnetic drive.

Engineering login, detailed technical information and fault finding

The following instructions are intended for use by a Competent Person Decontamination, Decontamination Technician or an Authorised Engineer Decontamination. These processes and procedures should not be attempted by an unqualified person.

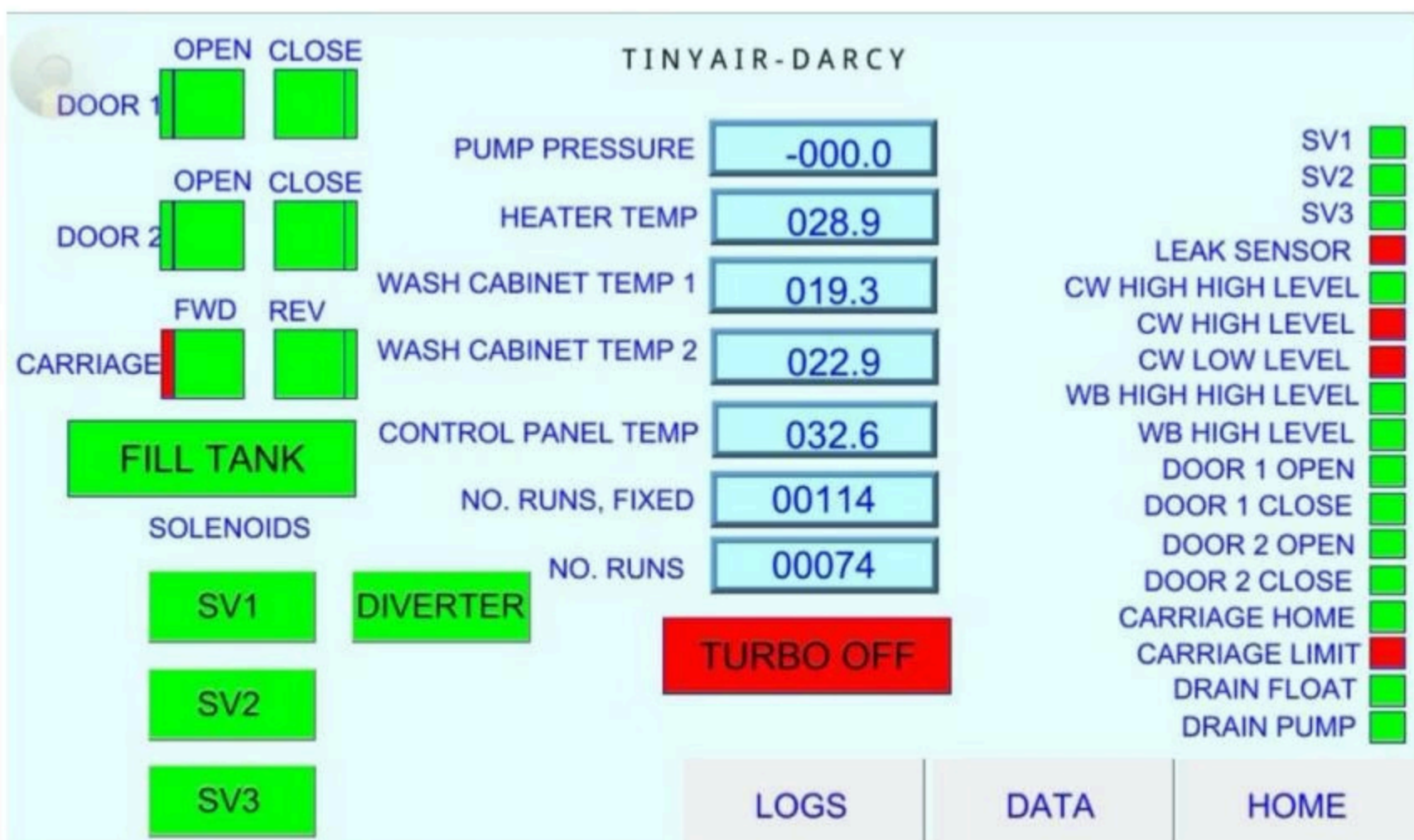
Engineering Login

- To login to the engineering back end of the HMI select the green LOGIN button at the bottom right hand of the touch screen.
- Login as shown on the screens below. Note some earlier versions of the software may require username to be in lower case.

To enter USER NAME and PASSWORD tap in the box to bring up the on-screen keyboard.

Engineering Screen

This screen allows technicians to watch the cycle data for repair, servicing and validation purposes.



Training

Ensure all users are trained to follow these IFU's.

Emergency procedures

Fire/ Smoke

- Do not place yourself or any other person in danger.
- Call 999
- If possible, switch the power supply and water supply off at the wall.
- If possible, use a CO2 extinguisher
- Instruct fire trained personnel that the lid of the unit will lift off to provide access.

Water Leak

- Isolate water supply and electricity at wall.
- Contact Tiny Air

