

Technical Data Package

February 24, 2023

E6430.00: INCUBATOR SHAKER SYSTEM

100V-120V, 60HZ, 20A, SINGLE PHASE



5900 Schooner Dr, Belleville MI 48111 – USA

TEL (800) 422-2558 – FAX (734) 665-9099

www.EberbachLabtools.com

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I. Machine Specifications



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Ia. Mechanical Overview

- Dimensions:
 - Length: 54.00" ± 0.50"
 - Width: 35.00" ± 0.50"
 - Height: 76.00" ± 1.00"
- Weight:
 - Unloaded (estimated): 1100lb ± 20lb
 - Fully loaded (estimated): 1200 ± 20lb
 - i. Approximate pressure: 91.5 PSF
- Temperature-controlled enclosure size: 40.5 cu ft
- Base designed for use with pallet jack for moving
 - Accessible from front and side
- Door features latching system to ensure tight seal
 - Aluminum sheet exterior with S/S sheet interior, no window
 - Door Options:
 - i. Standard, solid insulated door
 - ii. Glass door
 - iii. Blackout glass / Smart glass door
- Three (3) integrated, independently controlled shaker systems
 - Shaker stroke: 25mm ± 1mm
 - Shaker speed programmable, range = 30-135 RPM ± 2%
 - i. *Speeds over 135 RPM are not recommended without specifically engineered tops*
 - Max weight capacity: 35lb per shaker
 - i. See Load Capacity chart for specific load and speed limits
- NSF UL certification available upon request: +\$2,500

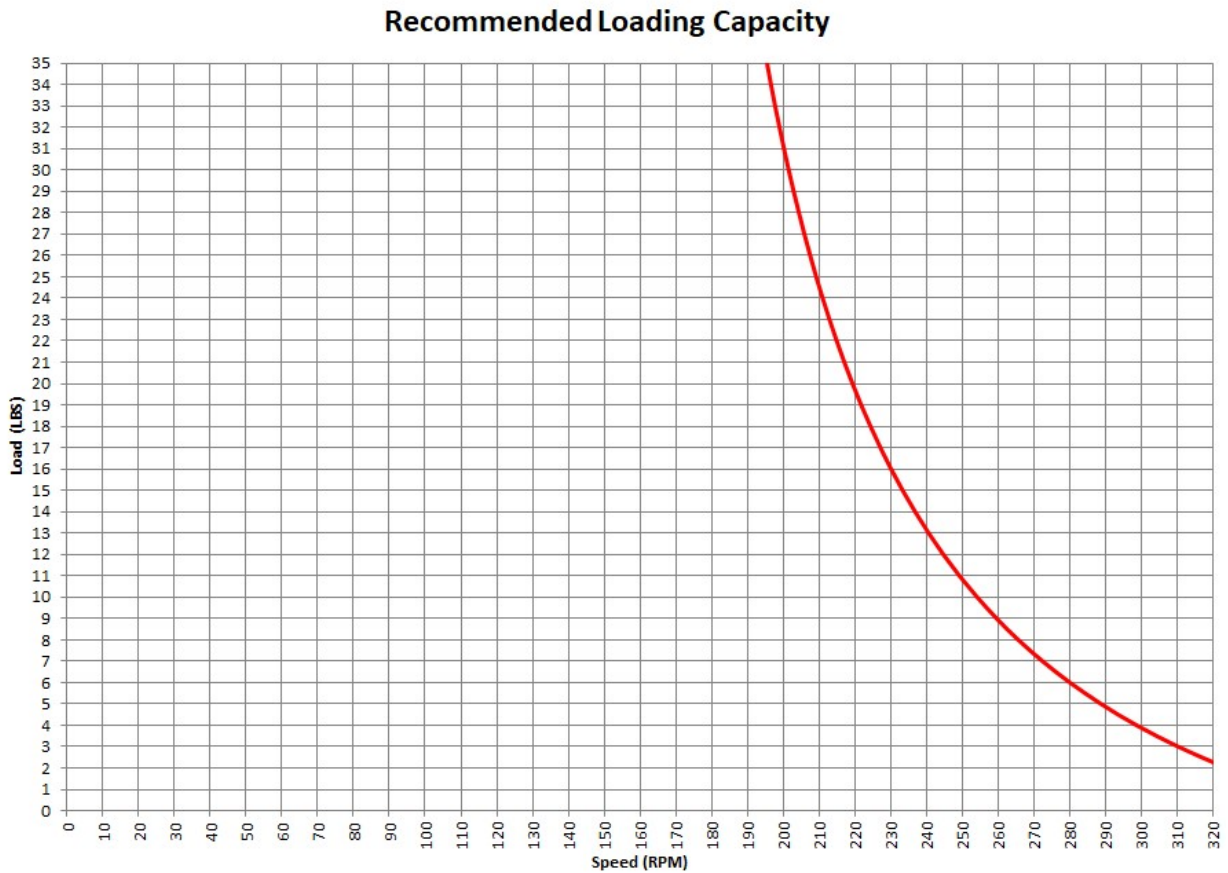
Ib. Electrical Overview

- 100V-120V, 60Hz, Single Phase
 - 115V NEMA 5-20P power cord
- Estimated cost of use:
 - 960W max draw during operation
 - \$120 monthly power cost
 - Based on full load consumption for 24 hours per day at \$0.17/kWh
- Washdown 9" HMI touch panel for machine control
- RJ45 Ethernet port for accessing ProfiNet system
- USB port for accessing data logs on HMI
- Internal UPS System
 - UPS keeps HMI powered for at least 5 minutes.
 - #1 priority is to return the shakers to the set speed
 - #2 priority is to hold the time - PLC and HMI need to stay powered on through all power outages for the specified time duration
 - Client power outage time to generator kicks in is 30~60 seconds max
 - HMI will monitor status of incoming power & resume all functions once power is restored. HMI will log the date and time of each power outage.

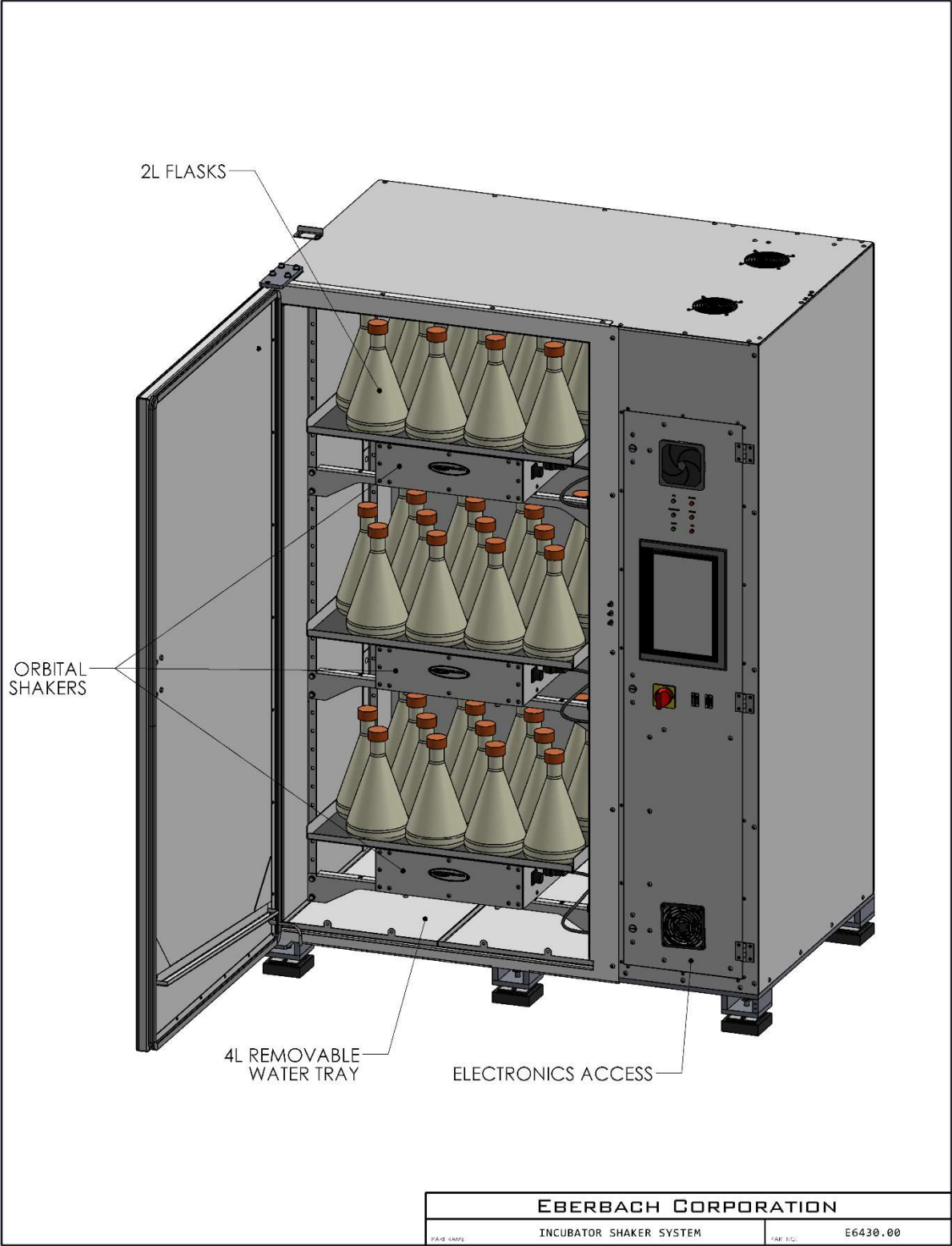
Ic. Maintenance

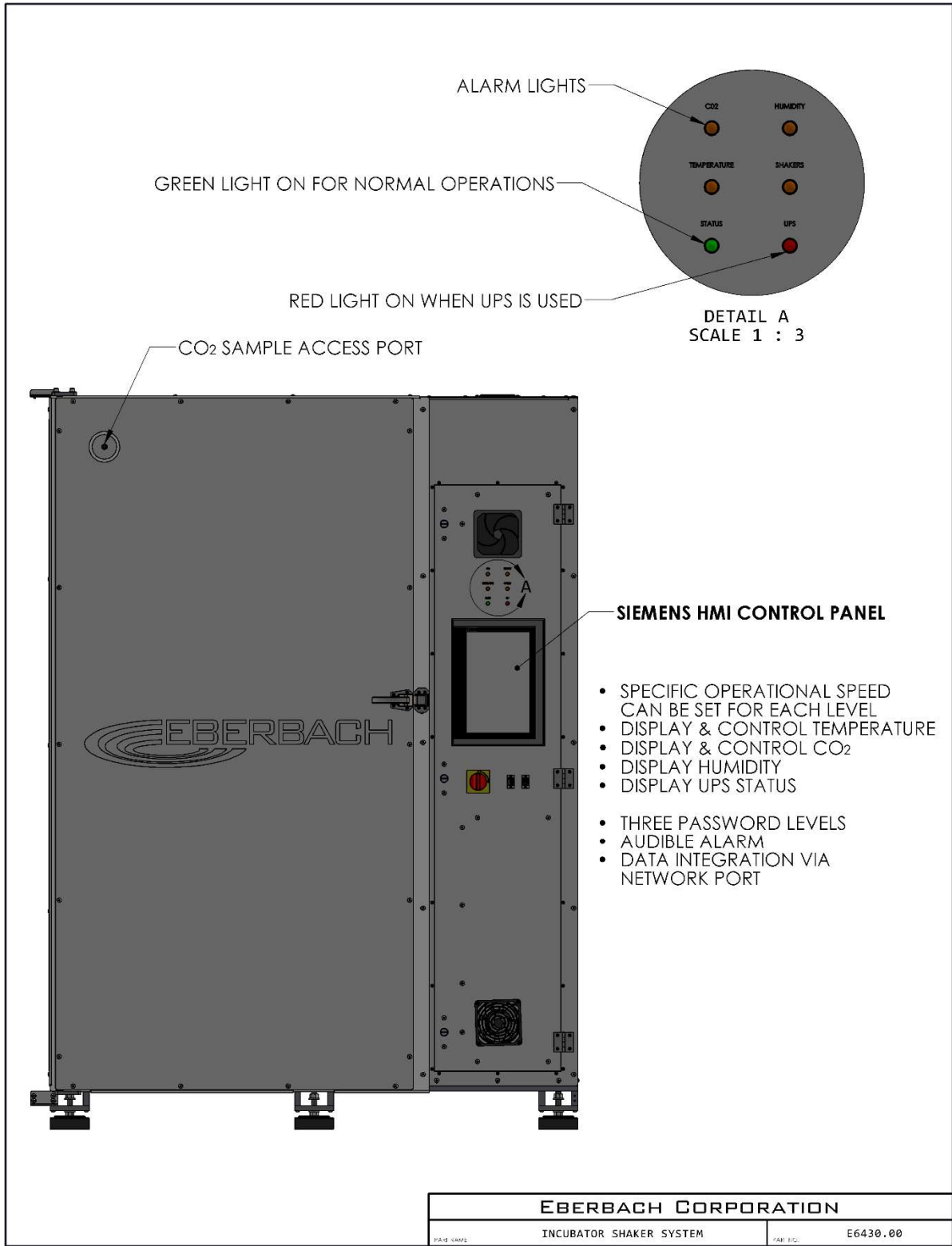
- Wipe exposed surfaces of machine with isopropyl alcohol twice per month or as needed.
- Keep touch screen free from dirt/debris.
- Ensure Cord Jacketing is not frayed or broken.

Id. Load Capacity Chart



Ie. Machine Renderings





CHAMBER CONTROLS

HUMIDITY

- MONITORS 1% INCREMENTS FROM 0 - 85% +/- 5%

CO₂

- ACCURACY: +/- 2%
- MEASURING RANGE: 0 - 20%
- 1/4" HOSE BARB CO₂ INLET ON BACK OF MACHINE
- MAX PRESSURE 125PSI

TEMPERATURE

- 0.1°C INCREMENTS FROM 15 - 40°C +/- 0.3°C

SHAKER SPEED

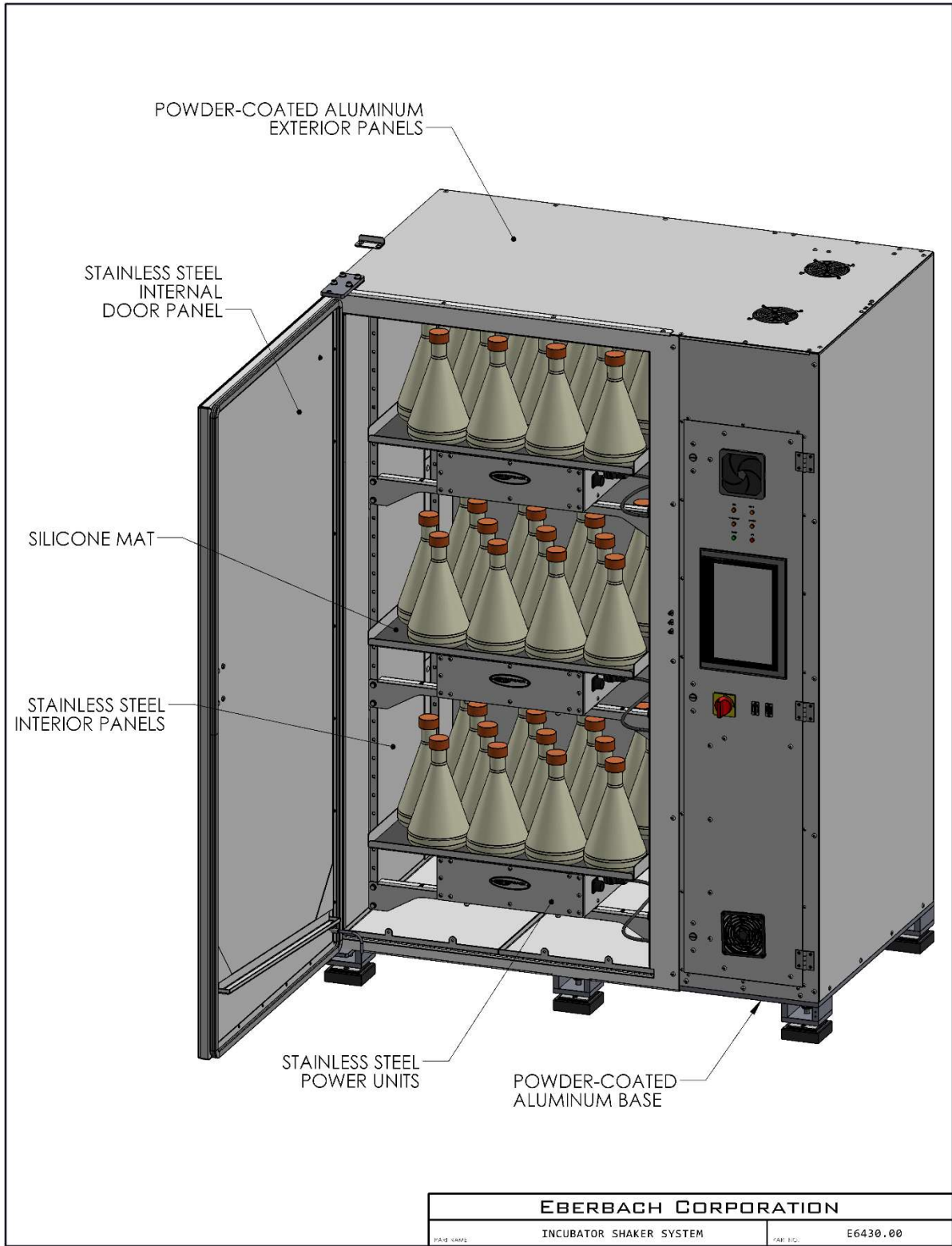
- 1 RPM INCREMENTS FROM 10 - 135 RPM +/- 2 RPM



EBERBACH CORPORATION

INCUBATOR SHAKER SYSTEM

E6430.00



If. **Control Specifications**

Humidity Monitoring

- Application Range
 - -50 – 100°C
 - 0 – 100 %RH
- Accuracy @ 23°C
 - ±0.8 %RH

CO₂ Control

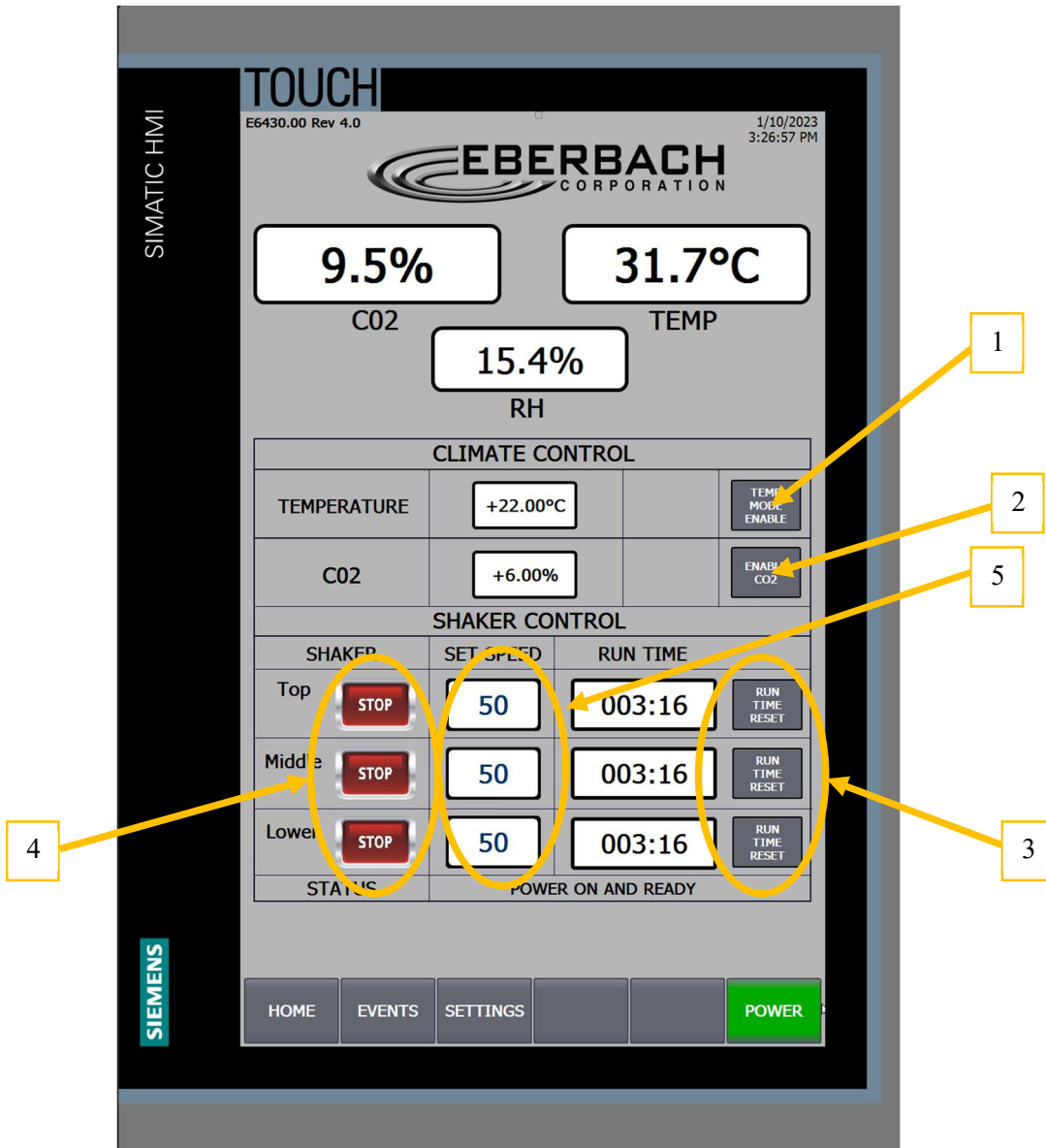
- Accuracy
 - At 5% vol. CO₂ ± 0.15 % CO₂
 - 0 – 8% vol. CO₂ ± 0.15 % CO₂
 - 0 – 20% vol. CO₂ ± 0.2 % CO₂
- Measurement range
 - 0 – 20% CO₂
- Application range
 - 15 – 40°C / 0 – 100 %RH / 700 – 1200 hPa
- Temperature dependence
 - ±10% of measured value
- Pressure dependence
 - ±0.15% of measured value/hPa
- Startup time
 - 60 s
- ¼” hose barb for CO₂ inlet located on back of the machine
- ¼” hose barb for CO₂ sample located on front of the machine
- Operating pressure of 15 PSI ± 5 PSI
- Max pressure cannot exceed 125 PSI

Temperature Control

- Heating and cooling for 0.1°C increments from 15 – 40°C ± 0.3°C

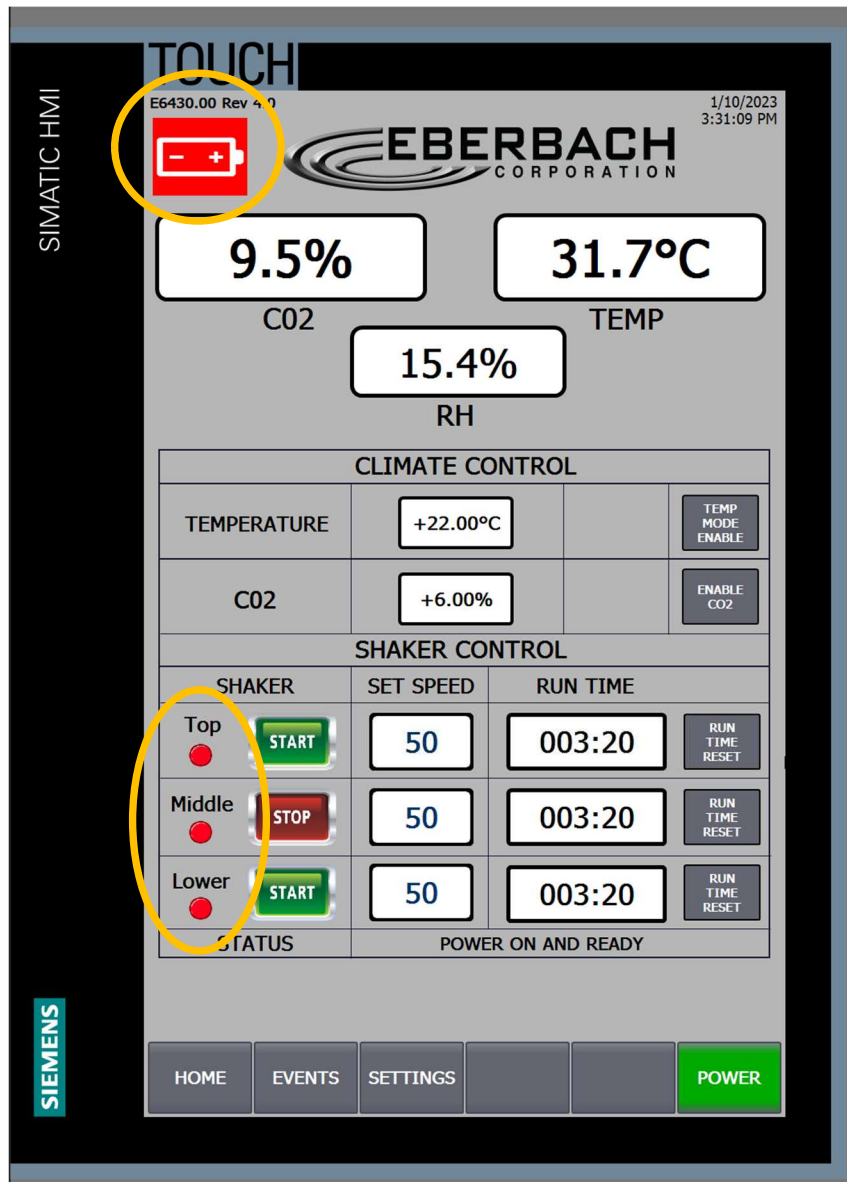
Ig. Controls

RUN SCREEN



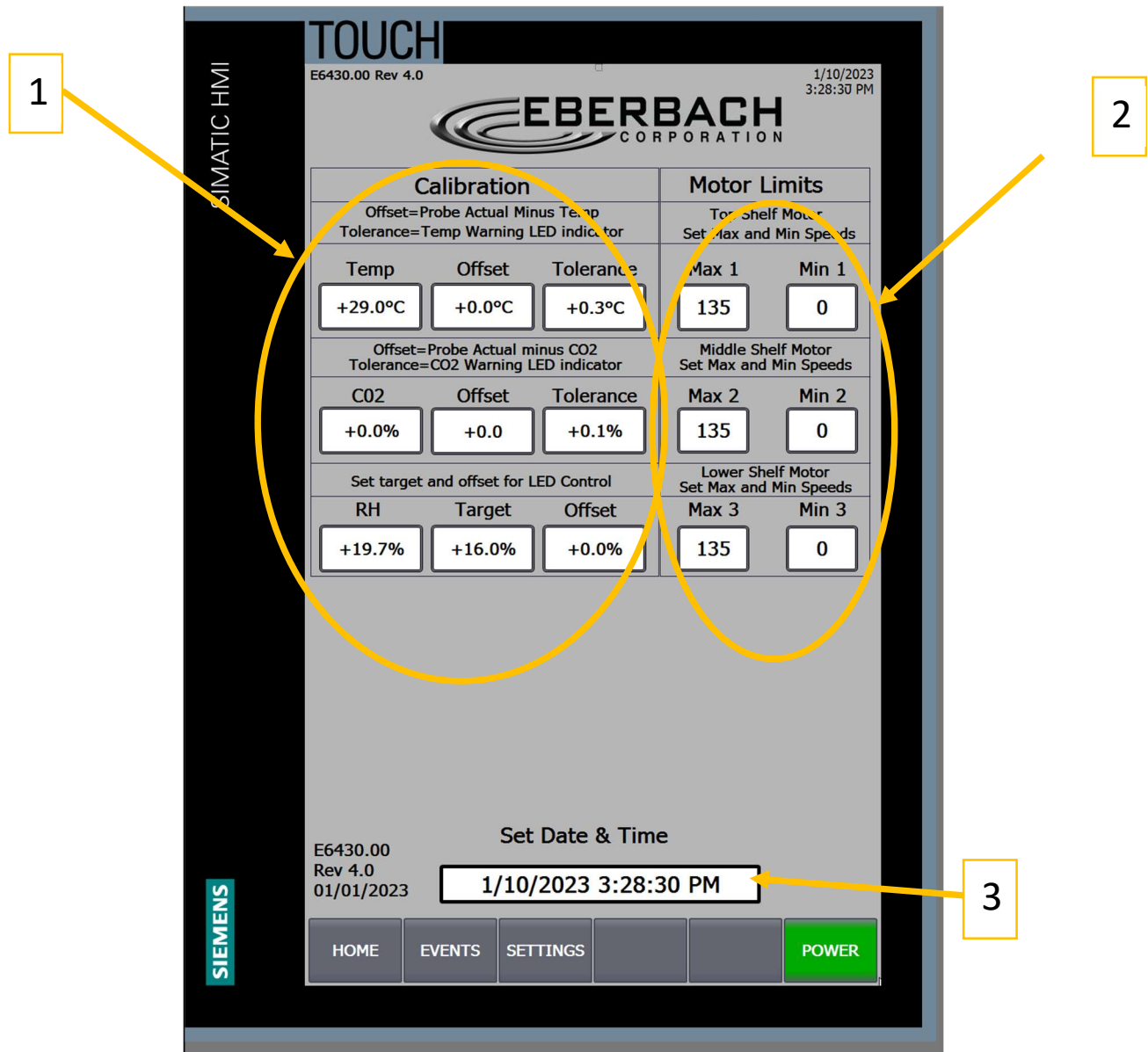
1. Temperature (Celsius)
2. CO2 Level (Percentage)
3. Run Time Reset Button
 - a. Note: Press the run time button reset time to (0:00:00)
4. Start/Stop button
 - a. Green Indicates Motor is active.
 - b. Red indicates Motor is not connected to drive/ power is disabled.
5. Motor Set Speed Button(s) (30-135 RPM)
 - a. Click the set speed button to choose a speed for the shaker power unit of choice.

UPC SCREEN



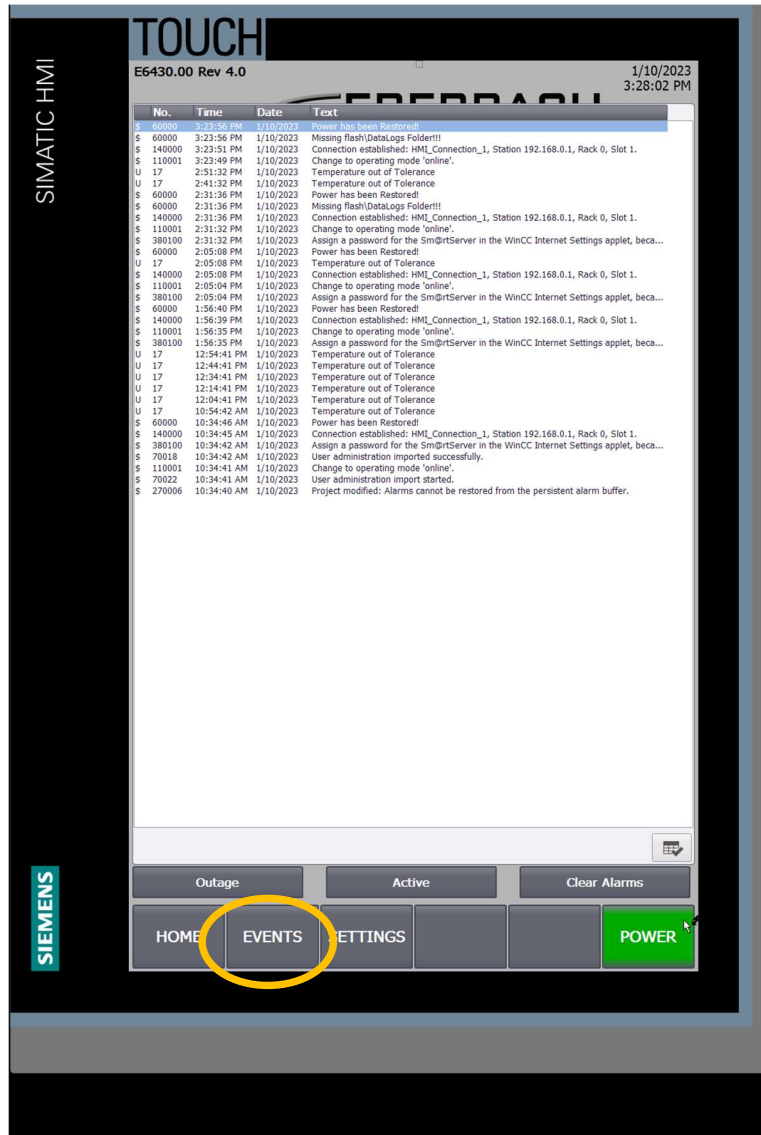
- When power is disconnected from the unit, UPC power will turn on and the red UPC symbol appears in the top left corner of the screen. UPC power will run for at least 5 minutes.
- The red lights next to each shaker label indicates loss of communication between the HMI and the shakers.

CLIMATE CONTROLS

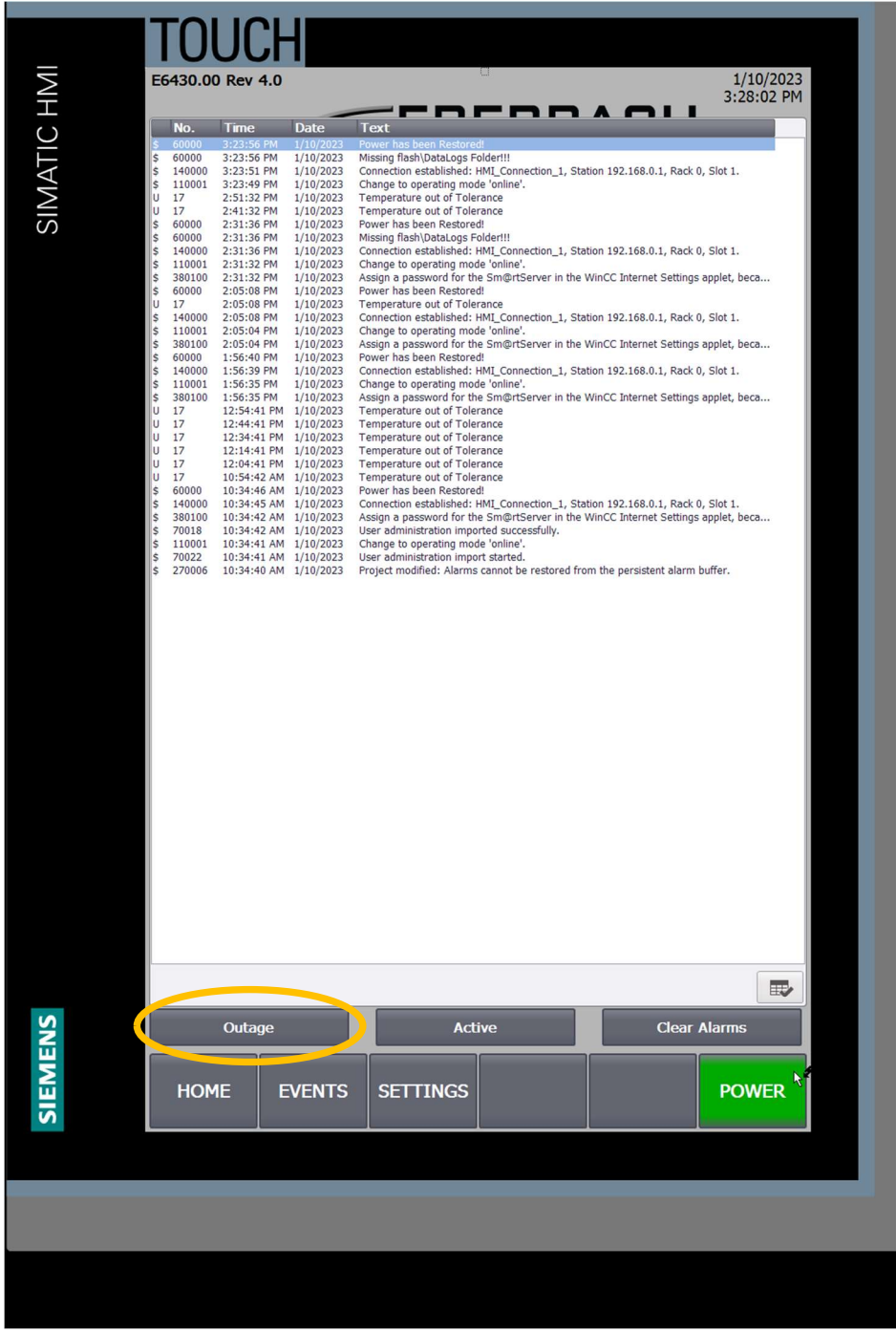


- 1) Probe Calibration/Settings
 - a. Each respective probe has the following:
 - i. Current Reading
 - ii. Offset
 - iii. Target Value
 - b. Pressing any of these boxes prompts a user input and can be changed
- 2) Motor Speed Limits
 - a. Max/Min 1 Corresponding with Motor 1 on run time screen (Bottom shaker)
 - b. Max/Min 2 Corresponding with Motor 2 on run time screen (Middle shaker)
 - c. Max/Min 3 Corresponding with Motor 3 on run time screen (Top shaker)
- 3) Date and Time
 - a. Touch to set date and time

ALARMS MENU



- The events menu can be accessed by pressing the events button
- This menu keeps track of events throughout the run time and is recorded with time and date stamps as well as the type in this menu.



- Outages will be recorded in this menu as shown.
 - Time and Date recorded for both power outage and restoration

II. Machine Testing Qualification & Validation



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IIa. Objective

The purpose of this protocol is to provide comprehensive document that validates the E6430.00 conforms with the quoted specifications; after manufacturing (FAT), prior to shipping (IQ), upon receipt at client's facility (OQ), and after installation at client's facility (SAT).

IIb. Scope

This technical data package includes inspection procedures and acceptance criteria of tests to be performed. The scope of this document is limited to the E6430.00.

IIc. Responsibilities

Responsibilities between Eberbach and Client are defined as follows:

Task	Responsible Group
Prepare FAT/IQ/OQ/SAT Documentation	Eberbach
Perform FAT	Eberbach
Provide FAT Data to Customer	Eberbach
Perform IQ/OQ/SAT	Client
Review & Verify the IQ/OQ/SAT	Client
Approve the IQ/OQ/FAT/SAT	Client

- Eberbach is responsible for:
 - Preparing the IQ/OQ/FAT/SAT documentation
 - Performing FAT
 - Provide FAT documentation to customer
 - Installation support
 - Use and Care manuals

- Client is responsible for:
 - Reviewing and approving this IQ/OQ/FAT/SAT documentation
 - Performing the IQ/OQ/SAT
 - All rigging activities required
 - All electrical installation requirements

IIId. Reference

- E6430.00 Use and Care

IIe. Factory Acceptance Test (FAT)

(Eberbach's Responsibility)

Step	Description	Specification or Acceptance Criteria	Result	
			Pass	Fail
1a	Validate Run, unloaded	Set level 1 shaker to run at 135 rpm. Speed must be within +/- 2 RPM for 5 min	<input type="checkbox"/>	<input type="checkbox"/>
1b	Validate Run, unloaded	Set level 2 shaker to run at 135 rpm. Speed must be within +/- 2 RPM for 5 min	<input type="checkbox"/>	<input type="checkbox"/>
1c	Validate Run, unloaded	Set level 3 shaker to run at 135 rpm. Speed must be within +/- 2 RPM for 5 min	<input type="checkbox"/>	<input type="checkbox"/>
2a	Validate Timed Run, unloaded	Set level 1 shaker for a 5-minute timed run @ 50rpm. Verify that it stops after 5 minutes.	<input type="checkbox"/>	<input type="checkbox"/>
2b	Validate Timed Run, unloaded	Set level 2 shaker for a 5-minute timed run @ 50rpm. Verify that it stops after 5 minutes.	<input type="checkbox"/>	<input type="checkbox"/>
2c	Validate Timed Run, unloaded	Set level 3 shaker for a 5-minute timed run @ 50rpm. Verify that it stops after 5 minutes.	<input type="checkbox"/>	<input type="checkbox"/>
3	Validate Temperature	Set the temperature to 32.0°C, must be within +/-0.3C	<input type="checkbox"/>	<input type="checkbox"/>
4	Validate CO ₂ %	Set the CO ₂ % to 10.0%, must be +/-0.2%	<input type="checkbox"/>	<input type="checkbox"/>
5	Validate Humidity	Check humidity display, must be within +/-0.8%	<input type="checkbox"/>	<input type="checkbox"/>
6	Confirm machine finish	Machine panels and base are free from scratches. (cGMP compliant)	<input type="checkbox"/>	<input type="checkbox"/>
7	Confirm machine finish	Confirm that there are no sharp corners on machine / accessories.	<input type="checkbox"/>	<input type="checkbox"/>
8	Validate stroke	Do the shakers provide a 25mm displacement? Must be within +/-1mm	<input type="checkbox"/>	<input type="checkbox"/>
9	Verify firmware version	Verify the firmware version: _____	<input type="checkbox"/>	<input type="checkbox"/>
10	Validate UPS	Cut power to the Machine for 5 min then re-apply power. Verify that the HMI logged the incident and remained powered.	<input type="checkbox"/>	<input type="checkbox"/>
11	Run Time	While unloaded, run all shaker systems for a minimum of 2 hours at 135 rpm.	<input type="checkbox"/>	<input type="checkbox"/>
12	Machine documentation Completed	Verify the Use and Care for the machine is completed and packaged with the machine.	<input type="checkbox"/>	<input type="checkbox"/>
13	Pictures and video	Take pictures and video of machine.	<input type="checkbox"/>	<input type="checkbox"/>

IIf. Installation Qualification (IQ)

(Client's Responsibility)

Step	Description	Specification or Acceptance Criteria	Result	
			Pass	Fail
1	Shipping package Inspection	Inspect shipped package for signs of damage that may have occurred during shipping. Keep packaging material until Operation Qualifications has been complete. Contact Eberbach if any shipping damage is observed.	<input type="checkbox"/>	<input type="checkbox"/>
2	Unpacking and Equipment inspection	Unpack and inspect accessories inside package to confirm there is no observed damage, and that all parts are accounted for as described in the use and care manual. Contact Eberbach if any damage is observed	<input type="checkbox"/>	<input type="checkbox"/>
3	Space Requirements	Measure installation space for placement of Shaker accessories. 54" x 35" (Width x Depth) is required for installation and operation	<input type="checkbox"/>	<input type="checkbox"/>
4	Electrical Power	Check for electrical requirements: 100-120V, 60 Hz, 20A and NEMA 5-20P compatible wall socket	<input type="checkbox"/>	<input type="checkbox"/>
5	CO ₂ PSI	Verify 125 PSI max at regulator. Verify 15+/-5PSI delivered to incubator.	<input type="checkbox"/>	<input type="checkbox"/>
6	Equipment set up	If no damage was identified in line 2 above, assemble the accessories to client shaker and complete electrical install. Contact Eberbach if any damage is observed.	<input type="checkbox"/>	<input type="checkbox"/>
7	Review FAT	Verify that FAT has been completed by Eberbach	<input type="checkbox"/>	<input type="checkbox"/>

IIg. Operation Qualification (OQ)

(Client's Responsibility)

Step	Description	Specification or Acceptance Criteria	Result	
			Pass	Fail
1	IQ completed	Has the IQ been performed by the client?	<input type="checkbox"/>	<input type="checkbox"/>
2	Inspect equipment upon receipt	Validate that the equipment was received in good condition and that there is no damage to the equipment or packaging.	<input type="checkbox"/>	<input type="checkbox"/>
3	Equipment set up	Unpack & assemble the equipment per IQ.	<input type="checkbox"/>	<input type="checkbox"/>
4	Equipment set up	Verify the equipment/machine set up is completed.	<input type="checkbox"/>	<input type="checkbox"/>
5	Begin SAT	Client to conduct SAT	<input type="checkbox"/>	<input type="checkbox"/>

IIh. Site Acceptance Test (SAT)

(Client's Responsibility)

Step	Description	Specification or Acceptance Criteria	Result	
			Pass	Fail
1a	Validate Run, unloaded	Set level 1 shaker to run at 135 rpm. Speed must be within +/- 2 RPM for 5 min	<input type="checkbox"/>	<input type="checkbox"/>
1b	Validate Run, unloaded	Set level 2 shaker to run at 135 rpm. Speed must be within +/- 2 RPM for 5 min	<input type="checkbox"/>	<input type="checkbox"/>
1c	Validate Run, unloaded	Set level 3 shaker to run at 135 rpm. Speed must be within +/- 2 RPM for 5 min	<input type="checkbox"/>	<input type="checkbox"/>
2a	Validate Timed Run, unloaded	Set level 1 shaker for a 5-minute timed run @ 50rpm. Verify that it stops after 5 minutes.	<input type="checkbox"/>	<input type="checkbox"/>
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5	Validate Humidity	Check humidity display, must be within +/-0.8%	<input type="checkbox"/>	<input type="checkbox"/>
6	Confirm machine finish	Machine panels and base are free from scratches. (cGMP compliant)	<input type="checkbox"/>	<input type="checkbox"/>
7	Confirm machine finish	Confirm that there are no sharp corners on machine / accessories.	<input type="checkbox"/>	<input type="checkbox"/>
8	Validate stroke	Do the shakers provide a 25mm displacement? Must be within +/-1mm	<input type="checkbox"/>	<input type="checkbox"/>
9	Verify firmware version	Verify the firmware version: _____	<input type="checkbox"/>	<input type="checkbox"/>
10	Validate UPS	Cut power to the Machine for 5 min then re-apply power. Verify that the HMI logged the incident and remained powered.	<input type="checkbox"/>	<input type="checkbox"/>
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12	Machine documentation Completed	Verify the Use and Care for the machine is completed and packaged with the machine.	<input type="checkbox"/>	<input type="checkbox"/>
13	Pictures and video	Take pictures and video of machine.	<input type="checkbox"/>	<input type="checkbox"/>

III. Performance Qualification

Eberbach provides custom engineering solutions. Please contact Eberbach for custom IQ/OQ/PQ for specific work.

III. Customer Sign Off

February 24, 2023

E6430.00: INCUBATOR SHAKER SYSTEM 100V-120V, 60HZ, 20A, SINGLE PHASE

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Buyer expressly acknowledges that the Products purchased pursuant to this Technical Data Package are “Custom Products” as described in the Terms.

The person executing this Technical Data Package on behalf of Buyer is an authorized representative of Buyer; this Technical Data Package has been duly and validly executed and delivered by Buyer and constitutes the legal, valid, and binding obligation of Buyer, enforceable against Buyer in accordance with its terms.

Name

Title

Signature

Date