



 *Sal*6830

## User Guide

MicroGEM Sal6830 Point of Care PCR System

For Use with MicroGEM Sal6830 SARS-CoV-2 Saliva Test



<b>WARNINGS AND SAFE USE</b>	<b>03</b>
<b>1 INTRODUCTION</b>	<b>05</b>
<b>2 MicroGEM Sal6830 Point of Care PCR System AT A GLANCE</b>	<b>09</b>
<b>3 GETTING STARTED - SETUP</b>	<b>11</b>
<b>4 SETTINGS MENU</b>	<b>13</b>
<b>5 RUNNING A TEST</b>	<b>16</b>
<b>6 EXPORT RESULTS</b>	<b>17</b>
<b>7 SOFTWARE UPDATES</b>	<b>20</b>
<b>8 ERRORS AND WARNINGS</b>	<b>21</b>
<b>9 SYMBOLS</b>	<b>23</b>
<b>10 ORDERING AND CONTACT INFORMATION</b>	<b>23</b>
<b>11 WARRANTY</b>	<b>24</b>

## WARNINGS AND SAFE USE

The following warnings are to be used as an aid in risk mitigation.



**Caution:** This product has not been FDA cleared or approved but has been authorized for emergency use by FDA under an EUA for use by authorized laboratories.



**Caution:** The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.



**Caution:** Laboratories within the United States and its territories are required to report all results to the appropriate public health laboratories



**Caution:** Use only the power supply and adaptor that are provided with the system. The correct powersupply and adaptor are required to maintain the safety and electromagnetic compatibility of the system. The power supply and adaptor are not serviceable.



**Caution:** The power supply and adaptor that are provided should only be used with the MicroGEM Sal6830 Pointof Care PCR System.



**Hot Surfaces:** Do not insert any part of the body into the Test Cartridge slot. Internal components maybe hot.



**Hot Surfaces:** The Test Cartridge may be hot when removing from the system following a test.



**Biological Hazard:** This equipment is intended to be used with potentially infectious samples. Use appropriate PPE when using this equipment and handling samples.



**Caution:** Always operate the system on a clean, flat, level, and stable surface that is not in direct sunlight. Do not drop the system. Ensure that air flow to the ventilation openings located on the front and back of the system is not restricted.














**Caution:** Never move the system while a test is in progress.



**Caution:** Follow proper infection control guidelines for handling all specimens and related items. Properly dispose of all contaminated waste according to federal, state, and local requirements.

## WARNINGS AND SAFE USE (Continued)

-  **Caution:** Do not disassemble or attempt to repair the MicroGEM Sal6830 Point of Care PCR System as there is a risk of damage to the system. This system does not contain serviceable parts and should be returned for repair. Disassembling the system will also void the warranty.
-  **Caution:** Only operate the system for its intended purpose and in accordance with this User Guide and warnings. If the system is used in a manner not specified in the User Guide, protection provided by the equipment will be impaired. This system (including power supply) is designed to operate within the manufacturer's specifications. Do not exceed the manufacturer specifications when in use.
-  **Caution:** Position the system with clear access to connectors. Keep connected cables clear of work areas such that tripping or catching will not pull the unit off its work bench. The main socket outlet intended for use with the MicroGEM Sal6830 Point of Care System power supply should be located near the system and be readily accessible. MicroGEM recommends that cables are disconnected when not in use for an extended period.
-  **Caution:** USB interface. If intended for connection to external equipment, please ensure that interfaces of such equipment are separated from mains by double or reinforced insulation and present no risk of electrical shock.
-  **Caution:** If any assay components are dropped, cracked, found to be damaged or open when received, DO NOT USE and discard.
-  **Caution:** Contamination of the work area with previous positive samples may cause false positive results. Manage human samples according to standard clinical practices. Clean system and surrounding surfaces according to instructions provided in Section 1.6, Maintenance & Cleaning.
-  **Caution:** To avoid contamination, do not move the MicroGEM Sal6830 Point of Care PCR System during a run or until all assay components have been removed from the system.
-  **Caution:** Always check the expiration date of consumables prior to running a test.
-  **Caution:** Keep wireless devices at least 11.81" (30cm) away from the system.
-  **Caution:** The MicroGEM Sal6830 Point of Care PCR System should not be exposed to the elements, such as sunlight, rain etc.
-  **Caution:** Do not disassemble the test cartridge. Dispose the test cartridge when the test is complete. Treat as human biohazardous material.

## 1 INTRODUCTION

### 1.1 Intended Use

The MicroGEM Sal6830 Point of Care PCR System is a fluorescence-based detection system for the automated processing and analysis for use with the MicroGEM Sal6830 SARS-CoV-2 Saliva Test.

This document describes the setup, configuration, and operation of the MicroGEM Sal6830 Point of Care PCR System.

**Caution:** Please ensure that the system is operated and used according to the CLIA requirements of the test.

### 1.2 Product Description

The MicroGEM Sal6830 Point of Care PCR System, for use with the MicroGEM Sal6830 SARS-CoV-2 Saliva Test, is an integrated sample processing, nucleic acid extraction and amplification system.

Consumables such as the Test Cartridge, Saliva Cup, Cap, and ID barcodes are required to run the system.

The Test Cartridge and Saliva Cup are pre-loaded with all reagents needed for extraction and amplification of the target nucleic acid, as well as internal controls to monitor the various assay steps.

To perform a test, the user deposits a specific amount of sample into the Saliva Cup and places the cap on the saliva cup. The operator then seals the saliva cup with the locking Cap and inserts it into the Test Cartridge. The fully assembled Test Cartridge is then inserted into the system ready for testing. Extraction, amplification, and detection is carried out by the system and results are automatically displayed on the system screen.

Additional MicroGEM Sal6830 SARS-CoV-2 Saliva Test information and workflows are detailed in the Instructions for Use (IFU).

## 1 INTRODUCTION (Continued)

### 1.3 System Specifications

<b>1.3.1 System</b>	
<b>Color Touch Screen</b>	<b>3.4 x 6" (86 x 154 mm)</b>
<b>Communications</b>	<b>1x USB port for data export</b>
<b>Data Storage</b>	<b>10,000 test results – 64GB Export via USB</b>
<b>Power Requirements</b>	<b>24V – 180W</b>
<b>Dimensions</b>	<b>15.8" W x 15.7" H X 13.8" D (403 mm W x 399 mm H x 348 mm D)</b>
<b>Weight</b>	<b>33lb (15 kg)</b>
<b>Operating Environment</b>	<b>Temperature range: 15-30°C (59-86°F) Humidity range: 20-80% relative humidity Altitude: 0-6,561.7' (0-2000 m)</b>
<b>Storage Environment</b>	<b>Temperature range: 15-30°C (59-86°F) Humidity range: 20-80% relative humidity</b>

## 1 INTRODUCTION (Continued)

### 1.3 System Specifications (Continued)

1.3.2 24V Power Supply and Adaptor	
<b>Rated Input Voltage</b>	<b>100 - 240 VAC</b>
<b>Rated Input Frequency</b>	<b>50/60 Hz</b>
<b>Rated Input Current</b>	<b>2.5-1.3 Amps</b>
<b>Operating Environment</b>	<b>As per system</b>
<b>Storage Environment</b>	<b>As per system</b>
<b>Output Voltage</b>	<b>24V</b>
<b>Output Current</b>	<b>9.2 Amps</b>

### 1.4 Unpacking

Unpack the MicroGEM Sal6830 Point of Care PCR System, taking care when lifting the system. There are carrying features at the front and rear of the system for assistance. Place on a clean, flat, level, and stable surface within reach of an electrical outlet. Place System in a location where the air vents located in the back of the instrument will not be blocked, at least 3.94" (10cm) from the nearest wall or blocking surface. Avoid placing the system in direct sunlight. Inspect for any obvious signs of damage. Report any damage immediately to MicroGEM technical support at [techsupportdx@microgembio.com](mailto:techsupportdx@microgembio.com). Allow the system to sit at operating temperature for at least 30 minutes before powering on.

### 1.5 System Calibration

The MicroGEM Sal6830 Point of Care PCR System is factory calibrated and does not require any further calibration and verification by the user.

## 1 INTRODUCTION (Continued)

### 1.6 Maintenance & Cleaning

The MicroGEM Sal6830 Point of Care PCR System is maintenance-free and has no user serviceable parts. In case of system failure or damage, contact MicroGEM technical support at [techsupportedx@microgembio.com](mailto:techsupportedx@microgembio.com).

MicroGEM recommends that the exterior system surfaces and the surfaces visible behind the door be cleaned after use.

The system should be cleaned with 70% isopropanol - available in commercial wipes or on a damp, lintfree cloth.

Do not spray or pour solution directly onto system when cleaning. Ensure no excess liquid is used when cleaning as it may damage the system.

Clean system and surrounding areas immediately after possible patient sample spills or contamination with 10% bleach on a damp, lint free cloth followed by 70% isopropanol available in commercial wipes.

Clean barcode reader using 10% bleach on a damp, lint free cloth.

**Do not use any other type of cleaner on the barcode reader.**

**Do not disassemble the system for cleaning.**

**Do not immerse in water or cleaning solutions.**

**Do not clean with soap or other solutions except for those listed above.**

### 1.7 Components

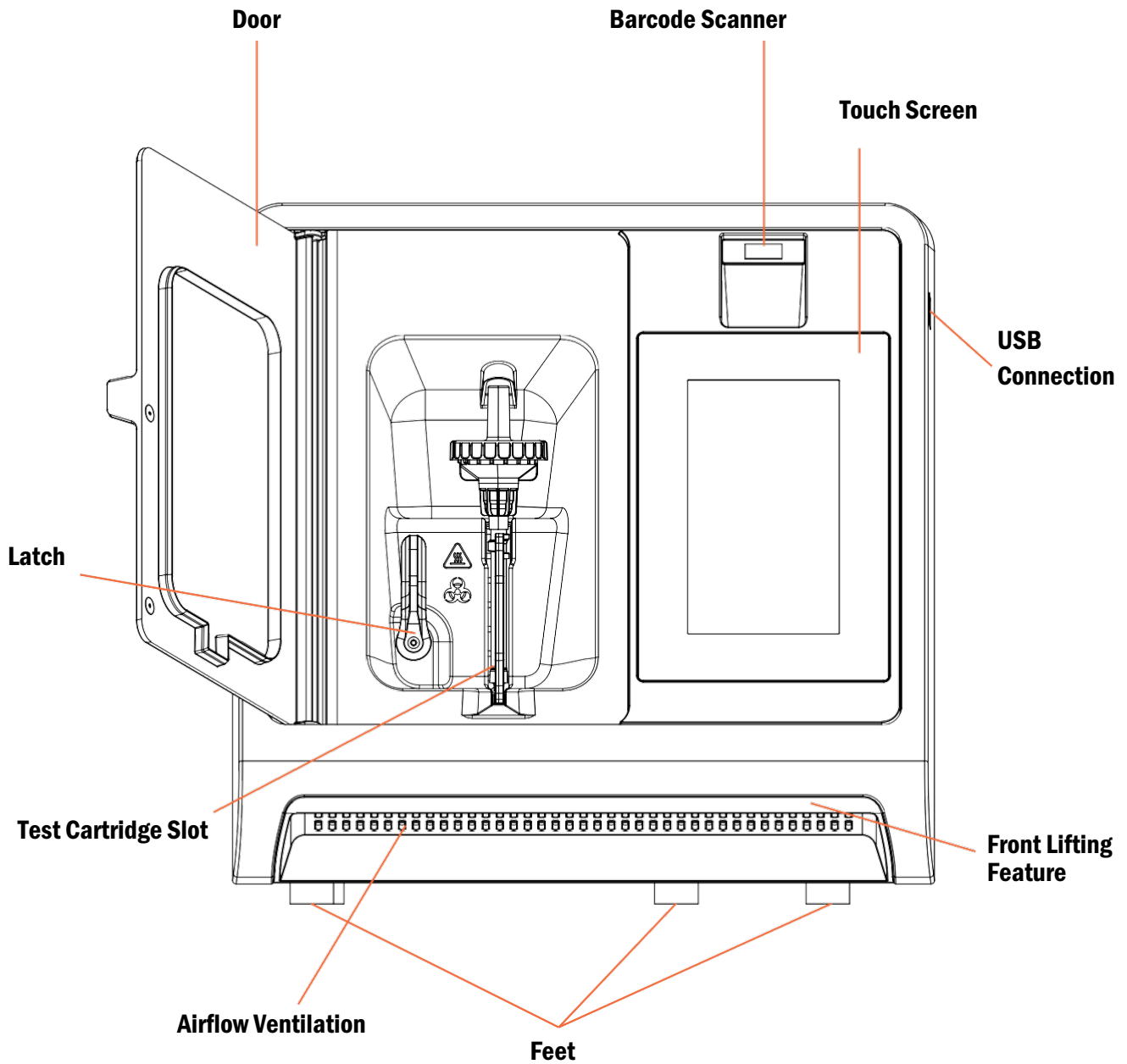
The following items are supplied with the MicroGEM Sal6830 Point of Care PCR System:

- Power Supply and Adaptor
- MicroGEM Sal6830 Point of Care PCR System Quick-Start-Card



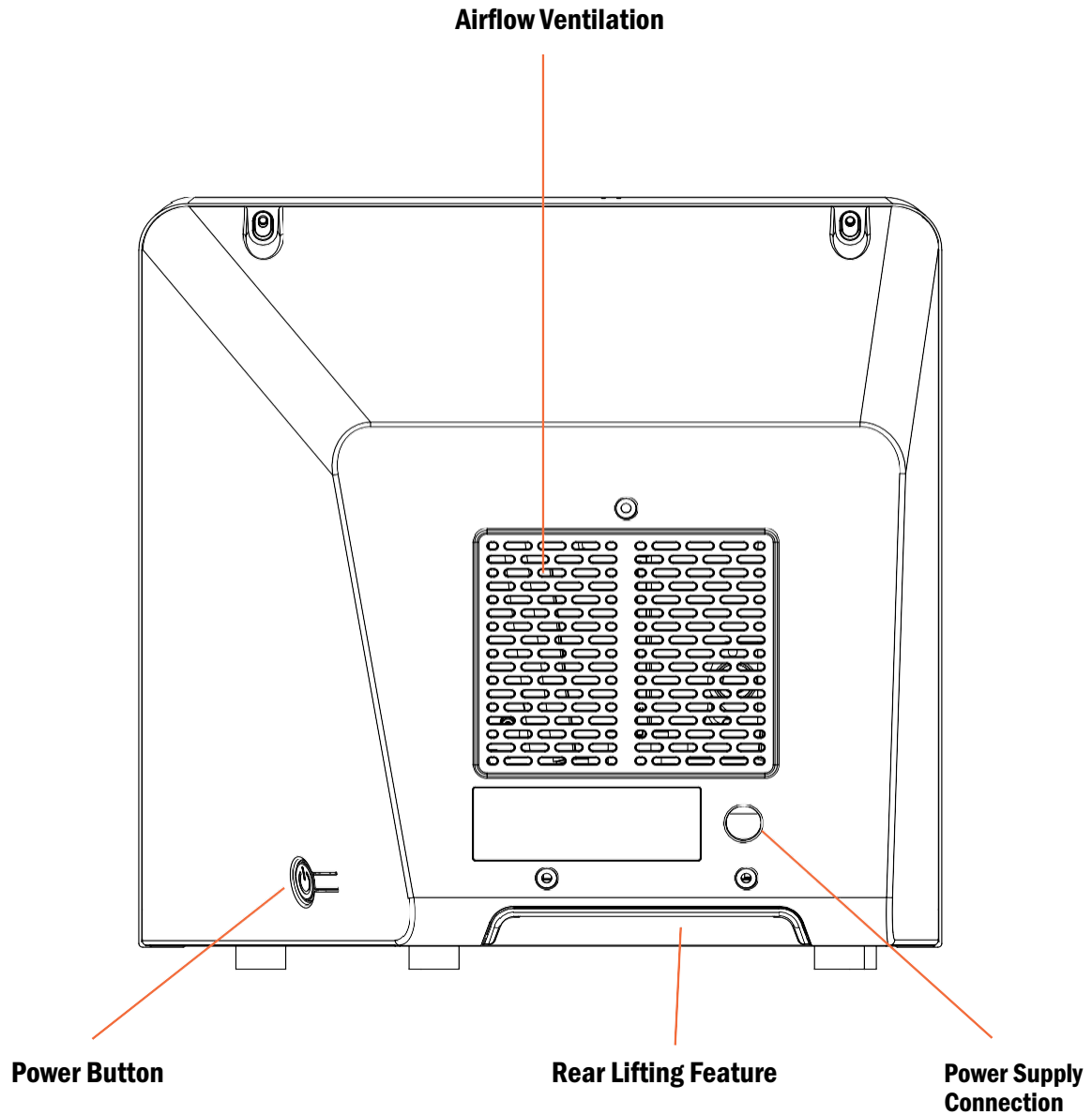
## 2 MicroGEM Sal6830 Point of Care PCR System AT A GLANCE

### MicroGEM Sal6830 Point of Care PCR System, Front View



2 MicroGEM Sa16830 Point of Care PCR System AT A GLANCE (Continued)

**MicroGEM Sa16830 Point of Care PCR System, Rear View**



### 3 GETTING STARTED – SETUP

#### 3.1 Initial Setup



1

Connect the 24V power supply to the system. Plug the adaptor into an appropriate electrical outlet (1).



2 and 3

**Power Up:** Once the power is connected, press the Power Button on the right side of the system to power up and start the system (2).

**Power Down:** Once the system is running, it may be turned off (shut down) by selecting SHUT DOWN from the Home Screen (3).

**System Optimization:** When the system has been powered off for more than 12 hours, the system will automatically start a SYSTEM OPTIMIZATION program (4). No interaction with the system is required during this step and a countdown timer will be displayed. The optimization step takes ~20 minutes to complete. It is recommended to keep the door closed during the System Optimization process as some interior surfaces are warm but opening the door will not affect the process.

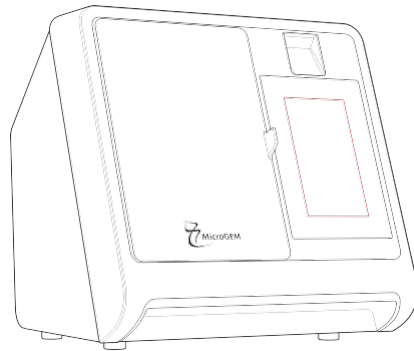


4

Leaving the system powered on or having it off for less than 12 hours will avoid the need for the system to run the optimization program. When the system is powered and idle, a background process ensures optimal operation. This process uses very little energy and is compatible with battery operation.

### 3 GETTING STARTED – SETUP (Continued)

#### 3.2 User Interface



5



Operation control of the MicroGEM Sal6830 Point of Care PCR System is performed using the system Touch Screen (5).

#### 3.3 Home Screen



6

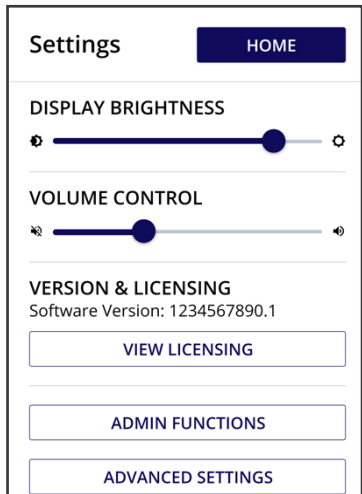
Home Screen (6) displays buttons for access to:

- Start New Test
- Shut Down
- Settings

#### 3.4 Before Running Your First Test

Before running your first test, it is important that the system is set up correctly. In order to do this, ensure that the system time and date have been updated (instructions on how to do this can be found on page 14).

## 4 SETTINGS MENU



7

### Settings Home > Settings

The Settings screen allows users to configure the instrument (7). Settings are saved even when power is off. Settings include:

- Display Brightness
- Volume Control
- Version & Licensing
- Admin Functions
- Advanced Settings:
  - Time
  - Date
  - Time Zone

### Adjust Display Brightness

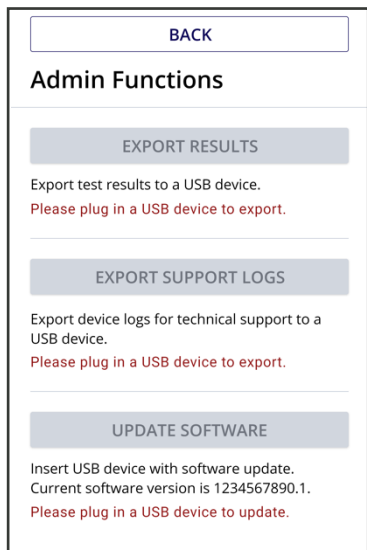
Use the touch slider to adjust the display brightness

### Adjust Volume Control

Use the touch slider to adjust the system volume

### View Licensing

Select VIEW LICENSING if access to licensing is needed



8

### Admin Functions Home > Settings > Admin

**Functions** The Admin Functions page allows the user to configure the instrument (8). Settings are saved even when power is off.

Settings include:

- Export Results
- Export Support Logs
- Update Software

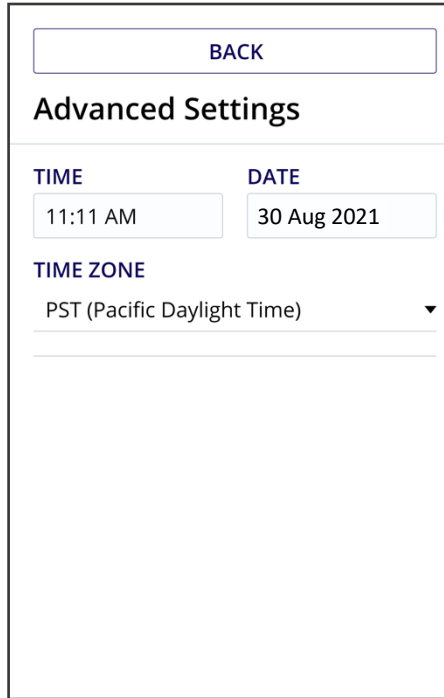
### Data Export

For exporting results, see section 6 on page 17

### Software Update

For software update, see section 7 on page 20

## 4 SETTINGS MENU (Continued)

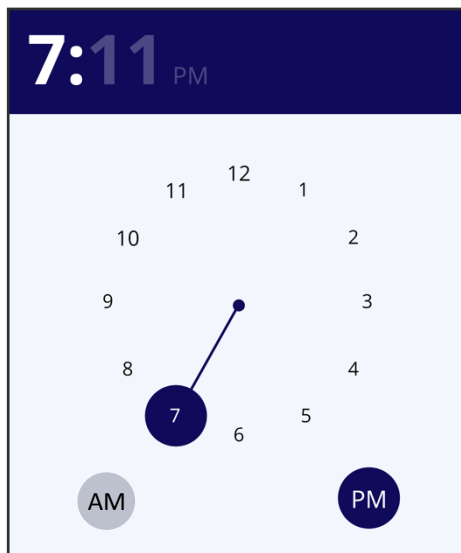


9

**Advanced Settings** Home > Settings > Advanced Settings  
 The Advanced Settings page allows the user to adjust Time and Date (9). Settings are saved even when power is off.

Settings include:

- Time
- Date
- Time Zone



10

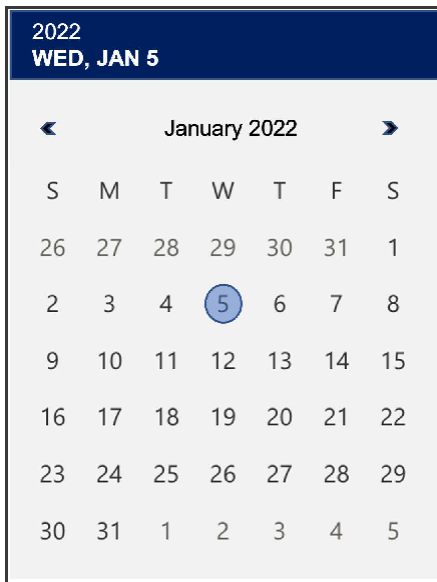
### Adjust Time

Press the Time box on the Advanced Settings page to bring up the System Clock (10).

Touch the screen to change the time and choose between AM and PM

Press off the Clock to return to the Advanced Settings page.

## 4 SETTINGS MENU (Continued)



11

### Adjust Date

Press the Date box on the Advanced Settings page to bring up the System Calendar (11).

Touch the screen to change the date and move between months. Press off the Calendar to return to the Advanced Settings page.



12

### Time Zone

Press the Time Zone box on the Advanced Settings page to bring up the Time Zone Selection List (12).

Select the desired Time Zone.

Press off the Time Zone Selection List to return to the Advanced Settings page.

When the above steps have been completed, the system should be powered down and turned back on. Confirm the settings are correct.

## 5 RUNNING A TEST



13

From the Home Screen, select the “Start New Test” button and follow the prompts (13).

It is essential that the on-screen prompts are followed throughout the testing process. See specific test product inserts for further information.



## 6 EXPORT RESULTS

### 6.1 Export Results via USB download.

Test results can be downloaded from the MicroGEM Sal6830 Point of Care PCR System via a USB Flash Memory Drive.

#### Download Sequence

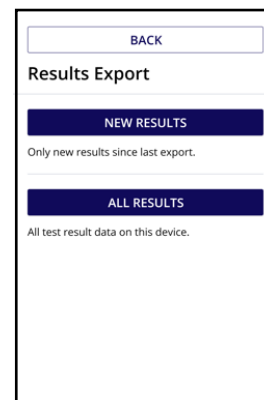
- STEP 1** From the Home Screen, select Settings>Admin Functions to load the Admin Functions screen.
- STEP 2** Attach USB flash memory drive via the USB port located on the right side of the System.
- STEP 3** Upon USB flash memory drive insertion, a message will appear in the EXPORT RESULTS section of the Admin Functions Screen.

If a valid USB Flash Memory Drive is inserted a “USB device detected, ready to export data” message will be shown.

- STEP 4** Select EXPORT RESULTS; this will load the Results Export page.
- STEP 5** From the Results Export page, select NEW RESULTS to export all results since the last export and ALL RESULTS to export all results on the system (14).

Upon selection, exporting will begin. Do not remove the USB Flash Memory Drive during this process.

- STEP 6** When complete, select OKAY to return to the Admin Functions Screen.
- STEP 7** Remove the USB flash memory drive.



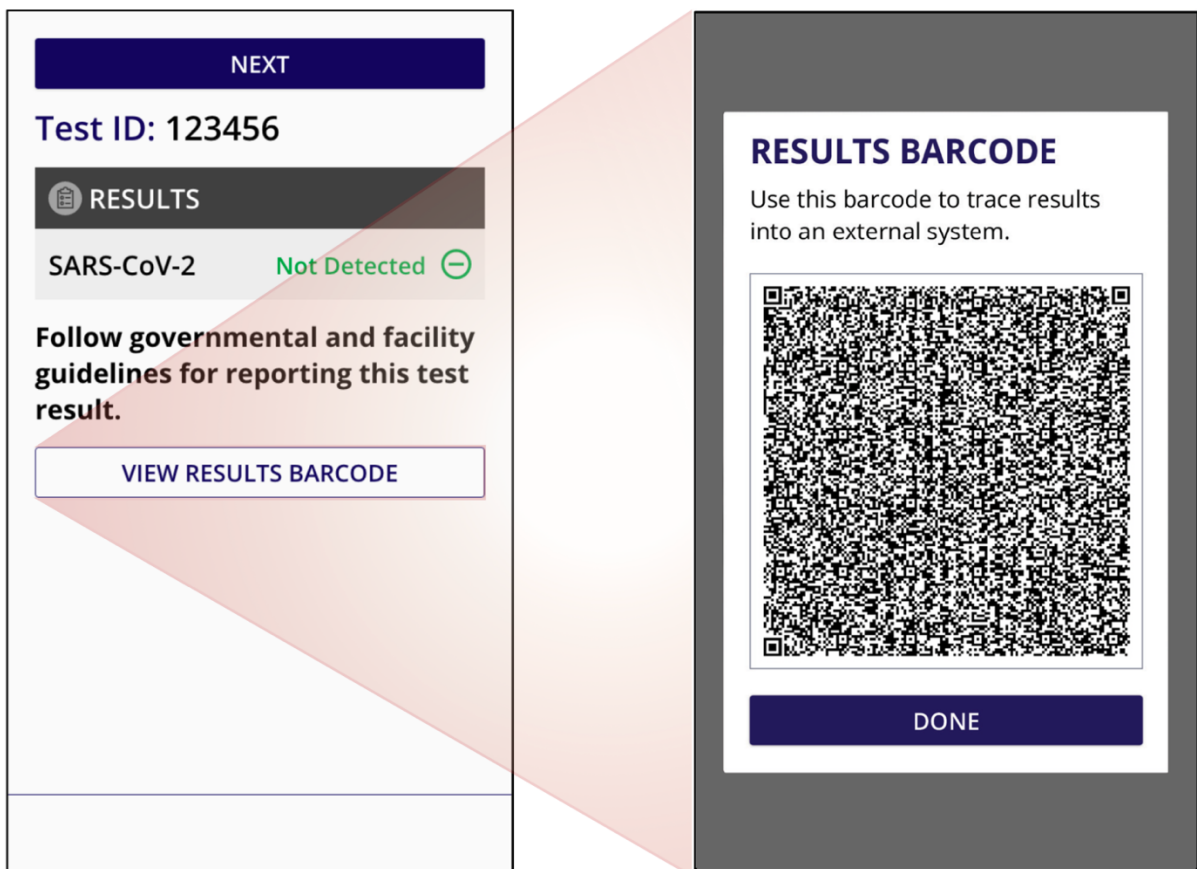
14

## 6 EXPORT RESULTS (Continued)

### 6.2 Export via QR Code

Individual test results can be downloaded from the MicroGEM Sal6830 Point of Care PCR System by scanning the QR code on the VIEW RESULTS PAGE (15) after the test is complete.

The QR code (15) may be scanned by an optional scanner available from Horiba Instruments to export into their Lite DM ver 3.0 middleware connectivity software. The results can also be exported to a USB device. Follow your facility procedures to report results.



15

### 6.3 Export Service Logs via USB Download

Service logs for technical support troubleshooting can be downloaded from the MicroGEM Sal6830 Point of Care PCR System via a USB Flash Memory Drive.

#### Download Sequence

- STEP 1** From the Home Screen, select Settings>Admin Functions to load the Admin Functions screen.
- STEP 2** Attach USB flash memory drive to the system via the USB port located on the right side of the system.
- STEP 3** Upon USB Flash Memory Drive insertion, a message will appear in the EXPORT SERVICE LOGS section of the Admin Functions Screen.
- If a valid USB Flash Memory Drive is inserted a “USB device detected, ready to export data” message will be shown.
- STEP 4** Select EXPORT SERVICE LOGS, this will load the Support Logs Export page
- STEP 5** From the Support Logs Export page select TROUBLESHOOTING DATA to export device data for troubleshooting and SERVICE LOGS to export service logs for technical support.
- Upon selection, exporting will begin. Do not remove the USB Flash Memory Drive during this process.
- STEP 6** When complete, select OKAY to return to the Admin Functions Screen.
- STEP 7** Remove the USB flash memory drive.

## 7 SOFTWARE UPDATES

### USB Software Update



Caution: Stored test data may be deleted during the software update process. Test results stored on the MicroGEM Sal6830 Point of Care PCR System must be exported prior to performing a software update.



Caution: DO NOT REMOVE USB DRIVE DURING SOFTWARE UPDATE. USB Flash Memory Drive can be removed from the MicroGEM Sal6830 Point of Care System as per the software update sequence below.

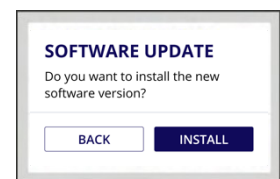
### Update Sequence

- STEP 1** Prior to software update, export test results stored on the system.
- STEP 2** From the Home screen, select Settings>Admin Functions to load the Admin Functions screen.
- STEP 3** Attach USB Flash Memory Drive with the selected software update to the system via the USB port located on the right side of the system.
- STEP 4** Upon USB Flash Memory Drive insertion, a message will appear in the SOFTWARE UPDATE section of the Admin Functions Screen (16).

If a valid USB Flash Memory Drive is inserted a “USB contains a valid software update” message will be shown.

If a “USB does not contain valid update package” message is shown, remove the USB FlashMemory Drive and insert correct USB Flash Memory Drive.

- STEP 6** Select UPDATE DEVICE.
- STEP 7** Select INSTALL to begin the software update.
- STEP 8** When complete, the system will reboot.
- STEP 9** Remove the USB Flash Memory Drive.
- STEP 10** From the Home screen, select Settings and confirm the Software Version number has updated to the new version being installed (17).



16

17

## 8 ERRORS AND WARNINGS

This section provides troubleshooting steps for specific error and warning codes. Once the steps listed below are executed, if the error or warning persists, contact MicroGEM Technical Support. Contact information can be found at the end of the User Guide.

### System Error

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**Error Name: System Error**

Description: A system error has occurred, please restart the system. If problem persists, contact support.

**Action: Repeat the test with a new kit and fresh saliva sample. If the issue persists, contact technical support at [techsupportdx@microgembio.com](mailto:techsupportdx@microgembio.com).**

### Data Export Error

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**Error Name: Data Export Failed**

Description: The data was not exported. The USB device may be full or in a read-only state.

**Action: Try again with a different USB device**

### Software Update Error

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**Error Name: Software Update Failed**

Description: The software update failed. Load a new software update package to the USB device and try again.

**Action: Load a new software update package to the USB device and try again.**

### Invalid Test Error

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**Error Name: Invalid Test**

Description: Unable to determine a result. Repeat the test.

**Action: Repeat the test with a new kit and fresh saliva sample.**

## 8 ERRORS AND WARNINGS (Continued)

### Test Interrupted Error

**Error Name: Test Interrupted**

Description: The test failed because the door was opened during the test.

**Action: Repeat the test with a new kit and saliva sample.**

### Cannot Save Settings Error

**Error Name: Cannot Save Settings**

Description: The settings you changed cannot be saved. Changes will be lost once instrument is restarted.

**Action: Restart the system and try again**

### Remove Cartridge Error

**Error Name: Remove Cartridge**

Description: Please remove the cartridge before starting a new run.

**Action: Remove the cartridge**

### Close Door Error

**Error Name: Close Door**

Description: Please close the door before starting a new run.

**Action: Close door**

### Insert Cartridge Error

**Error Name: Insert Cartridge**

Description: Please insert the cartridge securely before running a test.

**Action: Insert cartridge securely**

## 9 SYMBOLS

A complete list of relevant symbols may be found at  
[www.microgembio.com/covid-19/resources](http://www.microgembio.com/covid-19/resources).

## 10 ORDERING AND CONTACT INFORMATION

### Reorder Numbers

<b>REF</b>	<b>SCFMA</b>	MicroGEM Sal6830 Point of Care PCR System
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### Technical Support and Contact Information

Technical support is available by visiting our website at [www.microgembio.com/covid-19](http://www.microgembio.com/covid-19)  
or by email at [techsupportdx@microgembio.com](mailto:techsupportdx@microgembio.com)

Please have the following information available:

- Product Name
- Lot Number of the consumable
- Serial Number of the System
- Error Message
- Software Version

## 11 WARRANTY

### 1 Year Limited Warranty

The MicroGEM Sal6830 Point of Care PCR System is a fluorescence-based system for the processing and analysis of MicroGEM Sal6830 SARS-CoV-2 Saliva Tests. Proper adherence to the instructions in the User Guide is critical to proper operation.

**WARNING:** Failure to comply with the User Guide could lead to inaccurate results.

Manufacturer guarantees to the original purchaser of the system that the system is free from material defects for one year from the date of purchase. This warranty does not guarantee the uninterrupted operation of the system. Manufacturer's only liability and Purchaser's exclusive remedy under this warranty is that during the warranty period Manufacturer shall replace or repair, at no charge, and at the Manufacturer's sole discretion, any system with a defective component. Manufacturer makes no other warranties and expressly excludes any implied warranty of merchantability, noninfringement or fitness for a particular use.

There are no user-serviceable parts in the system. Tampering with any portion of the system, abusing the system, or using the system in a manner inconsistent with its User Guide will void this warranty. This warranty does not apply to any component that is damaged by improper storage in environmental conditions outside the recommended range, accident, or that is subject to alteration, misuse, tampering or abuse. Purchaser must file a warranty claim in writing and within the applicable warranty period to the Manufacturer.

Please contact technical support at [techsupportdx@microgembio.com](mailto:techsupportdx@microgembio.com) prior to returning any defective components. Where a return is required, a returns code will be provided. Returns received without a valid returns code will not be accepted.

Refer to Ordering and Contact Information section of the User Guide for additional information.





## MicroGEM Sal6830 Point of Care PCR System

### User Guide

 **MicroGEM**  
705D – Dale Avenue Charlottesville, VA, 22903  
[www.microgembio.com/covid-19](http://www.microgembio.com/covid-19)



This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions:  
(1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

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Pat: [www.microgembio.com/patent](http://www.microgembio.com/patent)

