

# SignipHy™ pH Monitoring System

## User Manual

Doc No. 120040-08



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# 1. Overview

The SignipHy™ pH Monitoring System is an accessory device that monitors pH. When the SignipHy TrakStation® is connected to the G210 InviCell Plus with SignipHy pH monitoring incubator, the SignipHy TrakPod® provides pH monitoring within the incubator chamber environment, without opening the chamber lid and without sample exposure. The SignipHy pH Monitoring System is an accessory to the G210 InviCell Plus with SignipHy pH monitoring bench-top incubator and the system consists of a SignipHy TrakStation, SignipHy TrakPod, SignipHy sv<sup>2</sup> Sensors and SignipHy qc<sup>2</sup> Alignment Tool. These items are all described in this document.

## Indication for Use

The G210 InviCell Plus with SignipHy pH Monitoring System is a bench-top incubator that is intended to provide a controlled environment at or near body temperature and gas levels (CO<sub>2</sub>, O<sub>2</sub>, and N<sub>2</sub>) for the development of gametes and/or embryos during In Vitro Fertilization (IVF) / Assisted Reproductive Technology (ART) treatments.

The G210 InviCell Plus with SignipHy pH Monitoring System includes an accessory for pH monitoring of surrogate samples of bicarbonate-based culture media used for ART procedures.

## Device Description

The SignipHy sv<sup>2</sup> Sensor is a small surrogate vessel into which a sample of the media can be put to track its pH. At the bottom of the sensor is a special membrane that contains a dye. This dye is affected by the pH of the media sample, and it reacts to light differently at different pH levels.

The sensor fits into the fiber optic fixture located inside of the G210 InviCell Plus with SignipHy pH monitoring culture chamber. To make a measurement, the SignipHy TrakPod sends flashes of light of a certain wavelength through the fiber optic fixture. The dye in the membrane reacts by sending back flashes of light at a different wavelength. The SignipHy TrakPod reads this result and calculates the pH of the media sample. The timing of this measurement can be set to be once per minute or once every 30 minutes.

The system includes:

- **SignipHy TrakStation:** This is a tablet computer running proprietary software. The software initiates pH readings, as well as stores and displays these pH measurements over time. Using an included USB 3.0 hub, up to eight (8) SignipHy TrakPods can be connected simultaneously to a SignipHy TrakStation.
- **SignipHy TrakPods:** The SignipHy TrakPod is the proprietary, LED-based, optical pH measurement instrument. The SignipHy TrakPod is mechanically supported within the chassis of the G210 InviCell Plus with SignipHy pH monitoring incubator and allows monitoring of one incubator chamber. It is a USB connected fluorescent measurement device with a fiber optic cable and fixture that connects to the SignipHy sv<sup>2</sup> Sensor inside

of an incubator. The SignipHy TrakPod and SignipHy sv<sup>2</sup> Sensor together detect the pH of a liquid sample.

- **SignipHy sv<sup>2</sup> Sensors:** The SignipHy sv<sup>2</sup> Sensor is a disposable. It is a small surrogate vessel into which a sample of the media can be put to track its pH. 100 µL of media and 150 µL of oil are used in the monitoring test. At the bottom of the sensor is a special membrane that is impregnated with a proprietary dye. This dye is affected by the pH of the media sample, and it reacts to light differently at different pH levels. The sensor fits into the fiber optic fixture. To make a measurement, the SignipHy TrakPod sends light flashes of a certain wavelength through the fiber optic fixture. The dye in the membrane reacts by sending back flashes of light at a different wavelength. The SignipHy TrakPod reads this result and calculates the pH of the media sample. A sensor is used for seven (7) days in a normal test with a pH reading frequency of 30 minutes. SignipHy sv<sup>2</sup> Sensors are provided in a kit of ten (10) individually pouched items. SignipHy sv<sup>2</sup> Sensors are Ethylene Oxide Sterilized.
- **SignipHy qc<sup>2</sup> Alignment Tool:** A fluorescent reference device for use in System Alignment and Quality Control. The SignipHy qc<sup>2</sup> Alignment Tool contains a fluorescent target with a stable and known fluorescent signal. Between each week of pH monitoring, the SignipHy qc<sup>2</sup> Alignment Tool is used to check that the SignipHy TrakPod fluorescent signal is still performing according to factory specifications. If any changes in the fluorescent signal are detected the SignipHy TrakPod can make adjustments to the detectors to restore it to appropriate performance levels. One SignipHy qc<sup>2</sup> Alignment Tool is needed for each lab and it is replaced annually.

The SignipHy pH Monitoring System's user interface is described in Section 6 - Menu Functions.

For a more detailed explanation of how the SignipHy pH Monitoring System uses fluorometric technology, see Section 9 - The Science Behind the SignipHy pH Monitoring System.

## Features of the SignipHy pH Monitoring System

The SignipHy pH Monitoring System monitors pH.

It is easy to perform routine quality control checks using the supplied SignipHy qc<sup>2</sup> Alignment Tool.

The SignipHy TrakStation provides several options for viewing and controlling data collection and adjusting the configurations.

Common things to do include:

- Start and end pH tests;
- Run QC Alignment tests;
- View current pH results and plots of pH history;
- Download data into CSV-formatted files to a USB drive;

- Set the frequency with which pH readings are to be taken (at 1- or 30-minute intervals);
- Add and remove SignipHy TrakPods;
- Perform the Site Standardization procedure and edit offset values.

## 2. Warnings and Precautions



Caution: Federal Law restricts this device to sale by or on the order of a physician or a practitioner trained in its use.

### Warnings



The SignipHy pH Monitoring System cannot be relied upon to measure pH outside of pH 6.8 – 7.6 range, as values outside the stated range may not be accurate. Consult the Troubleshooting section if pH values are reported outside this range.



The SignipHy pH Monitoring System is intended for use with bicarbonate buffered media at elevated CO<sub>2</sub> and temperature. HEPES or MOPS-buffered media should not be used with the TrakStation System. It is the user's responsibility to ensure the compatibility of the media being used. Use of non-compatible media may provide erroneous pH readings.



The SignipHy pH Monitoring System has been shown effective with media containing phenol red at concentrations up to 15 µg/ml. The system performance has not been shown with media containing phenol red concentrations above this level and may not provide accurate results.



Tablets connected to internet service may be susceptible to viruses - caution should be taken to reduce the risk of malware infecting your SignipHy TrakStation tablet.



Automatic updates to the SignipHy TrakStation tablet OS and to the web browser have been intentionally turned off as default factory settings. Manual updating could result in unknown or limited SignipHy TrakStation performance.



The SignipHy TrakPod emits light to perform pH measurements. The color of the light is green (518 nm). It has been shown that the light is very low intensity, is turned on for less than 10 seconds per 24 hours. The SignipHy sv<sup>2</sup> Sensor emits light when excited by the SignipHy TrakPod. The color of the light is red (600 nm peak, 550 to 650 nm). It has been shown that the emitted light is even lower intensity and is only present when excited (less than 10 seconds per 24 hours). Use of the 30 minute pH test frequency and placement of embryos further from the SignipHy TrakPod fiber optic will reduce light exposure to embryos. Furthermore do not operate the SignipHy TrakPod without a SignipHy sv<sup>2</sup> Sensor in place.



Electrical shock could occur if power adapters other than those supplied are used.



Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.



Exercise special care: do not use SignipHy sv<sup>2</sup> Sensors if packaging or sensor is damaged.



The SignipHy sv<sup>2</sup> Sensors are single use. Do not reuse sensors and do not stop and restart pH tests without changing the sv<sup>2</sup> Sensor between tests. Failure to do so may result in erroneous pH readings.

## Precautions



The media under an oil layer in SignipHy sv<sup>2</sup> Sensors takes time to equilibrate in a CO<sub>2</sub> environment. The pH of media without equilibration can be higher than the pH accuracy range for the system until completion of equilibration (10-24 hours). Readings prior to completion of equilibration may not be accurate.



When using media with an intended use time of less than 7 days, it is advised to change the SignipHy sv<sup>2</sup> Sensor with the same frequency of the media by ending the pH test and starting a new test with a new SignipHy sv<sup>2</sup> Sensor.



Use of a secure wireless network is recommended. Connection to network is optional but needed to enable some SignipHy TrakStation features including emailing data, sending pH alarms and remotely accessing the SignipHy TrakStation with other locally connected computers. The wireless connection in the SignipHy TrakStation is compliant with the 802.11a/g/n/ac protocol and all radio frequency transmissions are FCC certified for a class B digital device per Part 15 of the FCC rules. The wireless connection is provided by the tablet computer's standard WiFi connection using either 2.4 GHz or 5 GHz frequencies. The Quality of Service required is minimal; 100 kbps is sufficient to support optional network functions.

## Guidance and Manufacturer's Declaration – Electromagnetic Emissions

The G210 InviCell Plus with SignipHy™ pH Monitoring System is intended for use in the electromagnetic environment specified below. The customer or the user of the System should assure that it is used in such an environment.


Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR11	Group 1	The G210 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR11	Class A – Complies	The G210 is suitable for use in all establishments other than domestic and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A - Complies	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Class A - Complies	

## Guidance and Manufacturer's Declaration – Electromagnetic Immunity

The G210 InviCell Plus with SignipHy™ pH Monitoring System is intended for use in the electromagnetic environment specified below. The customer or the user of the System should assure that it is used in such an environment.

IMMUNITY Test	IEC 61326-1 Test level	Compliance level	Electromagnetic environment - guidance			
Electrostatic discharge (ESD) IEC 61000-4-2	± 4 kV contact ± 2, 4, 8 kV air	± 4 kV contact ± 2, 4, 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.			
Electrical fast transient/burst IEC 61000-4-4	± 1.0kV Burst Potential – Mains ± 0.5kV Burst Potential – Signals/Control	± 1.0kV Burst Potential – Mains ± 0.5kV Burst Potential – Signals/Control				
Surge IEC 61000-4-5	Line-Line: 0.5kV Combination Wave (1.2µS x 50µS Voltage, 8µS x 20µS Current) Line-Earth: 0.5kV & 1.0 kV Combination Wave (1.2µS x 50µS Voltage, 8µS x 20µS Current)	Line-Line: 0.5kV Combination Wave (1.2µS x 50µS Voltage, 8µS x 20µS Current) Line-Earth: 0.5kV & 1.0 kV Combination Wave (1.2µS x 50µS Voltage, 8µS x 20µS Current)				
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	Applied Levels					Minimum Performance Criteria Required
	Voltage Dips % Ut	% Reduction	Duration(s)	Period Cycles 50Hz	Sync Angle (Degrees)	
	0%	100%	-	0.5	0 and 180	B
	0%	100%	-	1	0 and 180	B
	70%	30%	0.5	25	0 and 180	C
	Voltage Interruption % Ut	% Reduction	Duration (s)	Period Cycles 50Hz	Sync Angle (Degrees)	
	0%	100%	5	250	0	C
Supplementary Information: None						



IMMUNITY Test	IEC 61326-1 Test level	Compliance level	Electromagnetic environment - guidance
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical commercial environment.
Conducted RF IEC 61000-4-6	3Vrms, 0.150-80Hz, 80% AM Modulation, 1s Dwell Time	3Vrms, 0.150-80Hz, 80% AM Modulation, 1s Dwell Time	Portable and mobile RF communications equipment should be used no closer to any part of the G210, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter  Recommended separation distance $d = [ 3.5 / 3 ] \sqrt{P}$ $d = [ 3.5 / 3 ] \sqrt{P}$ 80 MHz to 800 MHz
Radiated RF IEC 61000-4-3	3 V/m 80 to 1000 MHz  3 V/m 1400 to 2000 MHz  1 V/m 2000 to 2700 MHz	3 V/m   3 V/m   1 V/m	$d = [ 7 / 3 ] \sqrt{P}$ 800 MHz to 2.5 GHz  Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).  Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, <sup>a</sup> should be less than the compliance level in each frequency range. <sup>b</sup>  Interference may occur in the vicinity of equipment marked with the following symbol:  
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
<sup>a</sup> Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the G210 is used exceeds the applicable RF compliance level above, the G210 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the G210. <sup>b</sup> Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

### 3. First Time Setup and First Use

A new SignipHy TrakStation and the SignipHy TrakPod(s) will require a short procedure to align the units for the surrounding environment. Plan on spending about 15 minutes the first day and 15 minutes the second day for setup activities, which will include calibration of the device.

#### Components

##### SignipHy TrakStation

- Tablet
  - Power Supply
  - USB type C to barrel plug adapter
  - Detachable Keyboard
- 10 port USB Hub
  - Power Supply
  - USB cable
- 3x Magnetic Cloops for cable management
- USB Drive (with eIFU)
- 2x USB extension cables
- 1x USB type C adapter (if needed)
- Worldwide Power Adapters

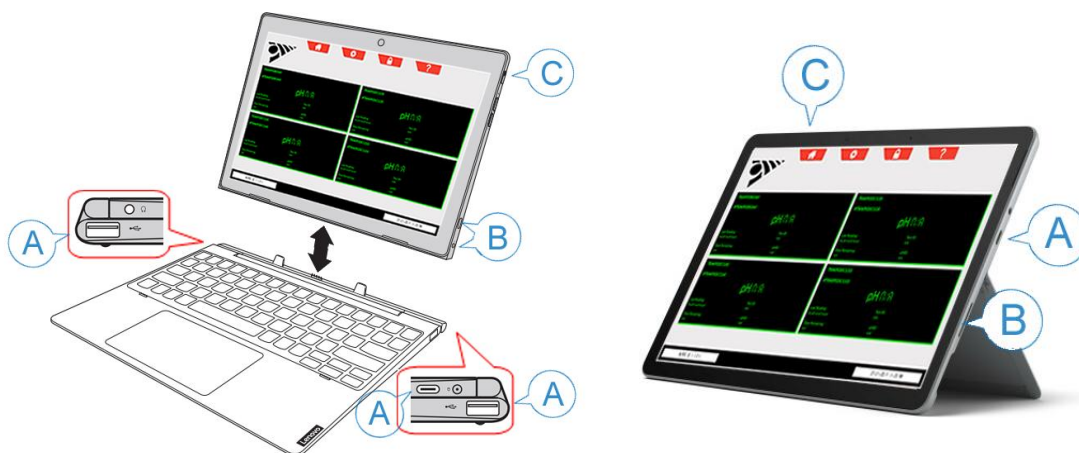
##### SignipHy TrakPod

- Fully integrated into the G210 InviCell Plus with SignipHy pH monitoring incubator, just connect a Mini USB Cable

#### Setup

Unpack the box and verify that all parts are present and in good condition.

1. Place the SignipHy TrakStation in a convenient location for the incubators that will be monitored.



**Pictured: SignipHy TrakStation Setup For Connections.**  
**Left - Lenovo model, Right – Microsoft model**

2. Plug the 10 port USB Hub into the SignipHy TrakStation (A above) using the USB cable, one of the USB extension cables and if applicable a USB type C adapter. The USB Hub can be located out of the way behind the incubator.



**CAUTION:** Your laboratory setup may require the use of extension cables. If a USB cable longer than 6 feet (1.8 meters) is needed, an active repeater is required on extension cables.

3. Plug in the power supply for the USB Hub.



**Pictured: Connections For USB Hub to Power Source**

4. Plug in the power supply for the SignipHy TrakStation (B above) and turn it on (C above).
5. If desired, plug a second USB extension cable into the USB Hub and position it for easy access connection of a USB drive to download data. Data can be retrieved by connecting the SignipHy TrakStation to the local internet if applicable or downloaded as a CSV file to an

external USB. See the Menu Functions Section for instructions to retrieve data (specifically the Pod Page and Remote Access).



**Pictured: USB Drive Connected to Hub**

6. The SignipHy TrakPod is installed inside the G210 InviCell Plus with SignipHy pH monitoring incubator. Plug in the USB cable between the SignipHy TrakStation's USB Hub and the designated USB port on the back of the incubator.



**Pictured: Back of G210 InviCell Plus with SignipHy pH monitoring incubator TrakPod to USB Hub Connection**

7. *Optional:* Use a USB extension cable as necessary to cover longer distances between the SignipHy TrakStation and SignipHy TrakPod. If a USB cable longer than 6 feet (1.8 meters) is needed, an active repeater is required on extension cables.
8. On the SignipHy TrakStation user interface, navigate to the Add/Remove Pods menu in 'Settings' and find the serial number of the newly-plugged-in Pod to add it to the SignipHy TrakStation display. For each connected SignipHy TrakPod, a user specified name can be assigned such as an incubator number or identification that is going to be used.
9. Repeat steps 6 through 8 as necessary for additional SignipHy TrakPods (up to eight (8) per SignipHy TrakStation).

## First Use

The first time the SignipHy TrakStation is used, the date and time should be checked and if needed, adjusted.



**CAUTION:** Windows Operating System tablet date, time, and network connections are configured at the operating system level. Adjusting other settings is not advised except at your own risk.



**CAUTION:** A new SignipHy TrakStation will also need to have the SignipHy qc<sup>2</sup> Alignment Tool assigned to it. These can both be performed in the Supervisor Screen (see Menu Functions Section Supervisor Screen). Check that the dashes are included in the entry of the SignipHy qc<sup>2</sup> Alignment Tool.

## Quality Control (QC) Test

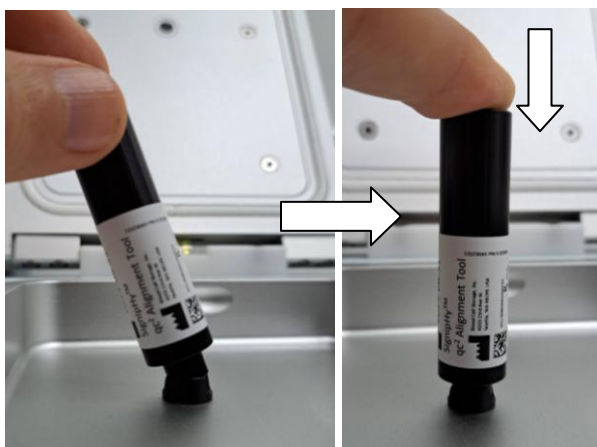
When first connected, each SignipHy TrakPod must have the initial QC Alignment test performed. For a full description of QC testing see 'Routine Workflow – QC Testing'.



**CAUTION:** Perform the initial QC Test before continuing with Site Standardization

### Initial QC Test

1. The QC test is run from the Pod menu or the 'Settings'. Select the Run QC Test window to proceed through the test. NOTE: The FIND FIBER button will cause the Pod to flash the LED several times to help locate which fiber optic might be associated with the chosen Pod.
2. Use a sterile non-linting tissue to remove any dust from the fiber optic surface. Don't use liquids on the fiber optic surface for this part of the test.
3. Remove the culture tray insert from the chamber.
4. Place the SignipHy qc<sup>2</sup> Alignment Tool on the fiber fixture. It can be helpful to apply downward pressure to the SignipHy qc<sup>2</sup> Alignment Tool for the test to ensure it is fully seated on the fiber optic fixture.



**Pictured: SignipHy qc<sup>2</sup> Alignment Tool on Probe**

5. Press the CONTINUE button: The SignipHy TrakPod will test the fluorescent signal and compare it to the assigned fluorescent levels.
6. The Screen will then display the result of the QC Test.

## Site Standardization

Site Standardization is a procedure performed on first installation of the SignipHy TrakStation systems and repeated if culture conditions are altered through a change in culture media, change in G210 InviCell Plus incubators, or a physical relocation. The site standardization requires a pH reference sample to complete.

### Why is Site Standardization Important?

During SignipHy TrakPod adjustment at the factory, several environmental factors are different than in clinical laboratory conditions including: CO<sub>2</sub>, medium composition, temperature, elevation, humidity, the condition of the incubator, and test equipment used by the manufacturer. Site standardization customizes pH monitoring values based on unique embryo culture conditions.

### What is a pH Reference Sample?

A pH reference sample is used during site standardization to align pH monitoring to the embryo culture conditions. It uses media used in the lab for embryo culture, and allows the SignipHy TrakStation to determine the unique laboratory pH used, based on environmental conditions and medium composition. A media sample prepared with oil overlay must be measured on a blood gas analyzer to provide a reference pH measurement following equivalent equilibration time.

### How do I Achieve Maximum System Accuracy?

Ensure that the incubator being used is properly calibrated for both CO<sub>2</sub> and temperature. To calibrate, consult the G210 InviCell Plus incubator operator's manual. Verify the incubator temperature and CO<sub>2</sub> concentration by an external method (i.e. Thermometer, Fyrite) before beginning the setup tests.

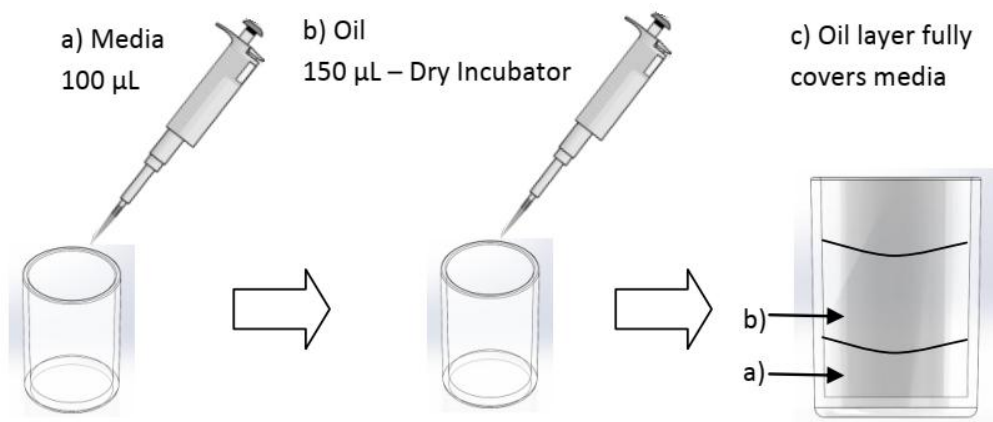
The SignipHy TrakStation system is factory-set for Universal IVF Media, 5% CO<sub>2</sub> and 37°C in Seattle, WA USA at an elevation of 46 Feet ASL. A tool to calculate pH changes is located at <http://fertility.coopersurgical.com/signiphy/support/signiphy/>.



If the incubator is moved to a different site, or the type of media monitored is changed, then the steps below must be executed. **CAUTION: It is recommended to always execute these steps when first setting up the system.**

## Site Standardization Preparation

1. Remove IVF medium and oil from refrigerator and let sit out for a few minutes while getting the sensors ready.
2. Remove three (3) SignipHy sv<sup>2</sup> Sensors aseptically from the sterilization pouches in which they arrived, and place the sensors in a petri dish or rack. Sensors should be easily removable from the holder to minimize the time that the incubator is open when reading the sensors.
3. Prepare the pH Reference Sample for Blood Gas Analysis.
4. Hold the sensor with the opening upward. Carefully pipette 100 µL of media down the side of the sensor. Avoid adding bubbles while doing this step. Also avoid touching the pipette tip to the membrane.
5. Pipette oil onto each of the sensors. It is recommended to use 150 µL for dry (non-humidified) Incubators. Touch the tip of the pipette above the surface of the medium and flow the oil onto the surface of the medium avoiding bubbles. It should spread out and completely cover the surface of the medium.



**Pictured: SignipHy sv<sup>2</sup> Sensor Preparation with Media and Oil**



**CAUTION:** It is critical to allow the sensors to equilibrate for a full 24 hours prior to performing site standardization. Avoid opening the incubator more than necessary during this initial equilibration time.

6. Place all sensors in the incubator and **let sit for 24 hours**. Settings should be the normal CO<sub>2</sub> levels and normal temperature near 37 °C.

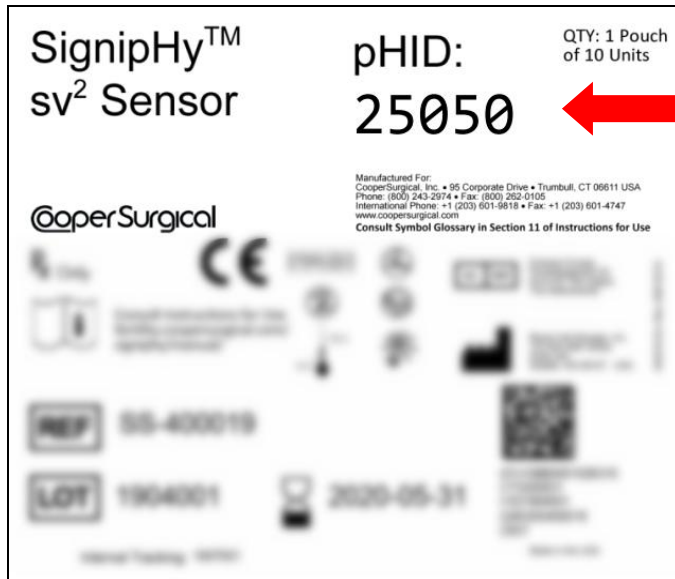
## Site Standardization Readings

1. To read the pH Reference Sample, have the blood gas analyzer calibrated and ready to read.
2. Remove the Reference Sample from the incubator and quickly (within 30 seconds) read the pH value. Record or remember the reference sample pH for use later in site standardization. *It is recommended to place the tip of the index finger over the top of the*



container or cap it while carrying it to the instrument. This will keep the pH as stable as possible in the lab atmosphere.

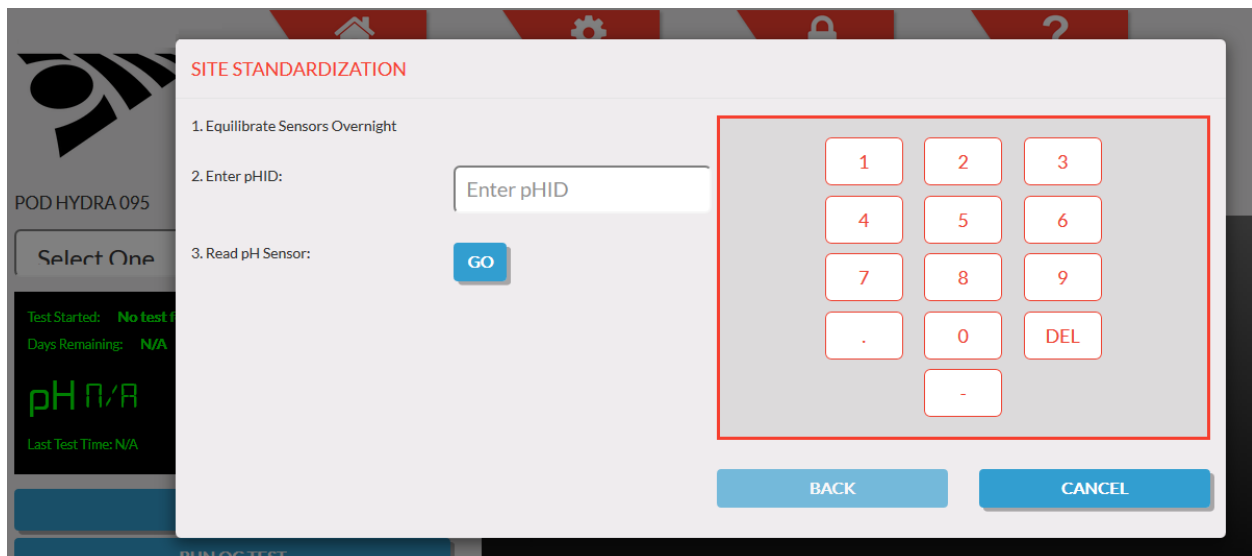
- Using the Site Standardization menu tool for the specific SignipHy TrakPod, Enter the pHID for the sensors being used. A lot specific pHID is printed on the kit packaging (25050 in the example below). Use the pHID on the packaging when setting up to read the pH.



**Pictured: Example SignipHy sv<sup>2</sup> Sensor label**



***CAUTION: The pHID 25050 is an example pHID used only for demonstration. Do not enter 25050 as the pHID for testing purposes. Enter the pHID that is provided on the labeling.***



**Pictured: Site Standardization Screen**



4. Measure each (1) sensor once in the incubator. Press the sensor into the fixture making sure the sensor is fully seated in the fixture. *Keep index finger covering the top of the sensor while pushing the Go button on the SignipHy TrakStation* as this lowers the amount of ambient light interacting with the sensor and ensures it is fully seated in the fixture.



**CAUTION:** Constant opening/closing of the incubator lid will lower the temperature and CO<sub>2</sub> in the incubator. Read all three (3) sensor readings quickly (within 30 seconds) when performing this step.

5. Upon completing the readings, use the checkboxes to select pH results from the sensor readings to average and push the average button. The software will then average the selected readings. Do not select a reading if there was an issue with taking that reading, such as the SignipHy sv<sup>2</sup> Sensor not being fully seated on fiber optic.

**SITE STANDARDIZATION**

1. Equilibrate Sensors Overnight

2. Enter pHID:

3. Read pH Sensor:

4. Select pH Reading Ave:

**pH READINGS**

1. 7.64	<input checked="" type="checkbox"/>	2. 7.64	<input type="checkbox"/>
3. 7.64	<input type="checkbox"/>	4. 7.64	<input checked="" type="checkbox"/>
5. 7.64	<input type="checkbox"/>	6. 7.64	<input checked="" type="checkbox"/>

**Pictured: Site Standardization Screen Continued.** The photo above shows six readings, normally only three readings are taken but if GO is pressed before the SignipHy sv<sup>2</sup> Sensor is placed on the fiber optic do not select that reading for the Average.

6. Enter the reference pH. The software will calculate the difference from the average readings and the reference reading to create an offset, allowing it to be SET for the SignipHy TrakPod. This offset is then applied to future pH reads for that SignipHy TrakPod.

**SITE STANDARDIZATION**

1. Equilibrate Sensors Overnight
2. Enter pHID:
3. Read pH Sensor:
4. Select pH Reading Ave:
5. Enter Reference pH:
6. Calculate Offset:
7. Set Offset:

Test Started: No test  
Days Remaining: N/A  
pH N/A  
Last Test Time: N/A

POD HYDRA 095

Select One

1 2 3  
4 5 6  
7 8 9  
. 0 DEL  
-

### Pictured: Site Standardization Screen Continued

7. If sensors are to be re-read on a different SignipHy TrakPod, place the sensors back into the incubator and allow them to re-equilibrate at temperature and CO<sub>2</sub>. Re-equilibration is essential for accuracy. The sensor out of the incubator slowly changes the pH levels because of temperature decreases- if the sensor is repeatedly read outside of the environment it will give varied results.

**NOTE:** For multiple incubators, it is not required to use three (3) new sensors for every SignipHy TrakPod. For example, with four (4) SignipHy TrakPods, Site Standardization can be performed by equilibrating four (4) sensors all in one incubator. Three (3) or four (4) sensors can be read on the first SignipHy TrakPod in the equilibrating incubator. The reference pH to enter is the pH measured in that incubator. Then the sensors can be moved quickly to the next incubator. Preferably allow as much time for the sensors to re-equilibrate in the incubator as the time spent moving between incubators. This is for temperature to return to ideal level. Then do site standardization on the second SignipHy TrakPod. Again, use the pH measured in the first incubator as the reference pH as the sensors' CO<sub>2</sub> levels will not have changed in a short period of time (5 to 15 minutes). Repeat with the third and fourth incubator in the same manner. Finally, place one (1) sensor on each SignipHy TrakPod and begin monitoring pH for the rest of the week.

This standardization protocol is specific to the media type used. If a different media type is to be used with the SignipHy pH Monitoring System then the protocol must be repeated for the new media type and the "Offset Values" must be adjusted accordingly.

## Why an Offset Value?

An “Offset Value” is required for every clinic and media type or incubator. This value corrects for the subtle differences between Seattle, WA (where the unit was manufactured) and the clinic where it is being used. Our Site Standardization protocol assures that the unit will agree with the pH measured from a reference blood gas analyzer for the media being used.

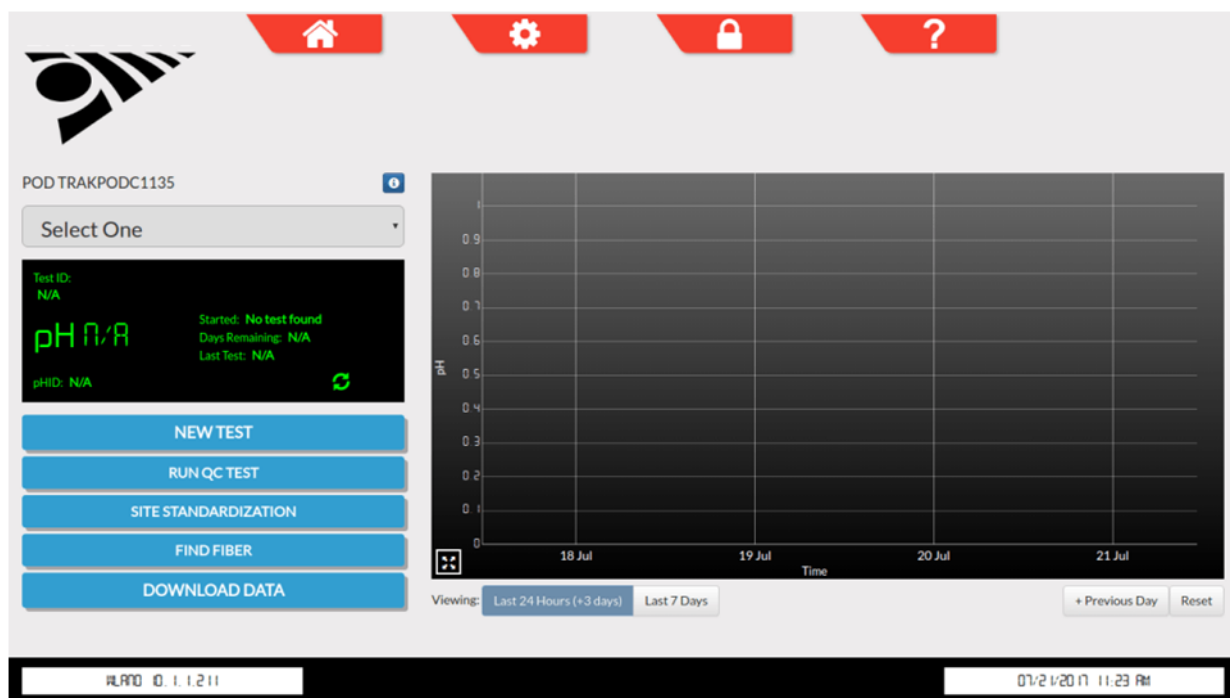
## 4. Routine Operation

### Work flow

The normal work flow when using the SignipHy TrakPod is as follows:

- Run a quality-control (QC) test before first use, and on a weekly schedule between pH testing runs;
- Before pH testing, set up and equilibrate the media sample and sensor allowing an overnight 10-24 hour period for equilibration;
- Place the sensor into the fiber fixture and start the pH testing. The instrument then reads the pH at either 30-minute or 1-minute intervals (which can be set using the CHANGE MEASUREMENT FREQUENCY setting);
- After 7 days of 30-minute pH testing or 3 days of 1-minute pH testing with a single sensor, stop the testing by pressing the END TEST button.

The user interface for each Pod has the functions needed for running pH tests, performing QC tests and other functions relevant to the Pod.



**Pictured: SignipHy TrakPod User Interface**

## Quality Control (QC) Testing

### What is the SignipHy qc<sup>2</sup> Alignment Tool?

The SignipHy qc<sup>2</sup> Alignment Tool is an aluminum tube containing a small amount of fluorescent dye. One SignipHy qc<sup>2</sup> Alignment Tool can be used on all the connected SignipHy TrakPods individually. When reading the SignipHy qc<sup>2</sup> Alignment Tool with the SignipHy TrakStation and SignipHy TrakPod, it gives a known and stable reading. Use it to make sure the Pod is operating correctly. It is recommended to take a QC measurement for each SignipHy TrakPod on initial installation, once a week during use prior to cleaning and disinfecting the chamber.

Keep the SignipHy qc<sup>2</sup> Alignment Tool protected in the provided bag when it is not being used. If it develops scratches or collects dust, it will not give a true reading. Replace the Alignment Tool when it reaches its expiration date (typically one year).



#### **CAUTION: Never try to open or repair the Alignment Tool.**

If the SignipHy qc<sup>2</sup> Alignment Tool has been damaged or a replacement is required, please contact CooperSurgical Technical Support by emailing [Service@origio.com](mailto:Service@origio.com) (International) or [Service@origio.us.com](mailto:Service@origio.us.com) (US). After expiration a SignipHy qc<sup>2</sup> Alignment tool can be disposed of in normal unregulated waste.

### Weekly QC Testing

1. Put serialized SignipHy qc<sup>2</sup> Alignment Tool on probe: Check the serial number of the qc<sup>2</sup> Alignment Tool matches with the serial number listed on the SignipHy TrakStation. It can be helpful to apply some downward pressure to the SignipHy qc<sup>2</sup> Alignment Tool for the test to ensure it is fully seated on the fiber optic fixture.



**CAUTION: DO NOT USE A SignipHy sv<sup>2</sup> SENSOR FOR A QC ALIGNMENT TEST, this will cause faulty pH readings.** If you attempt to use a SignipHy sv<sup>2</sup> Sensor for the QC Alignment Test, you will not be able to successfully complete alignment.

**RUN QC TEST**

Trakpod1

(Optional) Locate the active TrakPod by pressing Find Fiber. The probe will flash 3 times.

**FIND FIBER**

1. Clean fiber probe

2. Put black metal QC Tool (Z177) on probe

[Expires: 08-2021]

**CONTINUE**

**DONE**


**Pictured: Run QC Test From TrakPod Page**

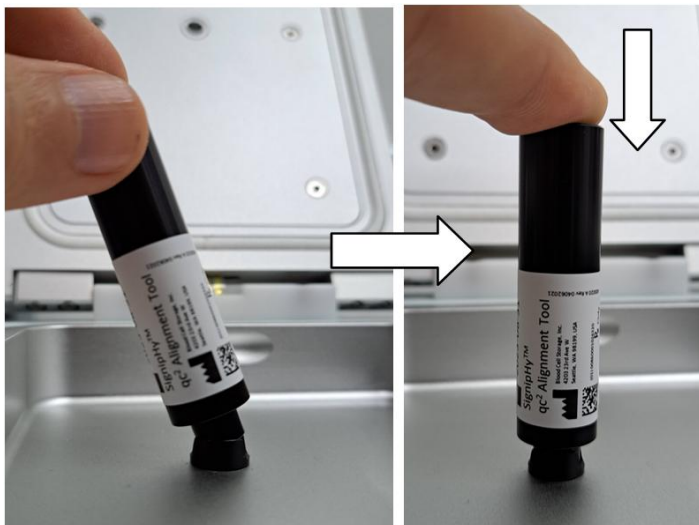
**NOTE:** The FIND FIBER button will cause the Pod to flash the LED several times highlighting the location of the fiber optic which might be associated with the chosen Pod.

2. Remove any dust from fiber optic surface with a sterile non-linting cloth.



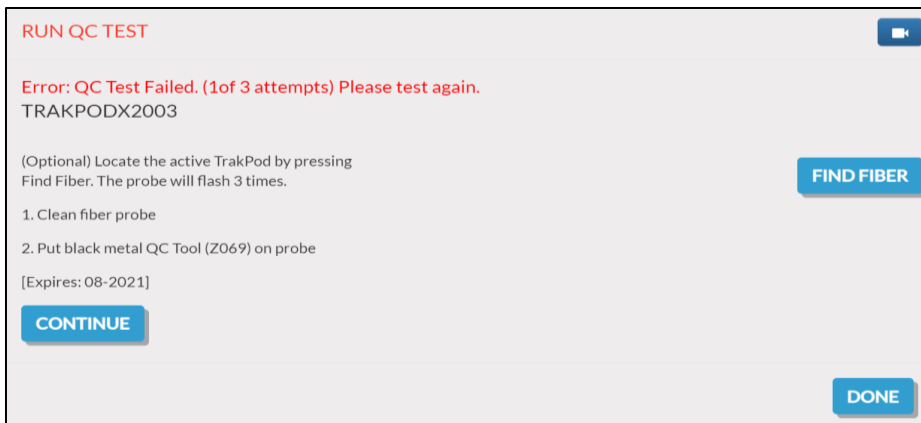
**Pictured: Wiping Fixture with a sterile non-linting cloth**

3. Regular weekly QC testing is performed like initial QC testing. The QC test is run from the Pod menu or the Settings  page. After selecting the QC test use the following window to proceed through the test. Make sure that the serialized SignipHy qc<sup>2</sup> Alignment Tool selected to run the QC Test on the SignipHy TrakPod is the same control sensor used for QC Testing.



**Pictured: SignipHy qc<sup>2</sup> Alignment Tool on Fixture**

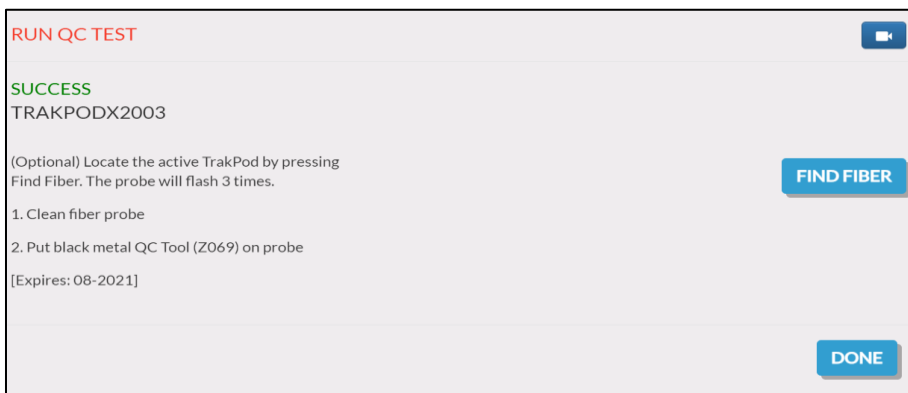
4. Press the CONTINUE button: The SignipHy TrakPod will test the fluorescent signal and compare it to the assigned fluorescent levels.
5. The Screen will then display the result of the QC Test.
6. If the test failed, a message about the failure will be displayed with an attempt counter.



**Pictured: QC Test Failure With Attempts Value**

*For a full list of potential failure cases, please see Section 7 Troubleshooting.*

7. The QC test should be rerun, paying careful attention to the cleanliness of the fiber, and the correct placement of the Alignment Tool in the fixture. Confirm that the correct TrakPod is being tested using the Find Fiber button.
8. Once confirming that the correct Trakpod is being tested, please repeat QC testing until all 3 attempts are completed.
9. After 3 failures, the TrakPod may be re-aligned. Re-align the TrakPod using the re-align TrakPod button. The TrakPod will then adjust the TrakPod to original alignment specifications.



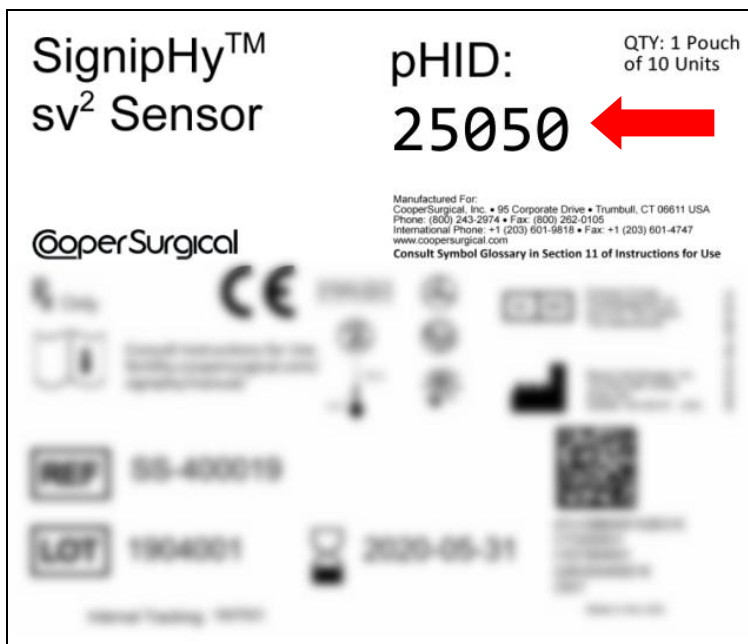
**Pictured: QC Test Success After Re-Alignment**

10. If failures persist, contact CooperSurgical Technical Support by emailing [Service@origio.com](mailto:Service@origio.com) (International) or [Service@origio.us.com](mailto:Service@origio.us.com) (US) or by using the Message Support Button in the Supervisor Menu.

## Regular pH Testing

Before beginning testing a media sample for pH, prepare the sensor and the sample as described. Preparation of a sensor is like the site standardization, but only requires one (1) SignipHy sv<sup>2</sup> Sensor per SignipHy TrakPod. Regular pH testing has a more flexible equilibration time range (> 10 hours) as the exact pH value for the first pH read is followed by continuous pH data for comparison, rather than used to create an offset value for the equipment.

1. Remove the SignipHy sv<sup>2</sup> Sensor aseptically from the sterilization pouch in which it arrived. A lot specific pHID is printed on the kit packaging (25050 in the example below). **Use the pHID on the kit packaging when setting up to read the pH.** The LOT and hour glass symbols refer to a lot number and the expiration date (prior to use) of the sensor, respectively.



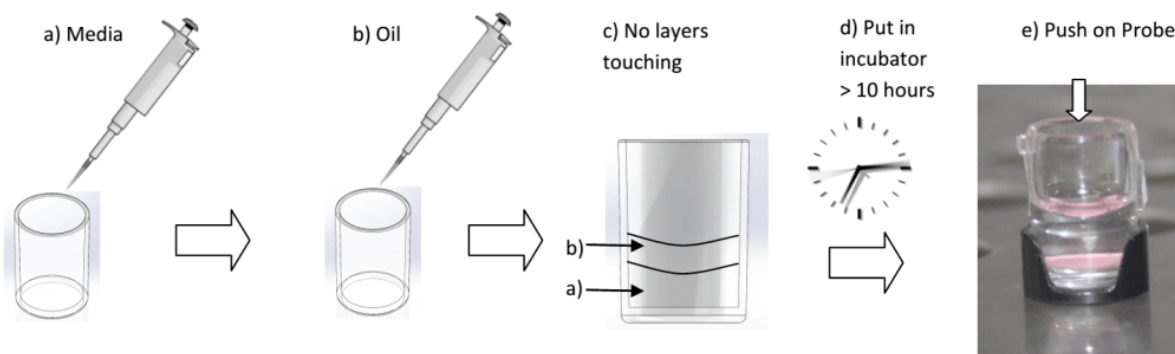
**Pictured: Example SignipHy sv<sup>2</sup> Sensor label**



**CAUTION:** *The pHID 25050 is an example pHID used only for demonstration. Do not enter 25050 as the pHID for testing purposes.*



2. Prepare the sensor as follows:



**Pictured: Sensor Preparation**

3. Media:

Use 100  $\mu$ L of media.

Hold the sensor with the opening upward. Carefully pipette media down the side of the sensor. Avoid adding bubbles while doing this step. It works best not to fully dispense the entire volume from the pipette tip. Also avoid touching the pipette tip to the membrane. The media is not to be pre-equilibrated.

4. Oil:

Use 150  $\mu$ L of oil.

Using an oil intended for cell culture, pipette an oil overlay onto the media. Avoid adding bubbles while doing so. Again, it works best not to fully dispense the entire volume from the pipette tip. The oil prevents the media from evaporating in the course of several days of pH monitoring. The oil must completely cover the media. Increase the volume of oil if the oil layer looks too thin. The oil volume does not interfere with the pH measurement. The larger volume of oil for dry (non-humidified) incubators helps to slow the media evaporation over the 7-day pH testing. It will increase the time needed for equilibration, but not beyond the 10-24 hours we recommend below.

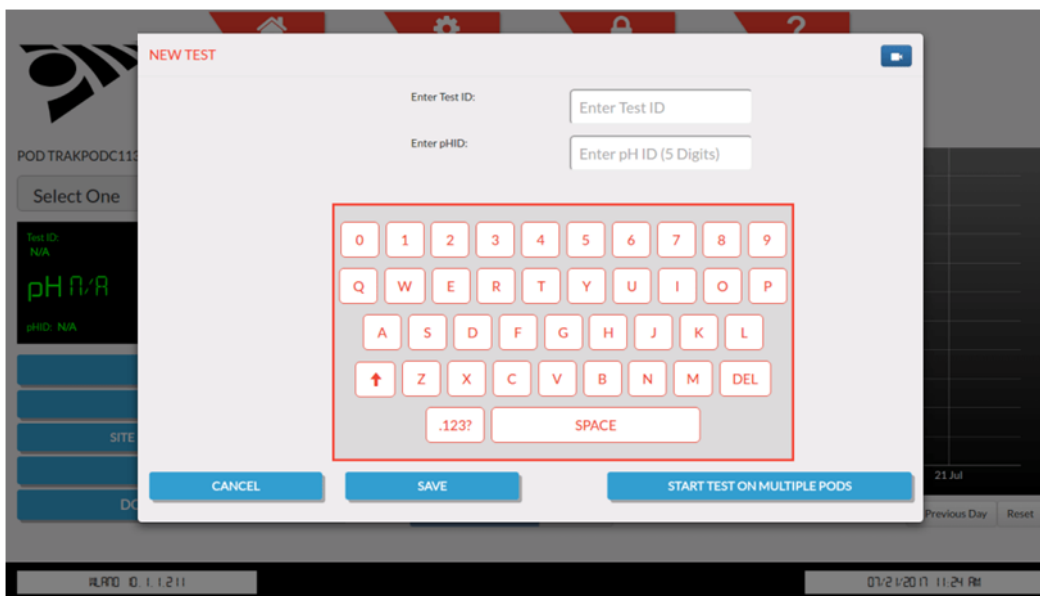
5. Place the SignipHy sv<sup>2</sup> Sensor in the incubator that will be monitored, and allow the sensor and the media to equilibrate in the environment overnight (10 to 24 hours). The following morning place the sensor in the fiber optic fixture and begin the pH monitoring. A Sensor with a 30-minute pH reading frequency can be used for seven days. Start a test from the TrakPod page with the NEW TEST button.




**CAUTION:** The media under an oil layer in SignipHy sv<sup>2</sup> Sensors takes time to equilibrate in a CO<sub>2</sub> environment. The pH of media without equilibration can be higher than the pH accuracy range for the system until completion of equilibration (10-24 hours). Readings prior to completion of equilibration may not be accurate.



**CAUTION:** The SignipHy pH Monitoring System cannot be relied upon to measure pH outside of pH 6.8 – 7.6 range, as values outside the stated range may not be accurate. Consult the Troubleshooting section if pH values are reported outside this range.



**Pictured: New test screen**

6. Enter a unique test ID and the pHID from the sensor package and press SAVE. The TrakPod will then start reading pH with the desired frequency. To take a reading at anytime, press the green refresh icon ).
7. Upon completion of the pH monitoring the SignipHy sv<sup>2</sup> Sensor may be disposed of in normal unregulated waste or a waste method that is used for consumed media.

### Additional Useful Guidelines:

- Bubbles may appear in the SignipHy sv<sup>2</sup> Sensor over time; this is only a problem when they are large and completely separate the membrane from the fluid in the sensor. In this case, dislodge the bubble with a pipette tip.
- The SignipHy TrakPods have an automatically applied drift correction. During use, the SignipHy sv<sup>2</sup> Sensor's pH level slowly decreases but this change is accounted for with the drift correction. The correction is based on the frequency of the reading and the amount of time a sensor has been testing.



**CAUTION:** Be sure to *end current tests and start new tests when a new SignipHy sv<sup>2</sup> Sensor is used*; otherwise, the old test's drift corrections will impact the pH readings of the new sensor and the reading will be inaccurate.

- Best practices for working with multiple G210 InviCell Plus with SignipHy pH monitoring incubators and SignipHy TrakPods is as follows:
  1. The day prior to ending pH tests prepare new SignipHy sv<sup>2</sup> Sensors and begin their equilibration.

2. At the end of 7 days (for the 30 minute test frequency), end all the pH tests and remove and discard the old SignipHy sv<sup>2</sup> Sensors so none of the fixtures have SignipHy sv<sup>2</sup> Sensors on them.
3. Run the QC Alignment Tests for each of the chambers followed by cleaning and disinfecting the chambers.
4. Place all the new SignipHy sv<sup>2</sup> Sensors onto the fixtures.
5. Start the new pH tests using the “Start Test on Multiple Pods” button of the “New Test” window.

Following these steps will prevent incorrectly running a QC Alignment Test on a chamber that still has an old s SignipHy v<sup>2</sup> Sensor in it.

## Shut Down and Storage

The SignipHy TrakStation can be shut down by holding the power button down to power it off. Then unplug the tablet and store it. The SignipHy TrakPod USB may be disconnected to shut it down and prepare it for storage.

Storage conditions for the electronics are 5 – 40°C (41 – 104°F) and 5 to 95% Humidity.

## Disposal and Recycling

The SignipHy TrakStation and SignipHy TrakPod contain electronics and should be recycled. Do not dispose of these items in normal waste. Contact the original tablet manufacturer or your local resources for electronics recycling options.

### Recyclable components

Component	Material
Housing (SignipHy TrakStation and SignipHy TrakPod)	Plastic
Screen (SignipHy TrakStation)	Glass
Printed circuit boards (SignipHy TrakStation and SignipHy TrakPod)	Enclosed electronic components mounted on PCB
Fiber optic cable (SignipHy TrakPod)	Plastic
Fixture (SignipHy TrakPod)	Aluminum

The SignipHy qc<sup>2</sup> Alignment Tool contains aluminum and may be recycled or it may be discarded in unregulated waste.

The SignipHy sv<sup>2</sup> Sensor may be discarded in normal unregulated waste or a waste method that is used for consumed media.

## 5. Cleaning and Disinfection

### SignipHy TrakStation

#### Cleaning

1. The exterior of the SignipHy TrakStation can be cleaned periodically. Turn off the SignipHy TrakStation, disconnect from power and disconnect the SignipHy TrakPods prior to cleaning the exterior surfaces.
2. Apply Oosafe Disinfectant Spray evenly to all surfaces of the SignipHy TrakStation. Allow the solution to sit on the surfaces for a minimum of one (1) minute.
3. Moisten a sterile non-linting cloth with purified or sterile water and wipe all surfaces for a minimum of one (1) minute. If needed, use additional cloths if cloths become visibly soiled.
4. Allow SignipHy TrakStation to air dry.
5. Visually inspect SignipHy TrakStation for the absence or presence of remaining soil. While inspecting, give particular attention to verifying soil has been removed from hard-to-clean areas. If soil is present, then repeat the manual cleaning steps until all visible soil is removed.
6. Reconnect power and cables and turn back on.

### SignipHy TrakPod

The SignipHy TrakPod fixture and fiber optic surface are cleaned and disinfected with the G210 InviCell Plus with SignipHy pH monitoring incubator chambers. Run the QC Alignment Test prior to cleaning and disinfecting. Follow instructions for cleaning and disinfecting the incubator that are found in the G210 InviCell Plus with SignipHy pH monitoring incubator user's manual.

### SignipHy sv<sup>2</sup> Sensors



**CAUTION:** The SignipHy sv<sup>2</sup> Sensors *cannot be cleaned, disinfected or reused.*

### SignipHy qc<sup>2</sup> Alignment Tool

#### Cleaning

The exterior of the SignipHy qc<sup>2</sup> Alignment Tools may be cleaned in the same manner as described for the SignipHy TrakStation above. Do not attempt to open or clean the inside of the SignipHy qc<sup>2</sup> Alignment Tools.

#### Disinfection

After the surfaces are clean and all visual soil has been removed, proceed with the following instructions to disinfect the surfaces as follows:

1. Apply Oosafe Disinfectant Spray evenly to all exterior surfaces of the SignipHy qc<sup>2</sup> Alignment Tool. Wait a minimum of 15 minutes for the surfaces to dry for best results.
2. Moisten a sterile non-linting cloth with purified or sterile water and wipe all disinfected surfaces for a minimum of one (1) minute.
3. Thoroughly dry all surfaces using a sterile, lint-free wipe or cloth, changing wipes / cloths when necessary to ensure the incubator surfaces are completely dry. Visually inspect the surfaces of the incubator to ensure all surfaces are clean and dry. Repeat drying steps if any moisture is visible.


## 6. Menu Functions

The SignipHy TrakStation is a menu driven user interface. The various available functions are described here. The touchscreen interface may be navigated with fingers, stylus or mouse as available.



**CAUTION:** Screen burn can occur when the same image is displayed for a considerable amount of time on the SignipHy TrakStation tablet. Use the Windows system settings to set the screen settings as desired.

### Home page

Access the home page by pressing the  icon.



**Pictured: Home Page**

On this page, the currently added pods are displayed with the most recently measured pH values. Pressing on the box around a Pod will select a specific page for the pod.

## Pod Page



### Pictured: Pod Page

The Pod page shows a summary of the start time, remaining time and current pH. A plot shows the pH history of readings that have been collected.

- Start a new test by pressing the NEW TEST button (changes to END TEST when a test is running).
- End the current test by pressing the END TEST button. After seven (7) days of pH monitoring with the thirty (30) minute frequency, or three (3) days with one (1) minute frequency, the current test will automatically end and a new sensor can be started.
- Do the QC test with the QC Alignment Tool by pressing RUN QC TEST.
- Perform the initial Site Standardization readings for the pH meter with the SITE STANDARDIZATION button.
- The FIND FIBER button causes the Pod LED to flash several times, highlighting the fiber optic associated with the chosen Pod.
- Download data from the device for this Pod or for all connected Pods with DOWNLOAD DATA. In this function, the data may also be emailed if the Tablet is configured for network connectivity.
- Adjust time displayed on plot using the buttons below the X-AXIS. Time and pH ranges can be adjusted by placing two fingers on the display screen and either spreading or joining together the two to adjust zoom level. Additional controls include:
  - **Multi-Touch Controls (For Tablet users):**  
Zoom In/Out: Two-Finger Pinch Zoom

- Pan: Single-Finger Drag
- Restore Autoscale: Double-Tap
- **Mouse Controls (For Remote Browser users):**
  - Zoom In: Click+Drag
  - Pan: Shift+Click+Drag
  - Restore Autoscale: Double-Click
- \*Zoom out is not possible past the auto-scaled pH range when using mouse controls.

## Settings

Access the settings page by pressing the  icon. The settings page allows adjustment of commonly changed settings on the SignipHy TrakStation.




### Pictured: Settings Screen

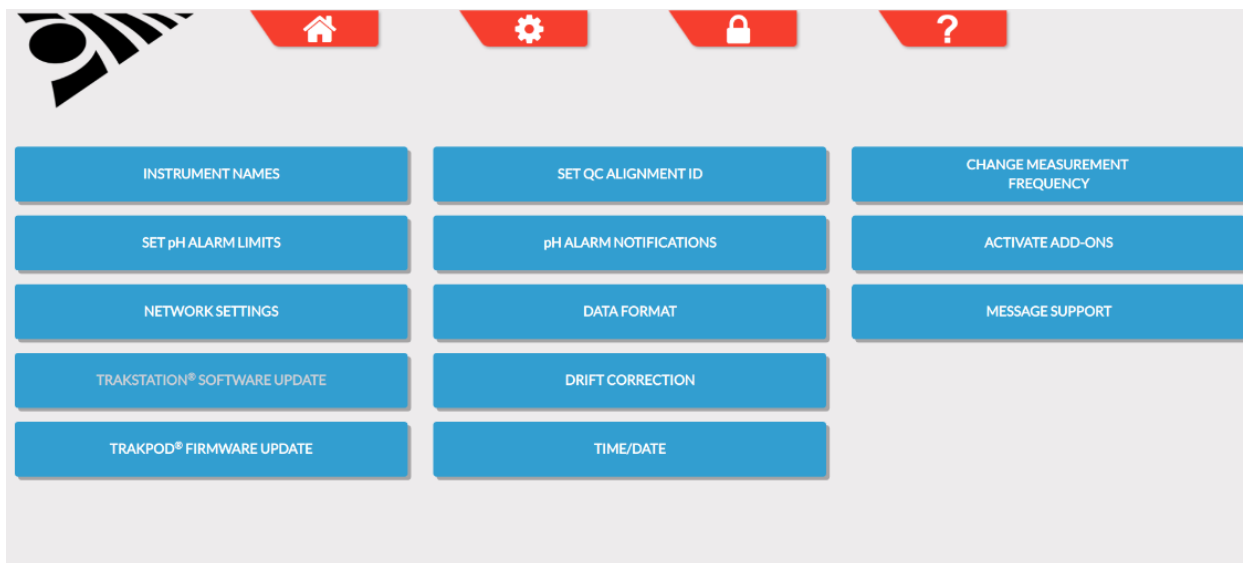
From this page a number of different functions can be implemented.

- **RUN QC TEST:** Perform QC test with the SignipHy qc<sup>2</sup> Alignment Tool. This should be done once per week. It can also be reached from the individual Pod page.
- **OFFSET VALUES:** View and adjust offset values assigned to each Pod through the Site standardization protocol.
- **ADD/REMOVE PODS:** Setup and remove SignipHy TrakPods from the SignipHy TrakStation interface.
- **ARRANGE PODS:** Change the order in which the connected SignipHy TrakPods are displayed on the SignipHy TrakStation interface.



## Supervisor Screen

Access the Supervisor page by pressing the  icon. Less common settings and those that only a supervisor should have access to changing are available on the supervisor screen. The default PIN for accessing the Supervisor page is 12345. This PIN can be changed using the on-screen menus options.



**Pictured: Supervisor Screen**


From this page a variety of settings can be adjusted including:

- **INSTRUMENT NAMES:** Change the names displayed for Pods. This can make referring to various SignipHy TrakPods easier when using identifiers for what incubator they are in.
- **SET pH ALARM LIMITS:** Set pH limits for each SignipHy TrakPod with personalized upper and lower acceptable values.
- **NETWORK SETTINGS:** Connect the SignipHy TrakStation to the local internet and specify IP address settings and wireless network keys if applicable. Use of a secure wireless network is recommended. Connection to network is optional but needed to enable some SignipHy TrakStation features including emailing data, sending pH alarms and remotely accessing the SignipHy TrakStation with other locally connected computers. The wireless connection in the SignipHy TrakStation is compliant with the 802.11a/g/n/ac protocol and all radio frequency transmissions are FCC certified for a class B digital device per Part 15 of the FCC rules. The wireless connection is provided by the tablet computer's standard WiFi connection using either 2.4 GHz or 5 GHz frequencies. The Quality of Service required is minimal; 100 kbps is sufficient to support optional network functions.
- **TRAKSTATION® SOFTWARE UPDATE:** When a new version of SignipHy TrakStation software is available, use the SOFTWARE UPDATE and either download

the software from the web (if the Tablet is configured to do so) or select the appropriate file from a connected USB drive and update the system

- **TRAKPOD® FIRMWARE UPDATE:** When a new version of SignipHy TrakPod firmware is available, use the FIRMWARE UPDATE and download the firmware from the web, load onto a USB drive, and select the appropriate file from the connected USB drive and update the connected pods.
- **SET QC ALIGNMENT ID:** Enter a new QC Alignment Tool or update the values for the QC Alignment Tool when it is replaced. On an annual basis the QC Alignment Tool is replaced with a new one and the fluorescent values for the new standard are programmed into the SignipHy TrakStation using this menu.
- **pH ALARM NOTIFICATIONS:** Configure an email address to send notifications when pH values are outside their intended limits.
- **DATA FORMAT:** Change the format of downloaded data. The downloaded CSV file can be separated by commas or semicolons, and additional items of data from each pH reading can be downloaded and queried.
- **DRIFT CORRECTION:** For some media types, a small increase or decrease in pH over time is noticed. This is an artifact of the fluorescent reading system. Use the DRIFT CORRECTION button to make updates to the correction factors used by the system. This should only be done at the advice and guidance from CooperSurgical support. Please contact [Service@origio.com](mailto:Service@origio.com) (International) or [Service@origio.us.com](mailto:Service@origio.us.com) (US) for assistance.
- **TIME/DATE:** Reset the time on the SignipHy TrakStation. If an internet connection is available, the time and date can be automatically updated by the SignipHy TrakStation. The tablet must be rebooted for time/date changes to be made effective in the TrakStation software.
- **CHANGE MEASUREMENT FREQUENCY:** Switch between a thirty (30) minute test frequency (seven (7) day sensor lifetime) and a one (1) minute test frequency (three (3) day sensor lifetime).
- **ACTIVATE ADD-ONS:** Enable and configure additional features of the SignipHy TrakStation, such as outputting pH data to a third-party lab monitoring platform.
- **MESSAGE SUPPORT:** Message and send all pH and system data to support from an internet-connected TrakStation. Please include required information for the support team such as location information, issue category, and a description of the issue.


## Help

Access the Help menu by pressing the  icon. Here there are answers to some of the common issues encountered when using the SignipHy TrakStation and SignipHy TrakPods.



### **Pictured: Help Screen**

Click an applicable question to get information about that particular question.

Additionally press the Mail Icon (  ) to message Support using the Support Team form. Please include required information for the support team such as location information, issue category, and a description of the issue. The TrakStation will email the files directly to the manufacturer. Please also forward the message to [Service@origio.com](mailto:Service@origio.com) (International) or [Service@origio.us.com](mailto:Service@origio.us.com) (US) to assist in diagnosing any ongoing troubles.

MESSAGE OUR SUPPORT TEAM

E-mail:  Clinic:

Name:  Phone:

Issue:

pH Data Analysis ▼

Please describe your issue in detail:

0 1 2 3 4 5 6 7 8 9

Q W E R T Y U I O P

A S D F G H J K L

↑ Z X C V B N M DEL

.123? SPACE

**Pictured: Message Support Screen**

## Remote Access

If the SignipHyTrakStation is network connected it is possible to access all the controls of the SignipHy TrakStation from a separate computer that is on the same network. Use a web browser and navigate to <http://###.###.###.###:8080/hydra/> where ###.###.###.### is the IP address of the SignipHy TrakStation which is network connected. This IP address can be found in the lower left corner of the SignipHy TrakStation page (10.1.1.201 in the example).

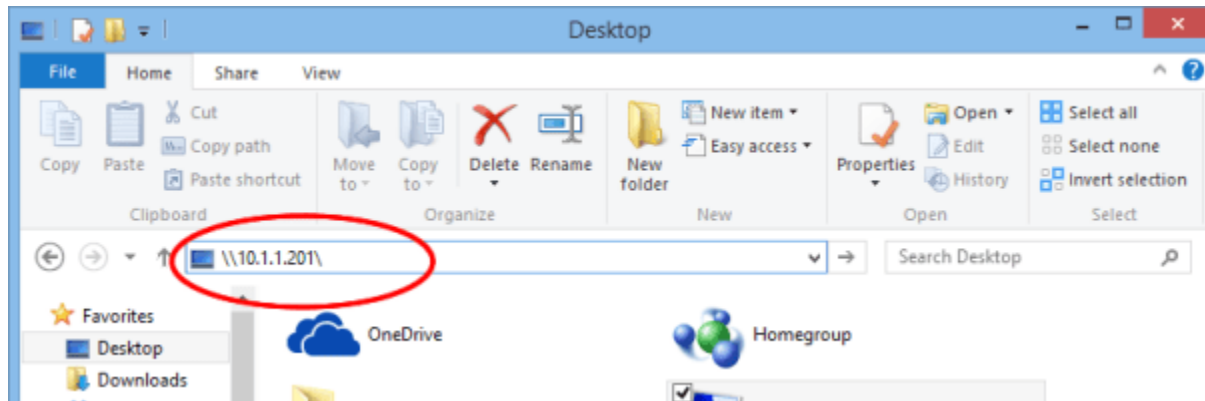


**Pictured: Remote Access IP address**

Check with an IT specialist/department if there are issues connecting from a separate computer and ensure that it is on the same network and that the settings of the network router being used are not blocking communication on port 8080.

It is also possible to access data files that have been downloaded to USB drives from a remote computer. In windows explorer type in the address bar `\\###.###.###.###\` where

###.###.###.### is the IP address of the SignipHy TrakStation which is network connected. If there are issues connecting to shared folders, check with IT department to ensure that ports 137, 138, 139 and 445 are not blocked.



**Pictured: Windows Explorer View of TrakStation IP**

Then navigate to the Logs folder where copies of all files saved to USB drives are located. These files will even be created when the download to USB button is pressed but no USB drive is connected to the SignipHy TrakStation.

## 7. Troubleshooting

Common issues with SignipHy TrakStation and SignipHy TrakPods as listed in the table below with possible remedies. In some cases the software issues experienced have already been solved in a recent software release. Check the update page for more information and to see if there are any updates available for the SignipHy TrakStation and SignipHy TrakPods.

Issue	SignipHy TrakStation Error message	Remedy
Connected SignipHy TrakPods not appearing on home screen.	NA	Check that the SignipHy TrakPods are properly added and saved to the Authenticated Pods list.
Red border surrounds SignipHy TrakPod(s) on home screen.	Error: Could not detect selected TrakPod! Check USB and Power cable connections. (Failed to Parse request)  Error: Internal Server Error (error)	This may impact only one SignipHy TrakPod or all SignipHy TrakPods. If only seen in one SignipHy TrakPod focus on that one SignipHy TrakPod's USB connections. Check all USB cable connections at the SignipHy TrakPod, USB hub, and TrakStation and power connection for USB hub. Especially check the USB cable connection at the back of the SignipHy TrakPod. If observed following a reboot of the SignipHy TrakStation, physically disconnect all of the SignipHy TrakPod USB cables from the USB hub and then reconnect them.
pH measurements are less than 6 or greater than 10.	NA	Check that a properly-prepared sensor containing media and oil is in the fixture. Ensure the correct pHID is being used.

Issue	SignipHy TrakStation Error message	Remedy
pH measurements are outside the 6.8 to 7.6 accuracy range	NA	<p>The pH accuracy of the SignipHy sv<sup>2</sup> Sensor outside the 6.8 to 7.6 pH range has not been demonstrated and should not be relied upon. High pHs likely need time for CO<sub>2</sub> to equilibrate in the SignipHy sv<sup>2</sup> Sensor. Low pHs could be caused by very high concentrations of CO<sub>2</sub>.</p> <p>Visit this page to see some common pH trends and match one to the conditions being experienced.</p> <p><a href="http://fertility.coopersurgical.com/signiphy/support/trakstation-ph-troubleshooting/">http://fertility.coopersurgical.com/signiphy/support/trakstation-ph-troubleshooting/</a></p> <p>Contact the support contacts with any additional questions.</p>
QC Alignment test produces errors	Error: No Signal (X of 3 attempts) Please ensure QC alignment tool is on fixture	Check the fixture assembly and presence of SignipHy qc <sup>2</sup> Alignment Tool. Confirm the correct fiber optic is being tested by pressing the “Find Fiber” button and observing 3 green flashes from the fiber optic fixture.
QC Alignment test produces errors	Error: Fail - Sensor on fixture (X of 3 attempts) Please use the black QC alignment tool	QC Alignment test recognized a SignipHy sv <sup>2</sup> sensor is on the fixture. Please remove any items that are in the fiber optic fixture and place the black QC alignment tool firmly in the fixture. Re-attempt QC testing.
QC Alignment test produces errors	Error: Low FR signal (X of 3 attempts) Please check fixture and test again.	Ensure SignipHy qc <sup>2</sup> Alignment Tool is sitting completely in the fiber optic fixture. Ensure correct serial number SignipHy qc <sup>2</sup> Alignment Tool is being used. Check the condition of the fiber optic cable, ensuring the fiber optic cable is not compressed or damaged.

Issue	SignipHy TrakStation Error message	Remedy
QC Alignment test produces errors	Error: QC Test failed (X of 3 attempts) Please test again.	QC test will allow for 3 failed test attempts before a realignment to change the gains of the TrakPod occurs. If an error code occurs after re-alignment, contact <a href="mailto:Service@origio.com">Service@origio.com</a> (International) or <a href="mailto:Service@origio.us.com">Service@origio.us.com</a> (US) to further resolve this issue.
Cannot run a QC Alignment Test	You cannot run a QC Test without setting a QC Alignment ID. Program QC Alignment ID in Supervisor menu!	Prior to first running a QC Alignment test the SignipHy qc <sup>2</sup> Alignment Tool information will need to be programmed in the supervisor's lock menu.
SignipHy TrakPods are not responding on SignipHy TrakStation interface.	Error:(error)	Communication service to SignipHy TrakPods has stopped unexpectedly, normally it will restart on its own. If this persists, reboot the SignipHy TrakStation
SignipHy TrakStation or SignipHy TrakPod update has error.	Error:(error)	If this appears during software update processes it means there is no USB flash drive detected.
SignipHy TrakStation screen shows signs of screen burn-in or displays ghost image of previous pH testing	NA	If screen burn is significant enough to affect everyday use, contact your support contacts to further resolve this issue or replace the SignipHy TrakStation tablet.
USB flash drive not recognized or working for data downloads	Error: Could not detect USB drive! Connect a TrakStation-support USB device and repeat data download. Or, access data file through email or remote access functions	The USB drive type or format may not be supported. Check this page for details: <a href="http://fertility.coopersurgical.com/signiphy/support/usb-drive-support/">http://fertility.coopersurgical.com/signiphy/support/usb-drive-support/</a>



Issue	SignipHy TrakStation Error message	Remedy
Cannot enter QC Alignment ID	Error: Input failed validation, please verify input and try again.  Error: QC Alignment ID not valid	The QC Alignment ID is not correctly entered. Check that the dashes are included in the entry and that zeros and the letter “o” are not mistaken.
Adding and Removing SignipHy TrakPods is not working.	localhost:8080 says: You must select an authenticated (or a non-authenticated) pod to add / remove / delete.	When adding or removing SignipHy TrakPods, be sure to select a SignipHy TrakPod prior to trying to change its status.
Forgot PIN for supervisor access	Incorrect PIN Please contact support [RESETCODE]	If the PIN has been changed from the default 12345 and the new PIN for accessing the locked settings has been forgotten, contact support with the reset code provided and the PIN can be changed with an override code.
pHID is not recognized by SignipHy TrakPod	Error: The pHID entered was not recognized. This TrakPod may only be used with COOPERSURGICAL pH sensors  Error: The pH reading request was denied by pod.	Check that the code is typed correctly. If the SignipHy TrakStation gives instruction to contact a CooperSurgical company representative, the SignipHy sv <sup>2</sup> Sensors being used are not compatible with the SignipHy TrakPod. For example: SignipHy TrakPods in G210 InviCell Plus with SignipHy pH monitoring incubators require SignipHy sv <sup>2</sup> Sensors obtained through a CooperSurgical representative.
pH seems unexpected either consistently off or changing over time in an unexpected way.	NA	Several different causes can be at play. Visit this page to see some common pH trends and match one to the conditions being experienced. <a href="http://fertility.coopersurgical.com/signiphy/support/trakstation-ph-troubleshooting/">http://fertility.coopersurgical.com/signiphy/support/trakstation-ph-troubleshooting/</a> Contact the support contacts with any additional questions.

Issue	SignipHy TrakStation Error message	Remedy
Wireless network connection has issues	The connection has timed out or Error:(error)	Wireless connection may have RF interference. Try connecting with a different frequency (5 GHz vs 2.4 GHz). Survey the site of use to determine the source of the disruption. Remove, reorient or relocate the interfering equipment. Increase separation between the TrakStation and the interfering equipment. Consult IT department about using a wired Ethernet connection.

Additional assistance troubleshooting is available from the support contacts. See Section 8 Support.

## 8. Support

SignipHy TrakStation and SignipHy TrakPod support can be obtained by emailing [Service@origio.com](mailto:Service@origio.com) (International) or [Service@origio.us.com](mailto:Service@origio.us.com) (US). Please include a description of the issue, any information about serial numbers and lot numbers of products in question and any log files that have been downloaded.

The technical support page for the SignipHy TrakStation is here:  
<http://fertility.coopersurgical.com/signiphy/support/>

The SignipHy TrakStation has no user serviceable components. Software updates for the SignipHy TrakStation can be obtained online for download here:  
<http://fertility.coopersurgical.com/signiphy/trak-update/>. It is recommended to run the most current software version, and support will be provided for users running the current software version as well as the prior version in the indicated timeframe noted on the update page.

The SignipHy TrakPod has no user serviceable components. Firmware updates are possible through the SignipHy TrakStation user interface. Download the appropriate files here:  
<http://fertility.coopersurgical.com/signiphy/trak-update/> and follow on screen instructions via the supervisor settings “TrakPod Firmware Update” function.

## 9. The Science Behind the SignipHy pH Monitoring System

The SignipHy pH Monitoring System technology is based on the principle that fluorescent dyes emit characteristic wavelength spectra at different pH levels.

The sensor is a modified optical cuvette that creates a liquid well in which the pH of a media sample can be tracked. The sensor fits into a fiber optic fixture and includes a special membrane located at the bottom of the liquid well. The membrane is impregnated with a fluorescent dye that emits characteristic wavelength spectra at different pH levels. Periodically, the instrument measures the pH of the sensor. (Choose the timing of this measurement to be at one or thirty-minute intervals.)

During measurement, the fiber optic delivers flashes of green light from a monochromatic light source to the sensor. The light excites the dye in the membrane and induces fluorescent light emission at two wavelengths. At 600 nm, the intensity of light emission varies with the pH of the media. At the second, reference wavelength, 568 nm, the emission does not depend on the pH.

The intensities of emissions at these two wavelengths are collected by photo-detectors in the SignipHy TrakPod. The instrument calculates the ratio of the two wavelengths and converts it to the pH. Using a ratio of emission intensities allows determining the pH independent of any varying characteristics of the particular instrument used. The instrument also uses the reading frequency and the duration of the test to make small automatic corrections to the pH signal.

## 10. Limited Warranty

CooperSurgical, Inc. warrants that this item will be free from defects in materials and workmanship for one year from the date of installation. If CooperSurgical (CSI) determines that the product fails to conform to that warranty during the one-year period, CSI will repair or replace the product, at CSI's discretion, free of charge.

To return the product to CSI, a customer must comply with CSI's Returned Goods Policy described in this manual and the warranty requires the customer to return the product to CSI in accordance with the CSI Returns Instruction. CSI will return products (that it repaired or replaced under warranty) to the same customer who returned those products, at CSI's expense F.O.B. the customer's facility. Under all other circumstances, CSI will return products to the same customer who returned those products at the customer's expense.

CSI's warranties do not cover damage caused by misuse, improper care, improper use of chemicals or cleaning methods, loss, theft, use of non-authorized parts servicing by non-authorized personnel or negligent or intentional conduct on the part of the owner or user of the product, nor do they cover normal wear and tear or general maintenance. Any modifications or changes to a product will void that product's warranty. CSI's warranties do not apply to any single- or limited-use, disposable or consumable components or items.

CSI is not responsible for, and the owner and operator of the product shall defend, indemnify and hold harmless CSI from and against, all claims, damages, and other losses resulting from the improper servicing, maintenance, repair use or operation of the product or the owner or operator's negligence or willful misconduct, and use of inadequate packing and packaging when returning product for repair.

The above warranties are in lieu of, and CSI hereby disclaims, all other warranties, express or implied, written or oral, with respect to CSI's products, including the warranties of merchantability and fitness for a particular purpose. No terms, conditions, understandings or agreements that purport to modify the above warranties or that make any additional warranties for any CSI's product shall have any legal effect unless made in writing and signed by an authorized CSI corporate officer.

CSI shall not under any circumstances be liable for lost profits, damages from loss of use or lost data, or indirect, special, incidental or consequential damages under its warranties or otherwise for any claim related to CSI's products, even if CSI has been advised, knew or should have known of the possibility of such damages. CSI's liability with respect to a product covered by a warranty or otherwise shall be limited in all circumstances to the purchase price of that product.

### Warranty Registration

To register this product, go to:

[fertility.coopersurgical.com/signiphy/contact/registration/](https://fertility.coopersurgical.com/signiphy/contact/registration/)

# 11. System Specifications and Symbols

## Specifications

Item	Value
Dimensions of SignipHy TrakStation (L x W x H)	Varies by model of tablet computer, typical dimensions based on 10" screen size. 25.0 cm x 17.5 cm x 0.9 cm (9.8 in x 6.9 in x 0.3 in)
Weight of SignipHy TrakStation	Varies by model of tablet computer, typical dimensions based on 10" screen size. 0.54 kg (1.2 lbs)
Minimum External connections	<ul style="list-style-type: none"> <li>• USB 3.0 Port (or Type C 3.0 Port with adapter)</li> <li>• DC-in jack</li> </ul>
Touchscreen	10" to 12" touch screen (1280 x 800 or better)
Power requirements	
SignipHy TrakStation AC power adapter	UL marked power adapter Input to power adapter: 100 – 240 V 50-60 Hz Output (varies by model of tablet computer): 5 to 19.5 V DC, 2 to 4 A
USB Hub AC power adapter	UL marked power adapter Input to power adapter: 100 – 240 V AC, 50 – 60 Hz 1.2 A Output: 12 V DC, 4 A

Item	Value
SignipHy TrakPod power	Input: DC power over USB connection 5 V DC, 0.5 A (standard USB 2.0)
Operating, Transport and Storage temperature	5 – 40°C (41 – 104°F)
Operating, Transport and Storage humidity	5-95% relative humidity, non-condensing (For the components outside of an incubator)
Operating environment	Intended for indoor use only Altitude not specified, Pollution Degree 2 See Section 2 for Electromagnetic environment







### SignipHy pH Monitoring System Performance Specifications

Item	Value
pH measurement accuracy and range	0.05 pH units within pH 6.80 to 7.60
pH resolution	0.01 pH units
pH Sensor lifetime	7 days of use with 30 minute reading frequency. 3 days of use with 1 minute reading frequency. Shelf life is labeled on the packaging of sensor.
Optical control	QC Alignment Tool (minimum 12 month lifetime)







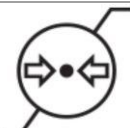



## Symbol Glossary







Symbols used in all labeling are summarized below in the table. The following Standards have been followed:

- (1) ISO 15223-1:2016 Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General Requirements.
- (2) 21 CFR 801.15 Medical devices; prominence of required label statements; use of symbols in labeling.
- (3) EMC 2004/108/EC Electromagnetic Compatibility Directive 2004/108/EC
- (4) EN 50419:2005 Marking of electrical and electronic equipment in accordance with Article 11(2) of Directive 2002/96/EC (WEEE)
- (5) 47 CFR Section 2.906 Federal Communications Commission, Declaration of Conformity

Symbol	Symbol Title	Symbol Description (Standard) and Reference Number
	Caution	Indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury. It may also be used to alert against unsafe practices. (1) 5.4.4
	Manufacturer	Indicates the medical device manufacturer. (1) 5.1.1
	Authorized Representative in European Community	Indicates the Authorized representative in the European Community. (1) 5.1.2
	CE Mark	Indicates the device is CE marked in accordance with the Low Voltage Device Directive 2006/95/EC and Electromagnetic Compatibility Directive 2004/108/EC (3) Annex V
	Date of Manufacture	Indicates the date when the medical device was manufactured. (1) 5.1.3
	Use-by date	Indicates the date after which the medical device is not to be used. (1) 5.1.4



Symbol	Symbol Title	Symbol Description (Standard) and Reference Number
	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified. (1) 5.1.5
	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified. (1) 5.1.6
	Serial number	Indicates the manufacturer's serial number so that a specific medical device can be identified. (1) 5.1.7
	Keep away from light	Indicates a medical device that needs protection from light sources. (1) 5.3.2
	Temperature limit	Indicates the temperature limits to which the medical device can be safely exposed. (1) 5.3.7
	Humidity limit	Indicates the range of humidity to which the medical device can be safely exposed. (1) 5.3.8
	Atmospheric pressure limitation	Indicates the range of atmospheric pressure to which the medical device can be safely exposed. (1) 5.3.9
	Consult instructions for use	Indicates the need for the user to consult the instructions for use. (1) 5.4.3
	Control	Indicates a control material that is intended to verify the performance characteristics of another medical device. (1) 5.5.2
	Recycle Electronic Equipment	Do Not Dispose of this equipment in normal trash. (4) 4.2

Symbol	Symbol Title	Symbol Description (Standard) and Reference Number
	FCC Declaration of Conformity	Certification mark employed on electronic device which indicates that EMC is under limits approved by FCC. (5)
	Prescription only	For the United States, this product is sale restricted only to medical practitioners licensed by the State where the practitioner will use the device (2) F
	Sterilized using ethylene oxide	Indicates a medical device that has been sterilized using ethylene oxide. (1) 5.2.3
	Do not re-use	Indicates a medical device that is intended for one use, or use on a single patient during a single procedure. (1) 5.4.2
	Do not re-sterilize	Indicates a medical device that is not to be re-sterilized. (1) 5.2.6
	Do not use if package is damaged	Indicates a medical device that should not be used if the package has been broken or damaged. (1) 5.2.8

## Intellectual Property

“SignipHy”<sup>TM</sup> is a registered US, Canadian and/or European trademark owned by CooperSurgical, Inc.

“TrakStation”<sup>®</sup>, “TrakPod”<sup>®</sup>, and “Innovations that make a difference”<sup>®</sup> are registered US, Canadian and/or European trademarks owned by Blood Cell Storage, Inc. (BCSI).

The TrakStation technology is covered by multiple issued and pending US and International equivalent Patents including but not limited to: US Pat. No. 7,608,460, 7,968,346, 8,148,167, 8,183,052, 8,497,134, 9,040,307, 9,062,205, 9,217,170; AU Pat. No. 2005277258; JP 特許番号 5017113; CN 专利号 ZL200580033961.1; IN Pat. No. 257667.