



TrakStation[®]
User's Guide
[Doc. No. 120030-15](#)

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1. Overview

The TrakStation® is a simple system that provides pH monitoring within a closed environment, such as an incubator, without opening and contaminating that environment. The TrakStation is intended for general laboratory use – **not for diagnostic use**. The overall system includes the TrakStation and TrakPods for use with the sv² sensors and qc² System Alignment Tool. These items are all described in this document.

Device Description

The sv² sensor cup is a small surrogate vessel into which you put a sample of the media whose pH you want to track. 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. To make a measurement, the machine 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 machine reads this result and calculates the pH of the media sample. You can set the timing of this measurement to be once per minute or once every 30 minutes.

The system includes

- **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) TrakPods can be connected simultaneously to a TrakStation.
- **TrakPods:** The TrakPod is the proprietary, LED-based, optical pH measurement instrument. One TrakPod is needed for each incubator chamber that is monitored. TrakPods have internal magnets, allowing them to be placed on the side of large format, cabinet style incubators. It is a USB connected fluorescent measurement device with a fiber optic cable and fixture that connects to the sv² Sensor inside of an incubator. The TrakPod and sv² Sensor together detect the pH of a liquid sample.
- **sv² Sensors:** The sv² sensor is a disposable. It is a small surrogate vessel into which you put a sample of the media whose pH you want to track. 100 µL of media and at least 50 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 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 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. Alternatively, it will only last three (3)

days if the pH reading frequency is one minute. sv^2 Sensors are provided in a kit of ten (10) individually pouched items.

- **qc² Alignment Tool:** A fluorescent reference device for use in System Alignment and Quality Control. The qc² System Alignment Tool contains a fluorescent target with a stable and known fluorescent signal. Between each week of pH monitoring, the qc² System Alignment Tool is used to check that the TrakPod fluorescent signal is still performing according to factory specifications. If any changes in the fluorescent signal are detected the TrakPod can make adjustments to the detectors to restore it to appropriate performance levels. One qc² System Alignment Tool is needed for each lab and it is replaced annually.

The TrakStation's user interface is described in [Section 6, Menu Functions](#).

For a more detailed explanation of how the TrakStation uses fluorometric technology, see [Section 9, "The Science Behind pH Monitoring."](#)

Features of the TrakStation

The TrakStation is easy to use, accurate, and reliable.

It is easy to do quality control checks on a routine basis, using a supplied alignment tool.

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

Common things you can 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 Pods;
- Perform the Site Standardization procedure and edit offset values.

2. Warnings and Precautions



The TrakStation is an accessory to benchtop and large format style incubators and is a prescription use only system. Consult with local regulations for restrictions on its use.



The TrakStation cannot be relied upon to measure pH outside of pH 7.0 – 7.6 range.



The TrakStation system is intended for use with bicarbonate buffered media at elevated CO₂ and temperature. HEPES-buffered media should not be used with the TrakStation System.



When using media with an intended use time of less than 7 days, it is advised to change the sv² Sensor cup with the same frequency of the media by ending the pH test and starting a new test with a new sv² Sensor cup.



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



Automatic updates to the 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 TrakStation performance.



The TrakStation software is not meant to collect or store patient data- the security of the tablet is determined by the security of data through customer WiFi Settings. The TrakStation is provisioned to enable WPA passkey authentication. The user is instructed to choose secure networks for WiFi connections.

3. First Time Setup and First Use

A new TrakStation and TrakPod(s) will require a short procedure to align the units for your environment. Plan on spending about 15 minutes the first day and 15 minutes the second day for setup activities.

Components

TrakStation

- Quick Reference Guide Startup Sheet
- Tablet
 - Power Supply
- 10 port USB Hub
 - Power Supply
 - USB cable
- Magnetic Mounting hardware
- 3x Magnetic Cloops for cable management
- USB Drive
- 2x USB extension cables
- 1x USB type C adapter (for Microsoft Surface and Lenovo only)
- 1x USB type C to barrel plug adapter (for Lenovo only)
- 1 x tablet keyboard (for Lenovo only)

TrakPod (Cabinet Style)

- Quick Reference Guide startup sheet
- TrakPod
- Mini USB Cable
- 1x Magnetic Cloop for cable management

TrakPod (Benchtop Style)

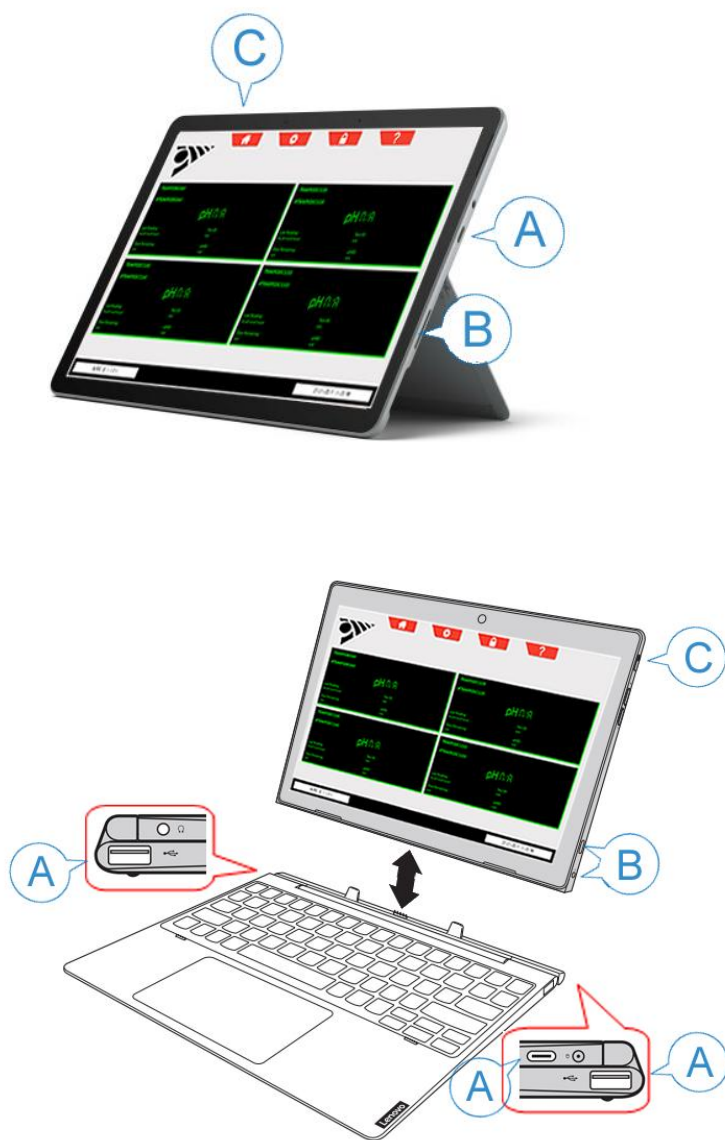
- Fully integrated into your benchtop incubator, just connect a Mini USB Cable

Setup



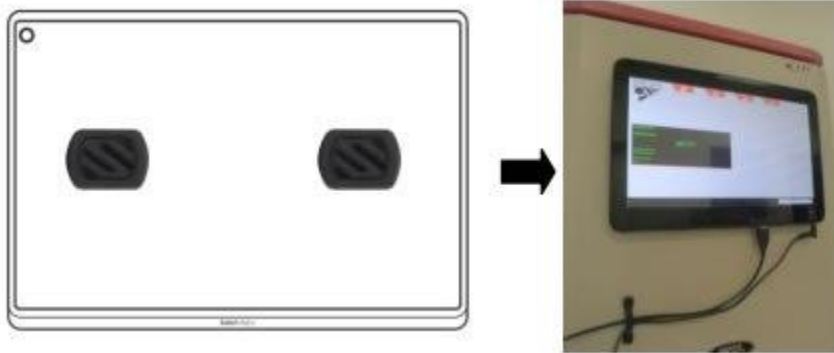
CAUTION: [Please watch the support video to see the step-by-step instructions for initial set-up.](#) Unpack the box and verify that all parts are present and in good condition.

1. **Option For Keyboard Attachment:** Connect power to the TrakStation tablet and turn on tablet power.



Pictured: TrakStation Setup For Connections (Microsoft Surface top, Lenovo bottom)

Option To Mount Tablet Without Keyboard: Mount the TrakStation in a convenient location for the incubators you will be monitoring. A magnetic mounting option is provided capable of holding the TrakStation on most stainless-steel incubator doors and sides. If the magnets are not already applied, affix the two Magic mounts positioned on the back of the TrakStation as pictured below. Clean the TrakStation surface with the provided wipe and press firmly for at least 30 seconds to allow best adhesion of magnets to tablet.



Pictured: Magic Mounts on Back of TrakStation

If needed, use the additional metal plates pictured below to affix to the incubator for better magnetic strength.



Pictured: Magic Mount Metal Plates



CAUTION: Do not put the metal plates on the TrakStation and the Magic mounts on the incubator. This will damage the TrakStation's hard drive.

2. Plug in the power supply for the TrakStation (B) and turn on the TrakStation tablet (C). The automatic start of TrakStation interface after windows boot up may take a few minutes.
3. Connect power to the USB Hub



Pictured: Connections For USB Hub to Power Source



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.

4. Plug the 10 port USB Hub into the TrakStation (A) 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 either behind or on top of the incubator. See below for proper USB HUB setup by tablet model type. **Optional:** For 1 TrakPod use USB-C adapter to connect the TrakPod directly.



Pictured: Lenovo/MS Surface to USB Hub



Pictured: Acer to USB Hub



Pictured: ASUS to USB Hub



Pictured: HP to USB Hub

5. If desired, plug a second USB extension cable into the USB Hub and position it for easy access connection of a USB drive (customer supplied) to download data. Data can be

retrieved by connecting the 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).

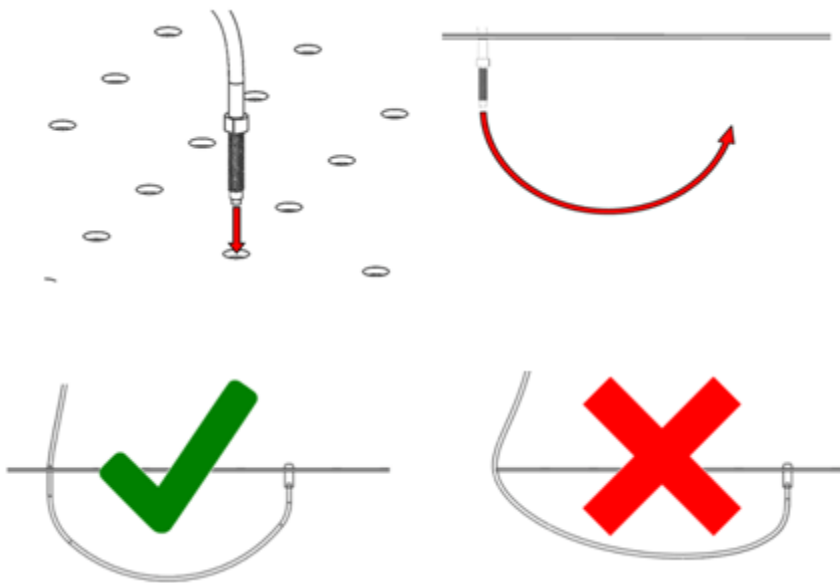


Pictured: USB Drive Connected to Hub

6. For Cabinet Style incubators, feed the TrakPod fiber optic cable into the access port of your incubator.



CAUTION: In order to prevent the fiber optic from being pinched by the self, feed the cable down through a hole in the shelf and gently loop it back up. Post installation be sure to remove the TrakPod cabling from the incubator shelf while moving any of the shelves.



Pictured: Fiber Optic Cable Routing

7. Choose one of the middle shelves in the incubator and mount the fiber optic fixture onto the shelf of the incubator. Loosely assemble the fixture to the supplied wingnut and fiber optic cable. Then screw the fixture all the way onto the fiber optic and tighten the wingnut to hold it in place on the incubator shelf.



Pictured: Fixture Installed on Incubator Shelf

8. Cut the stopper for the access port in such a way that the fiber optic can be placed into the stopper and seal the access port of the incubator. A slit or wedge cut are recommended.



OR



Pictured: Modified Stoppers

9. Place the TrakPod onto the side of the incubator using the internal magnets to hold the TrakPod on the incubator. Use the magnetic Cloops as needed to keep the USB cables in place and tidy.



Pictured: Trakpod Mounted on Incubator

CAUTION: The fiber optic cable must be handled with care during installation and handling of TrakPod units. This cable contains internal elements which can be irreparably broken if the cable is put under too much stress which may compromise TrakPod communicability and functionality. Do not over bend, twist, compress or pinch the cable.



DO NOT OVER BEND

10. Plug in the USB cable between the TrakStation's USB Hub and TrakPod. For Benchtop Style incubators: The TrakPod is already installed inside the incubator (if available). Plug in the USB cable between the TrakStation's USB Hub and the designated USB port on the back of the incubator.



Pictured: Cabinet TrakPod to USB Hub Connection

Optional: Use a USB extension cable as necessary to cover longer distances between the TrakStation and TrakPod. If a USB cable longer than 6 feet (1.8 meters) is needed, an active repeater is required on extension cables.



Pictured: Benchtop TrakPod to USB Hub

11. On the 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 TrakStation display. For each connected TrakPod, a user-specified name can be assigned such as an incubator number or identification that is going to be used.
12. Repeat steps 6 through 11 as necessary for additional TrakPods (up to eight (8) per TrakStation).



CAUTION: TrakPods should be connected, added, and assigned one at a time for optimal results.

First Use

The first time you use the TrakStation, 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 TrakStation will also need to have the qc² 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 qc2 alignment tool.

Quality Control (QC) Test

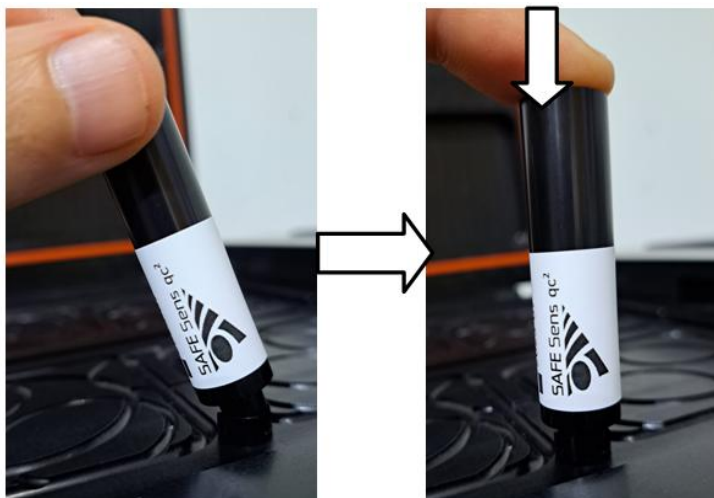
When first connected, each TrakPod must have the initial QC test performed. For a full description of QC testing see 'Routine Operations Workflow – QC Testing'.



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' menu. Select the Run QC Test option to proceed through the test. NOTE: The FIND FIBER button will cause the Pod to flash the LED several times and allow you to locate which fiber optic might be associated with the chosen Pod.
2. Use a lint free tissue like a Kimwipe to remove any dust from the fiber optic surface.
3. Place the qc² alignment tool on the fiber fixture. It can be helpful to apply downward pressure to the qc² for the test to ensure it is fully seated on the fiber optic fixture.



Pictured: qc2 Alignment Tool on Probe

4. Press the CONTINUE button: The 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.

Site Standardization

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

Why is Site Standardization Important?

During TrakPod adjustment at the factory, several environmental factors are different than in clinical laboratory conditions including: CO₂, 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 your embryo culture conditions. It uses media used in your lab for embryo culture and allows the TrakStation to determine your unique laboratory pH based on environmental conditions and medium composition. Recommended options for the pH reference sample include:

1. One additional disposable sensor with 150μL of IVF medium and sufficient oil to be read using a blood gas analyzer.

2. A medium sample created and read similarly to your previously protocol for pH measurement (such as using a pH electrode probe).
3. The Certificate of Analysis (CoA) value after duplicating the CO₂ settings from the certificate.



CAUTION: *We do not recommend solely using the CoA of the media as there is variance between media samples and the location of media manufacture.*

How Do I Achieve Maximum System Accuracy?

Ensure that the incubator being used is properly calibrated for both CO₂ and temperature. To calibrate, consult the incubator operator's manual for your specific model. Verify the incubator temperature and CO₂ concentration by an external method (i.e. Thermometer, Fyrite) before beginning your setup tests.



CAUTION: If using the CoA as a reference sample, it is also imperative that the incubator be set to the conditions (temperature and CO₂ concentration) listed for the certified culture media. If the incubator settings are different than those stated on the CoA, pH values logged by TrakStation may not be the same as listed on the CoA.

At BCSI, the TrakStation system is set for Universal IVF Media, 5% CO₂ and 37°C in Seattle, WA USA at an elevation of 46 Feet ASL. A tool to calculate pH changes is located [here](#).

If you are in most any other location or use any other media or have changes to your incubators, you must execute the steps below.



CAUTION: *BCSI recommends that you 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) 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 (see What is a pH Reference Sample? for recommended options).
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. BCSI recommends using 50 µL for Humid Incubators, and 150 µL for Dry 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: 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 your normal CO₂ levels and normal temperature near 37 °C.

Site Standardization Readings

1. To read the pH Reference Sample, have your external pH measurement tool calibrated and ready to read.
2. Remove your 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.
3. Using the Site Standardization menu tool for the specific TrakPod, Enter the pHID for the sensors being used. A lot specific pHID is printed on the blue kit packaging (25050 in the example below). **Use the pHID on your kit packaging when setting up to read the pH.**



Pictured: Example Sensor Label



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

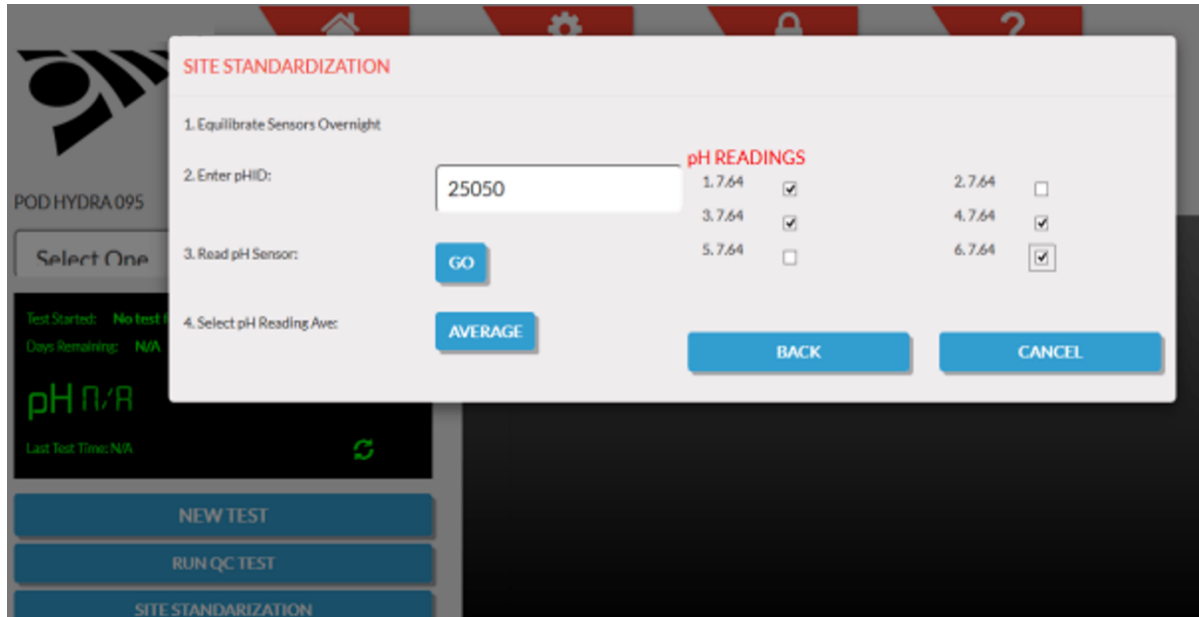
Pictured: Site Standardization Screen

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 TrakStation* as this lowers the amount of ambient light interacting with the sensor and ensures it is fully seated in the fixture.



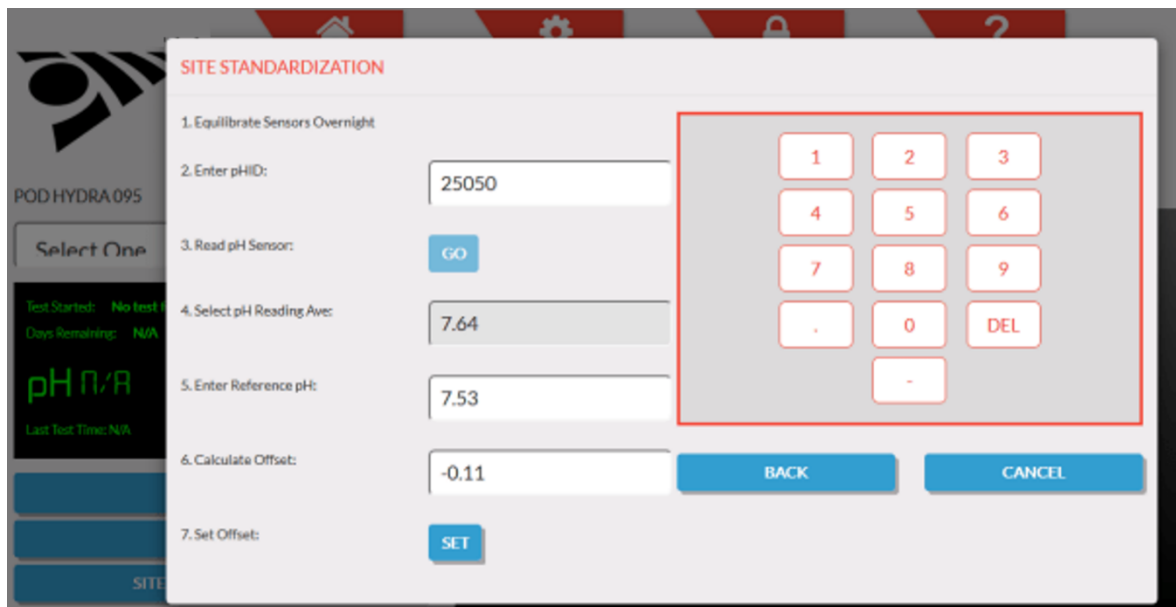
CAUTION: Constant opening/closing of the incubator door will lower the temperature and CO₂ in the incubator. Read all three (3) sensor readings quickly (within 30 seconds) OR allow time for the incubator and the sensor to re-equilibrate.

5. Upon completing the readings, use the checkboxes to select pH results from your sensor readings to average and push the average button. Do not select a reading if there was an issue with that reading.



Pictured: Site Standardization Screen Continued

6. Enter your reference pH. The software will calculate your offset and allow you to SET it for the TrakPod.



Pictured: Site Standardization Screen Continued

7. If sensors are to be re-read on a different TrakPod, place the sensors back into the incubator and allow them to re-equilibrate at temperature and CO₂. Re-equilibration is essential for accuracy. The sensor out of the incubator slowly changes the pH levels

because of temperature decreases- if you repeatedly read the sensor outside of the environment you will get varied results.

NOTE: For multiple incubators, it is not required to use three (3) new sensors for every TrakPod. For example, with four (4) 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 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 TrakPod. Again, use the pH measured in the first incubator as the reference pH as the sensors' CO₂ 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 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 TrakStation System you must repeat this protocol for the new media type and adjust your "Offset Values" accordingly.

Why an Offset Value?

Because the setup at BCSI was done under unique conditions, 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 your clinic. Our Site Standardization protocol assures that the unit is aligned for maximum precision and will match the CoA of the media being used for a specific cycle.

4. Routine Operation

Workflow

The normal workflow when using the 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 you can 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 interfaces for each Pod has the functions needed for running pH tests, performing QC tests and other functions relevant to the Pod ([See Pod Page](#)).



Pictured: TrakPod User Interface

Quality Control (QC) Testing

What is the QC Alignment Tool?

The quality-control (QC) alignment tool is an aluminum tube containing a small amount of fluorescent dye. One QC alignment tool can be used on all the connected TrakPods individually. When you read the alignment tool with the TrakStation and TrakPod, it gives a known and stable reading. You use it to make sure the Pod is operating correctly. It is recommended to take a QC measurement for each TrakPod on initial installation, once a week during use, and after cleaning or disinfecting the TrakPod components.

Keep the QC alignment tool protected in the provided bag when you are not using it. 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 you believe your QC alignment tool has been damaged or require a replacement, please contact BCSI Technical Support by emailing support@safesens.com.

Weekly QC Testing

1. Put Y#### control sensor on probe: Check the serial number of the qc² alignment tool matches with the serial number listed on the TrakStation. It can be helpful to apply some downward pressure to the qc² for the test to ensure it is fully seated on the fiber optic fixture.

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

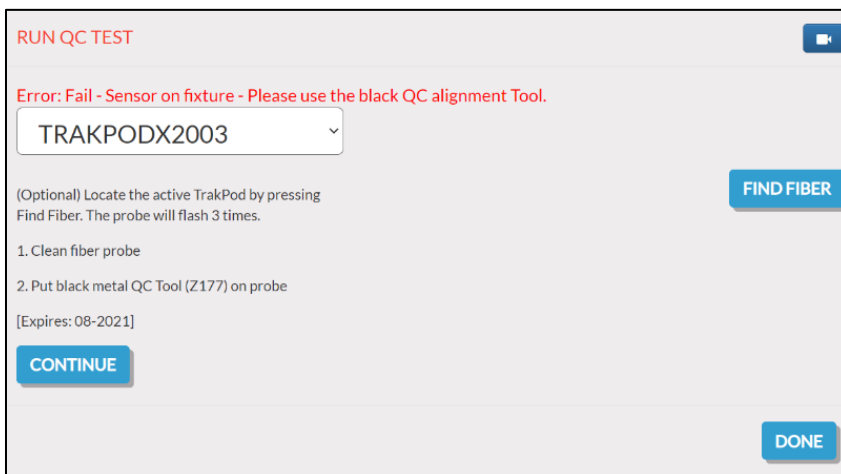
Pictured: Run QC Test From TrakPod Page

NOTE: The FIND FIBER button will cause the Pod to flash the LED several times and allow you to locate which fiber optic might be associated with the chosen Pod.



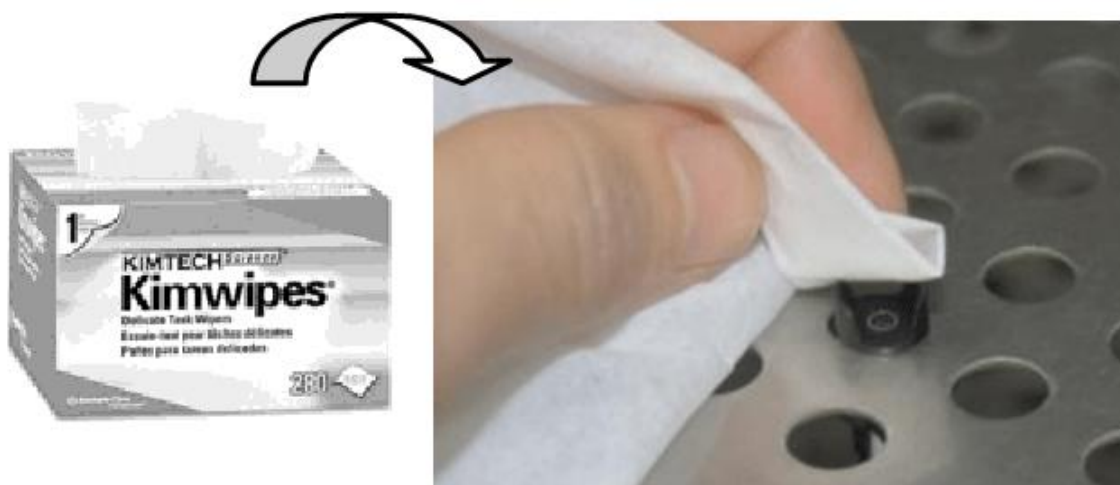
CAUTION: DO NOT USE A SV² SENSOR FOR A QC ALIGNMENT TEST- this could cause faulty pH readings.

If you attempt to use a sv² sensor for the QC Alignment Test, you will not be able to successfully complete alignment.



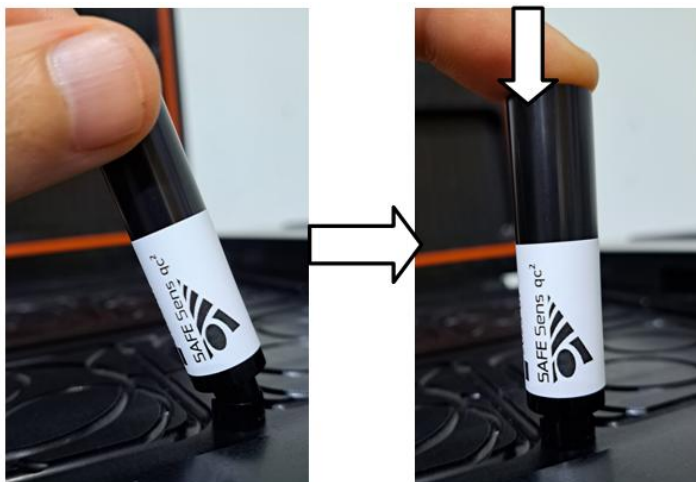
Pictured: QC Test Failure from Sensor on Fixture

2. Clean Fiber Probe: use a lint-free tissue like a Kimwipe to remove any dust from the fiber optic surface.



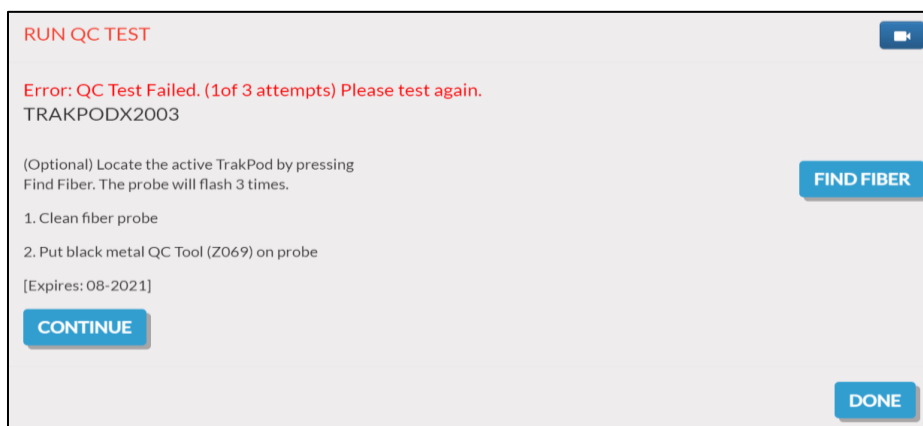
Pictured: Cleaning Fixture With a Wipe

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 qc² Alignment Tool selected to run the QC Test on the TrakPod is the same control sensor you are using for QC Testing.



Pictured: QC Alignment Tool on Fixture

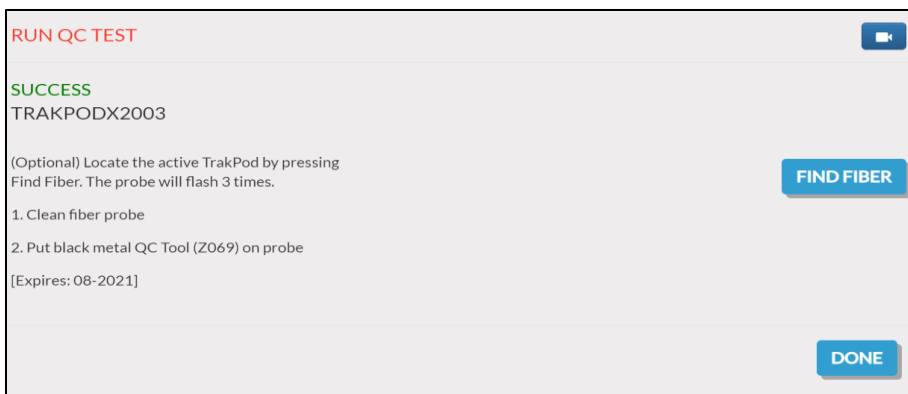
4. Press the CONTINUE button: The TrakPod will test the fluorescent signal and compare it to the assigned fluorescent levels.
5. The Screen will then display the result of the QC Test.
6. If the test failed, a message about the failure will be displayed with an attempt counter.



Pictured: QC Test Failure With Attempts Value

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

7. Typically, you should rerun the QC test, 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.



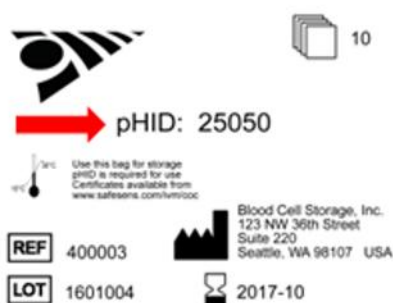
Pictured: QC Test Success After Re-Alignment

10. If failures persist, contact BCSI Technical Support by emailing support@safesens.com or by using the Message Support Button in the Supervisor Menu.

Regular pH Testing

Before you begin 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) sensor per 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 Sensor aseptically from the sterilization pouch in which it arrived. A lot specific pHID is printed on the blue kit packaging (25050 in the example below). **Use the pHID on the kit packaging when setting up to read the pH.** The LOT and hourglass symbols refer to a lot number and the expiration date (prior to use) of the sensor, respectively.

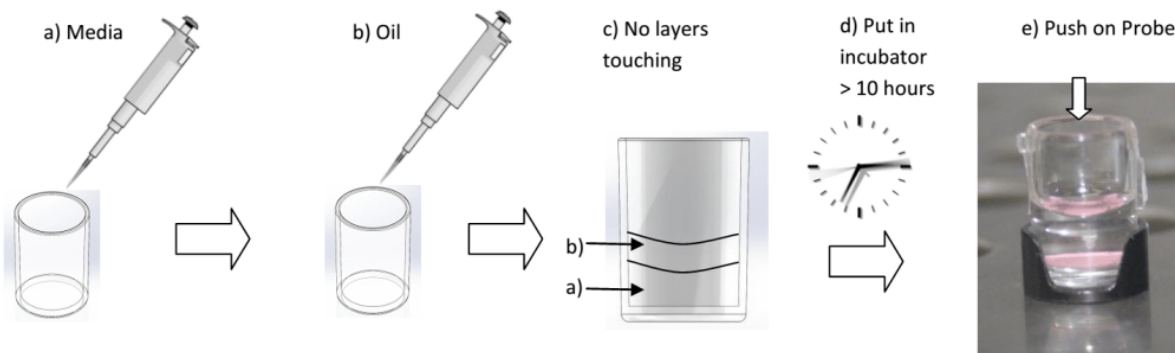


Pictured: Example Sensor Label



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

2. Prepare the sensor as follows:



Pictured: Sensor Preparation

3. **Media:**

Use 100 μ L of media.

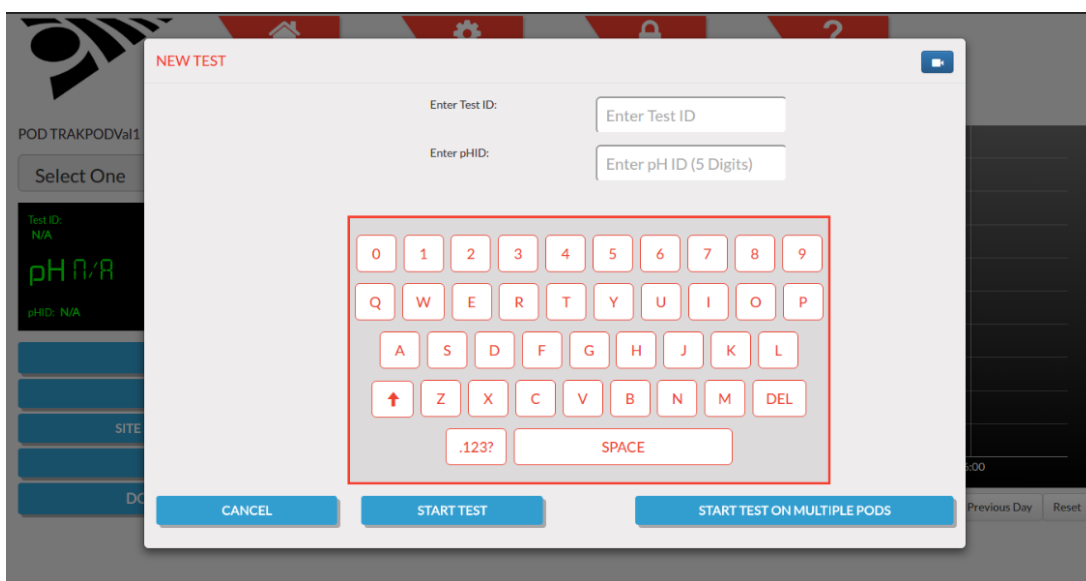
Hold the sensor with the opening upward. Carefully pipette media down the side of the sensor. Avoid adding bubbles while doing this step. It works best not to fully dispense the entire volume from the pipette tip. Also avoid touching the pipette tip to the membrane. The media is not to be pre-equilibrated.

4. **Oil:**


Use 50 μ L of oil for humidified incubators. Use 150 μ L of oil for dry incubators. 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 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 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.



Pictured: New Test Screen

6. Enter a unique test ID and the pHID from the blue sensor package and press SAVE. The TrakPod will then start reading pH with the desired frequency. To take a reading at any time, press the green refresh icon ).

Additional Useful Guidelines:

- Bubbles may appear in the 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 TrakPods have an automatically applied drift correction. During use, the 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 on test.



CAUTION: Be sure to *end current tests and start new tests when a new 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 Benchtop Incubators and TrakPods

1. The day prior to ending pH tests prepare new sv^2 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 sv^2 sensors so none of the fixtures have sv^2 sensors on them.
3. Run the qc^2 Alignment Tests for each of the chambers followed by cleaning and disinfecting the chambers.
4. Place all the new sv^2 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 sv^2 sensor in it.

Shut Down and Storage

The TrakStation can be shut down by holding the power button down to power it off. Then unplug the tablet and store it. The 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 TrakStation and 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 (TrakStation and TrakPod)	Plastic
Screen (TrakStation)	Glass
Printed circuit boards (TrakStation and TrakPod)	Enclosed electronic components mounted on PCB
Fiber optic cable (TrakPod)	Plastic
Fixture (TrakPod)	Aluminum

The qc² Alignment Tool contains aluminum and may be recycled or it may be discarded in unregulated waste.

The sv² Sensor may be discarded in normal unregulated waste or a waste method that is used for consumed media.

5. Cleaning and Disinfection

TrakStation

Cleaning

1. The exterior of the TrakStation can be cleaned periodically. Turn off the TrakStation, disconnect from power and disconnect the TrakPods prior to cleaning the exterior surfaces.
2. Apply Oosafe Disinfectant Spray evenly to all surfaces of the 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 TrakStation to air dry.
5. Visually inspect 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.

TrakPod

The TrakPod fixture component is cleaned and disinfected with the incubator chambers. Run the qc² alignment test prior to cleaning and disinfecting. Follow instructions for cleaning and disinfecting the incubator that are found in the incubator user's manual.

sv² Sensors



CAUTION: The sv² sensors *cannot be cleaned, disinfected or reused*.

qc² Alignment Tool

Cleaning

The exterior of the QC Alignment Tools may be cleaned in the same manner as described for the TrakStation above. Do not attempt to open or clean the inside of the QC Alignment Tools.

Disinfection

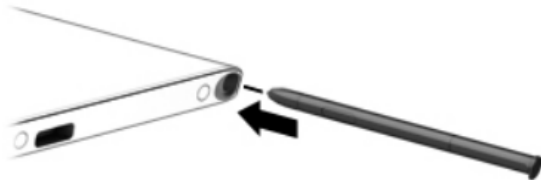
After the surfaces are clean and all visual soil has been removed, proceed with the following instructions to disinfect the surfaces as follows:

1. Promptly soak up excess liquid using a sterile cloth.

2. Apply Oosafe Disinfectant Spray evenly to all exterior surfaces. Wait a minimum of 15 minutes for the surfaces to dry for best results.
3. Moisten a sterile non-linting cloth with purified or sterile water and wipe all disinfected surfaces for a minimum of one (1) minute.
4. 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 TrakStation is a menu-driven user interface. The various available functions are described here. The touchscreen interface may be navigated with fingers or stylus. A stylus is included with the HP model tablet. A stylus is not included with any other model tablets.



Pictured: HP Stylus




CAUTION: Screen burn can occur when the same image is displayed for a considerable amount of time on the TrakStation tablet. There are several preventative measures that can prevent or minimize screen burn-in.

HP tablet users should consider a software input change for a screen saver as a preventative measure.

ACER and Lenovo tablet users can use the volume buttons to dim and turn off the screen backlight.

Windows tablet users can set 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 bring you to 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 System 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, allowing you to locate 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, you may also email the data 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

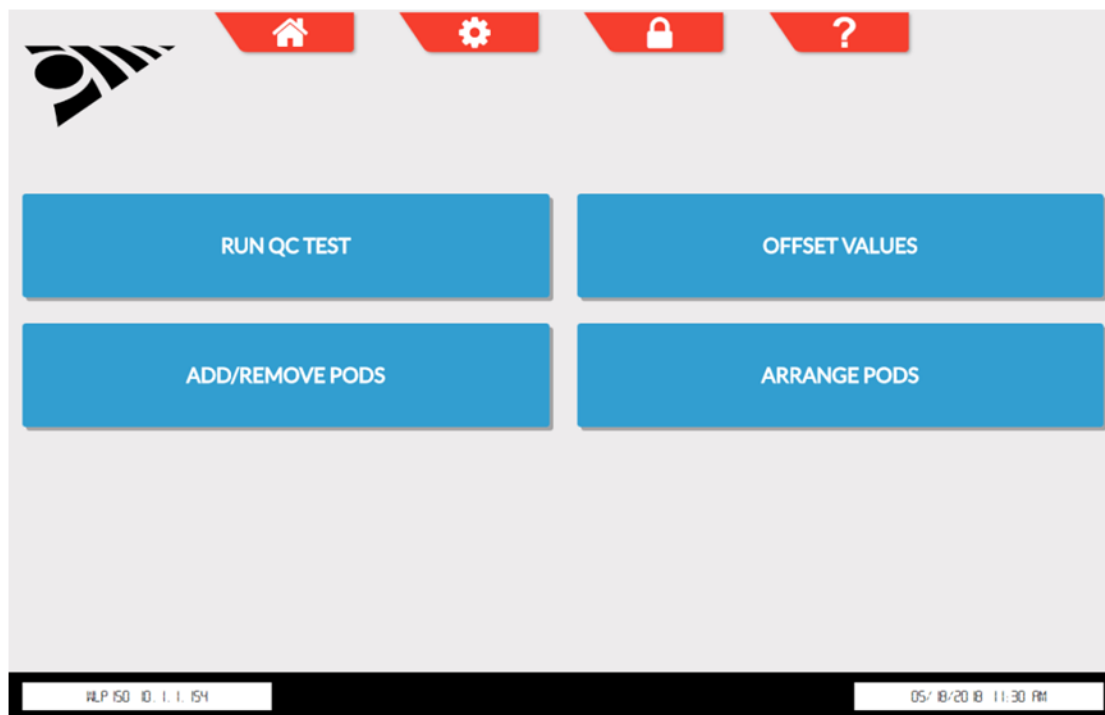
Pan: Shift+Click+Drag

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 you to adjust commonly changed settings on the TrakStation.




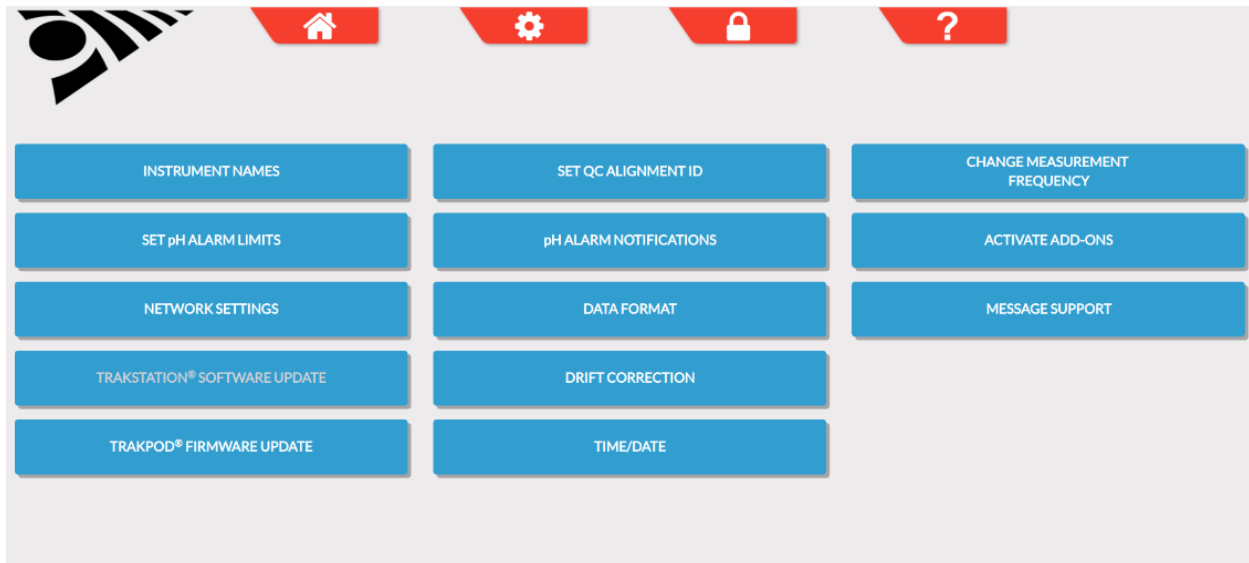
Pictured: Settings Screen

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

- **RUN QC TEST:** Perform QC test with the QC 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 TrakPods from the TrakStation interface.
- **ARRANGE PODS:** Change the order in which the connected TrakPods are displayed on the 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. You can change this PIN using the on-screen menus options.



Pictured: Supervisor Screen


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

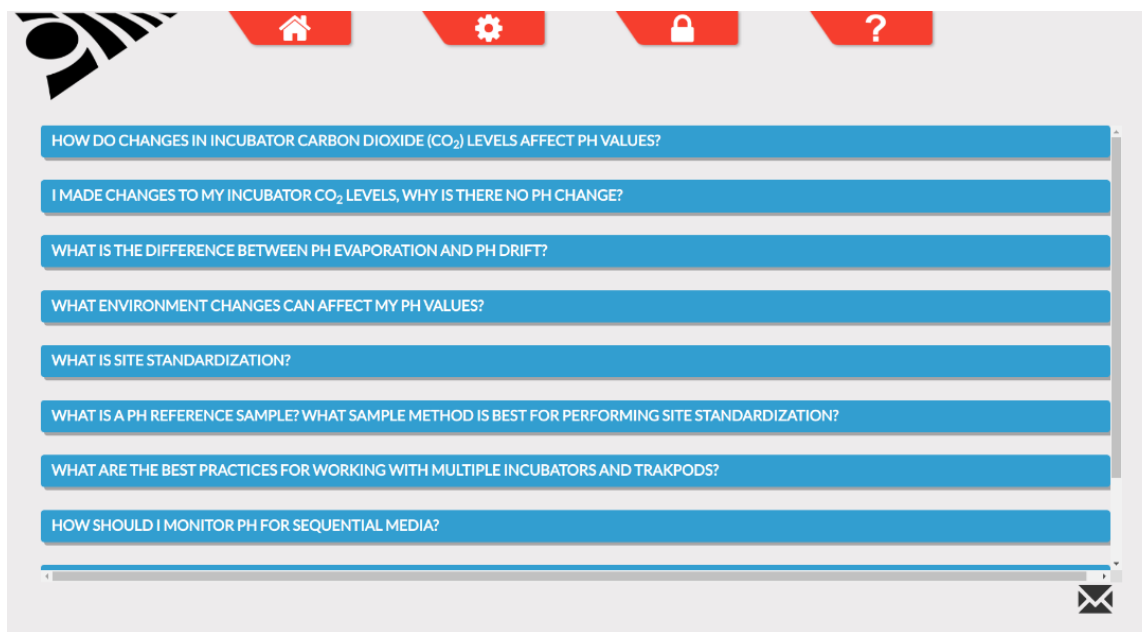
- **INSTRUMENT NAMES:** Change the names displayed for Pods. This can make referring to various TrakPods easier when using identifiers for what incubator they are in.
- **SET pH ALARM LIMITS:** Set pH limits for each TrakPod with your own upper and lower acceptable values.
- **NETWORK SETTINGS:** Connect the TrakStation to the local internet and specify IP address settings and wireless network keys if applicable.
- **TRAKSTATION® SOFTWARE UPDATE:** When a new version of 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 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 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 Blood Cell Storage, Inc. support. Please contact support@safesens.com for assistance.
- **TIME/DATE:** Reset the time on the TrakStation. If an internet connection is available, the time and date can be automatically updated by the 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 TrakStation, such as outputting pH data to a third-party lab monitoring platform.
- **MESSAGE SUPPORT:** Message and send all pH and system data to our support team from an internet-connected TrakStation. Please include required information for the support team such as location information, issue category, and a description of your issue.


Help

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



Pictured: Help Screen

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

Additionally press the Mail Icon () to message Support using our Support Team form. Please include required information for the support team such as location information, issue category, and a description of your issue.

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

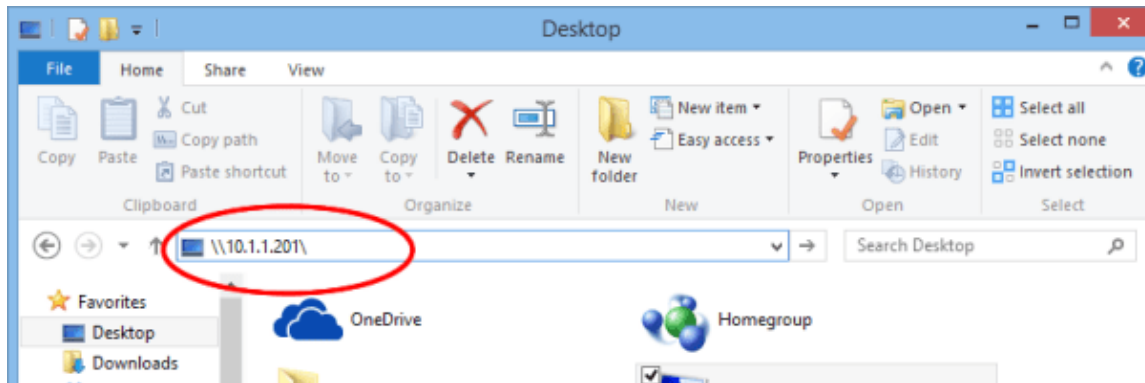
If your TrakStation is network connected it is possible to access all the controls of the TrakStation from a separate computer that is on the same network. Use a web browser and navigate to <http://###.###.###.###:8080/hydra/> where ###.###.###.### is the IP address of the TrakStation which is network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



Pictured: Remote Access IP Address

If you find issues connecting from a separate computer check with your IT department and ensure that it is on the same network and that your network router's settings 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 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 TrakStation.

7. Troubleshooting

Common issues with TrakStation and 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 you have the latest versions of software for your TrakStation and TrakPods.

Issue	TrakStation Error message	Remedy
Connected TrakPods not appearing on home screen.	NA	Check that the TrakPods is properly added and saved to the Authenticated Pods list.
Red border surrounds TrakPod(s) on home screen.	<p>Error: Could not detect selected TrakPod! Check USB and Power cable connections. (Failed to Parse request)</p> <p>Error: Internal Server Error (error)</p>	<p>This may impact only one TrakPod or all TrakPods. If only one TrakPod focus on that one TrakPod's USB connections.</p> <p>Check all USB cable connections at TrakPod, USB hub, and TrakStation and power connection for USB hub. Especially check the USB cable connection at the back of the TrakPod.</p> <p>If observed following a reboot of the TrakStation, physically disconnect all of the TrakPod USB cables from the USB hub and then reconnect them.</p>
pH measurements are less than 6 or 10.	NA	Check that a properly-prepared sensor containing media and oil is in the fixture. Ensure the correct pHID is being used.
QC Alignment test produces errors	Error: No Signal- Please ensure QC alignment tool is on fixture	Check fixture assembly and the presence of QC ² 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- Please use the black QC alignment tool	QC Alignment test recognized a test 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 qc ² Alignment Tool is sitting completely in the fiber optic fixture. Ensure correct serial number QC ² Alignment tool is being used. Check the condition of the fiber optic cable, ensuring the fiber optic cable is not compressed or damaged.
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 support 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 you will need to program the QC ² Alignment information in the supervisor's lock menu.
TrakPods are not responding on TrakStation interface.	Error:(error)	Communication service to TrakPods has stopped unexpectedly, normally it will restart on its own. If this persists, reboot the TrakStation
TrakStation or TrakPod update has error.	Error:(error)	If this appears during software update processes it means there is no USB flash drive detected.
TrakStation screen shows signs of screen burn-in or displays ghost image of	NA	If screen burn is significant enough to affect everyday use, contact your support contacts to further resolve

previous pH testing		this issue or replace the 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.
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 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 TrakPods, be sure to select a TrakPod prior to trying to change its status.
Forgot PIN for supervisor access	Incorrect PIN Please contact support [RESETCODE]	If you have changed your PIN from the default 12345 and forgotten your TrakStation PIN for accessing the locked settings, contact support with your reset code and the PIN can be changed with an override code.

pHID is not recognized by TrakPod	<p>Error: The pHID entered was not recognized. This TrakPod may only be used with [COMPANY NAME] pH sensors</p> <p>Error: The pH reading request was denied by pod.</p>	<p>Check that the code is typed correctly.</p> <p>If the TrakStation informs you to contact a certain company representative, the TrakPod you are trying to use requires sv² sensors which have been setup specifically for that product.</p> <p>For example: TrakPods in ESCO Miri Incubators require sv² sensors obtained through your ESCO representatives.</p>
pH seems unexpected either consistently off or changing over time in unexpected way.	NA	<p>Several different causes can be at play. Visit this page to see some common pH trends and match one to your conditions.</p> <p>Contact your support contacts with any additional questions.</p>

Additional assistance troubleshooting is available from your support contacts. See [Section 8 Support](#).

8. Support

TrakStation and TrakPod support can be obtained by emailing support@safesens.com. Please include a description of your issue, any information you have about serial numbers and lot numbers of products in question and any log files that you are able to download.

The technical support page for the TrakStation is [here](#).

The TrakStation has no user serviceable components. Software updates for TrakStation can be obtained online for download [here](#). BCSI recommends running the most current software version, and will support users running the current software version as well as the prior version in the indicated timeframe noted on the update page.

The TrakPod has no user serviceable components. Firmware updates are possible through the TrakStation user interface. Download the appropriate files [here](#) and follow on screen instructions via the supervisor settings “Update Pods” function.

9. The Science Behind pH Monitoring

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

The sv² 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. (You can 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 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 independently 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

Blood Cell Storage, Inc. (BCSI) warrants that, at the time of shipment, the instrumentation provided to the customer is free from defects in material and workmanship.

This limited warranty is conditioned upon the customer giving BCSI notice of any defect within two (2) years after shipment. This limited warranty will not apply if the instrumentation (a) has not been installed, used, or maintained in accordance with applicable instructions and manuals; (b) has been repaired or altered by unauthorized persons or misused, abused, accidentally damaged or subjected to operation for which it was not intended; or (c) has had its serial number altered or removed. This limited warranty does not apply to consumable items. Except as expressly stated herein, BCSI makes no other warranties, express or implied, including warranties of merchantability or fitness for particular purpose.

Under this limited warranty, BCSI at its option, will repair or replace any defective instrumentation. This is the sole remedy for any breach of warranty. Any instrumentation to be returned for repair or replacement must be properly packaged and shipped via prepaid freight in accordance with BCSI instructions. This limited warranty does not apply to the use of the instrument other than as described herein.

This limited warranty contains BCSI's sole obligation and liability related to the customer's use of the BCSI products. BCSI shall not be liable to the customer for any other remedies of damages, including special, indirect, incidental, and consequential damages, including, but not limited to, lost profits, whether based upon warranty, strict liability, tort, contract or otherwise. This limited warranty may not be changed in any way without the express written permission of BCSI.

Each provision of this agreement that provides for a limitation of liability, disclaimer of warranties, or exclusion of damages is to allocate the risks between the parties. This allocation is reflected in the pricing offered by BCSI to the customer and is an essential element of the basis of the bargain between the parties. Each of these provisions is severable and independent of all other provisions of this agreement. The limitations in this section will apply notwithstanding the failure of essential purpose of any limited remedy in this agreement.

Warranty Registration

To register your product, go to:

www.safesens.com/contact/registration/

11. System Specifications and Symbol Specifications

Item	Value
Dimensions of 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 TrakStation	Varies by model of tablet computer, typical dimensions based on 10" screen size.
Minimum External Connections	<ul style="list-style-type: none"> • USB 3.0 Port (or Type C 3.0 Port with adapter) DC-in jack
Touchscreen	10" to 12" touch screen (1280 x 800 or better)
Power requirements	
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
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
Operating, Transport and Storage humidity	5-95% relative humidity, non-condensing

TrakStation Performance Specifications









Item	Value
pH measurement accuracy and range	0.05 pH units within pH 7.00 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. (Typically one year from pHID assignment)
Optical control	QC Alignment Tool (minimum 12 month lifetime)





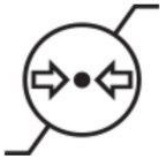




Certification


Item	Value
Safety class	Class A
FCC	Part 15 Subpart B Compliant
2014/30/EU	Electromagnetic compliant
2014/35/EU	Low voltage compliant
EN 61010 revision 3	Conforms
RoHS	Compliant

Symbol Glossary

Symbols used in all labeling are summarized below in the table.

Symbol	Symbol Title	Symbol Description
	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.
	Manufacturer	Indicates the device manufacturer.
	Authorized Representative in European Community	Indicates the Authorized representative in the European Community.
	Date of Manufacture	Indicates the date when the device was manufactured.
	Use-by Date	Indicates the date after which the device is not to be use.
	Batch Code	Indicates the manufacturer's batch code so that the batch or lot can be identified.
	Catalogue Number	Indicates the manufacturer's catalogue number so that the device can be identified.
	Serial Number	Indicates the manufacturer's serial number so that a specific device can be identified.

	Keep Away From Light	Indicates a device that needs protection from light sources.
	Sterilized using ethylene oxide	Indicates a device that has been sterilized using ethylene oxide.
	Temperature Limit	Indicates the temperature limits to which the device can be safely exposed.
	Humidity Limit	Indicates the range of humidity to which the device can be safely exposed.
	Atmospheric Pressure Limitation	Indicates the range of atmospheric pressure to which the device can be safely exposed.
	Consult Instructions For Use	Indicates the need for the user to consult the instructions for use.
	Control	Indicates a control material that is intended to verify the performance characteristics of another medical device.
	CE Marking	Signifies European technical conformity.
	Recycle Electronic Equipment	Do Not Dispose of this equipment in normal trash.

	FCC Declaration of Conformity	Certification mark employed on electronic device which indicates that EMC is under limits approved by FCC.
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Intellectual Property

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

The SAFE 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.