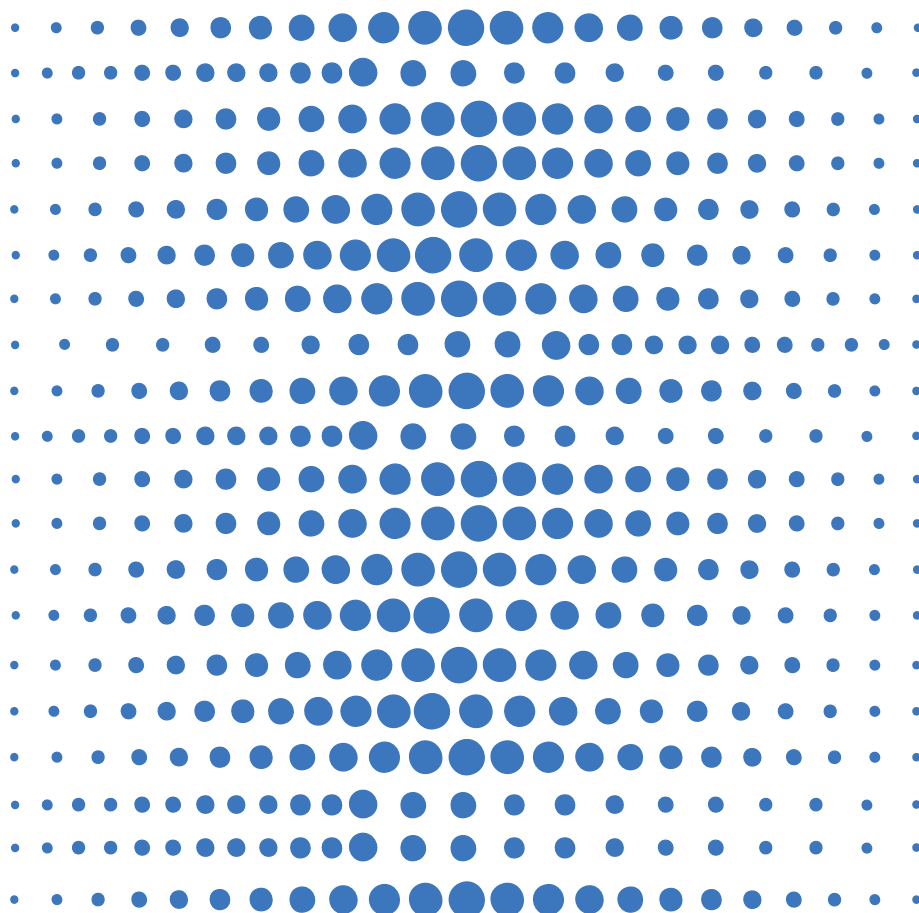




Hillrom™

**WELCH ALLYN
SURETEMP Plus
OEM module**



OEM implementation guide

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Product overview

Temperature is a critically important vital sign that most often affects patient treatment decisions. Various therapies and studies are initiated or withheld based on a patient's temperature. Therefore, determining a correct temperature is vital to patient care. SURETEMP® Plus thermometry provides fast and accurate temperature readings.

The Welch Allyn SURETEMP Plus module is a fully integrated, microprocessor-based thermistor thermometer design. This proprietary Welch Allyn predictive technology provides fast, accurate readings. Oral/axillary and rectal probes use single-use disposable probe covers that help to reduce cross-contamination.

The SURETEMP Plus module controls and acquires data from an external Welch Allyn proprietary thermometer. The SURETEMP Plus module calculates temperature measurements and outputs this data to a host system via a serial communications interface. (A *host system* is the vital sign device that the SureTemp Plus module is integrated into.)

Terminology

Patient temperature can be measured via an oral/axillary or rectal probe. A proprietary Welch Allyn predictive algorithm in conjunction with the thermistor-based thermometer is used for fast predictive-mode temperature measurement or monitor-mode temperature measurement.

Predictive temperature measurement: Thermometers that render a temperature reading before steady state is achieved are classified as Predictive Thermometers. Predictive Thermometers reduce the time required for measurement by using algorithms to predict what the temperature would be if the probe were left in place until steady state is achieved.

Monitor-mode temperature measurement: A function or mode of an electronic thermometer used to continuously monitor temperature until it reaches the thermal steady state (unchanging). The thermal steady state is achieved through an oral or rectal measurement in approximately 3 minutes and through an axillary measurement in approximately 5 minutes.

Intended use

The Welch Allyn SURETEMP Plus module is intended for use as a subsystem within a medical instrument or device. It is designed for use on adult (18 years and older) and pediatric (17 years and younger) patients. The module and its accessories should always be used as described in the host system operator's manual and only for the purposes intended.

The most common user is a nurse or skilled health-care professional (EMT, paramedic, respiratory therapist, clinical engineer, and so on).

Measuring principle

The Welch Allyn proprietary probe uses a negative temperature coefficient (NTC) thermistor and control circuitry in combination with the SURETEMP Plus module's predictive algorithm to calculate patient temperatures.

NTC thermistors have a large temperature coefficient of resistance and change in resistance as temperature changes. This predictable change in resistance is the basis for predictive thermometry.

The oral/axillary probe is pre-warmed to 34 °C (93 °F) upon extraction from the probe well. The probe-warmer circuitry heats the probe tip before taking a temperature reading to speed the convergence of the prediction algorithm. A fail-safe hardware shut-off circuit is included to ensure that the heater shuts down if a software failure occurs.

When the probe is placed in the mouth, the heat supplied by the mouth reduces pulse widths to zero.

The shape of the rising temperature curve is monitored and the best fit to a curve is found. When the curve fit is stable, the final predicted temperature is provided.

The module can determine the type of probe connected.

Warnings and cautions

The host system is responsible for communicating warnings and cautions regarding the OEM module to the end user. The following warnings and cautions are the result of risk assessment of the module. It is recommended that these warnings and cautions appear in your instructions for use.



WARNING The warning statements in this guide identify conditions or practices that could lead to illness, injury, or death. Warning symbols are yellow but will appear with a gray background in a black and white document.



CAUTION The caution statements in this guide identify conditions or practices that could result in damage to the equipment or other property, or loss of data.



WARNING Patient injury risk. Before taking a temperature, instruct the patient not to bite down on the probe as patient injury and damage to the probe may result.



WARNING Inaccurate measurement risk. Use only HILLROM probe covers. The use of other manufacturer's probe covers or no probe cover may produce temperature measurement errors and/or inaccuracy.



WARNING Patient injury risk. Inaccurate measurement risk. Oral/axillary probes (blue ejection button at top of probe) and blue removable probe wells are used for taking oral and axillary temperatures only. Rectal probes (red ejection button) and red removable probe wells are used for taking rectal temperatures only. Use of the incorrect probe and/or removable probe well could result in patient cross-contamination. Use of the probe at the wrong site will result in temperature errors.



WARNING Patient injury risk. When taking rectal temperatures, insert the probe tip only 5/8 inch (approximately 1.5 cm) inside the rectum of adults and only 3/8 inch (approximately 1 cm) inside the rectum of children to avoid the risk of bowel perforation.



WARNING Inaccurate measurement risk. Never take an axillary temperature through the patient's clothing. Probe contact with clothing, electrodes, bandages, or other material causes poor tissue contact. Carefully place the probe in the axilla, avoiding contact with other objects or material. Prolonged exposure of the axilla to ambient air can cause inaccurate temperature readings.



WARNING Never use a damaged temperature probe. The thermometer consists of high-quality precision parts and should be protected from severe impact or shock. Do not use the thermometer if you notice any signs of damage to the probe or instrument. If the thermometer probe is dropped or damaged, remove it from use and have it inspected by qualified service personnel.



WARNING Incorrect measurements can result in delayed or incorrect treatment. If you suspect that the thermometer is delivering inaccurate measurements, first review the instructions in the sections on temperature measurement in this manual for ways to avoid inaccurate measurements. If you still believe that the thermometer is inaccurate, contact a Hillrom Service center for accuracy check.



WARNING Inaccurate measurement risk. For rectal measurements, apply a thin layer of lubricant to probe cover, if necessary, for patient comfort. Use of excessive lubricant may affect reading accuracy.



WARNING Inaccurate measurement risk. To ensure optimal accuracy, always confirm that the correct mode and site are selected.



WARNING Patient injury risk. Do not exceed the recommended temperature measurement durations in Monitor (Direct) Mode. Continuous measurement durations of 3 minutes at the oral and rectal sites and 5 minutes at the axillary site are recommended for accurate measurement. Do not continuously measure beyond 10 minutes in any mode.



WARNING Cross-contamination or nosocomial infection risk. Thorough handwashing greatly reduces the risk of cross-contamination and nosocomial infection.



WARNING The unit automatically enters Monitor Mode if the probe is withdrawn from the probe well and is not replaced within 60 seconds of inactivity.



WARNING Avoid using the SURETEMP Plus adjacent to or stacked with other equipment or medical electrical systems because it could result in improper operation. If such use is necessary, observe the SURETEMP Plus and other equipment to verify that they are operating normally.



WARNING Cleaning solutions, including those that contain bleach, can cause skin irritation if not completely wiped clean from the probe or thermometer following cleaning.



CAUTION Liquids can damage electronics inside the thermometer. Prevent liquids from spilling on the thermometer. If liquids are spilled on the thermometer, dry off the thermometer with a clean cloth. Check for proper operation and accuracy. If liquids possibly entered the thermometer, remove the thermometer from use until it has been properly dried, inspected, and tested by qualified service personnel.



CAUTION Inaccurate measurement risk. Patient activities such as strenuous exercise, ingesting hot or cold liquids, eating, chewing gum or mints, brushing teeth, or smoking may affect oral temperature measurements for up to 20 minutes.



CAUTION Probe covers are disposable, non-sterilized, and single-use. Probes are also non-sterilized. Do not autoclave probes and probe covers. Ensure that probe covers are disposed of according to facility requirements or local regulations.



CAUTION To ensure optimal accuracy, always confirm that the correct axillary mode is selected.



CAUTION After a temperature is taken and the probe is returned to the probe well, the instrument reverts to the original measurement site mode.



CAUTION DO NOT immerse or soak the probe or probe well in any type of fluid.



CAUTION DO NOT use steam, heat, or gas sterilization on the probe or probe well.



CAUTION DO NOT use hard or sharp objects to clean the probe well. This could damage the probe well and cause the unit to not function properly.

Latex statement

The components of the SURETEMP Plus device that could contact the user or patient are not made with natural rubber latex. This includes all items that could be contacted during normal operation, and all other functions, such as user maintenance and cleaning, as are defined in the Instructions for use.

No internal components are known to be made with natural rubber latex.

OEM implementation

Introduction

The host system is responsible for the following:

- Converting temperature measurement units from Kelvin to Fahrenheit and Celsius
- Error message display
- Providing display of last temperature
- Meeting patient safety requirements

EMI/ESD protection

You can add ferrite beads and 10-nF capacitors to the assembly interconnect connections to prevent malfunction of the assembly from electromagnetic interference. Locate these capacitors near the interconnections to the SURETEMP Plus board.

Mechanical and software considerations

Do not place the SURETEMP Plus module where it is subject to heat or electrical noise generating devices.

The probe connector has a debounce of 0.2 seconds when going from no-probe to any other state, and a 0.2 second debounce when going to no-probe from any other state. Therefore, the host must take this delay into consideration when waiting for the assembly to respond to a probe change

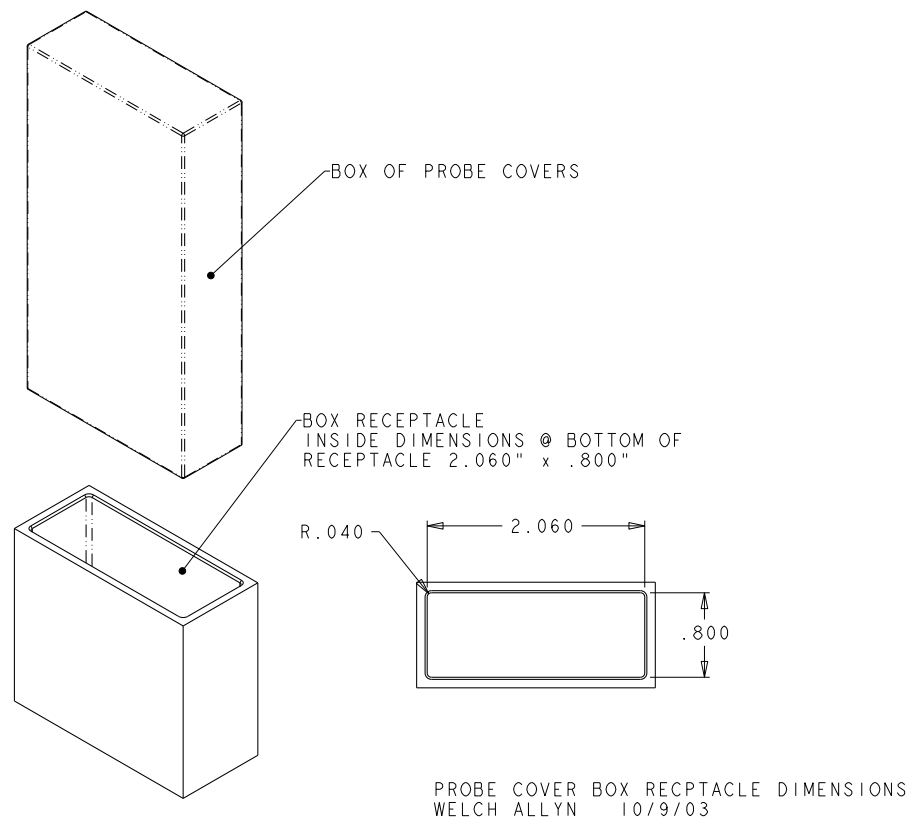
The module must be located such that the probe tip is at or near ambient temperature. The host is responsible for maintaining this requirement.

See **“Thermometry module” on page 13** and **“Probe connector detail” on page 13** for the mechanical drawings of the dimensions and design of the module.

A Programmable Ambient Bias is a feature provided with the module software to help minimize the impact caused by any offset in probe tip temperature versus ambient temperatures. See **“Programmable ambient bias” on page 67** for details.

Refer to the drawing below (Figure 1) for details concerning the probe cover box receptacle required to hold the probe cover box.

Figure 1. Probe cover box receptacle



Mount the SURETEMP Plus module within 30° of probe-well vertical to help prevent the probe from falling out of the well during transport or movement of the finished device.

Allow for ventilation of the module and probe well to avoid excessive heat build-up. Add ventilation slots for adequate air movement to keep the probe tip at ambient room temperature.

Note Keep the probe and probe covers at ambient room temperature. Measurement accuracy is negatively affected if the probe tip and the probe covers are not kept at ambient room temperature.

Consider ergonomics when designing the finished product to avoid damaging the probe tip during removal and replacement into the well. The majority of probe problems stem from mishandling the probe or cord. It is recommended that the probe connector be mounted so that the probe cord is not stressed and does not interfere with other device accessories.

The host must integrate a mechanical lock for the probe connector. [See "Probe connector detail" on page 13.](#)

Host connector interface

The module interfaces the host system through a single 6-pin interface:

SURETEMP Plus module connector	Molex 52271-0679 or equivalent
Standard ZIF cable- same side, 1-mm pitch	Parlex AWM Style 20566 or equivalent

Table 1: Host connector pin descriptions

Pin	Description	Note
J1-1	RXD	Module Receive from Host. Levels follow Vcc and ground.
J1-2	TXD	Module Transmit to Host. Levels follow Vcc and ground.
J1-3	HOST-WAKEUP-BAR	Active Low. The host must wait 500 ms after asserting the host wake-up before sending a command.
J1-4	RESET-BAR	Active Low. Hold low for 1 μ s to insure correct power-up.
J1-5	GND	Ground.
J1-6	Vcc	3.3 (-0.135) VDC to 5.0 (+0.30) VDC. Ripple not to exceed 100 mV peak-to-peak.

Probe connector

The SURETEMP Plus module includes an eight-pin right-angle EDAC connector for the probe connection. This eliminates the need for a special wiring harness.

However, should the host have to remotely mount the probe connector, an available option replaces the EDAC with a Standard ZIF cable connector, MOLEX part number 52271-0890 or equivalent. This option requires the integrator to create a circuit board to contain the MOLEX and EDAC connectors and then mount it remotely from the OEM module.

Keep added resistance in the remote probe connector to an absolute minimum. All connectors must be gold-plated and non-intermittent to prevent additional resistance build-up in series with the probe connection. Probe ID, probe thermistor, and heater control are negatively affected and system performance is compromised if the added resistance is too high.

Power requirements

The system employs a heater in the oral/axillary probe tip to speed the warming process and reduce measurement times.

Table 2 depicts typical power requirements of the SURETEMP Plus module and probe. Min and max operating current and time to ready state apply to the entire operating voltage ranges.

Table 2: Power requirements

Operating Voltage	Operating Current Non-Heating		Operating Current Heating (max)		Sleep Current	Time to Ready State	
	min	max	min	max	Typical	min	max
3.3V–5.0V	8mA	9.4mA	109mA	120mA	7.5mA	1.6s	6s

Serial communications interface

The SURETEMP Plus board is a command-driven OEM module capable of communicating with a host system over an asynchronous serial communication line. The host system can set the module to asynchronous mode, and can start the temperature cycle by removing the probe from the well. The SURETEMP module sends data packets without additional intervention by the host system.

The host must initiate all other communication with the SURETEMP module. See [“Communications protocol” on page 29](#) for details.

Asynchronous operation

The SURETEMP Plus module can be easily configured to send unsolicited temperature packets to the host. The serial protocol offers an asynchronous command that causes the module to send unsolicited temperature packets upon removal of the probe from the well. The packets will continue until the probe is returned to the well or until the module times out.

Figure 2 is the state diagram for the monitor mode of the SURETEMP Plus thermometer. This sequence diagram covers the state changes for the algorithm during active monitor mode and ends with display of temperature. See [“Module operation” on page 18](#) for more information.

Figure 2. State diagram: Monitor

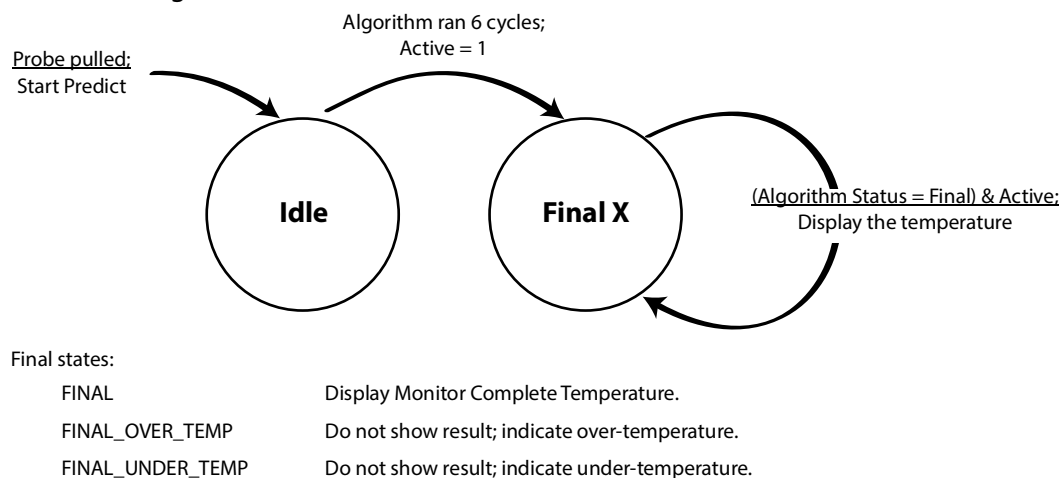
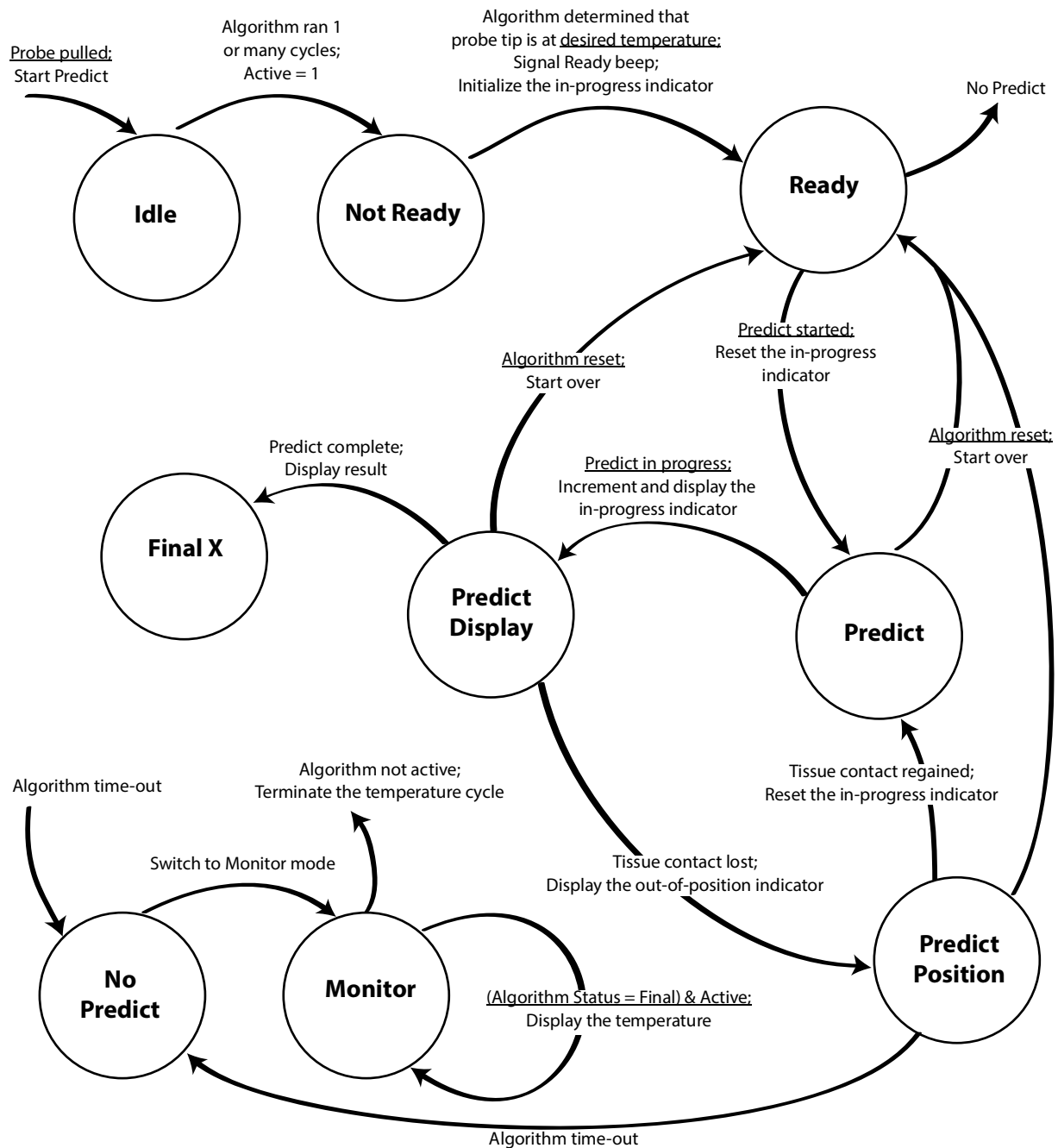


Figure 3 is the state diagram for the monitor mode of the SURETEMP Plus thermometer. This sequence diagram covers the state changes for the algorithm during active predict mode and ends with display of temperature. See [“Module operation” on page 18](#) for more information.

Figure 3. State diagram: Predict



Final states:

FINAL

Display Predict Complete Temperature.

FINAL_OVER_TEMP

Do not show the result; indicate over-temperature.

FINAL_OVER_TEMP_POSITION

FINAL_UNDER_TEMP

Do not show the result; indicate under-temperature.

FINAL_UNDER_TEMP_POSITION

FINAL_POSITION

Show the final temperature with an out-of-position indication.

Figure 4. Thermometry module

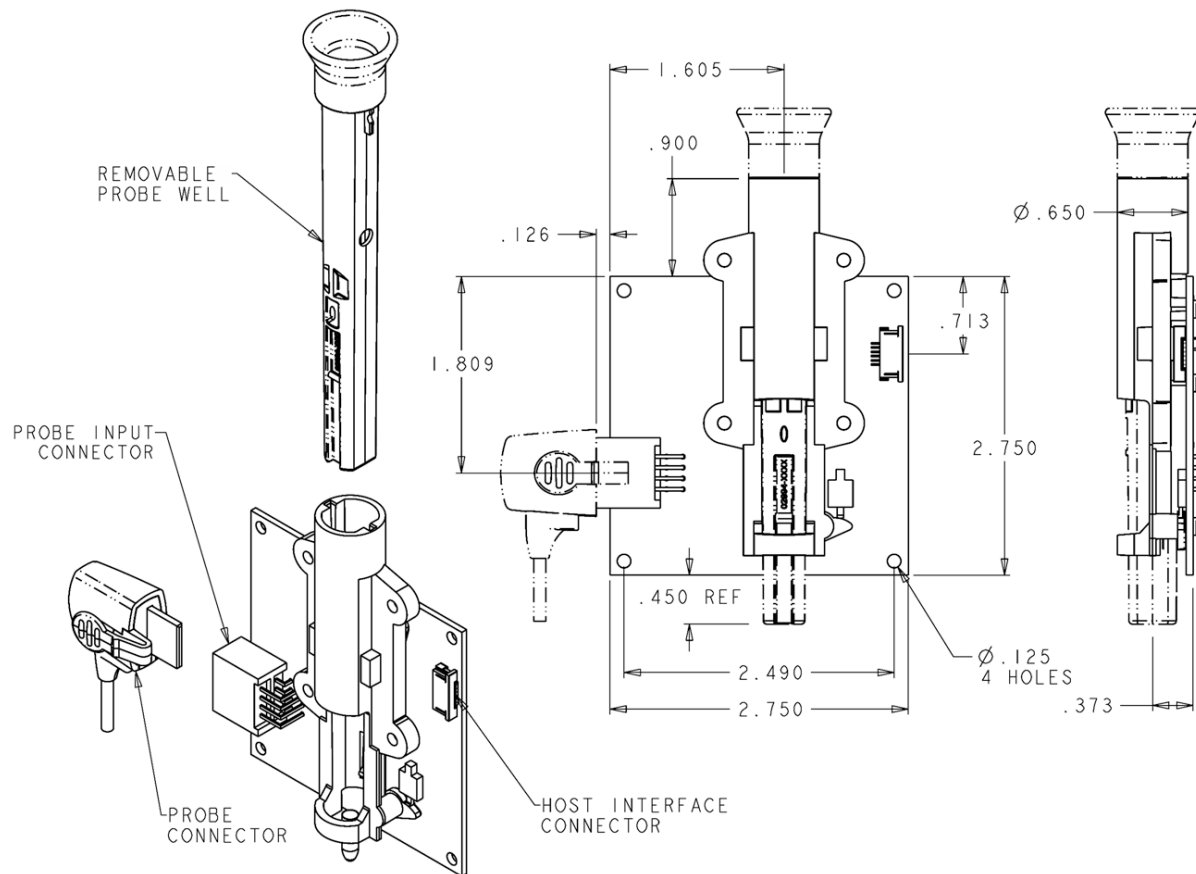
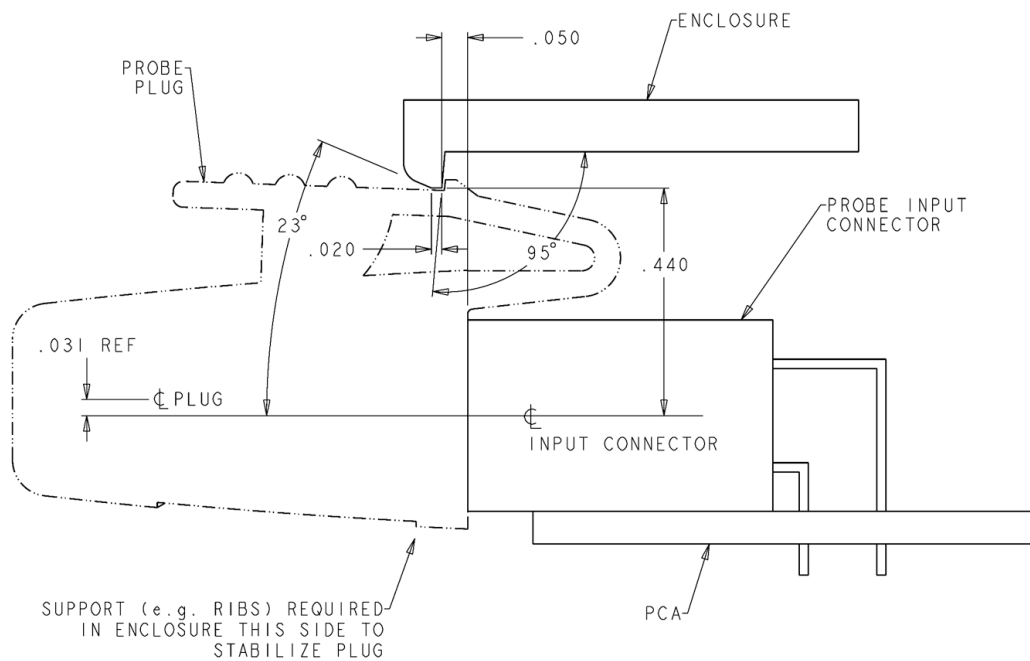


Figure 5. Probe connector detail



Guidelines

Welch Allyn strongly recommends that you follow these guidelines for making the SURETEMP Plus technology consistent across all implementations.

The host system should consider the advantages that the SURETEMP Plus handheld device offers as a standard in predictive thermometry. User recognition is an important factor when selecting a technology to include in a host system.

The Welch Allyn handheld devices have been setting expectations as to how the technology is used in other products. It is in the best interest of Welch Allyn and the OEM customer to make the look, feel, and usage consistent for this technology when integrated into other medical devices.

To assure consistency, consider the following topics:

- Temperature site indication
- Audible signals
- In-progress indication
- Algorithm indication

Temperature site indication

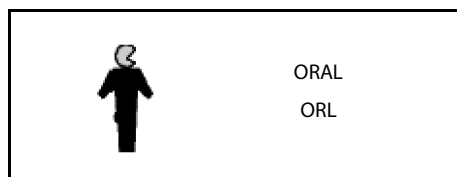
Always provide an indicator to inform the user which measurement site is selected in the device. Options for displaying the temperature-taking sites are described below.

Note: If icons are used, the FDA requires that they be described in English. This can be accomplished by adding a label to the finished device that defines the icons.

Oral mode

Preferred	To indicate the oral mode, display an upright body icon with a flashing head and the word ORAL . See “Acceptable ways to display the oral mode” on page 14 .
Acceptable	If a graphical display cannot be accomplished, display the word ORAL or the abbreviation ORL .
Not acceptable	To provide no indication, or to use any other abbreviation (such as O, OR, OL) or other inappropriate indicator, is not acceptable.

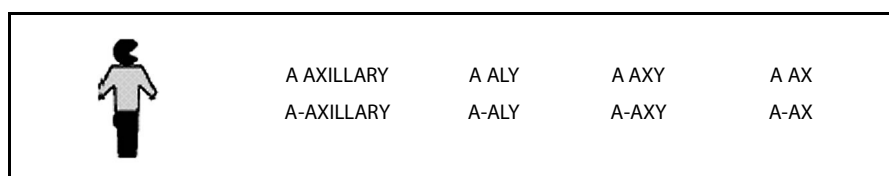
Figure 6. Acceptable ways to display the oral mode



Adult axillary mode

Preferred	To indicate the adult axillary mode, display an upright body icon with a flashing upper body and the words ADULT AXILLARY . See “Acceptable ways to display the adult axillary mode” on page 15.
Acceptable	If a graphical display cannot be accomplished, display the words ADULT AXILLARY or the abbreviation A AXILLARY , A ALY , A AXY , A AX , A-AXILLARY , A-ALY , A-AXY , or A-AX .
Not acceptable	To provide no indication, or to use any other abbreviation or inappropriate indicator, is not acceptable.

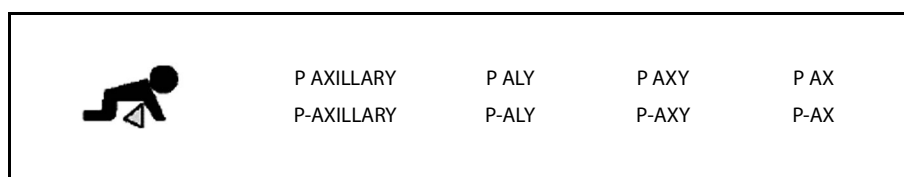
Figure 7. Acceptable ways to display the adult axillary mode



Pediatric axillary mode

Preferred	To indicate the pediatric axillary mode, display a kneeling body icon with a flashing arrow pointing to the axilla (Figure 8) and the words PEDIATRIC AXILLARY .
Acceptable	If a graphical display cannot be accomplished, display the words PEDIATRIC AXILLARY or the abbreviation P AXILLARY , P ALY , P AXY , P AX , P-AXILLARY , P-ALY , P-AXY , or P-AX .
Not acceptable	To provide no indication, or to use any other abbreviation or inappropriate indicator, is not acceptable.

Figure 8. Acceptable ways to display the pediatric axillary mode

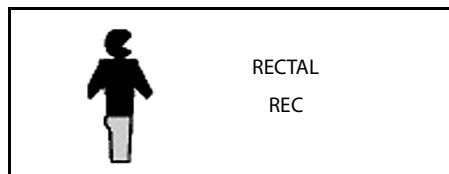


Rectal mode

Preferred	To indicate the rectal mode, display an upright body icon with a flashing lower body (Figure 9) and the word RECTAL .
------------------	---

Acceptable	If a graphical display cannot be accomplished, display the word RECTAL or the abbreviation REC .
Not acceptable	To provide no indication, or to use any other abbreviation or inappropriate indicator, or to use the word ANAL, is not acceptable.

Figure 9. Acceptable ways to display the rectal mode



Monitor mode

Monitor Mode continuously displays the temperature of the probe for as long as the probe remains in place at the measurement site and remains within the operating patient temperature range. The patient's oral and rectal temperature reaches final equilibrium in approximately three minutes in the Monitor Mode. Axillary temperature reaches equilibrium in approximately five minutes in the Monitor Mode. Oral/Axillary and Rectal measurement modes time out after ten minutes of Monitor mode.

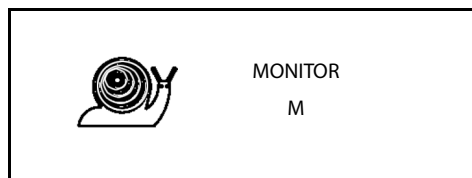
The device enters Monitor Mode for several reasons:

- If the probe is withdrawn from the probe well and is not replaced within 60 seconds of inactivity.
- When a patient's temperature in Normal Mode cannot correctly be measured.
- Directly from a host command (for the purpose of testing, etc).

Monitor mode indication

Preferred	To indicate the monitor mode, display a snail icon (Figure 10) and the word MONITOR .
Acceptable	If a graphical display cannot be accomplished, display the word MONITOR or the abbreviation M .
Not acceptable	To provide no indication, or to use any other abbreviation or indicator, is not acceptable.

Figure 10. Acceptable ways to display the monitor mode



Functional description

Introduction

The SURETEMP Plus module provides the interface to the host system, manages power requirements, calculates measurements, and regulates probe heater circuitry.

This section describes the function of the SURETEMP Plus module and describes how it is integrated into a host system:

- **“OEM implementation” on page 7** describes the hardware interface and power requirements.
- **“Communications protocol” on page 29** describes the SURETEMP Plus module communications protocol.

Module integration

The SURETEMP Plus module is designed for integration into a host system. The design intent is to have the module located such that the probe tip and the probe covers are as close to ambient air temperature as possible. Consequently, the host must provide only one interface cable to the SURETEMP Plus module. A flex circuit connector is populated on the module. The host is responsible for the flex circuit design and procurement since every implementation is unique.

Power supply connections

The SURETEMP Plus module requires one power connection:

3.3 (-0.135) VDC to 5.0 (+0.30) VDC
Ripple not to exceed 100 mV peak-to-peak

A ‘low voltage’ error occurs below 3.00 VDC; a ‘high voltage’ error occurs at 5.375 VDC.

Host serial configuration

A simple system configuration consists of the SURETEMP Plus module connected to a host processor via a serial interface. TXD and RXD are logic level UART connections for transmitting and receiving data. Pull-up resistors for RXD and TXD are located on the module. The communication protocol and host serial commands are described in detail in **“Communications protocol” on page 29**.

Module operation

The SURETEMP Plus module has two temperature methods that can be set via host commands: normal (predictive) or monitor.

In addition, the SURETEMP Plus module utilizes different algorithms based on probe type and measurement modes commanded by the host. Oral, pediatric axillary, and adult axillary modes are available in conjunction with the oral/axillary probe. Rectal temperatures are available only when a rectal probe is connected to the module. For details concerning the commands available in the communications protocol, see Figure 2 **“State diagram: Monitor” on page 11** and Figure 3 **“State diagram: Predict” on page 12**.

Time-outs

All time-outs return the module to the standby state. After three minutes in standby, the module drops into the sleep state.

The time-outs listed in this table return the thermometer to its standby (or idle state), where no measurement modes are active. The standby state terminates the monitor or predict mode to save power while the system waits for a probe pull.

Table 3: Time-outs

Time-out	Period Before Transition	Next State
Power Reset	4 seconds	Standby
Probe Connect	5 seconds	Standby
Monitor Mode (oral and rectal probes)	10 minutes	Standby
Predict Completion	30 seconds	Standby
Error	5 seconds	Standby
Standby	3 minutes	Sleep

Temperature probes

Two types of probes are available for use with the SURETEMP Plus module: an oral/axillary probe, and a rectal probe.

The SURETEMP Plus board detects probe type: oral/axillary or rectal. The following are approximate times for predictive temperatures.

- Predictive oral temperatures are measured using oral/axillary probes in combination with the predictive mode, providing a temperature reading in approximately 4-6 seconds.

- Adult axillary predictive temperatures are measured using oral/axillary probes in combination with the adult axillary mode, providing a temperature reading in approximately 12-15 seconds.
- Pediatric axillary predictive temperatures are measured using oral/axillary probes in combination with the pediatric axillary mode, providing a temperature reading in approximately 10-13 seconds.
- Rectal temperatures are measured using rectal probes which give a predictive temperature in approximately 10-13 seconds.

The probe type is communicated to the SURETEMP Plus board by a proprietary probe connection interface. The axillary/oral probe incorporates a warming resistor in the tip to warm the probe before placement in the mouth or axilla, thus speeding response.

Probe type recognition allows the microprocessor to initiate the proper algorithm for converting a thermistor measurement into a temperature. It also allows the use of minor differences in prediction parameters tailored to the temperature-taking site to help increase speed.

Probe well and switch

Probe well

The removable probe well is part of the SURETEMP Plus module. The integrated design allows the host to mount the probe and the module in the same environment, and eliminates the host requirements typically associated with the probe-well integration.

The integrated well design also eliminates the need for additional wiring between the module and probe well, saving the host design time and reducing development risk.

Oral/axillary probes (identified by a blue ejection button at the top) and blue oral/axillary removable probe wells are used for taking oral and axillary temperatures only. Rectal probes (red ejection button) and red rectal removable probe wells are used for taking rectal temperatures only.

Cycle initiation switch

An optical switch is part of the integral probe well included with each module. No additional items are required from the host.

Probe well switch

A mechanical switch is used to enable a measurement cycle when a probe well is properly inserted into the probe-well shroud, and to disable a measurement cycle when a probe well is not inserted into the probe-well shroud.

Specifications

The Welch Allyn SURETEMP Plus module is a fully integrated microprocessor-based thermistor thermometer designed to take oral, adult axillary, pediatric axillary, and rectal temperatures.

The OEM module acquires patient temperature data using a proprietary Welch Allyn thermometer and requires power and control from a host system. The SURETEMP Plus module calculates temperature and outputs this data to a host system via a serial communications interface. A proprietary Welch Allyn algorithm in conjunction with the thermistor-based thermometer provides predictive temperature readings. The board requires a single voltage input and generates all the necessary internal control voltages.

Table 4: Module specification

Characteristic	Specification
Physical	
Size	2.75" x 2.75" (69.85 mm x 69.85 mm)
Clearance	0.30" (7.6 mm) including board thickness, not including connectors
Orientation	+/- 30° from top position
System Performance	
Predict Measurement Times (Approximate) *	
Oral	4-6 seconds
Adult axillary	12-15 seconds (18 years and older)
Pediatric axillary	10-13 seconds (17 years and younger)
Rectal	10-13 seconds
	* Predict time depends on probe placement and patient condition. Predict times do not include tissue contact-detection time or the time needed to place the probe into the measurement site.
Temperature Accuracy (Monitor Mode)	+/- 0.2 °F (0.1 °C)
Patient Temperature Range	Oral: 308.71K (35.56C) to 313.71K (40.56C) Pediatric Axillary: 307.59K (34.44C) to 313.71K (40.56C) Adult Axillary: 307.59K (34.44C) to 313.71K (40.56C) Rectal: 302.04K (28.89C) to 315.37K (42.22C)
Calibration	Calibration Key is available for module verification purposes, and the Welch Allyn 9600 Calibration Tester is available for total system verification.

Characteristic	Specification
Environmental	
Ambient Operating Range	
Temperature	50 to 104 °F (10 to 40 °C)
Humidity	15 to 95% relative humidity (non-condensing)
Ambient Shipping/Storage Range	
Temperature	-4 to +122 °F (-20 to +50 °C)
Humidity	15 to 95% relative humidity (non-condensing)
Interface	
Input Voltage	3.3 VDC (-0.135 VDC) to 5.0 VDC (+0.3 VDC)
Current	See “Power requirements” on page 10.
Maximum Ripple Voltage	100 mV peak to peak
Communication	Inverted/Non-Buffered TTL Asynchronous 9600 Baud 8 Data Bits 1 Stop Bit Full Duplex No Parity
Connector	MOLEX 52271-0690 1 – RXD 2 – TXD 3 – HOST-WAKEUP-BAR 4 – RESET BAR 5 – GND 6 – VCC
Probe Well	Integrated

Verification testing

Introduction

This section provides calibration verification procedures for the module and probe.

Calibration verification

Testing module only

This procedure provides a convenient means of testing the thermometer module only. It requires the use of the Welch Allyn SURETEMP Plus Calibration Key.

Procedure

Follow the instructions on the Cal Key tag.

1. Extract the probe and disconnect it from the probe input connector.
2. Insert the SURETEMP Plus Calibration Key into the probe connector receptacle and observe the readings.
3. Insert a probe shaft into the probe well and then remove it to initiate a temperature-taking cycle.

Note: For a correctly calibrated module, the Cal Key value should read $97.3^{\circ}\text{F} \pm 0.2^{\circ}\text{F}$.

4. Remove the Calibration Key and reinstall the probe connector plug.
5. Return the probe into the well.

Note This Cal Key Test does not test the probe. To test the probe, use the 9600 Calibration Tester.

Testing the module and the probe

The Welch Allyn 9600 Calibration Tester ([see “Part numbers” on page 27](#)) for the appropriate part number) provides a convenient means of testing the entire thermometer system, module and probe.

To test the system, follow the instructions provided with the 9600 Calibration Tester.

Regulatory

Introduction

The Welch Allyn SURETEMP Plus board is a medical device component. It cannot fully meet medical device standards and regulations until it is integrated into a host system. The Welch Allyn SURETEMP Plus board can meet the following standards when properly integrated into a host system. It is the responsibility of the host system to ensure that the integrated system can meet these standards and regulations:

- UL 2601-1 (leakage current as measured with probe cover on probe)
- IEC 60601-1, IEC 60601-1-2 (Mounting configuration dependent)
- CAN/CSA 22.2 No. 601.1 (Mounting configuration dependent)
- ASTM E 1112-00 (2000 revision) Accuracy and temperature ranges
- REGULATION (EU) 2017/745 (EU MDR)
- I.S. EN ISO 80601-2-56:2017 + A1:2020

OEM responsibility

An additional consideration is the inclusion of an isolated power supply. Although the probe is required to have a probe cover applied during use, the probe can come into inadvertent patient contact, and may require an isolated power supply to meet patient safety requirements.

The responsibilities of the OEM include (but are not limited to) the following:

- Compliance of the host system with all appropriate safety requirements of IEC 60601-1 (EN60601-1), its amendments and applicable standards.
- Compliance with appropriate performance standards, including thermometry standards ASTM E1112-00 and IS EN ISO 80601-2-56.
- Fusing of power supplied to the SURETEMP module or other similar protection be provided in the event of a short circuit.
- Maintenance of creepage and clearance distances from primary to ground and secondary circuits after installation, as defined in IEC60601-1 (EN 60601-2).
- Maintenance of minimum isolation/insulation clearances specified in IEC 60601-1 (EN60601-1) when mounting the SURETEMP Plus module and any off-board components must be maintained after installation.
- Inclusion of instructions for disinfecting, cleaning, and/or safe disposal of accessories in the Instructions for use for end users.
- Inclusion of warnings and cautions identified in this implementation guide in the Instructions for use.

- Completion of all safety and performance testing after full implementation into the final form or device.

The SURETEMP Plus module has undergone clinical testing for adults and pediatric patients in a representative host system, as well as testing for EMC and vibration and mechanical shock in a Welch Allyn reference device.

The table below offers, as a guideline, a summary of the relevant regulatory requirements for a medical device with a predictive thermistor-based thermometer.

Note This manual provides the below table as a guideline. The manufacturer of the host system that integrates the SURETEMP Plus module is responsible for making sure that the host system and the host-supplied operator's manual comply with all applicable regulations and safety requirements for the region(s) in which it is sold.

Table 5: Regulatory test descriptions and standards

Test Description	Standard
Electromagnetic Compliance	EN 60601-1-2
Storage Tests	ASTM E1112-00 EN 12470-3
Temperature shock - in use	EN 12470-3
Vibration Tests	ISTA Procedure 1A
Thermal Response Time	EN 12470-3
Thermometry Standard	I.S. EN ISO 80601-2-56
Long-term Stability	EN 12470-3
Mechanical Shock	EN 12470-3
Drop Test	EN 60601-1
Clinical test results (including accuracy)	Host responsibility

Part numbers

Components from Welch Allyn

Table 6: Welch Allyn part numbers

Description	Part Number
SURETEMP Plus Module	21327-1000
Oral Probe/Well Kit (includes Well and Probe)	02895-000
Rectal Probe/Well Kit (includes Well and Probe)	02895-100
Probe Covers Case (40 boxes of 25 per box)	05031-110
Calibration Key (for use with SURETEMP Plus module only)	06138-000
CD, SURETEMP Plus Module OEM Implementation Manual (only)	97134-0000
9600 Calibration Tester (110V)	01800-210
Tester, Calibration 9600 Plus	01802-110

Components from other vendors

Table 7: Welch Allyn part numbers

Description	Part Information
Probe Connector (2x4 right angle)	EDAC PN 392-008-559-201 or equivalent
Flex Circuit/ ZIF cable, AWM Style 20566, 1mm pitch	Parlex Corporation Laminated Cable Products One Parlex Place Methuen, MA 01844 Tel: (978) 685-4341

Communications protocol

Introduction

The SURETEMP Plus module is a command-driven module communicating with a host system over an asynchronous serial communication line. The host initiates communications by sending a command block; the SURETEMP Plus module always responds with a response block.

The SURETEMP Plus module and the host system are referred to below as “module” and “host” respectively.

The protocol description includes three main sections:

Packet Structure	Describes the protocol.
Commands and Responses	Describes the commands.
Command and Response Examples	Provides examples.

Communications interface

9600 baud rate
8 data bits, no parity, 1 stop bit
full duplex
Asynchronous using standard non-return to zero (NRZ) format
Non-isolated module power and communications are provided at J1

System EEPROM

The system EEPROM contains system configuration and operational constants that are encoded by Welch Allyn. While the majority of parameters pertain to Welch Allyn manufacturing and operational defaults, the OEM can customize some parameters, such as the following, to accommodate requirements:

Thermometer Algorithm	The algorithm—oral or axillary—used when the oral probe is installed. (Default: Oral)
Temperature Method	Predictive or monitor mode. (Default: Predictive)
Programmable Ambient Bias	Temperature difference between ambient and the probe tip. (Default: 0.56)
Clinical Pause	The monitor continues automatically from Predictive to Monitor mode during clinical testing. (Default: disabled)

Two possible approaches to changing the defaults:

- Implement a factory procedure in which the host's ATE sets the values once and then saves the values to the EEPROM on the module.
- During each power-up and initialization of the host device, the host sets the module parameters in RAM and does not write them to EEPROM.

The Command and Response descriptions (page 36) contain further information.

Packet structure

Transmission of host commands and module responses is via packets, or message blocks. All messages are in binary format and are aligned on byte boundaries. The following structures represent Command/Response message blocks.

Endian format

All command blocks, response blocks, and data size are in little-endian format, least-significant byte first. Command codes are in big-endian format, most-significant byte first.

3-byte preamble	0x03, 0x02, 0x10
2-byte command code	CC-high, CC-low
1-byte type code	TT-high
2-byte data size	SS-low, SS-high
X bytes of response data	(format depends on command)
1-byte checksum	0xYY

For a brief description of endianness, with examples, see page 51.

Command block

3-byte preamble	0x03, 0x02, 0x10
2-byte command code	CC-high, CC-low
1-byte type code	TT-high
2-byte data size	SS-low, SS-high
X bytes of response data	(format depends on command)
1-byte checksum	0xYY

Response block

3-byte preamble	0x03, 0x02, 0x10
2-byte command code	CC-high, CC-low
1-byte type code	TT-high
2-byte data size	SS-low, SS-high
X bytes of response data	(format depends on command)
1-byte checksum	0xYY

Type codes

0x01	Identifies the message as a Command
0x02	Indicates Good Response
0x03	Indicates Bad Response (NAK)

Data types

Data types used throughout are derived from the base data types found in the C programming language and are listed below.

Character arrays

Arrays of ASCII characters are treated as standard C strings, terminated by the null character. Note that in some instances, the array returned may contain characters beyond the null terminator; ignore these characters.

Simple data types

Data Type	C Language Base Data Type	Format
int8	char	signed, 8-bit
int16	short or short int	signed, 16-bit
int32	long	signed, 32-bit
uint8	unsigned char	unsigned, 8-bit
uint16	unsigned short	unsigned, 16-bit
uint32	unsigned long	unsigned, 32-bit
float32	float	signed, 32-bit IEEE floating-point format
ansichar	char	signed/unsigned 8-bit

byte	unsigned char	unsigned, 8-bit
word	unsigned short	unsigned, 16-bit
boolean	unsigned char	unsigned, 8-bit

Complex data types (structures)

TEMP_STATUS

Type	Description	Values/Units
uint16	POST status	00: No errors 255: POST error code not yet ready See “Error codes and recovery” on page 71 for additional codes.
uint16	POST Tests	The bit mapping for the tests. 0: not performed, 1: performed 15: Data Bus Test 14: Address Bus Test 13: Device Physical Memory Address Test 12: Segments Test 11: Thermistor Test 10: Heater Test 09: Spare 08: Spare 07: Spare 06: Spare 05: Spare 04: Spare 03: Spare 02: Spare 01: Spare 00: Spare

TEMP (33 data bytes)

Type	Description	Values/Units
float32	"Final/Predicted" temperature	in °Kelvin
float32	Current Probe Temperature	in °Kelvin
uint16	Current Heater Count/PWM	0-999
uint16	Sample Counter - 173 mS/sample	
int8	Method	0: Normal 1: Monitor 2: Clinical
int8	Algorithm	0: Oral 1: Rectal 2: Pediatric Axillary 3: Cal Key 4: Adult Axillary
int8	SURETEMP state	0: Idle 1: Not Ready 2: Ready 3: Predict 4: Predict display 5: Predict position 6: Final 7: Final position 8: Final over temp 9: Final over temp position 10: Final under temp 11: Final under temp position 12: No predict (monitor mode) 20: Error status
int16	Error code	0: No error See "Error codes and recovery" on page 71.
boolean	active	Probe out and Active
int8	Physical probe type connected	0: Oral/Axillary 1: Cal Key 2: Rectal 3: No Probe
float32	Current Probe Resistance	in Ohms
float32	ambient_temp	Ambient temp used in final result (Kelvin)
float32	ptb_resistance	PTB resistance read at beginning of a cycle
uint16	battery	Battery voltage in hundreds of volts. e.g. 4.5 = 450. This is the battery voltage actually given to the SURETEMP algorithm.

TEMP (19 data bytes)

Type	Description	Values/Units
float32	"Final/Predicted" temperature	in °Kelvin
float32	Current Probe Temperature	in °Kelvin
uint32	Sample Counter - 173 mS/sample	
int8	Method	0: Normal 1: Monitor 2: Clinical
int8	Algorithm	0: Oral 1: Rectal 2: Pediatric Axillary 3: Cal Key 4: Adult Axillary
int8	SURETEMP state	0: Idle 1: Not Ready 2: Ready 3: Predict 4: Predict display 5: Predict position 6: Final 7: Final position 8: Final over temp 9: Final over temp position 10: Final under temp 11: Final under temp position 12: No predict (monitor mode) 13: End normal status 20: Error status
int16	Error code	0: No error See "Error codes and recovery" on page 71.
boolean	active	Probe out and Active
int8	Physical probe type connected	0: Oral/Axillary 1: Cal Key 2: Rectal 3: No Probe

Checksum calculation

The checksum is a single-byte summation of all the data, including the control characters (preamble, command, type, byte count, data, and so on).

After computing the checksum, send the negative of the checksum.

When receiving a message, sum all of the characters (including the checksum) into an unsigned 8-bit variable. The resulting summation must be zero, since the checksum equals the negative value of all the bytes (excluding the checksum).

The following code sample sends bytes over the link:

```
extern void response(unsigned short size, const void *data)
{
    unsigned char cksum;
    unsigned char *ptr, c;

    /* Initialize checksum */
    ptr = (unsigned char*) data;
    cksum=0;
    while (size- -)
    {
        c = *ptr;
        put_byte(c);           /* Send data byte */
        cksum += c;           /* Update checksum */
        ptr++;                /* Bump pointer to next byte to send */
    }
    put_byte(-cksum);         /* Send the negative of the checksum */
}
```

Commands and responses

(2900) Send serial number

Causes the module to send its serial number to the host.

Command Code (hex)

2900

Data

<u>Size (bytes)</u>	<u>Type</u>	<u>Description</u>
0	N/A	None

Response Data

<u>Size (bytes)</u>	<u>Type</u>	<u>Description</u>
11	ansichar	Module Serial Number (10 ASCII characters + null terminator)

(2913) Send temperature method

Causes the module to send to the host the current temperature method. This flag is used to specify whether the current temperature-taking method is normal predictive or monitor.

Command Code (hex)

2913

Data

<u>Size (bytes)</u>	<u>Type</u>	<u>Description</u>
0	N/A	None

Response Data

<u>Size (bytes)</u>	<u>Type</u>	<u>Description</u>
1	int8	0: Normal (predictive) 1: Monitor

(2936) Send module software version

Causes the module to send the host the software version number of the specified module.

Command code (hex)

2936

Data

<u>Size (bytes)</u>	<u>Type</u>	<u>Description</u>
1	int8	Module 0: SURETEMP Plus module software version 1: Reserved 2: SURETEMP Plus algorithm 3: Reserved 4: Reserved XX - Undefined

Response data

<u>Size (bytes)</u>	<u>Type</u>	<u>Description</u>
N	ansichar	Bytes to specify the software version.

Notes

The software version is returned as an ASCII string and is of varying length (and format) dependent on the module specified. The length is guaranteed never to be longer than 127 bytes plus a null terminator. If a module is not present then an array of null characters is returned. This command returns a "Data Range" error if the specified module is undefined.

(2945) Send thermometer probe mode

Causes the module to send the current thermometer probe mode to the host. This setting defines the algorithm to be used the next time a temperature is taken with an oral/axillary probe connected.

Command code (hex)

2945

Data

<u>Size (bytes)</u>	<u>Type</u>	<u>Description</u>
0	N/A	None

Response data

<u>Size (bytes)</u>	<u>Type</u>	<u>Description</u>
1	int8	0: Oral/Axillary 1: Pediatric Axillary 2: Adult Axillary

(2949) Send default thermometer probe mode

Causes the module to send the default thermometer probe mode setting. The default thermometer probe mode defines the algorithm to be used when an oral/axillary probe is connected to this device.

Command code (hex)

2949

Data

<u>Size (bytes)</u>	<u>Type</u>	<u>Description</u>
0	N/A	None

Response data

<u>Size (bytes)</u>	<u>Type</u>	<u>Description</u>
1	int8	0: Oral 1: Pediatric Axillary 2: Adult Axillary 3: Use last

(2A06) Save data to EEPROM

Causes the module to save the RAM copy of the configuration record to the EEPROM.

Command code (hex)

2A06

Data

<u>Size (bytes)</u>	<u>Type</u>	<u>Description</u>
0	N/A	None

Response data

<u>Size (bytes)</u>	<u>Type</u>	<u>Description</u>
0	N/A	None

(2A07) Recall data from EEPROM

Causes the module to copy the configuration record in EEPROM to RAM.

Command code (hex)

2A07

Data

<u>Size (bytes)</u>	<u>Type</u>	<u>Description</u>
0	N/A	None

Response data

<u>Size (bytes)</u>	<u>Type</u>	<u>Description</u>
1	int8	0: EEPROM data was good X: Any other number is an error code.
1	boolean	Spare always 0

(2A12) Set temperature method

Causes the module to set the current temperature method from the host, forcing the module into the host-specified mode.

Command code (hex)

2A12

Data

<u>Size (bytes)</u>	<u>Type</u>	<u>Description</u>
1	int8	0: Normal (Predictive) 1: Monitor

Response data

<u>Size (bytes)</u>	<u>Type</u>	<u>Description</u>
0	N/A	None

Notes

This command returns an “Invalid operation in this context” error if the temperature probe is out of the probe well, and returns a “Data Range” error if the specified temperature method is undefined. This command has effect only in a predict cycle, and can be used only to transition the monitor from predict mode to monitor mode.

(2A35) Set thermometer probe mode

Causes the module to set the current probe mode from the host.

Command code (hex)

2A35

Data

<u>Size (bytes)</u>	<u>Type</u>	<u>Description</u>
1	int8	0: Oral 1: Pediatric Axillary 2: Adult Axillary

Response data

<u>Size (bytes)</u>	<u>Type</u>	<u>Description</u>
0	N/A	None

Notes

The probe mode controls whether the oral, pediatric axillary, or adult axillary algorithm is to be used with an oral/axillary probe. This command has no effect if the current probe type is rectal.

(2A37) Set default thermometer probe mode

Causes the module to set the default probe mode from the host. This flag is used to define what algorithm the device defaults to when an oral/axillary probe is connected to the device.

Command code (hex)

2A37

Data

<u>Size (bytes)</u>	<u>Type</u>	<u>Description</u>
1	int8	0: Oral/Axillary 1: Pediatric Axillary 2: Adult Axillary 3: Use Last Algorithm

Response data

<u>Size (bytes)</u>	<u>Type</u>	<u>Description</u>
0	N/A	None

Notes

Use the "Save Calibration Data to EEPROM" command defined in for (2A06). [See "\(2A06\) Save data to EEPROM" on page 38.](#)

(3000) Restart module

Causes the module to reboot.

Command code (hex)

3000

Data

<u>Size (bytes)</u>	<u>Type</u>	<u>Description</u>
0	N/A	None

Response data

<u>Size (bytes)</u>	<u>Type</u>	<u>Description</u>
0	N/A	None

(3101) Send digital input status

Causes the module to send the status of all the device's digital inputs to the host. This is a short representation of all of the switches and buttons on the device. 1 is pressed or closed, and 0 is released, or open.

Command code (hex)

3101

Data

<u>Size (bytes)</u>	<u>Type</u>	<u>Description</u>
0	N/A	None

Response data

<u>Size (bytes)</u>	<u>Type</u>	<u>Description</u>
2	uint16	Each bit represents a different button or switch on the device. 15: Reserved 14: Reserved 13: Reserved 12: Reserved 11: Reserved 10: Probe switch 09: Probe attached 08: Probe well inserted 07: Spare 06: Spare 05: Spare 04: Spare 03: Spare 02: Spare 01: Spare 00: Spare

(3109) Erase event log

Causes the module to erase the event log and return it to the empty state.

Command code (hex)

3109

Data

<u>Size (bytes)</u>	<u>Type</u>	<u>Description</u>
0	N/A	None

Response data

<u>Size (bytes)</u>	<u>Type</u>	<u>Description</u>
0	N/A	None

(3503) Lock thermometer probe

Locks or unlocks access to the module's Thermometer probe switch. Once locked, the probe switch can be turned on or off via the "Set Temperature Probe" command.

Command code (hex)

3503

Data

<u>Size (bytes)</u>	<u>Type</u>	<u>Description</u>
1	boolean	0: Unlocked 1: Locked

Response data

<u>Size (bytes)</u>	<u>Type</u>	<u>Description</u>
0	N/A	None

(3604) Set temperature probe

Causes the unit to simulate the removal or replacement of the temperature probe.

Command code (hex)

3604

Data

<u>Size (bytes)</u>	<u>Type</u>	<u>Description</u>
1	boolean	0: Probe in holder (not ready for reading) 1: Probe removed from holder (ready for reading)

Response data

<u>Size (bytes)</u>	<u>Type</u>	<u>Description</u>
0	N/A	None

Notes

To use this command, the temperature probe should normally be locked.

(9401) Send thermometer status no clear

Causes the module to return a status block. The status block indicates what the module is doing and reports any error conditions.

Command code (hex)

9401

Data

<u>Size (bytes)</u>	<u>Type</u>	<u>Description</u>
0	N/A	None

Response data

<u>Size (bytes)</u>	<u>Type</u>	<u>Description</u>
4	TEMP_STATUS	Status block see TEMP_STATUS (page 32) for details

Notes

This command does not clear POST errors.

(9413) Send mode pause for clinical device

Causes the module to send the number of milliseconds between the final predict temperature and its transfer into monitor mode to the host. The host can control the transfer time from predict mode to monitor mode.

Command code (hex)

9413

Data

<u>Size (bytes)</u>	<u>Type</u>	<u>Description</u>
0	N/A	None

Response data

<u>Size (bytes)</u>	<u>Type</u>	<u>Description</u>
2	int16	0 = Disabled; do not automatically switch to monitor mode after a predict. This is because without a pause the user would never see the final predicted temperature. Limits 0-10,000 where 10,000 = 10 seconds max. (Value in milliseconds).

(9415) Send default thermometer mode

Causes the module to send to the host the default thermometer mode. This allows the user to specify which method of taking temperature readings we enter when the probe is pulled, normal predictive mode, or monitor mode.

Command code (hex)

9415

Data

<u>Size (bytes)</u>	<u>Type</u>	<u>Description</u>
0	N/A	None

Response data

<u>Size (bytes)</u>	<u>Type</u>	<u>Description</u>
1	int8	0: Normal (Predictive) 1: Monitor

(9416) Send 690 event log

Causes the module to send between 0 and 10 bytes of data back to the host depending on the number of errors in the event log. 10 is the maximum size of the event log, but if it is partially empty then the response could be less than 10 bytes in length.

Command code (hex)

9416

Data

<u>Size (bytes)</u>	<u>Type</u>	<u>Description</u>
0	N/A	None

Response data

<u>Size (bytes)</u>	<u>Type</u>	<u>Description</u>
≤ 10	uint8	All errors are 1-byte. See page 71 for a mapping between log numbers and display number.

(941A) Send programmable ambient bias

Causes the module to send the programmable ambient bias to the host.

Command code (hex)

941A

Data

<u>Size (bytes)</u>	<u>Type</u>	<u>Description</u>
0	N/A	None

Response data

<u>Size (bytes)</u>	<u>Type</u>	<u>Description</u>
4	float32	The device's ambient bias. It is different in the OEM applications and must be updated.

(941C) Send temperature record

Causes the module to send the current temperature record to the host. The temperature record is updated every 173 milliseconds.

Command code (hex)

941C

Data

<u>Size (bytes)</u>	<u>Type</u>	<u>Description</u>
0	N/A	None

Response data

<u>Size (bytes)</u>	<u>Type</u>	<u>Description</u>
33	TEMP	Recall Temperature See TEMP (page 33)

Note

Asynchronous messages are in the format of the <941C> response blocks, but data size is either 19 or 33 bytes, as specified by command <9434>.

(9433) Set mode pause for clinical device

Enables the host to set the number of milliseconds the device pauses after a predict temperature before switching to monitor mode. The transfer to monitor mode occurs after the host-specified delay.

This is appropriate during clinical testing when comparing a predicted temperature to a monitored temperature. It makes the final predict measurement available for a period before the module switches to monitored mode and begins sending new temperature values.

Command code (hex)

9433

Data

<u>Size (bytes)</u>	<u>Type</u>	<u>Description</u>
2	int16	0 = Disabled Do not automatically switch to monitor mode after a predict; without a pause the user would never see the final predicted temperature.

Response data

<u>Size (bytes)</u>	<u>Type</u>	<u>Description</u>
0	N/A	None

Notes

Use the "Save Calibration Data to EEPROM" command (page 38) to save permanently to EEPROM.

(9434) Set asynchronous messages enabled

Causes the module to send asynchronous messages to the host when they are ready. By default this option is disabled on startup of the system. Once it is enabled, the temp record is sent every 173 milliseconds until one of the following occurs:

- The temperature cycle becomes inactive
- A command is sent to disable the mode
- Power is removed from the module

In asynchronous mode, the module might not respond immediately to messages from the host. Avoid continuous polling of the module when asynchronous messages are enabled and a temperature cycle is active.

Command code (hex)

9434

Data

<u>Size (bytes)</u>	<u>Type</u>	<u>Description</u>
1	int8	0: To disable asynchronous messages 1: To enable 33-byte asynchronous messages 2: To enable 19-byte asynchronous messages

Response data

<u>Size (bytes)</u>	<u>Type</u>	<u>Description</u>
0	N/A	None

Notes

Once enabled, asynchronous messages are sent when they are ready. (The TEMP record is the only asynchronous message; see page 33 and page 34.)

Data description (0, 1, or 2) can be switched at any time.

(9435) Set default thermometer mode

Causes the module to read the default thermometer mode from the host. The default mode specifies whether the device enters normal predictive mode or monitor mode when the probe is pulled.

Command code (hex)

9435

Data

<u>Size (bytes)</u>	<u>Type</u>	<u>Description</u>
1	int8	0: Normal (Predictive) 1: Monitor

Response data

<u>Size (bytes)</u>	<u>Type</u>	<u>Description</u>
0	N/A	None

Notes

Use the "Save Calibration Data to EEPROM" command (page 38) to save permanently to EEPROM.

(943A) Set programmable ambient bias

Causes the module to get from the host the programmable ambient bias.

Command code (hex)

943A

Data

<u>Size (bytes)</u>	<u>Type</u>	<u>Description</u>
4	float32	The ambient bias for the device It is different in the OEM applications and must be updated.

Response data

<u>Size (bytes)</u>	<u>Type</u>	<u>Description</u>
0	N/A	None

Data records

All data records are in binary format and are aligned on byte boundaries.

Command and response strings examples

This section provides examples of command and response strings for some of the more commonly used commands. It also provides a brief description, with examples, of endianness.

Endianness

Big-endian numbers

In big-endian machines—typical of Motorola® processors—the high-order byte is first:

Command Code (Word): 0x94 0x1C = 0x941C

Little-endian numbers

In little-endian machines—typical of Intel® processors—the low-order byte is first:

Byte Count (Word): 0x13 0x00 = 0x0013.

In IEEE 754 little-endian floating-point numbers, the least-significant byte is first:

Decimal	Hexadecimal
100.0	00 00 C8 42
-100.0	00 00 C8 C2
0.5	00 00 00 3F
-1.75	00 00 E0 BF
0.56	29 5C 0F 3F
0.0625	00 00 80 3D

IEEE 754 data format

The IEEE 754 floating-point data format consists of four contiguous bytes: a 23-bit signed binary mantissa and an 8-bit biased binary exponent:

Bits	Description
0	Sign of the mantissa (0 = positive; 1 = negative)
1 - 8	Exponent (8-bit unsigned value) (The implied binary point is between bits 8 and 9.)
9 - 31	Mantissa

Converting a string of bytes to a floating-point number

1. Swap the bytes to the endian format used by processor on which the software is running.
2. In C, cast the number to a float

These steps are shown in the following code sample:

```
float f;                // Where you want the result converted...
unsigned char s[5];      // Array holding the message starting at the float data element unconverted.
unsigned char d[5];      // Array holding the message starting at the float data element converted to
                        // the endianness of the processor.

// For little-endian processors (Intel x86, Pentium, etc.)....
// Move data from source to destination.

d [0] = s [0];
d [1] = s [1];
d [2] = s [2];
d [3] = s [3];
f = (float) *((float *) (&d[0]));

// For big-endian processors (Motorola CPU32, etc.)....
// Move data from source to destination.

d [3] = s [0];
d [2] = s [1];
d [1] = s [2];
d [0] = s [3];
f = (float) *((float *) (&d[0]));
```

String examples

(2900) Send serial number

Causes the unit to send its serial number to the host.

Command String **03 02 10 29 00 01 01 00 00 C0**

Preamble	03 02 10
Command code	29 00
Type code	01 (command)
Data size	01 00 (1 byte of data, L H format)
Data	00
Checksum	C0

Response String **03 02 10 29 00 02 0B 00 30 33 30 36 31 30 30 35 00 00 00 26**

Preamble	03 02 10
Command Code	29 00
Type Code	02 (good response)
Data Size	0B 00 (0B = 11 bytes, L H format)
Data	30 33 30 36 31 30 30 35 00 00 00 (10 ASCII characters + null terminator, where sn = 0306100500)
Checksum	26

(2936) Send module software version

Causes the unit to send the host the software version number of the specified module.

Note The software version is returned as an ASCII string and is of varying length (and format) dependent on module specified. The length is guaranteed never to be longer than 127 bytes plus a null terminator. If a module is not present then an array of null characters is returned.

Command String 03 02 10 29 36 01 01 00 02 88

Preamble	03 02 10
Command	29 36
Type code	01 (command being sent)
Data size	01 00 (where data size = 2 bytes in a L H format)
Data	02 (2 decimal identifies SURETEMP OEM Module)
Checksum	88

Response String 03 02 10 29 36 02 04 00 37 2E 35 00 EC

Preamble	03 02 10
Command Code	29 00
Type Code	02 (good response)
Data Size	04 00 (4 bytes L H)
Data	37 2E 35 00 (4 ASCII characters + null terminator = 7.5)
Checksum	EC

(2A12) Set temperature method

Causes the unit to read the current temperature method from the host. This specifies whether the device enters into normal predictive or monitor mode when a probe is pulled.

Example:

Command String 03 02 10 2A 12 01 01 00 01 AC

Preamble 03 02 10

Command Code 2A 12

Type code 01 (command being sent)

Data size 01 00 (1 byte being sent)

Data 01 (1 byte where 01 = Monitor, 00 = Normal predict)

Checksum AC

Response String 03 02 10 2A 12 02 00 00 AD

Preamble 03 02 10

Command Code 94 34

Type Code 02 (good response)

Data Size 00 00 (0 bytes returned)

Data None

Checksum AD

(3503) Lock thermometer probe

Locks or unlocks access to the module's Thermometer probe switch. Once locked, the probe switch may be turned on or off via the "Set Temperature Probe" command.

Example:

Command String 03 02 10 35 03 01 01 00 01 B0

Preamble 03 02 10

Command Code 35 03

Type code 01 (command)

Data size 01 00 (1 byte being sent)

Data 01 (where 1 locks probe switch, 0 unlocks probe switch)

Checksum B0

Response String 03 02 10 35 03 02 00 00 B1

Preamble 03 02 10

Command Code 35 03

Type Code 02 (good response)

Data Size 00 00 (0 bytes returned)

Data None

Checksum B1

(9401) Send thermometer status no clear

Causes the unit to return a status block. The status block indicates what the unit is doing and reports any error conditions.

Example:

Command String 03 02 10 94 01 01 00 00 55

Preamble 03 02 10

Command Code 94 01

Type code 01 (command being sent)

Data size 00 00 (0 bytes being sent)

Data None

Checksum 55

Response String 03 02 10 94 01 02 04 00 FF 00 00 EC 65

Preamble 03 02 10

Command Code 94 01

Type Code 02 (good response)

Data Size 04 00 (4 bytes returned)

Data FF 00 00 EC = a two-word status (See below.)

Checksum 65

The data size of 04 00 is a word consisting of a value of 0004. The status of FF 00 00 EC is two words. (See [TEMP_STATUS structure, page 32.](#))

The "POST Status" of FF 00 is the value of 00FF, which is 255 POST not yet available.

The "POST Tests" field of 00 EC is the value of EC00 (L H format) where the upper bit of the E represents bit 15. (EC00 is 1110 1100 0000 0000.)

The bit mapping for the tests: 0: not performed, 1: performed

- 15: Data Bus Test - 1
- 14: Address Bus Test -1
- 13: Device Physical Memory Address Test- 1
- 12: Segments Test- 0
- 11: Heater Analog Test- 1
- 10: Heater Fail-safe Test- 1
- 09: Spare- 0
- 08: Spare- 0
- 07: Spare- 0
- 06: Spare- 0

05: Spare- 0

04: Spare- 0

03: Spare- 0

02: Spare- 0

01: Spare- 0

00: Spare- 0

(941C) Send temperature record - 19 data bytes

Causes the unit to send to the host the current temperature record. The temperature record is updated every 173 milliseconds.

Command String 03 02 10 94 1C 01 00 00 3A

Preamble	03 02 10
Command Code	94 1C
Type code	01 (command being sent)
Data size	00 00 (0 bytes being sent)
Data	None
Checksum	3A

**Response String 03 02 10 94 1C 02 13 00 00 00 00 00 76 AF
99 43 4E 00 00 00 00 00 02 00 00 01 00 D4**

Preamble	03 02 10
Command Code	94 1C
Type Code	02 (good response)
Data Size	13 00 (19 Decimal Bytes)
Data	
Final/Predicted Temperature	00 00 00 00 (IEEE 32-bit Float = 0.0 °K)
Current Probe Temp	76 AF 99 43 (IEEE 32-bit Float = 307.370789 °K)
Sample Counter	4E 00 00 00 (unsigned 32-bit)
Method	00 (8-bit where 0 is Predict Method/Mode)
Algorithm	00 (8-bit where 0 is Oral)
SURETEMP state	02 (8-bit where 2 is Ready)
Error code	00 00 (unsigned 16-bit where 0 means no error)
Active	01 (Boolean where 1 = Active)
Physical probe type connected	00 (8-bit where 0 is Oral/Axillary Probe Type)
Checksum	D4

(941C) Send temperature record - 33 data bytes

Causes the unit to send to the host the current temperature record. The temperature record is updated every 173 milliseconds.

Command String 03 02 10 94 1C 01 00 00 3A

Preamble	03 02 10
Command Code	94 1C
Type code	01 (command being sent)
Data size	00 00 (0 bytes being sent)
Data	None
Checksum	3A

Response String 03 02 10 94 1C 02 21 00 00 00 00 00 76 AF 99 43 4E 00 23 00 00 00 02 00 00 01 00 EF 9E 52 46 5d 4D 94 43 51 12 3D 46 43 BD 01 59

Preamble	03 02 10
Command Code	94 1C
Type Code	02 (good response)
Data Size	21 00 (33 Decimal Bytes)

Data

Final/Predicted Temperature	00 00 00 00 (IEEE 32-bit Float = 0.0 °K)
Current Probe Temp	76 AF 99 43 (IEEE 32-bit Float = 307.370789 °K)
Current Heater Count/PWM	4E 00 (Not important for the OEM user)
Sample Counter	23 00 (unsigned 16-bit = 35 Decimal)
Method	00 (8-bit where 0 is Predict Method/Mode)
Algorithm	00 (8-bit where 0 is Oral)
SURETEMP state	02 (8-bit where 2 is Ready)
Error code	00 00 (unsigned 16-bit where 0 means no error)
Active	01 (Boolean where 1 = Active)
Physical probe type connected	00 (8-bit where 0 is Oral/Axillary Probe Type)
Probe Resistance	EF 9E 52 46 (Not important for the OEM user)
Ambient Temp	5D 4D 94 43 (IEEE 32-bit Float = 296.604401 °K)
PTB Resistance	51 12 3D 46 43 (Not important for the OEM user)

Battery Voltage	BD 01 (unsigned 16-bit in hundreds of volts - 4.45 V)
Checksum	59

(9434) Enable asynchronous messages

Causes the unit to send the host the asynchronous messages when they are ready. By default this option is disabled on startup. Once it is enabled, the messages are sent when they are ready until the messages are disabled or until power is removed from the unit.

Command String 03 02 10 94 34 01 01 00 01 20

Preamble	03 02 10
Command Code	94 34
Type code	01 (command being sent)
Data size	01 00 (1 byte being sent)
Data	01
Checksum	20

Response String 03 02 10 94 34 02 00 00 21

Preamble	03 02 10
Command Code	94 34
Type Code	02 (good response)
Data Size	00 00 (0 bytes returned)
Data	None
Checksum	21

(943A) Set programmable ambient bias

Causes the module to get the programmable ambient bias from the host.

Command String **03 02 10 94 3A 01 04 00 00 A2 33 3F 04**

Preamble 03 02 10

Command Code 94 3A

Type code 01 (command being sent)

Data size 04 00 (4 bytes being sent)

Data 00 A2 33 3F (IEEE float 0.701691)

Checksum 04

Response String **03 02 10 94 3A 02 00 00 1B**

Preamble 03 02 10

Command Code 94 3A

Type Code 02 (good response)

Data Size 00 00 (0 bytes returned)

Data None

Checksum 1B

Quick start

Introduction

This reference provides a quick start to typical SURETEMP Plus module operation. The intent is to provide a reference to the simplest method to implement the SURETEMP Plus module. Note that this should not be considered as the only way to implement the module. The host has many choices to consider with regard to power management, thermometer/temperature modes, error handling, biotech or service, and other features.

The SURETEMP Plus serial communications protocol is defined beginning on [page 29](#).

Typical start-up sequence

It is assumed for this section that the user is familiar with the module's power requirements and mechanical interface. It is also assumed for the following steps that the host leaves all of the module's default settings unchanged from the factory settings.

1. The host applies power to module at J1.
2. The module performs the POST, which typically takes 2-4 seconds. It is best to wait 2 seconds before sending requests to the module to ensure it has time to initialize the serial communications interface.
3. The host sends <9401> Send Thermometer No Clear command to monitor the progress of POST. The module responds with <9401> Send Thermometer No Clear response.

The <9401> response includes a Temp Status byte to declare the POST still in progress or the POST complete.

- If no POST error is detected, the host continues to Step 5.
 - If a POST error is detected, the host will have to determine whether to proceed or indicate service.
4. The host can elect to set various features of the module to customize the operation based on the application. For example, the host can use the <2A12> Temperature Method command to select whether the device enters into normal predictive or monitor mode when a probe is pulled.

It might also be desirable to use the <3503> Lock Probe Switch in order to temporarily control access to probe use while the host is setting various functions during initialization. (Use <3604> to set the probe in the well after locking the probe switch.)

5. The host sends <9434> Enable Asynchronous Messages command. The module responds with <9434> Enable Asynchronous Messages response.
6. The probe is removed from the well and a probe cover applied.

7. The module sends unsolicited <941C> Temperature Record packets as soon as the probe is removed from the well.
8. The host monitors the state byte in the Temp packets. When the module goes from Not Ready to Ready, the host can sound an audible tone or beep to signify that the oral/axillary probe is ready to be inserted into the patient's mouth. At this point, the probe is inserted. If the probe is not inserted, the module remains in predict mode for one minute, and then moves to the Monitor mode. It remains in Monitor mode until the cycle is inactive.
9. The host monitors temp state and error message bytes within the <941C> Temperature Record packets or until the time-out is reached.
10. A Final Predict Temperature is included by the module in the temp packet. The <941C> Temp Record packets continue until the Probe is returned to the well or times out.

Programmable ambient bias

Introduction

The Predictive Thermometry Algorithm uses the starting temperature of the probe cover to calculate an accurate temperature prediction. Probe cover temperature is estimated by measuring the temperature of the probe tip as it is removed from the probe well (holster). This methodology relies on the temperature of the probe tip when in the holster to be equivalent to the temperature of the probe covers. The relationship between probe tip and probe cover temperatures has system design ramifications when integrating the SURETEMP module into a new device. The most reliable way to achieve this equivalence is to integrate the SURETEMP probe holder and probe covers in a way that assures both remain at room temperature.

This can be a design challenge due to self-heating inside the host device when the device is running. To provide a modest amount of design flexibility, the module has a "programmable ambient bias" feature that must be properly set to match the expected temperature difference between the probe covers and the holstered probe tip during normal operation of the system.

The programmable ambient bias can be used to compensate for temperature differences between the probe-tip environment (when in the well) and the probe cover temperatures. The bias value depends on a given host system's thermal rise of the holstered probe's temperature and the temperature of the probe covers. Once a "programmable ambient bias" is determined for a given host system, that value can be used in all SURETEMP Plus modules integrated into that specific host system.

Use the following procedure to determine the "programmable ambient bias." This requires temperature testing of the finished device to verify the value and consistency over a range of environment temperatures.

Host device temperature testing

Perform this testing on actual hardware or representative prototype during a "normal" use profile. For example, if it is normal for the finished device to run on batteries and the device when charging is warmer, use the non-charging scenario. Air movement around the device should be minimized. Keep the unit away from fans and drafts to enable the unit to reach a stable operating temperature.

1. A dummy temperature probe (not electrically plugged into the device) is inserted into the probe well to control the switch. An active (plugged-in) probe is outside of the well, soaking in room ambient temperature for at least 5 minutes. The active probe tip must not be touching any surface; it must be free and clear and acclimated to room ambient temperature.
2. When the system operating temperature has stabilized, pull the dummy probe from the well and read ambient temp data from the temp packet. This number is recorded as the room ambient temperature

3. The same active probe used to determine ambient temperature above is now placed into the well of the finished device and allowed to soak for at least 5 minutes in the device/probe well ambient.
4. The active probe is pulled from the well, and the host collects the ambient temp from the temp packet. This number is recorded as the probe well ambient temperature for later use.
5. After the temperature pair is collected, perform the same procedure over a series of temperatures (such as 75F, 85F, 95F, 105F) to verify that the temperature deltas are consistent across the device operating range. If the deltas are not consistent, the design team must revise the implementation of the SURETEMP Plus module within the design and consider changes that will allow the probe tip and probe covers to remain closer to the true ambient temperature. *Example: Design venting into the host product to allow for temperature equalization throughout the areas where the probe holster and probe covers reside.*

Note The previous ambient temp is held by the SURETEMP Plus module for 3 minutes. At the end of the 3 minutes, the module gets a new ambient temp from the first probe reading prior to heating the tip. This means that the probe must be in the well without interruption for 3 minutes to collect a new ambient temp.

Calculating the bias

Calculate the bias value as:

Probe ambient in well (°K) minus Probe ambient out of well (°K).

The differential number can then be converted to IEEE floating point, and then converted into the corresponding 4 bytes needed for the (943A) Set Ambient Bias Command. For example:

Probe Well ambient temperature = 26C (299.1 °K)

Room ambient temperature = 24C (297.1 °K)

Difference = 2 °K

Data 00 00 00 40 (= 2.0 IEEE float)

Host sends 03 02 10 94 3A 01 04 00 00 00 00 40 D8

Saving ambient bias

Either of the following approaches to applying the programmable ambient bias is acceptable.

- Implement a factory procedure where the host's ATE sets this value once via the 943A command and then follows with the 2A06 command to write the bias value to the module's EEPROM.

OR

- During each power-up and initialization of the host device, the host sends 943A to set the module's ambient bias in RAM (rather than saving it to EEPROM)

Module Factory Default: The SURETEMP Plus module has a default value of 0.56 K. The SURETEMP system is sensitive to a maladjusted ambient bias value. Test data show, for every 1 degree C the device reads the ambient too high, the predict result will be lower by 0.045 and vice versa.

Error codes and recovery

Table 8 defines the SURETEMP Plus module error codes. Recovery attempts are suggested if the status indicates a fault condition. The errors are grouped into the following classes:

- Probe
- Module
- Ambient
- Battery/Voltage
- Patient

Recovery attempts may include the host initializing a reset.

Table 8: Error codes and recovery

Error	Class	Possible Cause	Action
21	Probe	Temperature conditions are such that the probe is located above 112°F/43.3°C. Defective probe tip where heater is too close to thermistor.	Correct probe tip conditions. If problem persists, replace probe. If problem still persists, replace module.
22	Probe	Excessive heater energy. Heater not working. Could have taken too long to predict.	Try another predict cycle. If problem persists, replace probe.
24	Ambient	Ambient temperature too high.	Check internal temperature at probe well. Verify ambient temperature does not exceed operating specification.
25	Ambient	Ambient temperature too low.	Check internal temperature at probe well. Verify ambient temperature does not exceed operating specification.
27	Battery/Voltage	Battery or power-supply voltage exceeds algorithm maximum value.	Verify that the supply voltage is within specification.
28	Battery/Voltage	Battery or power supply voltage below algorithm minimum value.	Verify that the supply voltage is within specification.
32	Probe	Thermistor pulled away from the tip or heater broken.	Try another predict cycle. If problem persists, replace probe.
33	Probe	Probe not responsive. Probe not characterized/calibrated.	Replace probe.
34	Probe	Probe not characterized/calibrated.	Replace probe.
45	Probe, Module, Patient	Measurement below allowable temperature values and far below the low ambient or patient limits.	Patient or environmental temperature conditions may be too low. Verify conditions at 80°F and 50°F respectively. If conditions are valid and problem persists, replace probe. If problem still persists replace module.

Error	Class	Possible Cause	Action
46	Probe, Module, Patient	Measurement above allowable temperature values and way beyond the high ambient and/or patient limits.	Patient or environmental temperature conditions may be too high. Verify conditions at 110°F and 104°F respectively. If conditions are valid and problem persists, replace probe. If problem still persists replace module.
47	Module	Internal calibration resistor (RCAL) on the board is damaged.	If problem persists, replace module.
48	Module	Internal calibration resistor (RCAL) on the board is damaged.	If problem persists, replace module.
49	Module	Internal circuit validation resistor (PTB) on the board is damaged.	If problem persists, replace module.
50	Module	Internal circuit validation resistor (PTB) on the board is damaged.	If problem persists, replace module.
51	Module	A/D measurement timed out and did not finish in the allotted time slot.	If problem persists, replace module.
52	Probe	Probe not characterized/calibrated.	Replace probe.
59	Battery/Voltage	Battery or power-supply voltage below algorithm maximum value.	Verify that the supply voltage is within specification.
60	Battery/Voltage	Battery or power supply voltage exceeds algorithm minimum value.	Verify that the supply voltage is within specification.
61	Module	Reference voltage circuit detected to be under voltage or unstable.	If problem persists, replace module.
62	Module	Module not calibrated.	Replace the module.
63	Module	Probe well missing or not installed properly.	Re-insert probe well or check for alignment problem.
65	Module	Problem saving to the module's EEPROM.	Verify that the supply voltage is correct. Try to make changes again. If problem persists, replace module.
66	Module	The module's or the probe's error detection mechanism detected an error.	Verify that the supply voltage is correct. Try again. If problem persists replace indicated component.
67	Module	Problem reading the module's EEPROM or saving to the module's EEPROM.	Verify that the supply voltage is correct. Try to make changes again. If problem persists, replace module.
68	Module	Problem reading the module's EEPROM or saving to the module's EEPROM.	Verify that the supply voltage is correct. Try to make changes again. If problem persists, replace module.
69	Module	Problem reading the module's EEPROM or saving to the module's EEPROM.	Verify that the supply voltage is correct. Try to make changes again. If problem persists, replace module.
70	Probe	Problem reading the probe's EEPROM.	Verify that the supply voltage is correct. If problem persists, replace probe.
74	Module	Internal error. Module will try to initialize the module's EEPROM if detects that it has not been initialized before.	If problem persists, replace module.

Error	Class	Possible Cause	Action
75	Probe	Cannot read the probe's EEPROM correctly or the probe left the factory without being tested.	Verify that the supply voltage is correct. If problem persists, replace probe.
78	Module	Problem reading the module's EEPROM or saving to the module's EEPROM.	If problem persists, replace module.
79	Module	Problem reading the module's EEPROM or saving to the module's EEPROM.	If problem persists, replace module.
80	Module	Software is trying to turn off the probe heater but the heater feedback signal says it is still on.	If problem persists, replace module.
81	Module	Software is trying to turn on the probe heater but the heater feedback signal says it is still off.	If problem persists, replace module.
82	Module	HTR_Q on and HTRC are off but still have voltage.	If problem persists, replace module.
83	Module	HTR_Q is tri-stated with HTRC enabled and have heater power.	If problem persists, replace module.
84	Module	Turned Q&C on and heater voltage not high enough.	If problem persists, replace module.
85	Module	Heater hardware fail-safe should have turned off but did not turn off.	If problem persists, replace module.

Cleaning

Cleaning the probe

Wipe the probe and cord regularly with a cloth dampened with an appropriate healthcare low- or intermediate-level cleaner/disinfecting wipe that incorporates either a 1:10 sodium hypochlorite (bleach) solution or isopropyl alcohol as the active disinfection ingredient. Follow wipe manufacturer's instructions for appropriate use, contact times and applicable warnings and precautions.

As needed, clean the probe and cord with a 70% isopropyl alcohol solution, a 10% chlorine bleach solution, or a nonstaining disinfectant.



CAUTION Do not immerse or soak the probe in any type of fluid.



CAUTION Do not use steam, heat, or gas sterilization of the probe.



CAUTION Do not autoclave the probe.

Cleaning the probe well

Remove the probe well from the unit. Unplug the latching probe connector to prevent the device from consuming power while you are cleaning the probe well.

Clean the inner and outer surfaces of the probe well by swabbing the surface with a cloth dampened with a 1:10 sodium hypochlorite (bleach) solution or isopropyl alcohol solution as the active disinfection ingredient. Clean the probe well's outer surface by swabbing or wiping the surface with one of the solutions mentioned above.



CAUTION Do not use hard or sharp objects to clean the probe well. Hard or sharp objects can damage the probe well, which could cause the unit to fail.



CAUTION Do not use steam, heat, or gas sterilization on the probe well.



CAUTION Do not autoclave the probe well.



CAUTION Thoroughly dry all surfaces before reassembling the instrument.

To reassemble: Reconnect the latching probe connector to the thermometer. Be sure that the connector snaps into position. Reinstall the probe well in the device and snap the probe well into position. Insert the probe into the probe well.

Appendix A: Frequently asked questions

1. During monitor mode, if I push then pull the probe from the probe well very quickly (less than 1 second), the module continues to stay in monitor mode, is this expected?

No. See “Module operation” on page 18.

2. Is the Snail icon used for monitor mode mandatory?

The snail icon is a recommendation for the SURETEMP Plus technology to provide consistency for users who are familiar with the handheld thermometer. There is no requirement to use the recommended icons. Whatever icons/messaging are chosen, it is the integration team’s responsibility to carry out the appropriate usability testing.

3. Which temperature values shall be displayed, recorded, and stored for the finished temperature measurement- the predictive measurement value or monitor measurement dynamic value?

When in predict mode, the handheld thermometer should only display the final predict temperature. After a transition to monitor (direct) mode, the final temperature becomes an approximate one-second average of the probe temperature. During direct mode that value should be displayed.

Which values to store is not defined by the SURETEMP Plus technology. For example, the SURETEMP Plus handheld only stores the most recent predict measurement. Monitor (Direct) mode measurements are not stored, because there is no mechanism to determine when a direct mode reading is complete. The SURETEMP handheld workflow is that the clinicians will record the temperature they measure from monitor (direct) mode after the required delay time and before the probe is returned to the well. The thermometer does not latch that temperature because it is unknown when the probe was placed in the measurement site to start the timer.

If you wish to be able to lock in monitor (direct) mode measurement, there are a few items that need to be considered.

- How will you get an indication that the probe is in the patient site so that any decision logic you have does not fire inaccurately if the clinician is delayed in placing the probe?
- When the probe is removed from the site and returned to the well, the temperature begins to drop. That temperature is not accurate because it has begun to be affected by the ambient air temperature. The SURETEMP plus does not provide a mechanism to latch a monitor (direct) mode measurement. You would need to use a workaround to latch that measurement on your display outside of the module.
- What gets stored when you have both? The monitor (direct) mode readings are typically more consistent and accurate because you wait for the temperature to reach equilibrium. Predict temperatures are an estimate of the equilibrium temperature based on a subset of the temperature rise curve, so they will not be as consistent. We do not dictate what temperature to store. You will have to determine that based on the workflows you support for your device.

4. After the integration of OEM into the device, how should we test it during production for the integrated assembly? Is there any test guidance or test specification to build the tester for mass production?

All SURETEMP OEM modules are calibrated and functionally tested before leaving our production facility. This should limit the testing you need to perform. The following list is a subset of our functional tests that could be implemented to ensure that once built the module is functional.

- The (9401) command “Send Thermometer Status No Clear” can be used to ensure that the power-on self-tests did not detect an error.
- The (3103) command “Send Digital Input Status” can be used to test the 3 switches on the OEM implements.
- Each switch could be actuated and confirmed that the hardware detects the changes.
- The last test that could be considered would be to use a SURETEMP Plus calibration key to confirm that the modules take accurate measurements and were not damaged in a way that makes them inaccurate.

5. When using an oral/axillary probe If we do not set probe mode, what probe mode should be used?

Use command 0x2949 to get the default thermometer probe mode. This will communicate what will be used the next time the probe is pulled. See “(2949) Send default thermometer probe mode” on page 38 for commands and responses. It is essential to understand how the last used algorithm is used. For example, if the user changes the algorithm during a reading that is the algorithm that will be used the next time the probe is pulled. If the module is powered off, it defaults to ORAL for that mode. It is up to the integration team if they care to implement it or not. For the handheld (non-integrated device) it makes sense because it is approximately a year before the batteries are changed, so the device never powers off. In an integrated system, it is probably powered off a lot. So, it makes less sense.

6. After predict measurement is complete, and after 30s, the module will enter standby, if 0x2A12(Set temp method 1) is sent to the module to enter monitor mode, it does not work. But I find that if I send 0x3503(Lock thermometer probe), 0x3604(Set temp probe 1), then sleep 100ms, then send 0x2A12(Set temp method 1), the module can enter monitor mode. If not sleep 100ms, the module cannot enter monitor mode, why?

And 3 minutes after predict is complete, the module will enter sleep, then send 0x3503 0x3604 0x2A12, and the monitor will enter predict mode again, why?

Locking the probe state with 0x3503 should not change the state of the system. However, the 0x3604 message will generate a probe out-of-well event. How this is processed depends on the current state of the system. It is possible that the 100ms delay allows that request to shift into a window where it is guaranteed to be processed. In general, the description above is not a normal use scenario, so there are some timing nuances that would need to be considered.

The last part of this question is due to the timing. The act of sending 0x3604 generates a probe pull message instructing the system to transition from the standby state to the predict state. This action is done on all probe pulls. The predict state has some rules around whether it goes to predict vs monitor mode. Also, some tests are performed as part of the probe pull process that delays the start of an actual measurement. The last request of 0x2a12 is being received before the system has transitioned to the active state. For this step to work properly, you should wait until you start receiving messages indicating that the system has transitioned to the active state before sending the 0x2a12 command, otherwise this command may have no effect.

7. What does error code 23 mean?

The error code 23 is used for conditions in which the software has not set up the algorithm properly.

8. During predict mode or monitor mode, when changing the measurement site, will it impact module behavior?

Only during predict when the state is NOT_READY, READY, or PREDICT can the measurement site be changed. It is blocked in other instances. The measurement site has no effect during monitor mode because that is just a live display of the probe temperature and to use it for measuring body temperature you must wait for steady-state. So, the measurement site does not need to be known.

9. For ready and predict completion beep, are there detailed specifications? For example, the frequency? Duration?

Ultimately the integration team needs to make the decision on what works best for their device and is acceptable through their usability testing. We do not enforce a specific performance.

10. What is the temperature condition when report SURETEMP state as "Final over temp" and "Final under temp"?

FINAL_OVER_TEMP is for temperatures over 43.3C.

FINAL_UNDER_TEMP is for temperatures under 26.7C