

TEMPERATURE RECORDER

Vaccine Refrigerator Temperature Recorder with 30day summary display compliant to WHO PQS specification E006/TR06.3

vaxtag (TRID30-7FW)



PRODUCT SPECIFICATION

Doc Ver 1.2 Released: 29th July 2014

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Document Revision History

Ver	Date	Author	Details
1.0	01/06/11	CW	Initial release.
1.1	20/6/13	CW	Corrected details of start delay in page 6, Starting the Recorder
1.2	29/7/14	CW	'vaxtag' product name changes

Overview

The *LogTag®* vaxtag is intended for use as the principle means for monitoring storage conditions in vaccine refrigerators in intermediate stores and health facilities and is specifically configured and packaged to be compliant to the World Health Organisation (WHO) PQS specification E006/TR06.3. The device may also be used as a secondary back-up device in cold rooms

The device features a data logging memory storing up to 7770 temperature readings and a separate rolling 30 day statistical max/min reading and duration memory.

During recording the display shows the current temperature (of the most recent reading), the status (within or outside the acceptance range), an alarm trigger summary of up to the last 30 days (today and 29 days previous) of recording, the current time and battery status.

If a reading is outside the pre-set "Alarm" limits an alarm is generated and a "day alarm indicator" appears on the display.

This display arrangement is designed to show 'at a glance' if temperature excursions have occurred for both the current reading and up to 30 days in the past. Details of any excursions can be checked directly by inspecting the statistics history on the recorder's display or in more detail by downloading the logged data.

Logged temperature data can be downloaded via a standard LogTag Interface to the free companion software *LogTag Analyzer* which provides facilities for displaying data in chart, table or statistical formats and allows electronic archiving, export or transmission of the data in support of sophisticated data management systems.

Button Actions Overview



Review/Mark button

Press to enter REVIEW mode and then press again to advance through the day statistics.

This action also places an inspection mark in the log if recording is active

Start/Clear/Stop button

Press to start recording

Press to clear alarm (if function enabled)

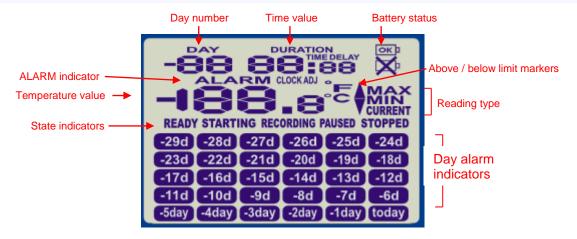
Press to Stop recording (if function enabled)

Press to exit day summary review.

Start/Stop/Clear button functions require the button to be pressed continuously for 4 seconds and then released when the related flashing indicator stops flashing. This reduces the possibility of vibration or a load being placed on the recorder that causes permanent or intermittent button press to falsely trigger a function.

Review mode is exited immediately by pressing the STOP button.

Display Overview



Display item	Description				
Temperature value	Temperature value (in °C or °F)				
Reading type	CURRENT = the temperature of the last reading taken MAX = The maximum reading in a given 24hour period MIN = The minimum reading in a given 24hour period				
Above/below limit indicators	Up arrow marker appears when the temperature displayed is above the specified upper temperature limit Down arrow marker appears when the temperature displayed is below the specified lower				
	temperature limit				
ALARM indicator	ALARM appears when an alarm is triggered.				
Time value	The time (in HH:MM) can be current time, time remaining to start of a delayed start or duration of a given max or min value above/below the specified limits.				
	The value displayed is indicated by the following :-				
	TIME = displaying Current Time (READY and RECORDING modes).				
	TIME DELAY = displaying remaining time to recording start when a DELAYED START time has been configured (STARTING mode)				
	DURATION = displaying duration of a given MAX or MIN statistic above/below the limits in a given day. (REVIEW mode)				
	Performs battery test h	ourly.			
Battery status	displayed when battery is tested OK.				
	displayed when battery is tested LOW.				
	READY	Ready to start recording			
State indicators	STARTING	Preparing to start recording. If a delayed start is configured then displays time remaining to recording start.			
	RECORDING	Recording			
	PAUSED	Max/Min statistics collection paused due to button press activity			
	STOPPED	Recording has stopped			
Day alarm indicators	The display is organized with a table of 'day alarm indicator' segments named "Today" to "-29d" which are switched on when a given day has an alarm trigger present.				
Day number	The day number of the currently selected day statistic is displayed when in Review mode. TODAY is DAY 0, yesterday is day '-1'. Can be configured to display the total number of days collected while recording.				

Alarm triggering and function.

A visual alarm trigger is displayed if one or more of the configured alarm trigger conditions have been met. An alarm trigger condition can be a single violation reading (a reading above the upper or below the lower threshold value), a set of consecutive violation readings or a total of violation readings encountered (called 'accumulative').

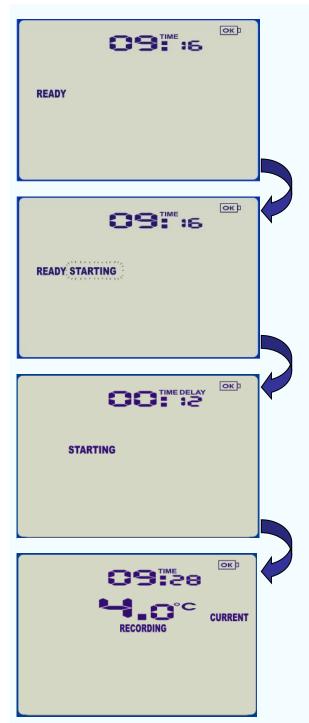
The device is factory preconfigured with the following alarm settings:

- Low alarm : Exposure to a single (i.e consecutive) temperature event of -0.5°C or below for 60 minutes.
- High alarm: Exposure to a single (i.e consecutive) temperature event of +8°C or above for 10 hours.

Real time clock

The time shown on the recording display is linked to the recorder's internal real time clock. A *day change* occurs when the display time rolls through midnight (i.e 00:00) and this is the main function of the display clock.

Starting the recorder



Recorder in READY mode

The recorder must be in Ready mode for it to be started.

In Ready mode the recorder displays the time, battery status and the READY icon.



Press and hold the Start button and observe that the STARTING icon starts flashing.

The button needs to be held down until the flashing stops (normally 4-6 seconds however can be longer if the button is not continuously depressed)



Release the Start button when the STARTING icon stops flashing

The recorder enters STARTING mode. The recorder begins a 12 minute start delay. The time remaining to recording start is shown on the display.

After the start delay has timed out then the recorder enters RECORDING mode.

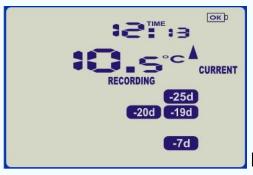
The display shows the current temperature, current time, battery status and any alarm triggers and is updated each time a log is taken.

Recording Display

The normal recording mode display displays the current temperature of the last log taken so is updated at the same rate as the logging interval.

The current time, battery status and alarm trigger day summary are displayed.

Some recording display examples are shown below :-



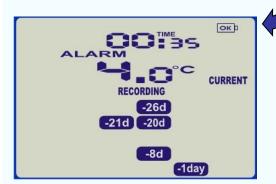
The recorder shows alarm triggers 7, 19, 20 & 25 days ago.

The current temperature is over the upper limit (as indicated by the up arrow) but the duration of this temperature excursion has not yet triggered an alarm.



20 Minutes later





-20d -19d

today

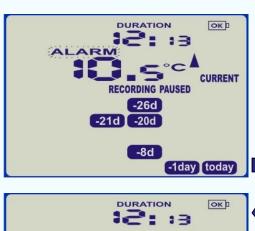


12 hours later

The temperature has returned to the acceptable range but the alarm remains present. (i.e has not been inspected and cleared)

The day summary has shifted by 1 day as the display time has gone through midnight (00:00).

Clearing an alarm





The ALARM icon will flash.

Wait until the flashing to stop then release the button within 2 seconds to clear the flagged alarm.

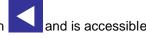


Note

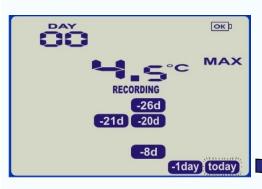
Only the **ALARM** icon can be cleared, the day alarm icons remain as they are part of the statistic summary.

Reviewing day statistics

The Review of day statistics history is accessed by pressing the REVIEW button in RECORDING and STOPPED modes.



An example of a reviewing days statistics is shown below :-





Pressing *Review* button displays current day's max statistic.

The "Today" segment flashes and 'Day 00' is shown to indicate the 'Today' selection.

In this screen example the selected day (Today) does not have any recordings that are outside the acceptance range.





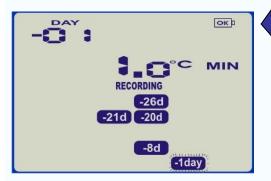
Pressing *Review* button again displays the day's minimum statistic.





Pressing the *Review* button again displays the next previous day's max statistic.

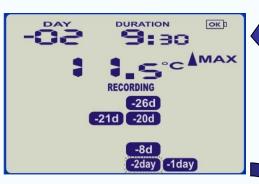
In this screen example the selected day has recordings that are above the upper limit and the duration value shows the amount of time recorded above the limit. The max statistic is above the upper limit so the up arrow is shown and an alarm was triggered by this statistic as indicated by the ALARM text shown.





Pressing the *Review* button again displays the day's minimum statistic.

The min statistic is not below the lower limit and did not trigger an alarm.







Pressing the *Review* button again displays the next previous day's max statistics.

The "-2day" day marker flashes and DAY '-02' is displayed.

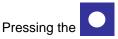
In this screen example the selected day does have recordings that are above the upper limit however did not exceed the alarm trigger durations so only the up arrow is shown and no ALARM trigger has occurred



Pressing the Review button again displays the day's minimum statistic.

Each time the *Review* button is pressed the cursor advances to the next previous day.

If less that 30 days of recordings have been collected so far then the day marker only advances as far as there is data available after which the next press rolls the summary back to the statistic for Today



button at any time reverts the display back to the *normal* mode.

The display will revert back to normal mode after 30 seconds of no button activity.

Note

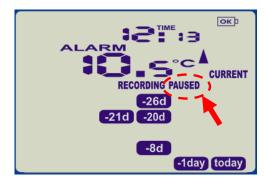
- 1. If exposure to alarm temperatures occurs in a continuous period of time that is cut with the day shift (midnight) then the time count continues and if the alarm period is finally exceeded then the day in which the time count was completed is displayed with day alarm indicator and the time exposure split appropriately over the two days.
- 2. The duration values above or below the specified High/Low temperature are always displayed. Presence of a day alarm trigger marker means that exposure to an alarm temperature for a continuous period greater than the configured trigger duration has occurred on that day.

Paused function

The recorder is configured to suspend processing of readings for alarms and max/min statistics for a period of two temperature samples after button press activity. Depending on when the button press occurs this will be an actual time detail of 12min ~ 17min:59sec.

This allows the user to review the current statistics or clear an alarm without causing a false alarm or statistic while handling the recorder.

Paused processing is indicated on the display by the PAUSED icon being present as shown in the display example below :-



Note

Data logging continues but each log that is taken during the paused period is flagged and labelled as paused. Logs that are flagged as 'paused' are not used in the summary statistics.

Adjusting the display clock

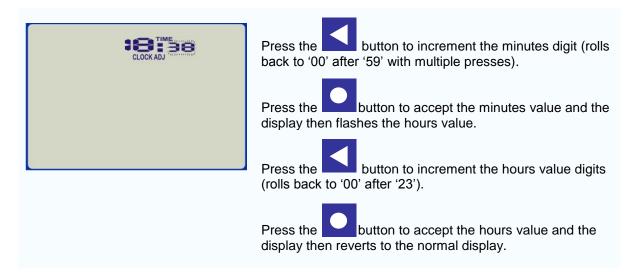
The display clock of the recorder can be set to the correct time zone either by using LogTag Analyzer software or directly using key actions on the recorder itself.

The clock can be adjusted to local time by pressing the and buttons together continuously for a period of 8 seconds.

During this button press period **CLOCK ADJ** icon flashes. Release the buttons when the flashing stops to enter clock adjustment mode.

The display then changes as shown in the example below with the minutes digits flashing.

In the example below the hours is 18 and the minutes is 38:-



NOTE: It is advised that the real time clock Hours is only adjusted when in STOPPED or READY modes (i.e not recording) to avoid large shifts in day boundary data.

If a display clock adjustment is made while in *RECORDING* mode then the next log taken records a flag indicating a time change took place.

Changes to the display clock do not affect the internal real time UTC+timezone offset value so the logged data does not experience time gaps.

Specifications

LogTag Part code	TRID30-7FW
Rated Operating Temperature Range	-30°C ~ +60°C (-22°F ~ +140°F)
Rated accuracy	Better than $\pm 0.5^{\circ}\text{C}$ ($\pm 0.9^{\circ}\text{F}$) for better for measurements from -20°C ~ $\pm 40^{\circ}\text{C}$ (-4°F ~ $\pm 104^{\circ}\text{F}$) - $typically~\pm 0.3^{\circ}\text{C}~(0.6^{\circ}\text{F})$ Better than $\pm 0.8^{\circ}\text{C}~(\pm 1.5^{\circ}\text{F})$ for other measurements - $typically~\pm 0.5^{\circ}\text{C}~(0.9^{\circ}\text{F})$.
Rated temperature resolution on LCD	0.1°C(0.2°F) for measurements -30°C ~ +40°C (-22°F ~ +104°F) 0.2°C(0.4°F) for measurements above +40°C (+104°F)
Recording Capacity	Data logging memory: 7770 logs (32 days @ 6min logging) Day summary statistics memory (for display on LCD): up for 30 days of Max/Min and duration values
Sampling Interval	Factory set to 6 minutes
Logging modes	Factory set to 'continuous' wrap around recording
Logging start options	Factory set to Push button start.
Alarm triggering	 Low alarm: Exposure to a single temperature event of -0.5°C or below for 60 minutes. High alarm: Exposure to a single temperature event of +8°C or above for 10 hours
Read time clock accuracy	Quartz crystal locked real time clock. Rated accuracy ±25ppm @ 25°C (equiv to ±2.5 seconds/day) Rated temperature coefficient is -0.034±0.006ppm/°C (i.e typically +/- 0.00294seconds/day/°C)
Download Time	Typically with full memory in less than 5 secondss depending on computer or readout device used.
Environmental	IP65 (when vertically mounted or hung)
Power source	3V Lithium-Manganese Dioxide extended temperature chemistry
Battery life	typically 2 years of operation. This assumes day statistics are reviewed on the display no more that once daily for no longer than 30 seconds each time.
Size	93mm(H) x54.5mm(W)x8.6mm(T)
Weight	43grams
Case Material	Polycarbonate
EMC Compliance	Complies with EC EMC directives (EN50081-1:1992 & EN 61000-6-1:2001) Complies with FCC Part 15 Subparts A and B.
FDA 21CFR Part 11 Compliance	Designed to comply with FDA 21CFR Part 11 (Digital signatures)
WHO PQS Compliance	Tested and certified compliant to WHO PQS specification E006/TR06.3.
RoHS 2002/bl/NZ	Manufactured to meet the European RoHS Directive
Reader Interface	Standard LogTag Interface cradle