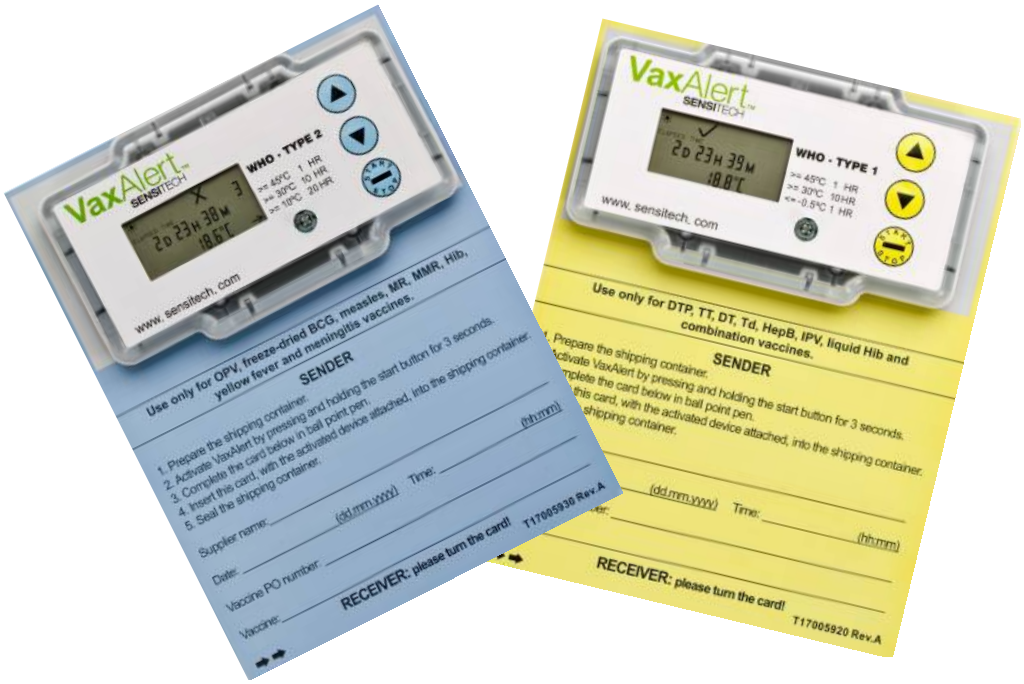
Step-by-step interpretation of 10-day electronic temperature monitoring devices for international vaccine shipments:

VaxAlert™



World Health Organization

REVISION HISTORY		
Date	**Reason**	**Approved by**
11 November 2009	Final version issued for comments	Ü. Kartoğlu

INTRODUCTION

According to WHO *Guidelines on the international packaging and shipping of vaccines* (WHO/IVB/05.23) a 10-day electronic temperature monitoring device should be included in each international vaccine shipping carton[1].

10-day electronic temperature monitoring devices show when, and to what extent, the set temperature conditions have been violated. There are two different types of devices.

Type I device with YELLOW backing card

Type I device accompanies the DTP, DT, TT, Td, HepB, IPV, liquid Hib and combination vaccines, with the following temperature alarm settings:

Temperature	Alarm type	Period for triggering the alarm
>= 45°C	single event	1 hour
>= 30°C	Cumulative	10 hours
<= -0.5°C	single event	1 hour

Type II device with BLUE backing card

Type II device accompanies the OPV and freeze-dried BCG, measles, MR, MMR, lyophilized Hib, yellow fever and meningitis vaccines, with the following temperature alarm settings:

Temperature	Alarm type	Period for triggering the alarm
>= 45°C	single event	1 hour
>= 30°C	cumulative	10 hours
>= 10°C	cumulative	20 hours

If not stopped manually, the devices stop automatically when they reach a recording interval of 10 days.

[1] CCM will only be included in the case of dry ice being used as coolant (electronic temperature monitoring devices do not perform in extremely cold temperatures).

Standard backing cards, as described in the Performance, Quality and Safety (PQS) performance specification for electronic shipping indicators WHO/PQS/E06/TR07.1), are shown below. Backing cards come in three languages: English, French and Spanish. The colour code is set for the type of device, meaning that different language versions in Type 1 will all come in YELLOW.

The text enclosed in <arrow brackets> will be replaced with the appropriate product-specific name or description.

Type 1 – on light yellow card
Front face

Mount device here
and this way up

Use only for DTP, TT, DT, Td, HepB, IPV, liquid Hib and combination vaccines.

SENDER

1. Prepare the shipping container.
2. Break off the twin label with bar code and stick it onto the shipping documents.
3. Activate <DEVICE NAME> by <describe activation procedure for device> with a start delay of 1 hour.
4. Complete the card below in ballpoint pen.
5. Insert this card, with the activated device attached, into the shipping container.
6. Seal the shipping container.

Supplier name:
_____

Date: _____ ___ Time:_____
dd:mm:yyyy hh:mm

Vaccine PO number: _____

Vaccine:
_____

RECEIVER: please turn the card!
⇨⇨

Type 2 – on pale blue card
Front face

Mount device here
and this way up

Use only for OPV, freeze-dried BCG, measles, MR, MMR, Hib, yellow fever and meningitis vaccines.

SENDER

1. Prepare the shipping container.
2. Break off the twin label with bar code and stick it onto the shipping documents.
3. Activate <DEVICE NAME> by <describe activation procedure for device> with a start delay of 1 hour.
4. Complete the card below in ballpoint pen.
5. Insert this card, with the activated device attached, into the shipping container.
6. Seal the shipping container.

Supplier name:
_____

Date: _____ ___ Time:_____
dd:mm:yyyy hh:mm

Vaccine PO number: _____

Vaccine:
_____

RECEIVER: please turn the card!
⇨⇨

BACK FACE (English)

Type 1 - Back face

RECEIVER

1. On arrival, remove <DEVICE NAME> from the shipping container immediately.
2. <Describe stop procedure for device>.
3. Read the LCD display and follow the instructions as described below.

OK DISPLAY

<clearly illustrate OK screen display>

If OK, use vaccines normally.

ALARM DISPLAY

<clearly illustrate alarm screen display>

If <DEVICE NAME> displays an alarm, please proceed according to the decision table below:

Alarm temperature	**What to do with vaccines:**
>= 45° C	Contact procurement agency
>= 30° C	Contact procurement agency
<= -0.5° C	Conduct shake test. Use vaccines if passes. Inform procurement agency of test result.

Assembled and distributed by [company name and web address]

Type 2 - Back face

RECEIVER

1. On arrival, remove <DEVICE NAME> from the shipping container immediately.
2. <Describe stop procedure for device>.
3. Read the LCD display and follow the instructions as described below.

OK DISPLAY

<clearly illustrate OK screen display>

If OK, use vaccines normally.

ALARM DISPLAY

<clearly illustrate alarm screen display>

If <DEVICE NAME> displays an alarm, please proceed according to the decision table below:

Alarm temperature	**What to do with vaccines:**	
	OPV only	Other vaccines
>= 45° C	Contact procurement agency	Contact procurement agency
>= 30° C	Contact procurement agency	Contact procurement agency
>= 10° C	Contact procurement agency	Accept

Assembled and distributed by [company name and web address]

This guide describes step-by-step what to do when you receive an international vaccine shipment.

REMOVING and STOPPING THE VaxAlert™ DEVICES

When you receive an international vaccine shipment, you must open ALL cartons to remove the devices. This has to be done one-by-one.

Each device has a bar code. Box number 1 should contain, along with shipping documents, a list of box numbers with the bar code\serial number of corresponding devices included in each box. When you open a box and remove the electronic device, you must also write down the box number on the backing card for easy reference.

STOPPING THE VaxAlert™ DEVICE
Open **ALL** shipping cartons and repeat the following steps for each electronic device:

PRESS the **STOP** button for 5 seconds. When stopped, ☀ symbol indicating measurement mode should disappear and ● symbol will appear at the right top corner of the screen.
When stopped the screen looks as follows: 

After stopping the devices, you need to check the alarm status of each one.
The **"OK" screen** is displayed as follows:

√ sign is seen at the top middle of the screen

If there are any ALARMS the **ALARM** screen is displayed as follows:

X is displayed at the top middle of the screen. The event counter (1 through 9) is displayed the top right side of the screen indicating the total number of alarm events, and the → symbol(s) at the right edge of the display indicate which alarm(s) have been activated.

If there are any alarms, **write down the time you stopped the device on the backing card.** This is important when you refer to the device after you stopped it. It will help you to calculate the precise time of violation.

Make a **photocopy** or **scan** the device to document the **ALARM** status. In each image, indicate the number of the box that the device was in.

Include all necessary information in the **Vaccine Arrival Report (VAR).**

If there are any **ALARMS**, fill in the **Alarm Reporting Form** and attach it to the **VAR**.

Send the **VAR** with **photocopies** or **printed images** from scanned devices and the **Alarm Reporting Form** to the **"procurement agency".**

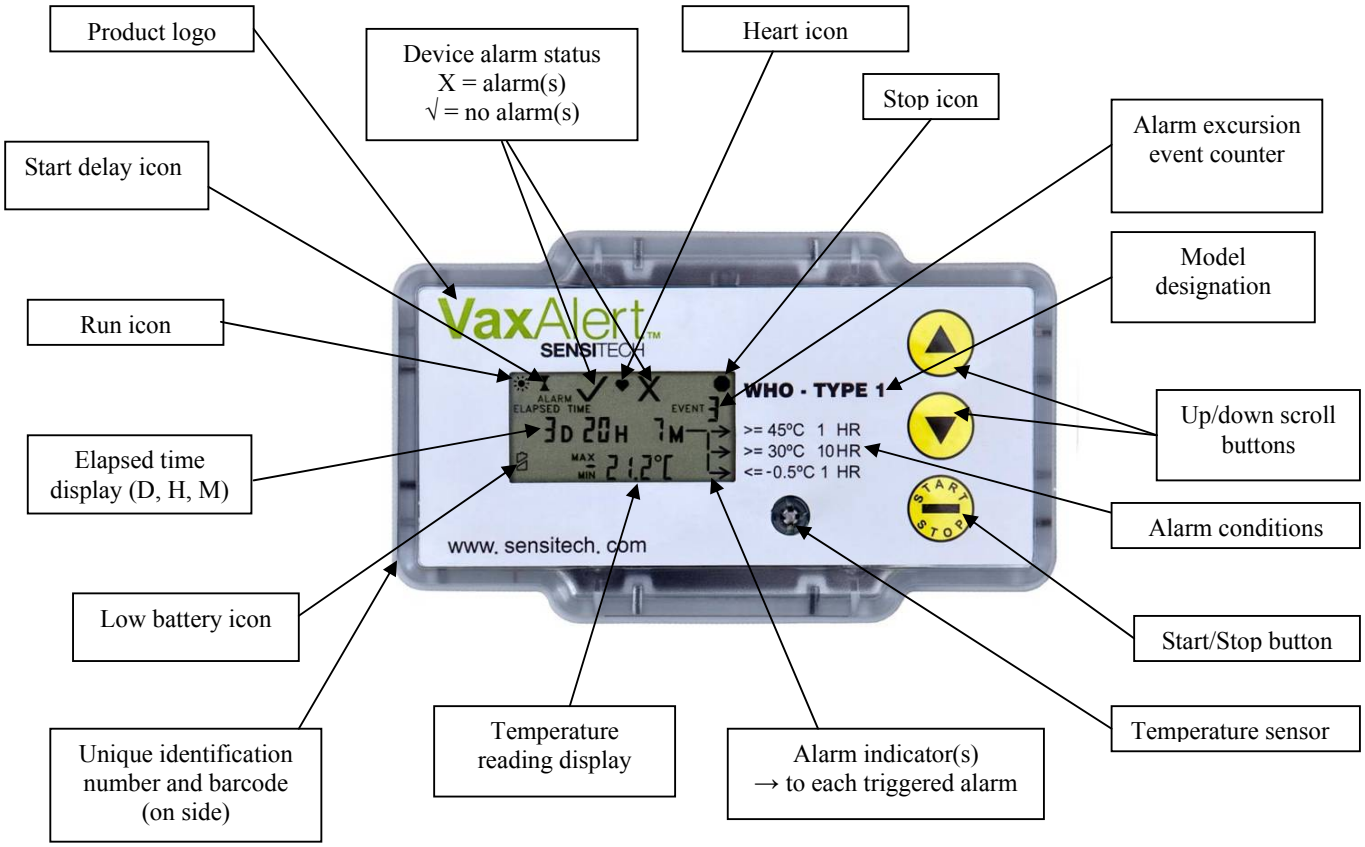
On the following pages, you will find product-specific information regarding display of information and using the **HISTORY** mode to see details of temperature violations.

VaxAlert™

WHO/PQS/E06/10

The figure below illustrates the VaxAlert™ indicator with all screen icons simultaneously displayed and with the supporting and navigational information on the product label. This display image is not representative of the device in the use environment. (See following sections for additional information)

VaxAlert™ Display and Operation Features:

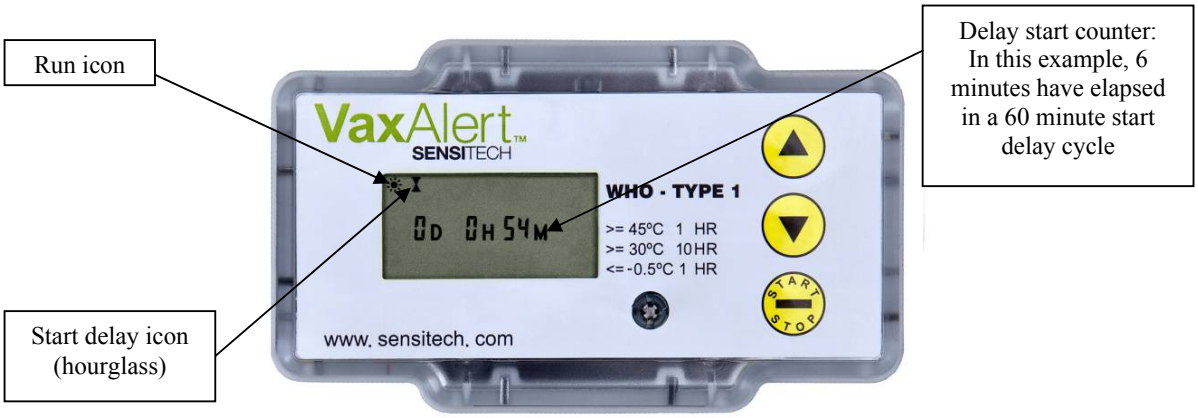


Step-by-step user guide for the VaxAlert™

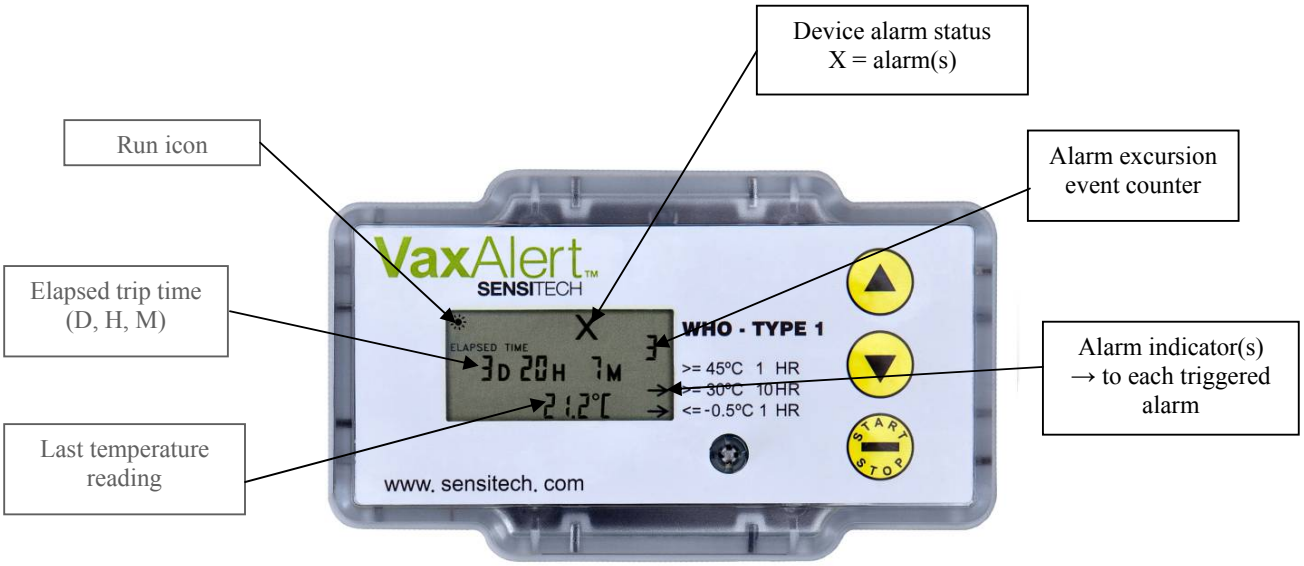
Starting the VaxAlert™:

1. Prior to starting the VaxAlert™, the display will present a blinking heart icon (♥), to indicate the device is powered and ready to start

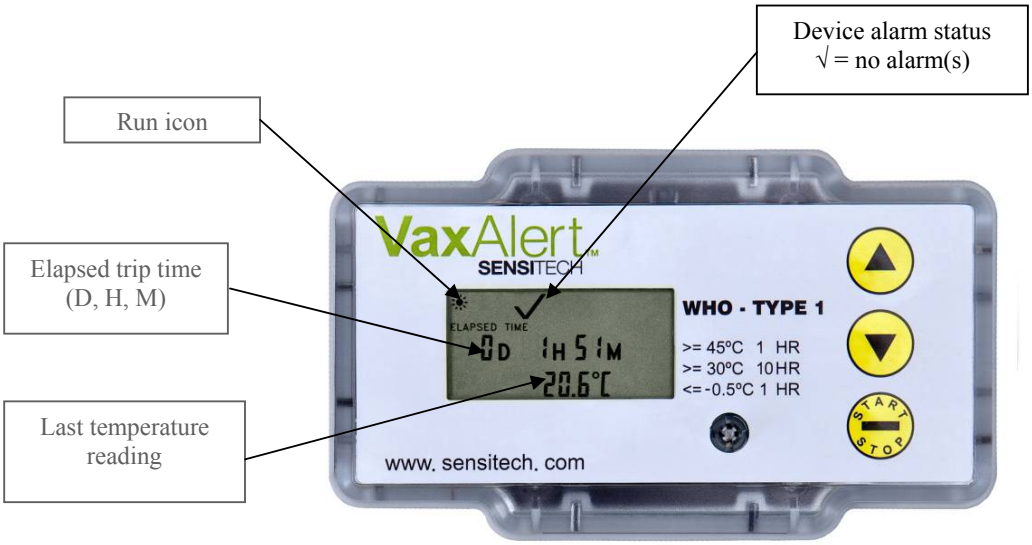
2. Press and hold the Start/Stop button for 3 seconds. The device will respond with an audible tone and display the start delay screen as shown below (run icon (☀) and start delay icon (⧗) are displayed). The display will count down the programmed start delay time until 0 minutes remain. At the end of the start delay countdown, the start delay icon will turn off and the VaxAlert™ will enter measurement (run) mode.



3. In measurement mode, the VaxAlert™ display will present elapsed trip time, last measured temperature, and alarm condition/excursion event information (if alarm activity is recorded).



VaxAlert™ in measurement mode with alarms

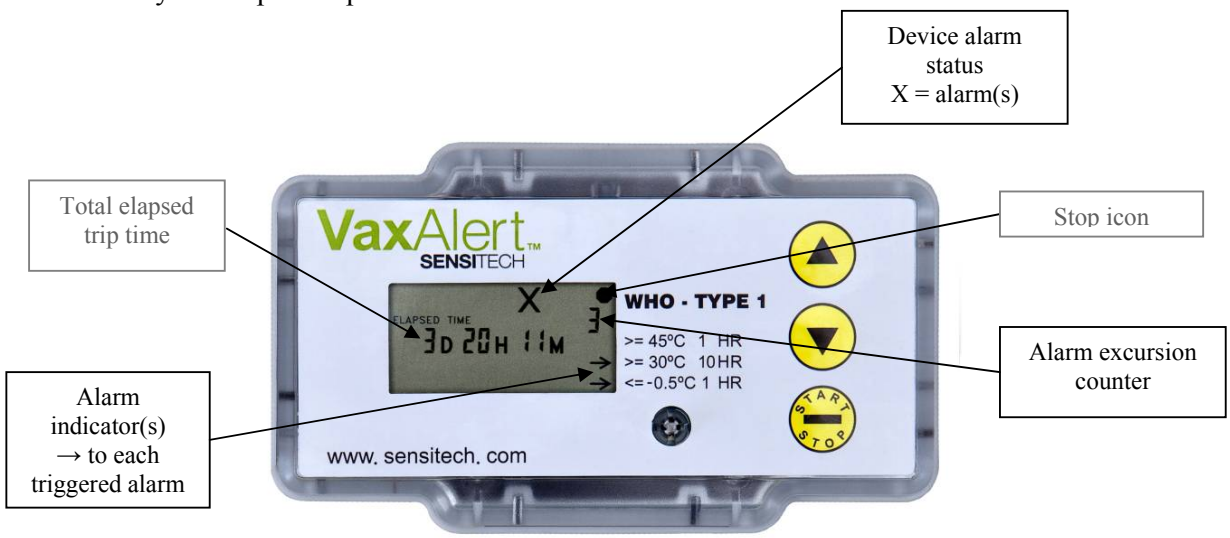


VaxAlert™ in measurement mode without alarms

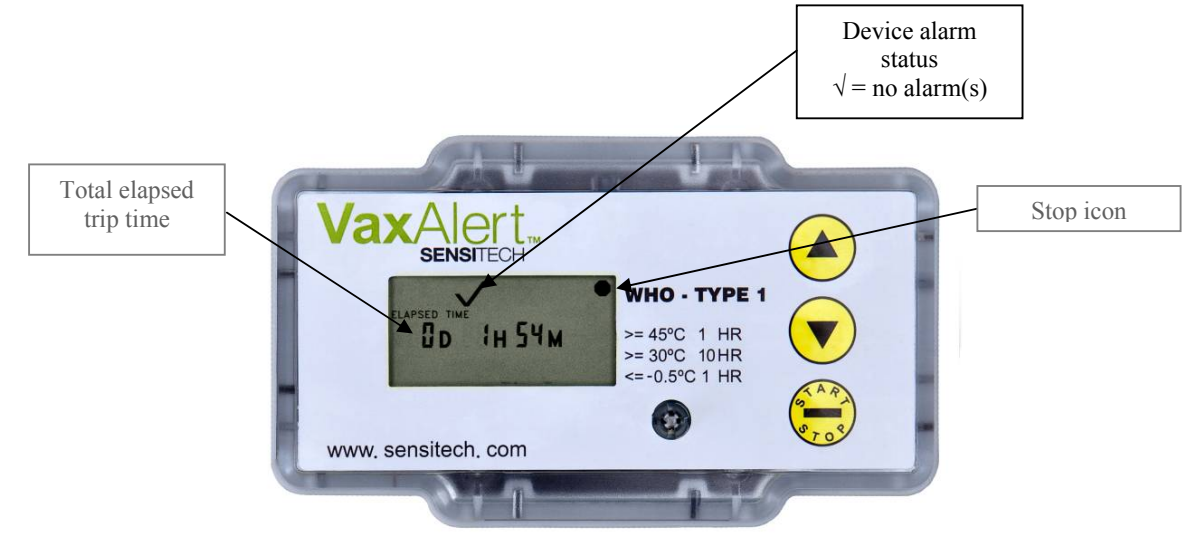
Stopping the VaxAlert™:

1. Note that each shipping carton contains a VaxAlert™ device, so you must open **ALL** boxes. Remove the device from each carton and proceed to step 2.

2. Press and hold the Start/Stop button for 3 seconds. The VaxAlert™ will emit an audible tone and display the stop mode screen as shown below (stop icon (●) is displayed) **NOTE:** The VaxAlert™ is programmed to automatically stop after 10 days of elapsed trip time.



VaxAlert™ in STOP mode with alarms



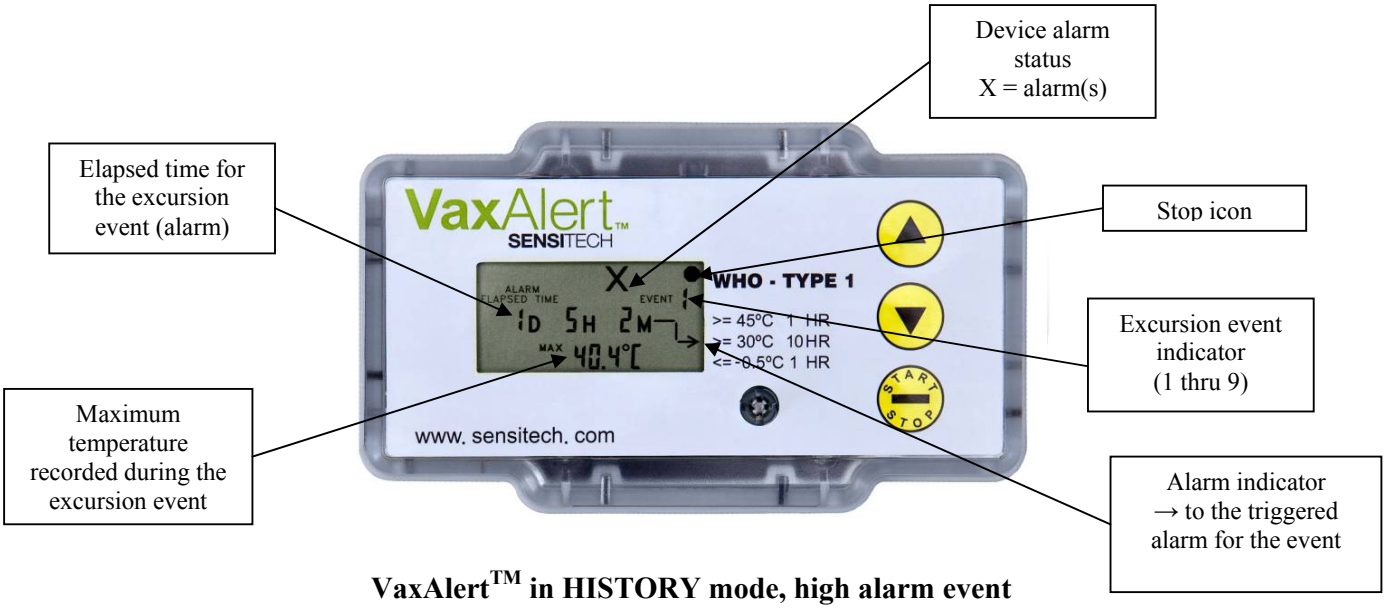
VaxAlert™ in STOP mode without alarms

Retrieving alarm event information from the VaxAlert™ (HISTORY mode):

1. If the VaxAlert™ experiences alarm events (excursions), the device will record detailed information for up to nine total alarm events (three for each of the alarm settings). The alarm history information will be retained in the VaxAlert™ and can be viewed for a minimum of six months after stopping the device.

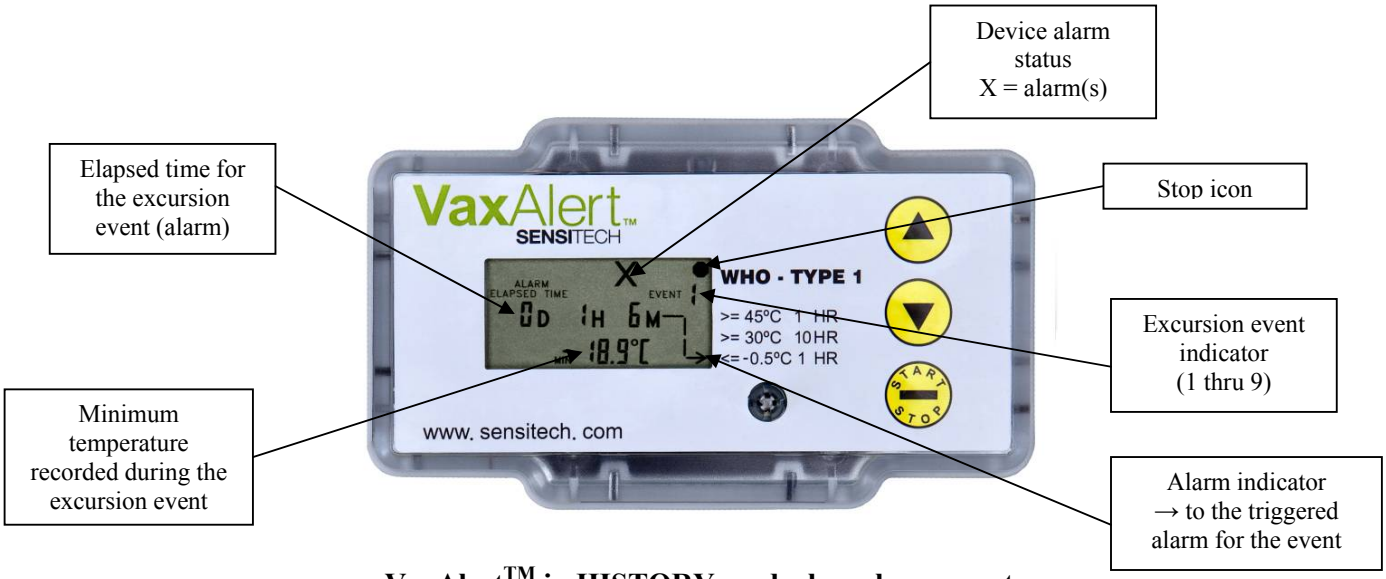
2. To view the alarm event history, press the ▲ or ▼ scroll buttons (in stop or measurement mode). The VaxAlert™ will emit an audible tone and display a history mode screen as shown below. Repeated presses of the ▲ or ▼ scroll buttons will cycle the alarm event history screens through all recorded alarm events (up to 9 maximum events).

3. During history mode operation, the screen will return to the stop or measurement mode screen if no additional button presses are initiated within 15 seconds. If the VaxAlert™ has not recorded any alarms, activating the ▲ or ▼ scroll buttons will not impact the display.



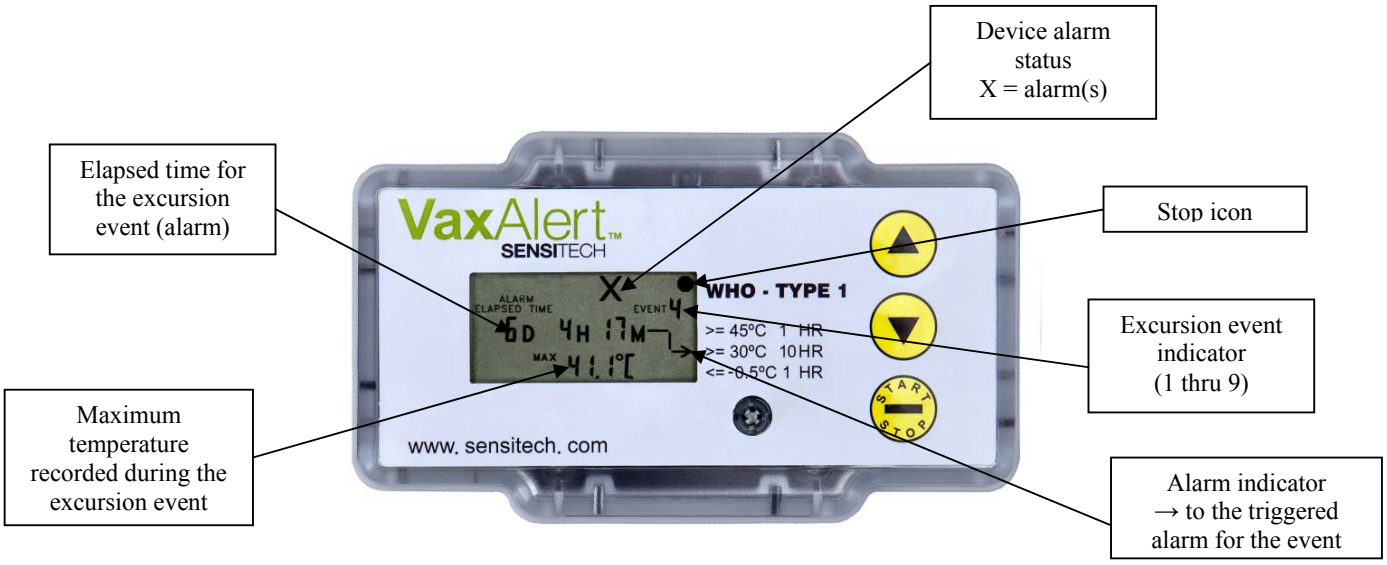
VaxAlert™ in HISTORY mode, high alarm event

In the example above, the first alarm event for this trip is a >= 30ºC, 10 HR alarm at 1 day, 5 hr and 2 minute elapsed time. The maximum temperature recorded during the >= 30ºC 10 HR alarm event is 40.4ºC.



VaxAlert™ in HISTORY mode, low alarm event

In the example above, the first alarm event for this trip is a <= -0.5ºC, 1 HR alarm at 0 day, 1 hr and 6 minute elapsed time. The minimum temperature recorded during the <= -0.5ºC 1 HR alarm event is -18.9ºC.



VaxAlert™ in HISTORY mode, high alarm event

In the example above, the fourth alarm event for this trip is a >= 30ºC, 10 HR alarm at 6 day, 4 hr and 17 min elapsed time. The maximum temperature recorded during the >= 30ºC 10 HR alarm event is 41.1ºC.

Battery Notes:

The VaxAlert™ contains a CR Lithium battery. Please observe the following safety precautions.

a. Dispose of or recycle the battery in accordance with your local regulations.
b. Do not expose the device to extreme temperatures as this may lead to the destruction of the battery and could cause injury.
c. Keep out of the reach of children.
d. Battery status is indicated on the screen at the bottom left corner. Accuracy and proper function of the device cannot be assured once the low battery signal icon is displayed.

VACCINE ARRIVAL REPORT (VAR)[1]

This report is to be filled in by authorized staff, ratified by the Store Manager or the EPI Manager, and forwarded to the procurement agency <u>within three days</u> of vaccine arrival. Use one report for each vaccine in the shipment.

COUNTRY	
REPORT No.	

Date of report	

Place, date and time of inspection	Name of cold store, date and time vaccines entered into cold store

PART I — ADVANCE NOTICE

MAIN DOCUMENTS	Date received by consignee	Copy airway bill (AWB)	Copy of packing list	Copy of invoice	Copy of release certificate
Pre-advice		[redacted]	[redacted]	[redacted]	[redacted]
Shipping notification		Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐

List other documents (if requested)	

PART II — FLIGHT ARRIVAL DETAILS

AWB Number	Airport of destination	Flight No	ETA as per notification		Actual time of arrival	
			Date	Time	Date	Time

NAME OF CLEARING AGENT: _____ ON BEHALF OF: _____

PART III — DETAILS OF VACCINE SHIPMENT

Purchase Order No.	Consignee	Vaccine description (Type and doses/vial)	Manufacturer	Country

Vaccine				Diluent/droppers			
Lot Number	Number of boxes	Number of vials	Expiry date	Lot Number	Number of boxes	Number of units	Expiry date

(Continue on separate sheet if necessary)

	Yes	No	Comments
Was quantity received as per shipping notification?	☐	☐	
If not, were details of short-shipment provided prior to vaccine arrival?	☐	☐	

[1] Adopted from the Standard UNICEF Vaccine Arrival Report from WHO *Guidelines on the international packaging and shipping of vaccines* (WHO/IVB/05.23)
No. = Number
WHO recommends all UN agencies, countries and non-governmental organizations procuring vaccines adopt this report.

Report No.	

PART IV — DOCUMENTS ACCOMPANYING THE SHIPMENT

Invoice	Packing list	Release certificate	Vaccine Arrival Report	Other
Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐	
Comments				

PART V — STATUS OF SHIPPING INDICATORS

Total number of boxes inspected:				
Coolant type:	Dry ice ☐	Icepacks ☐	No coolant ☐	
Temperature monitors present:	VVM ☐	Cold-chain card ☐	Electronic device ☐	Type: _____

PROVIDE BELOW DETAILS OF STATUS <u>ONLY</u> WHEN PROBLEMS ARE OBSERVED
(in addition fill in ALARM REPORTING FORM if there are any ALARMS in electronic devices):

Box Number	LOT NO	Alarm in electronic device				Cold-chain monitor				Date/time of inspection
		>=45^{0}C	>=30^{0}C	>=10^{0}C	<=-0.5^{0}C	A	B	C	D	

(Continue on separate sheet if necessary)

PART VI — GENERAL CONDITIONS OF SHIPMENT

What was the condition of boxes on arrival?	
Were necessary labels attached to shipping boxes?	
Other comments including description of alarms in electronic devices: (continue on separate sheet if necessary).	

PART VII — NAME AND SIGNATURE

_____ _____ _____ _____

Authorized Inspection Supervisor DATE Central store or EPI Manager DATE

For Procurement Agency office use only

Date received by the office: _____ Contact person: _____

Guidelines for completing the Vaccine Arrival Report

The Vaccine Arrival Report (VAR) is a comprehensive record of cold-chain conditions during transport and of required compliance with shipping instructions. Recipient governments and procurement agencies (UNICEF country offices, UNICEF Supply Division, PAHO Revolving Fund), are responsible for the report, and for taking appropriate action if problems are reported (e.g. follow-up with the manufacturer, forwarding agent, WHO, etc.).

Use one report form for each shipment and for each vaccine in the shipment. In shipments containing diphtheria–tetanus–pertussis (DTP)–Hepatitis B (HepB) and *Haemophilus influenzae* type b (Hib) vaccines, use one form for DTP–HepB and a separate form for Hib. *In the case of short-shipments (where parts of the original quantities are not delivered), complete a separate report for each part delivered.*

Complete the form as described below. In the header boxes at the top of the form, enter the name of the recipient country, the report number, and details of place and date of inspection and storage. The report number is an internal number for organizing records; compile it as follows: country code; year; number for each report (e.g. BUR–2005–001 for one vaccine; BUR–2005–002 for a second vaccine, etc.). In the case of a short-shipment, the numbers for the separate deliveries would be, for example, BUR–2005–003.1, BUR-2005-003.2, etc.

Part I — Advance notice

I.1 Enter dates and details of documents received in advance of the vaccine shipment.

Part II — Flight arrival details

II.1 Fill in details of expected and actual arrival times for the shipment.

II.2 Fill in the name a) of the clearing agent and b) for whom the agent acts (e.g. the Ministry of Health, UNICEF or WHO).

Part III — Details of vaccine shipment

III.1 Fill in details of the order (purchase order number, consignee, vaccine description etc.).

III.2 For each batch of vaccine included in the shipment, record:
- a) the number of shipping boxes;
- b) the number of vials;
- c) the expiry date.

The number of boxes you enter should always match the number of boxes shown in the packing list. If it does not, note under *Comments* if advance notice of a change in the quantity was provided. It is not necessary to count the number of individual vaccine packs in each shipping box for this report.

III.3 For the diluents and droppers (if included) with each batch of vaccine in the shipment, record:
- a) the number of shipping boxes;
- b) the number of vials;
- c) the expiry date.

The information for III.2 and III.3 is also in the packing list.

Note: Diluents for freeze-dried vaccine and droppers for oral polio vaccine (OPV) are integral parts of the vaccine, so always include them on the same form. If diluent/droppers are delivered separately, consider it a short-shipment.

Part IV — Documents accompanying shipment

The packing list should indicate which box contains the shipping documents (usually Box 1).

IV.1 If this information is not included in the packing list or in documents sent separately by courier, pouch or other means, note this under *Comments*.

IV.2 Verify that all necessary documents are present and complete the form accordingly.

Note: If the lot release certificate is missing, do not use the vaccines; keep them on hold in cold storage until the relevant document has been obtained from the vaccine manufacturer.

PART V — Status of shipping indicators

Inspect the temperature monitors in all boxes before putting vaccines into cold storage. For very large shipments, or when immediate storage in the shipping boxes is required, check a representative number of boxes before placing the shipment in the cold store. Complete inspection of all boxes the next day, or as soon as possible thereafter; under *Comments*, note the date and time when the complete inspection took place.

Note: In this report, enter the information below (V.1) *only* for boxes in which the temperature monitor shows a change that indicates potential damage to vaccines (alarm indication in the electronic device, or cold-chain monitor card as per vaccine/threshold table in card).

V.1 Enter:
- a) the number of boxes inspected (this should equal the total number in the shipment);
- b) the type of coolant used;
- c) details of any temperature exposure detected.

V.2 Photocopy or scan LCD screens in electronic devices that show alarm status and attach to the report.

V.3 Clearly identify vaccines in boxes in which the indicator shows exposure to temperatures that risk damage and keep them in the cold room for further assessment of their condition. Do not discard vaccines until assessment is completed.

PART VI — General conditions of shipment

VI.1 Indicate if the shipping boxes were received in good condition and if all necessary labels on the outside of the shipping boxes were present; add any comments.

PART VII — Name and signature

VII.1 The authorized person responsible for the inspection and the Central Store Manager or the EPI Manager should sign this report.

VII.2 Send the form, completed and signed, to the procuring agency (UNICEF country office, Ministry of Health, or WHO country office) within three days of arrival of the vaccine.

Reporting ALARM details in international vaccine shipments

A special form has been designed for the purpose of reporting alarm details displayed in electronic devices. This form should ONLY be filled in if any alarms have occurred, and should be attached to the Vaccine Arrival Report (VAR). A clear photocopy and/or printed copy of the scanned image of the electronic devices displaying alarm status should be attached to this form.

ELECTRONIC DEVICE ALARM REPORT FORM

Country		Date of report	

Type of device: Q-tag 2 plus ☐ VaxAlert ☐

Type of vaccine	

Box no	Serial number	Time stopped	Elapsed transit time	>=45^{0}C 1 hour		>=30^{0}C 10 hrs		>=10^{0}C 20 hrs		<=-0.5^{0}C 1 hr	
				Time	^{o}C	Time	^{o}C	Time	^{o}C	Time	^{o}C

Use additional pages if necessary.

Guidelines for completing the Electronic Device Alarm Report Form

Country	Enter name of the country.
Date of report	Enter date of report.
Type of device	Mark the type of device by ticking the appropriate box.
Type of vaccine	Enter the type of vaccine, e.g. BCG, OPV, measles or DTP-HepB.
Box number	Write the number of the box (carton) that the electronic device was taken out of, e.g. 001, 002, … 099.
Serial number	Write down the serial number of the electronic device from the bar code/serial number, e.g. 10000001 for Q-tag 2 plus, and W15908000245 for VaxAlert. Note that the serial numbers of the devices can be found on the front surfaces of the Q-tag 2 plus and on the side of the VaxAlert devices.
Time stopped	Enter the local time you stopped this particular device in 00hrs:00min format.
Elapsed transit time	Enter elapsed transit time.
Time	Enter time displayed in HISTORY mode for each alarm. For the Q-tag 2 plus the trigger time of the alarm is displayed as 000 hrs. 00 mins., e.g. 62:40 or 067:32. For VaxAlert devices the day is elapsed alarm time is displayed as days, hours, minutes. For all VaxAlert devices enter the time as 00(day):00(hr.):00(min.), e.g. 01:12:15 would mean that the alarm was triggered 1 day 12 hours and 15 minutes following activation.
^{o}C	Enter minimum or maximum temperatures displayed for each alarm, e.g. 34.7^{o}C, 13.5^{o}C, or -4.5^{o}C.

If any of the alarms are repeated in the same electronic device, enter this information in a new row.

SIMULATION

You have received a DTP-HepB shipment accompanied by electronic devices. In box Number 5 the device displayed ALARM status. Different alarm situations will be given in the following pages with explanations on how to carry this information on to the reporting form.

Country	<enter name of the country>	Date of report	<enter date>

Type of device		
	Q-tag 2 plus	☐
	VaxAlert	☒

Type of vaccine	DTP-HepB

Box no	Serial number	Time stopped	Elapsed transit time	>=45^{0}C 1 hour		>=30^{0}C 10 hrs		>=10^{0}C 20 hrs		<=-0.5^{0}C 1 hr	
				Time	^{o}C	Time	^{o}C	Time	^{o}C	Time	^{o}C
5	W15908000245	15:35	03:20:11			01:03:48	38.1			00:01:06	-18.9