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					
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 ☐
Spytemp II OMS ☐
3M TX01/02 ☐

Type of vaccine	

Box no	**Serial number**	**Time stopped**	**Elapsed transit time**	**>=45°C 1 hour**		**>=30°C 10 hrs**		**>=10°C 20 hrs**		**<=-0.5°C 1 hr**	
				Time	**°C**	**Time**	**°C**	**Time**	**°C**	**Time**	**°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, S1-OMS1/ 1860 for Spytemp II OMS, and TX01-0000149 for 3M TX01/02. Note that the serial numbers of the devices can be found on the front surfaces of the Q-tag 2 plus and 3M TX01/02 devices, and on the reverse of the Spytemp II OMS attached to the backing card.
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 and Spytemp II OMS devices, the trigger time of the alarm is displayed as 000 hrs. 00 mins., e.g. 62:40 or 067:32. In 3M TX01/02 devices the day is separately displayed as 00 and time is given only in 00 hrs. and 00 mins. For all 3M 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.
°C	Enter minimum or maximum temperatures displayed for each alarm, e.g. 34.7°C, 13.5°C, or -4.5°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 ☒
Spytemp II OMS ☐
3M TX01/02 ☐

Type of vaccine	DTP-HepB

Box no	Serial number	Time stopped	Elapsed transit time	>=45°C 1 hour		>=30°C 10 hrs		>=10°C 20 hrs		<=-0.5°C 1 hr	
				Time	°C	Time	°C	Time	°C	Time	°C
5	10000001	15:35	86:27			067:32	34.7			011:20	-4.2

HISTORY mode displaying the time of alarm triggering.

HISTORY mode displaying the maximum temperature recorded during violation.

HISTORY mode displaying the time of alarm triggering.

HISTORY mode displaying the minimum temperature recorded during violation.

Example of completed reporting form with repeating alarms in the same device

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

Type of device	Q-tag 2 plus ☒ Spytemp II OMS ☐ VaxAlert ☐	**Type of vaccine**	DTP-HepB

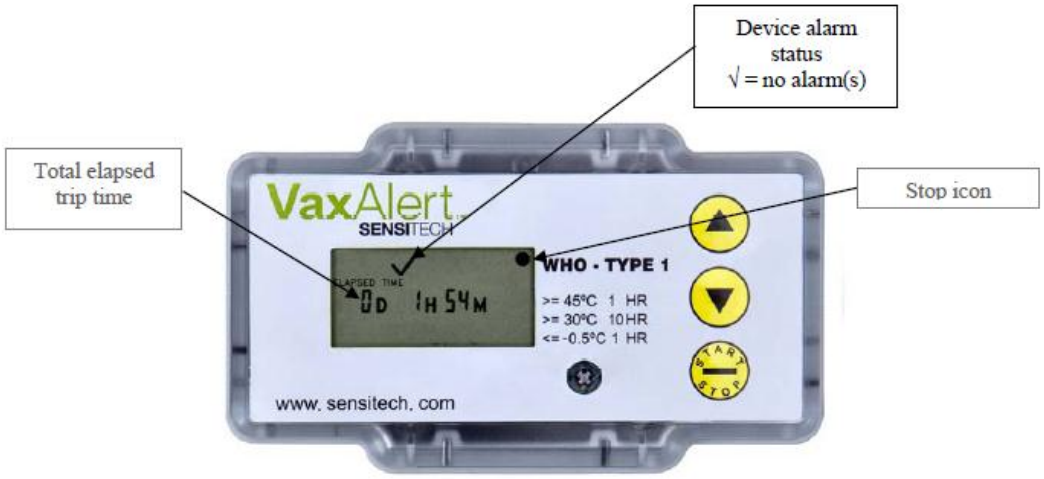
Box number	**Serial number**	**>=45^{0}C 1 hour**		**>=30^{0}C 10 hrs**		**>=10^{0}C 20 hrs**		**<=-0.5^{0}C 1 hr**	
		Time	**^{o}C**	**Time**	**^{o}C**	**Time**	**^{o}C**	**Time**	**^{o}C**
5	10000012			44:53	31.7			12:15	-3.0
								27:35	-4.7
7	10000019			17:44	32.5			13:15	-3.5

Step-by-step user guide for the VaxAlert™

Stopping the VaxAlert:

1. 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



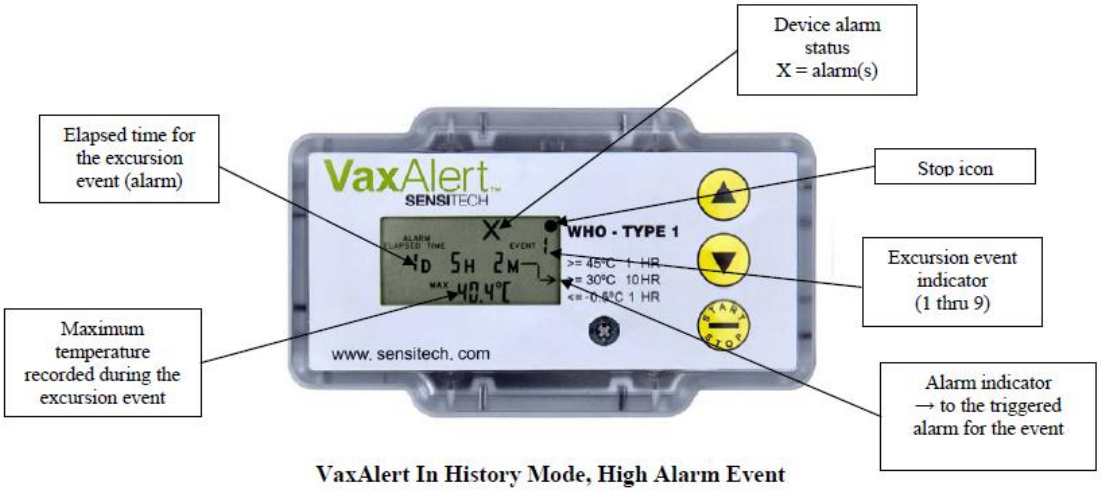
VaxAlert In Stop Mode Without Alarms

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.

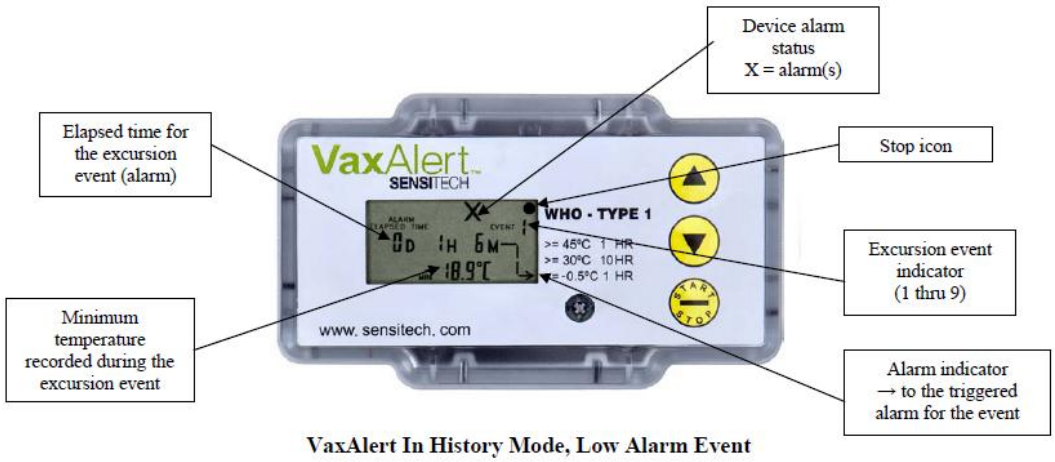
2. To view the alarm event history, press the ▲ or ▼ scroll buttons (in stop or measurement mode). The VaxAlert will emit an audible tone and display a history mode screen as shown below. Repeated presses of the ▲ or ▼ scroll buttons will cycle the alarm event history screens through all recorded alarm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



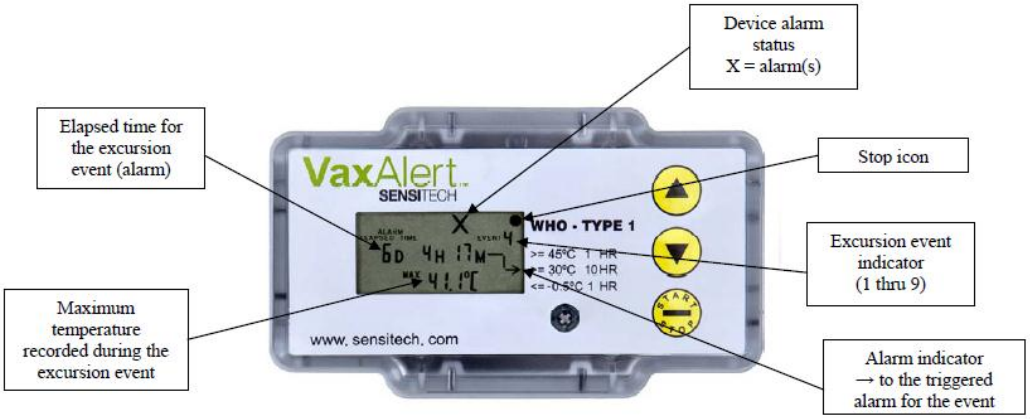
VaxAlert In History Mode, High Alarm Event

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



VaxAlert In History Mode, Low Alarm Event

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



VaxAlert In History Mode, High Alarm Event

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