PQS performance specification

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Contents

1. Scope

This specification describes the performance requirements for *electronic shipping indicators* to be used to monitor time-temperature exposure inside vaccine shipping containers during transport from the vaccine manufacturer'swarehouse to the receiving country's primary vaccine store.

2. Normative references

Use most recent version

EMAS: European Union Eco-Management and Audit Scheme.
EN 12830: 2018 Temperature recorders for the transport, storage and distribution of chilled, frozen, deep-frozen/quick-frozen food and ice cream. Tests, performance and suitability.
European Union Directive 2002/96/EC: Waste Electrical and Electronic Equipment.
IEC 60529: 2019 Consolidated Edition 2.1 (incl. am1): Degrees of protection provided by enclosures (IP Code).
ISO 14001: 2015 Environmental management systems - Requirements with guidance for use.
ISO 9001: 2015 Quality Management Systems – Requirements.
ISO/IEC 17025: 2017 General requirements for the competence of testing and calibration laboratories.
6th edition (2020) Guidelines on the international packaging and shipping of vaccines,

3. Terms and definitions

Data retention period: The period following the de-activation of the device usingthe 'stop' function during which it must be possible to recover the data recorded during the recording period.
EPROM: Electrically erasable, programmable, read-only memory.
In writing: means communication by letter, fax or email.
LCD: Liquid Crystal Display.
LED: Light-Emitting Diode.
Legal manufacturer: The natural or legal person with responsibility for the design, manufacture, packaging and labeling of a product or device before it isplaced on the market under their own name, regardless of whether these operations are carried out by that person himself or on their behalf by a third party.
Montreal Protocol: Montreal Protocol on Substances that Deplete the Ozone Layer.
NIST: United States National Institute of Standards and Technology.
Primary vaccine store: Store which receives vaccine directly from the vaccine manufacturer.
Receiver: The person or organization responsible for receiving the vaccine shipment.
Recording period: The period between the activation of the device using the'start' button or switch and the de-activation of the device using the 'stop' button or switch.
Reseller: A commercial entity, licensed to act on behalf of a legal manufacturer, and which carries product liability and warranty responsibilitiesno less onerous than those carried by the legal manufacturer.
Sender: The manufacturer responsible for packing and shipping the vaccine.
Shipping container: Insulated packaging used for shipping vaccines, as describedin the WHO document: *Guidelines on the international packaging and shipping of vaccines.* WHO/IVB/05.23.
Storage life: In relation to non-replaceable batteries is the period measured fromthe date of delivery of the device to the sender to the time at which the 'start' function is activated.

4. Requirements

4.1 General

Single use pre-programmed electronic time-temperature data logger with non-replaceable battery to accompany vaccine shipments from the vaccine manufacturer's warehouse to the receiving country's primary vaccine store. Thelogger must be able to display the shipment's time-temperature exposure withoutneed for downloading to a PC and without need for a separate reading device.

Devices that have an additional download function will be acceptable, but a download function is unnecessary, will not routinely be used, and does not formpart of this specification.

Devices under this specification are supplied in up to five versions/device variants:

- **Type D:** Programmed with alarm settings suitable for the international shipment of COVID-19 vaccine (Comirnaty) and Ebola vaccine (Ervebo). The devices could be

probeless or with probe.

- **Type C:** Programmed with alarm settings suitable for the international shipment of COVID-19 vaccine (Corbevax, AstraZeneca, Covishield, CoronaVac, and BIBP), DTP, DT, TT, Td, HepA, HepB, IPV, liquid Hib, influenza seasonal (liquid), JE (liquid), Meningococcal ACYW-135 (liquid), OCV, HPV, PCV (other than Prevenar), Rabies, RV (Liquid and other than Bharat liquid).
- **Type A/B:** Programmed with alarm settings suitable for the international shipment of BCG, COVID-19 vaccine (Janssen, Moderna), Ebola vaccine (Mvabea and Zabdeno), Hib (lyophilized), influenza seasonal (lyophilized), JE lyophilized, measles, MR, MMR, meningococcal A, meningococcal ACYW 135 (lyophilized), OPV, rabies (lyophilized), rotavirus (Bharat liquid and lyophilized – other than RotaTeq), rubella, varicella, and yellow fever vaccines.
- **Type Rotateq:** Rotateq only
- **Type Prevenar:** only for Prevenar 7 and 13 -valent conjugated vaccine

Type A/B, type C, type D devices with probes, type rotateq, and type Prevenar may be offered with a minimum 40-day recording period. Probeless type D may be offered with a minimum 20-day recording period.

It must be possible to photocopy the logger display as a permanent record of the shipment's arrival status. A legible copy must be produced using a photocopier, scanner or all-in-one printer.

4.2 Performance

4.2.1 Operating temperature range

Limits	Types A/B, C, Rotateq and Prevnar	Type D		
		Device		Probe temperature measurement range
		Probeless	With probe	
Upper limit	+55°C	+30°C	+30°C	+30°C
Lower limit	-30°C	-95°C	-30°C	-95°C

4.2.2 Accuracy

Accuracy	Types A/B, C, Rotateq and Prevnar	Type D	
		Probeless	With probe
Temperature	±0.5°C or better within the range of -5°C to +25°C ±1°C within the ranges -20°C to -5°C and +25°C to +55°C	±1.5°C or better within the range -95°C to -30°C ±1.0°C within the ranges -30°C to -5°C ±0.5°C or better	±1.0°C within the ranges -30°C to -5°C ±0.5°C or better within the range of -5°C to +30°C

		within the range of -5°C to +30°C	
Time	± 10 seconds per day or better	± 10 seconds per day or better	± 10 seconds per day or better

Probe sensor accuracy range ±1.5°C or better from -90°C to +30°C and ±2.0°C or better from -95°C to 0°C.

4.2.3 Resolution

- ±0.2°C or better within the range -20°C to +55°C for A/B, C, Rotateq and Prevnar types.
- ±0.5°C or better over full temperature measurement range for type D.

4.2.4 Power source

Non-replaceable battery.

4.2.5 Sensor

Electronic. The devices with sensor must have single sensor (external) and must be serialized as a single system (both the monitor and the probe).

4.2.6 Memory

EPROM or equivalent non-volatile solid-state memory device.

4.2.7 Product response time

For types A/B, C, type D devices with probe, Prevnar and Rotateq devices T90 10 minutes maximum in accordance with **EN12830**.

For probeless type D devices T90 20 minute maximum in accordance with **EN12830**.

4.2.8 Unit of measurement

Temperatures must be recorded and displayed in degrees Centigrade.

4.2.9 Calibration

Each product is to be covered by a Certificate of Traceability and Calibration. The traceability declaration is to confirm that the measurement standards and instruments used during calibration of the product are traceable to an **ISO/IEC17025** accredited testing laboratory, to NIST, or to another internationally recognized standards agency.

4.2.10 Logging interval

The device must measure the storage temperature at intervals not exceeding 10

minutes. As a minimum the device must log the first instance of a time-temperature-violation for each alarm type equaling or exceeding the threshold parameters set out in Clause 4.2.12. Devices that can log more than one instance of each type of time-temperature violation will not be excluded.

4.2.11 Logging start delay

60-minute start delay function after user activation to allow the device to equilibrate with the temperature inside the shipping container before it starts to record temperatures.

4.2.12 Alarm settings

The device must be pre-programmed with the following alarm settings:

- **Type D:**

Alarm type	***Time-temperature alarm threshold***	***Period of exposure***
High threshold	>= -60°C single event	1 hour
Low threshold	<= -90°C single event	1 hour

- **Type C:**

Alarm type	***Time-temperature alarm threshold***	***Period of exposure***
High threshold	>= 45°C single event	1 hour
Medium threshold	>= 30°C cumulative exposure	10 hours
Low threshold	<= -0.5°C single event	1 hour

- **Type A/B:**

Alarm type	***Time-temperature alarm threshold***	***Period of exposure***
High threshold	>= 45°C single event	1 hour
Medium threshold	>= 30°C cumulative exposure	10 hours
Low threshold	>= 10°C cumulative exposure	20 hours

- **Type rotateq:**

Alarm type	***Time-temperature alarm threshold***	***Period of exposure***
High threshold	>= 27°C single event	1 minute
Medium threshold	>= 17°C cumulative exposure	2 hours
Low threshold	<= -25°C 1 single event	1 minute

- **Type prevenar:**

Alarm type	***Time-temperature alarm threshold***	***Period of exposure***
High threshold	>= 40°C single event	1 hour
Medium threshold	>= 30°C cumulative exposure	10 hours
Low threshold	<= -0.5°C single event	1 hour

4.2.13 Casing

Non-corrodible plastics or metal case.

4.2.14 IP rating

Protection of the product not less than **IEC 60529**: IP64.

4.2.15 Battery

Non-replaceable battery capable of powering the device in accordance with the following criteria:

- Minimum storage life of 18 months before 'start' for A/B, C, Rotateq and Prevnar types, and 12 months for Type D.
- Minimum recording period: 40 days for A/B, C, D with probe, Rotateq and Prevnar types, and 20 days for Type D probeless.
- Minimum data retention period after 'stop': 6 months.

4.2.16 Electromagnetic compatibility

Operation of the device must be unaffected in the normal electromagnetic compatibility environment in which it is intended to work, taking into account disturbance generated by adjacent apparatus, which is compliant with relevant ISO, EN, or other internationally recognized standards. Information required to ensure uninterrupted use of the device must be contained in the user instructions. The device and its power source must conform to all relevant requirements issued by the International Air Transport Authority (IATA) and must not interfere with aircraft electrical or electronic systems[1]

4.3 Environmental requirements

4.3.1 Ambient temperature range during transport and storage

-30°C to +55°C with device inactivated for A/B, C, D (probeless and with probe), Rotateq and Prevnar types.

4.3.2 Ambient humidity range during transport, storage and use

0% to 95% RH.

4.3.3 Resistance to electrical storms

The functionality of the device must not be affected by intense electrical storm activity.

4.3.4 Impact resistance

Product to withstand 5 drops from 1 metre onto a concrete floor, with battery in place, without physical damage or loss of calibration.

[1] http://www.iata.org/whatwedo/cargo/dangerous_goods/Documents/Guidance-Document-on-the-Transport-of-Li-Batt-2012-V1.1.pdf

4.3.5 Vibration

Product to withstand 30 minutes on a programmable vibrating table without physical damage or loss of calibration.

4.4 Physical characteristics

4.4.1 Overall dimensions

Not critical provided volume of the device does not exceed 150 cubic centimeters when detached from shipment information card.

4.4.1 Weight

Not critical.

4.5 Interface requirements

4.5.1 Software compatibility

For devices with additional download function):

- If the software requires an interface with a proprietary spreadsheet program,the list of compatible programs must include all releases of Microsoft Excelcurrently supported by Microsoft.
- The software must be compatible with all Microsoft PC operating systemscurrently supported by Microsoft.

4.6 Human factors

4.6.1 Activation

The device is to be activated by the sender at the beginning of the recording period by means of a ‘start’ button or switch mounted on the unit.

4.6.2 De-activation

The device is to be de-activated by the receiver at the end of the recording period by means of a ‘stop’ button or switch mounted on the unit. If the 'stop' button or switch is not de-activated, the device should automatically default to the de-activated state at the end of the 40 day (20 days in probeless type D) recording period, as applicable. The 'stop' button or switch should be designed to prevent inadvertent de- activation - for example by contact with a shifting load.

4.6.3 User interface

The device is to have an LCD display screen, with or without LEDs, capable of showing the following information:

- Activation status.

- Post activation battery status, or clearly marked expiry date in the formatmm/yyyy.
- Overall alarm status: whether or not an alarm condition of any kind hasoccurred since the device was activated.
- Time-temperature alarm status: the status of each of the three time-temperature alarm thresholds specified in Clause 4.2.12 at the time when the‘stop’ button is activated.
- Total elapsed transport time in days and hours or in hours measured fromdevice activation to device de-activation.
- Shipment history: A history of the shipment capable of showing details of atleast one time-temperature limit violation for each alarm type including the first time-temperature-violation of each alarm type.
- The LCD must either show all this information together on a single display screen or the user must be able to access the information on sequential screens by means of a button mounted on the product. In the latter case, the overall status of the indicator (‘OK’, or ‘Alarm’) must be permanently displayed on every screen. Flashing displays are not acceptable because theycannot be photocopied.
- The display must be capable of being photocopied or transferred wirelessly to a smartphone or computer in order to provide a hardcopy or softcopy record of the status of the device upon arrival. For devices in which data cannot be wirelessly transferred to a phone or computer, the display must not incorporate any flashing or blinking symbols or lights.
- Alarm symbols must not be language-dependent and must be easily understood by untrained users. Acceptable symbols include, but are notconfined to, the following:
- Tick’ or ‘OK’ symbol for shipments where no temperature violation hasoccurred, as graphic below:

or

‘Cross’ or ‘Crossed OK’ symbol for shipments where any type of temperature violation has occurred, as graphic below:

or

- As a battery saving measure, the display may switch off automatically when not required, provided it can be activated by the user by means of a push button.

4.6.2 Type identification

All devices are to be clearly identified by type in a manner which avoids the risk that the wrong type of device will be packed by the sender.

Acceptable identification includes, but is not confined to, the following information:

- Printed identification of the type, including indication of minimum recording period (40-day for A/B, C, Rotateq and Prevnar types, and 20 day for probeless type D).
- Different colored casings.

4.6.4 Shipment information card

Mount the device on a moisture resistant backing card, using moisture resistantadhesive. The card material must accept indelible markings in ball point pen.

The width of the card must be at least the same as the length of the device, subject to a minimum width of 7.5cm. The length of the card must not exceed 14cm. The card design must follow the generic format and colours set out in **Annex 1** (yellow for Type C and Prevenar®, blue for Type A/B and Rotateq®, and green for Type D). User instructions are to be available either in English, French or Spanish language, as requested by the customer. Text is to be in a high legibility font – minimum 8 point, colour black.

4.7 Materials

4.7.1 Ozone depleting chemicals

During manufacture and assembly of the printed circuit boards and final assembly of the product do not use any substance included in **Annex A, B** or **C** of the Montreal Protocol.

4.7.2 Other restricted materials

The product and its constituent components, including batteries, must notcontain lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls (PBB) or polybrominated biphenyl ethers (PBDE).

4.8 Warranty

The product is to be covered by a warranty covering the designed lifetime of the device in the event of any component failure not caused by mechanical damage.

4.9 Servicing provision

The product is to be maintenance-free.

4.10 Disposal and recycling

The manufacturer is to provide information to the buyer on the hazardous materials contained within the system and suggestions for resource recovery/recycling and/or environmentally safe disposal. For the European Union WEEE compliance in accordance with European Union Directive **2002/96/EC** is mandatory.

4.11 Instructions

User instructions in Arabic, English, French, Mandarin Chinese, Russian and Spanish. Where relevant the software manual may be in hard copy format or supplied with the software on CD.

4.12 Training

No requirement.

4.13 Verification

In accordance with PQS Verification Protocol **E006/TR06-VP.2**

5. Packaging

Materials used for packaging the finished product are to be free of ozone-depleting compounds as defined in the Montreal Protocol.

6. On-site installation

Not applicable.

7. Product dossier

The legal manufacturer or reseller is to provide WHO with a prequalification dossier containing the following:

- Dossier examination fee in US dollars.
- General information about the legal manufacturer, including name and address.
- Unique identification reference for the product.
- Full specifications of the product being offered, covering all the requirements set out in this document, including details of product marking and traceability and documentary evidence of claimed battery life.

- Certified photocopy of Certificate of Traceability and Calibration traceable to an **ISO/IEC 17025** accredited testing laboratory, to NIST, or to another internationally recognized standards agency.
- Certified photocopies of all type-approvals obtained for the product, including CE marking and the like.
- Certified photocopies of the legal manufacturer's **ISO 9001** quality system certification.
- Where relevant, certified photocopies of the legal manufacturer's **ISO 14001** certification, EMAS registration or registration with an equivalent environmental audit scheme. Conformity with an environmental audit scheme is not mandatory; however preference will be given to manufacturers who are able to demonstrate compliance with good environmental practice.
- Where available, laboratory test report(s) proving conformity with the product specifications.
- One sample of the product, complete with data connection lead and software, where offered.
- Indicative cost of the product per unit, per 10 units and per 100 units EXW (Incoterms 2000).

8. On-site maintenance

Not applicable.

9. Change notification

The legal manufacturer or reseller is required to advise WHO in writing of any changes which adversely affect the performance of the product after PQS prequalification has taken place.

10. Defect reporting

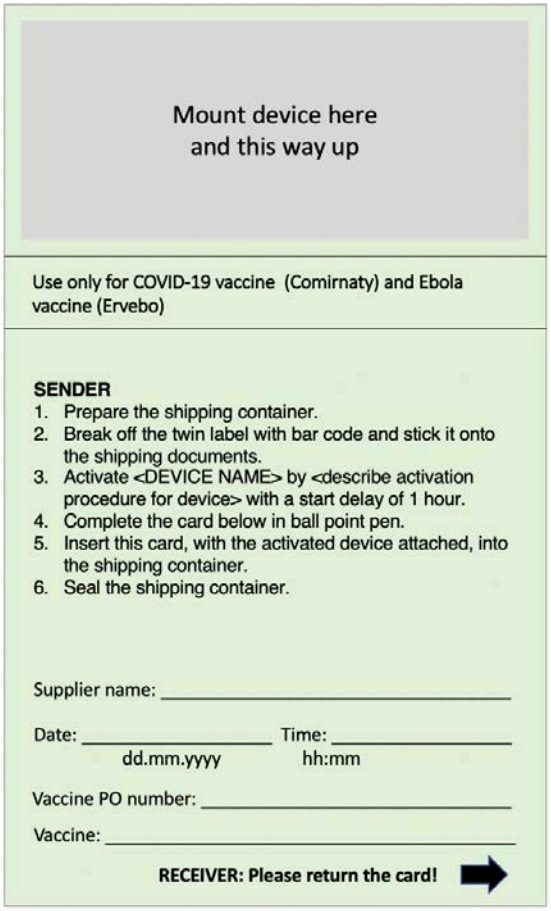
The legal manufacturer or reseller is required to advise WHO and the UN purchasing agencies in writing in the event of safety-related product recalls, component defects and other similar events.

Annex 1 – Shipment information card

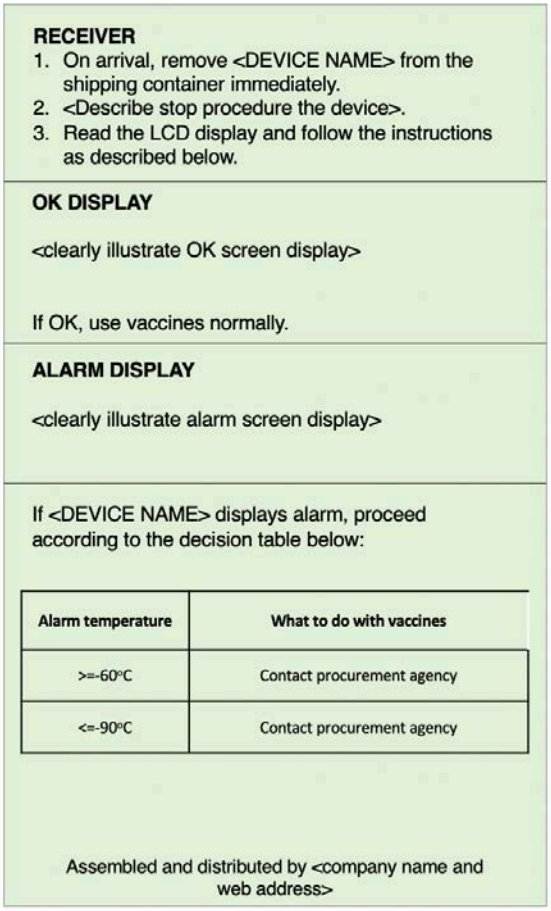
Notes:

1. Card colour is to match the colours shown here: Pantone 100 ‘light yellow’ for Type C; Pantone 279 ‘UN blue’ for Type A/B; and Pantone 621 C for Type D.
2. English, French and Spanish language versions are shown. With the exception of text in <arrow brackets>, manufacturers must use the exact wording shown in this annex.
3. The text enclosed in <arrow brackets> must be replaced with the appropriate product-specific name or description. Manufacturers are responsible for the correct translation of these passages.

TYPE D (ENGLISH)

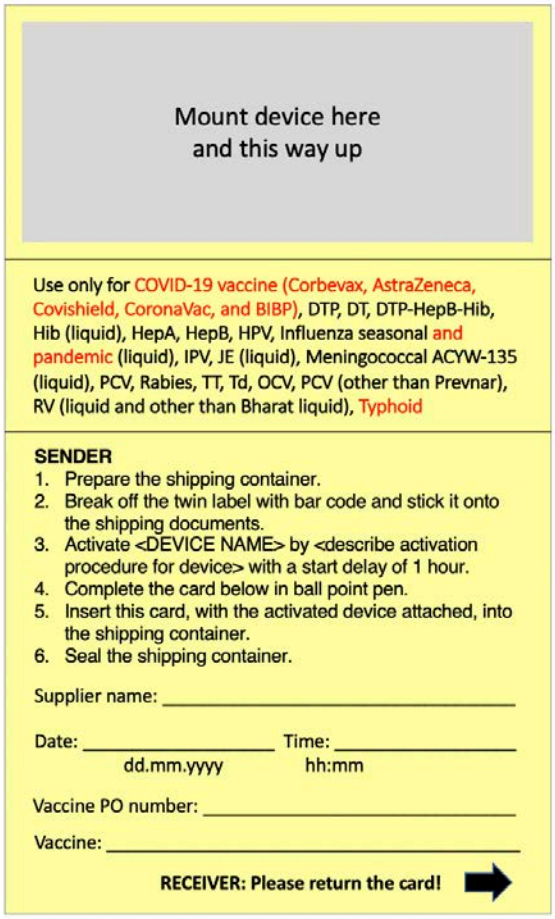


Front face

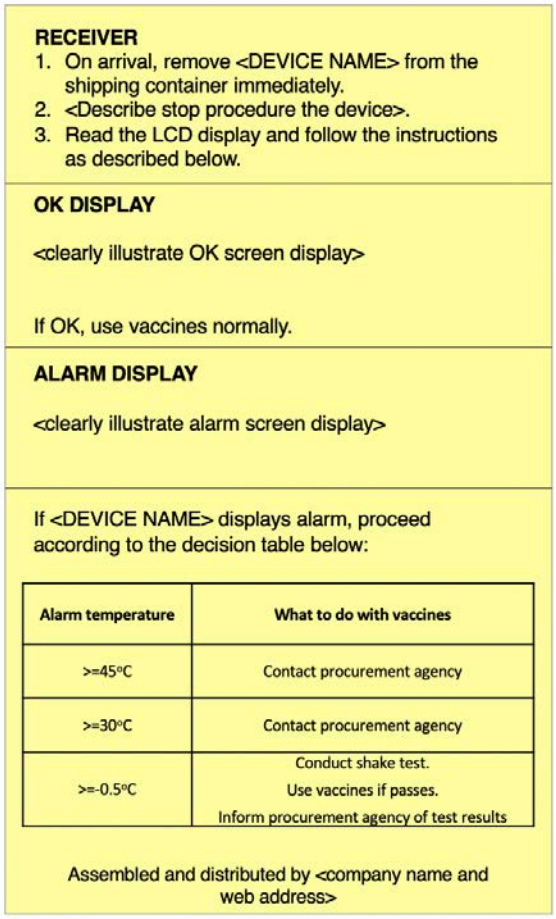


Back face

TYPE C (ENGLISH)

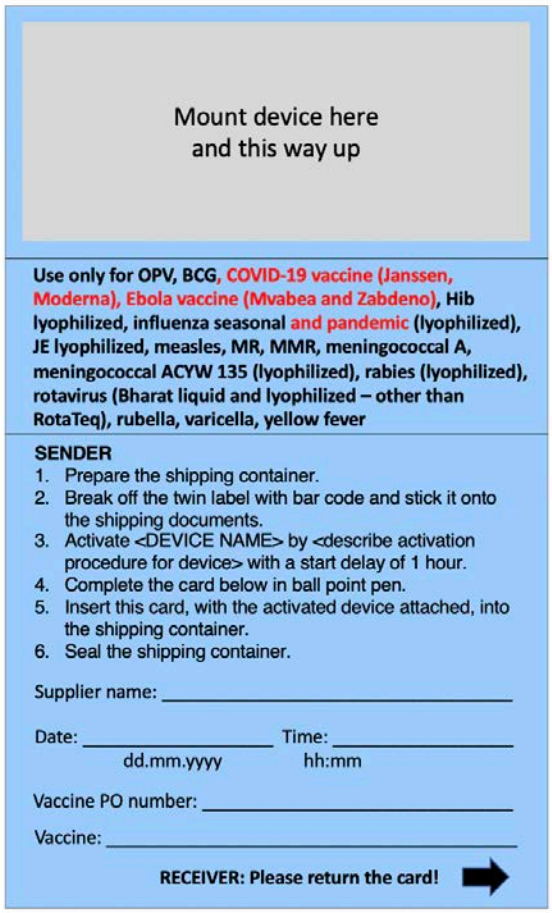


Front face

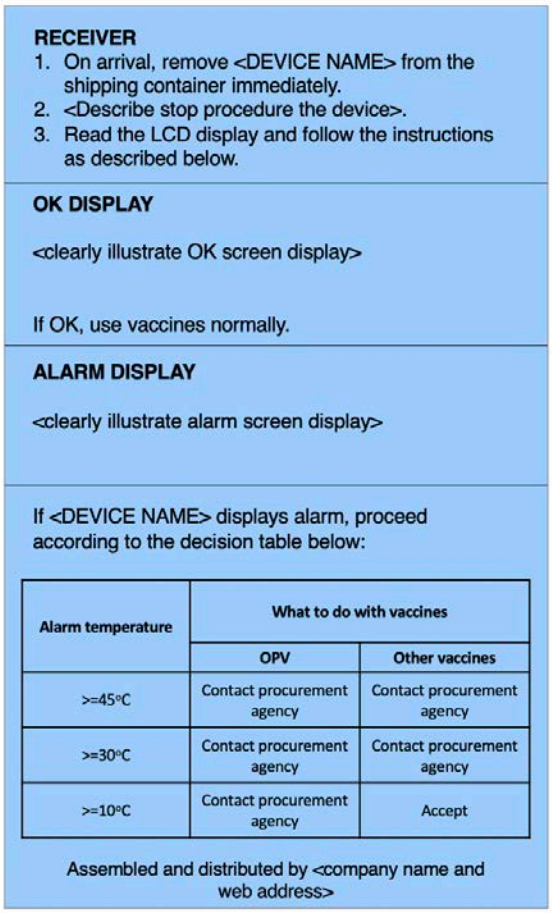


Back face

TYPE A/B (ENGLISH)



Front face



Back face

TYPE PREVENAR (ENGLISH)

Mount device here
and this way up

Use only for Prevnar®

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 ball point pen.
5. Insert this card, with the activated device attached, into the shipping container.
6. Seal the shipping container.

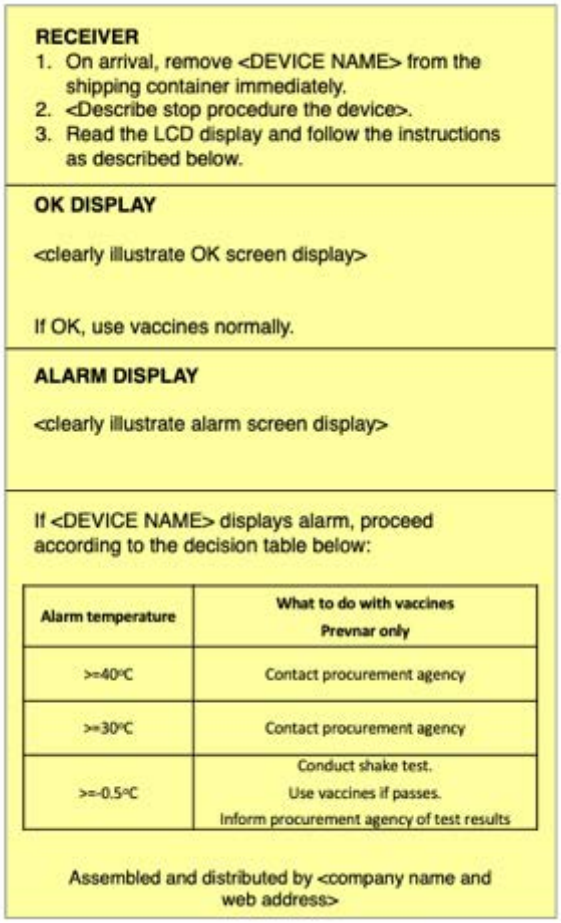
Supplier name: _____

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

Vaccine PO number: _____

Vaccine: _____

RECEIVER: Please return the card!



RECEIVER

1. On arrival, remove <DEVICE NAME> from the shipping container immediately.
2. <Describe stop procedure the 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 alarm, proceed according to the decision table below:

Alarm temperature	What to do with vaccines Prevnar only
>=40°C	Contact procurement agency
>=30°C	Contact procurement agency
>=-0.5°C	Conduct shake test. Use vaccines if passes. Inform procurement agency of test results

Assembled and distributed by <company name and web address>

TYPE ROTATEQ (ENGLISH)

Mount device here
and this way up

Use only for RotaTeq®

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 ball point pen.
5. Insert this card, with the activated device attached, into the shipping container.
6. Seal the shipping container.

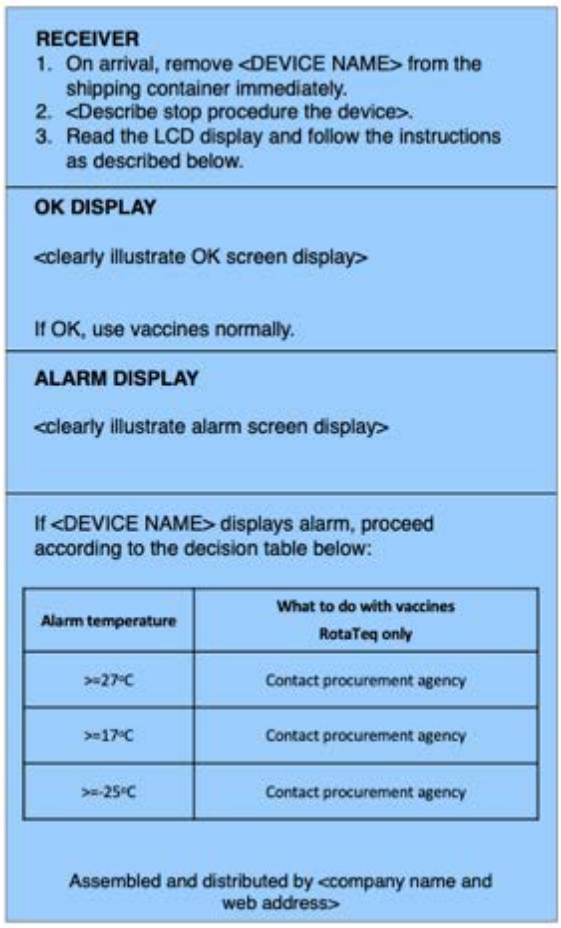
Supplier name: _____

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

Vaccine PO number: _____

Vaccine: _____

RECEIVER: Please return the card!



RECEIVER

1. On arrival, remove <DEVICE NAME> from the shipping container immediately.
2. <Describe stop procedure the 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 alarm, proceed according to the decision table below:

Alarm temperature	What to do with vaccines RotaTeq only
>=27°C	Contact procurement agency
>=17°C	Contact procurement agency
>=-25°C	Contact procurement agency

Assembled and distributed by <company name and web address>

FRENCH and SPANISH versions of all cards to be included here

Revision history			
Date	Change summary	Reason for change	Approved
12 Jul 2006	4.1: type descriptions. 4.2.2: temperature. 4.2.8: minor change. 4.2.12: type descriptions. 4.2.16 added. 4.6.3: minor changes and addition. 4.6.4: minor change. 4.6.5: re-drafted with card illustration in Annex 1. New clause 4.7.2. 4.7.3 and 4.7.4 deleted. 5: 'CFC' changed to 'ozone-depleting'.	In response to final review comments. EU RoHS Directive material restrictions incorporated.	Yes (UK)
29 Nov 2006	Annex 1: Notes added. French and Spanish versions added. "What to do" section on the back face of the shipment information card changed to "contact procurement agency"	Initial information was to contact only UNICEF, whereas other procurement agencies may also be using the same device.	Yes (30 November 2006, UK - PQS secretariat)
01 Dec 2006	Annex 1 French and Spanish versions added	French and Spanish language versions added	Yes (01 December 2006 - UK PQS secretariat)
05 Dec 2006	"Assembled and distributed by [company name and web address]" information is added to backing cards.	Add missing information on assembly and distribution to backing cards.	Yes (05 December 2006 - UK PQS secretariat)
17.09.2012	2: Dated references note added. 4.1: List of vaccines extended for Type 1 and Type 2. 20 day recording period option added. 4.2.15 : 20 day recording period option added. 4.2.16 : IATA requirements statement added. 4.6.2: 20 day recording period option added. 4.6.4: Product identification amended to include recording period. Annex 1: Pantone colour codes added. List of vaccines extended for Type 1 and Type 2	General update. New vaccines introduced since original issue.	
16/11/2012	5.4.5 Test 5: Threshold accuracy test Shipment information cards	Correction accuracy Update of the cards	DM
16/10/2014	Shipment information cards	Updated with JE vaccines	DM
24/06/2020	Shipping indicator	renaming from Type 1 & Type 2 to type C & Type A/B	IG
8/06/2021	Shipping indicator	Correction of errors in naming	IG
Enter date	4.1. General - Type D is added. New vaccines are added to type A/B and type C. 4.2.1. Operating temperature range - type D information is added 4.2.2. Accuracy – type D is added 4.2.3. Resolution – type D is added	New type device for ultra-low temperature COVID-19 and Ebola vaccine (Ervebo) New COVID-19 vaccines	IG

	4.2.12. Alarm settings – type D is added 4.2.15. Battery – Type D information is added 4.3.1. Ambient temperature range during transport and storage – Type D information is added Annex 1. Shipment information card – Type D is added, revisions are done on Types A/B and C.		