

Introduction of Fridge-tag[®]

Improving temperature monitoring in refrigerators



Guidelines on preparations for introduction and programme adjustments required

Background

To ensure the optimal potency of vaccines, careful attention is needed in handling practices at the country level. These include storage and transport of vaccines from the primary vaccine store down to the end-user at the health facility, and further down at the outreach sites. WHO recommends that all vaccines should be stored at between +2°C and +8°C at all immunization points in the periphery (health centres, health houses, hospitals, and clinics). Liquid formulations of vaccines containing diphtheria, pertussis, tetanus, hepatitis B, *Haemophilus influenzae* type b, IPV and their combinations should not be frozen [1-3].

Practices exposing vaccines to both high and sub-zero temperatures are widespread in both developed and developing countries at all levels of health systems [4-15]. The most recent systematic literature review of vaccine freezing highlights that accidental freezing is wide spread and occurs across all segments of the cold chain [16]. In this review between 14% and 35% of refrigerators or transport shipments were found to have exposed vaccine to freezing temperatures.

Temperature monitoring in the vaccine cold chain is critical in ensuring that vaccines are kept under optimal cold chain conditions. General practice for temperature monitoring in vaccine refrigerators at the periphery is to use a thermometer (stem thermometer or bi-metal thermometer). A thermometer, however, only provides a snapshot of the temperature at the point in time when it is checked, and cannot be considered as an "appropriate" monitoring tool¹. When checked and a temperature value of between +2°C and +8°C is found, health workers may erroneously conclude that the vaccines are safe since this snapshot reading only provides a value when it is checked and by no means covers the rest of the day/night period. Unless a temperature excursion is seen at the time the temperature is checked with a regular thermometer, almost all temperature violations go unnoticed.

To improve temperature monitoring at the periphery, the Performance, Quality and Safety (PQS)² project in Immunization, Vaccines and Biologicals Department has approached temperature monitoring device manufacturers to develop a temperature monitoring device with the following features:

- Capacity to store the last 30-day temperature recordings that can be checked through a history mode and read through an LCD display (not downloadable)
- Preset alarms for high (above +8°C over 10 hours continuously) and low (-0.5°C and lower for 1 hour continuously) temperature exposures
- Display the highest and lowest temperatures reached as well as their duration compared to preset alarms through the history mode - for details of the performance specifications of the device see WHO/PQS/E06/TR06.1 [17].

Fridge-tag[®] was the first model prequalified by the WHO - prequalified on 30 September 2007 and revalidated on 5 May 2009 [18].

Compared to the regular thermometers, the Fridge-tag[®] has the following advantages:

- Uninterrupted temperature monitoring in the refrigerator
- Data retention for the last 30 days
- Easy handling, no software or computer needed to analyze the data

¹ Merriem-Webster Dictionary defines "monitoring" as "to watch, keep track of, or check usually for a special purpose" which includes continuity and/or regularity within its concept.

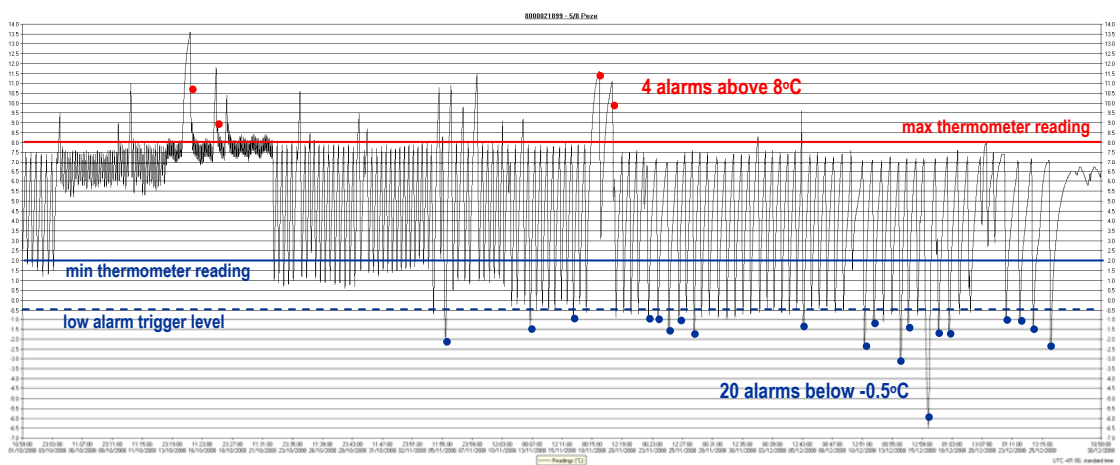
² PQS is a prequalification system of devices and equipment used in immunization services in WHO, that establishes design, performance specifications and verification protocols for devices/equipment.

- Pre-set alarms to warn health workers if there are any violations
- Detailed information on violations (minimum and maximum temperatures reached and the duration of violation in hours and minutes)

Through Fridge-tag[®] health workers have real control of temperatures in refrigerators and can take informed decisions if there are any alarms. For details of the Fridge-tag[®] features, please see Annex I.

In a field study conducted in 2008, health centres with thermometers were found to miss almost all cold chain violations above +8°C and below -0.5°C. The below graphic illustration displays a three-month temperature data logger recordings as well as manual recording of thermometer readings.

Figure 1. Comparison of thermometer and electronic data logger readings



In this health centre, no violations were caught up by the thermometer whereas if Fridge-tag[®] was used, four alarms above +8°C and 20 alarms below -0.5°C were going to be recognized [19].

Is Fridge-tag[®] expensive?

The Fridge-tag[®] costs approximately USD 20 a piece with a two years of shelf life following maximum of one year in storage before activation. Comparing its price with a thermometer without taking into account the level of information it provides is simply not correct. In the above example (Figure 1), the thermometer was unable to spot any of the violations. If a freeze-indicator was used in the refrigerator, you would need a total of 20 freeze-indicators for a 3-month period to spot the problems which would cost you around USD 90. However, freeze-indicators would only warn you with the negative temperature alarms but not with the violations above +8°C. In this example, thermometer would fail to warn you on any of the alarms - in this sense it really does not matter how cheap are the thermometers, because they do not provide necessary information for your health workers to take informed decisions.

Therefore, it is always worth to invest USD 20 for a temperature monitoring device in every two years for invaluable vaccines you keep in your refrigerator.

Is Fridge-tag[®] a supervisory tool?

The Fridge-tag[®] is primarily designed to help health workers to have full control of temperature monitoring in refrigerators including night, weekends and holidays. It gives necessary information to health workers to take informed decisions to correct the problem. It holds the recorded information for the last 30 days. Although the primary objective of the device is not for supervision, through the 30-day retained data feature, it can be used during supervisory visits to discuss cold chain violations, corrective measures to be taken to expand and enhance the capacities of health workers using them.

Can Fridge-tag[®] be used in cold rooms?

The Fridge-tag[®] is primarily designed for refrigerators. Although it can be used in cold rooms, WHO recommends other temperature monitoring systems for the cold rooms. The best option for cold rooms are the programmable electronic temperature monitoring and event logger systems. At minimum, wall mounted pen recording thermometers should be used. In both options, temperatures can be viewed at any time and data is continuously recorded both for documentation and future reference purposes.

What are the impacts of Fridge-tag[®] introduction on immunization programme?

The following areas should be considered carefully for a successful introduction of this new technology. It should be noted that procuring this device and distributing it will not solve any problem. New technologies may be good but without careful planning, they will not work.

Finance: The Fridge-tag[®] costs approximately USD 20 that is good for a 2-year period. This means in every two years, all devices should be replaced. The life of the device is guaranteed if storage prior to activation is not more than one year following production. It is advised that within 18 months of first introduction of Fridge-tag[®], a new batch to replace the functioning ones should be ordered. This will give you approximately six months of storage time. Immediate replacement should be for the devices giving "Low Battery" alarm. This order for replacement of devices should be repeated in every two years. Necessary budget lines should be established not to run short of devices.

Storage: Once arrived, all devices should be kept at room temperature in a dry storage area. This storage area should not be exposed to direct sunlight. It should be noted that very low and very high temperatures during storage will reduce the shelf life of the battery. Devices usually are shipped by manufacturer within a week of production, and the production date is indicated on the reverse side of the device. This production date should be taken into account in arranging stocks not to exceed one year of storage time from the production date.

Training: Effective use of Fridge-tag[®] requires an initial training that would not last more than half a day. This learning session could also be used as to distribute the devices. It should be noted that without this initial training, no devices should be distributed to any health centre. In order to increase effective learning, it is also advised that in one training session, number of participants should be kept below 25. This would give chance for each participant to ask questions for clarification, and facilitators to spend more time with participants. It also allows one-on-one interaction with some hands-on practices with some preset devices. WHO has developed a video on the Fridge-tag[®]. This video contains

illustrated information on how to set up the device and how to use the history function. It is strongly recommended that this video is used during the training session. If requested WHO will provide a master video on miniDV for dubbing in the local language. English version of the video can be downloaded from the following WHO link (209MB Quicktime movie file):



http://terrance.who.int/mediacentre/videos/ivb/FridgeTag_SON.mov

The video can be watched as streaming video from the following link:

http://video.who.int/streaming/FridgeTag_SON.wmv

How to activate and read the Fridge-tag[®] is given in Annex II.

This session should also be used to introduce a new temperature monitoring chart. Annex III provides a detailed learning session plan for 25 participants. As indicated in the Annex III, all necessary handouts and preset devices should be prepared beforehand for a successful session. If necessary, an additional session on how to

conduct shake test should be added (Annex VII).

Temperature monitoring chart: The existing temperature monitoring charts will not be enough to record data derived from the Fridge-tag[®]. It is important that with the introduction of Fridge-tag[®] the temperature monitoring charts should be changed. All staff including supervisors should be trained on the use of this new temperature monitoring chart. Enough copies of the chart should be printed prior to the training, and should be distributed to all during the training session. Suggested temperature monitoring chart is given in Annex IV.

Corrective measures to be taken when there is an alarm: Clearly defined steps should be made available to all staff in response to alarms by the Fridge-tag[®]. These steps should include what needs to be done when there is alarm, firstly to understand the root cause of the problem, then to introduce the corrective actions. Annex V provides list of "what to do"s in such situations. These should be included in the training programme, and preferably be also made available as job aids to be hang on the wall or on the door of the refrigerator.

Where is the best place for Fridge-tag[®] in the refrigerator?

First of all, once you introduce Fridge-tag[®] to the refrigerator, remove the old thermometer. It will only bring confusion.

The best location for Fridge-tag[®] in the refrigerator is the shelf that you keep your freeze-sensitive vaccines such as HepB or combination vaccines.

Should all the devices be activated at the central level and then distributed to staff?

As explained above, Fridge-tag[®] should not be distributed to any of the health workers without a training session on how to use the device and fill in the new temperature monitoring chart as well as explaining what to do when there is an alarm. Since staff have to gather for a training session, this could be used as an opportunity for them to activate their own devices. However, you should keep in mind that, from the moment of activation until the time the Fridge-tag[®] will be placed in the refrigerator, it will be exposed to ambient to ambient temperature and will record this. If this period exceeds the preset alarm time periods, such as

10 hours over +8°C, the device will show an alarm. Such alarms should be ignored both by the staff and the supervisors.

Do health workers need to read the history every day?

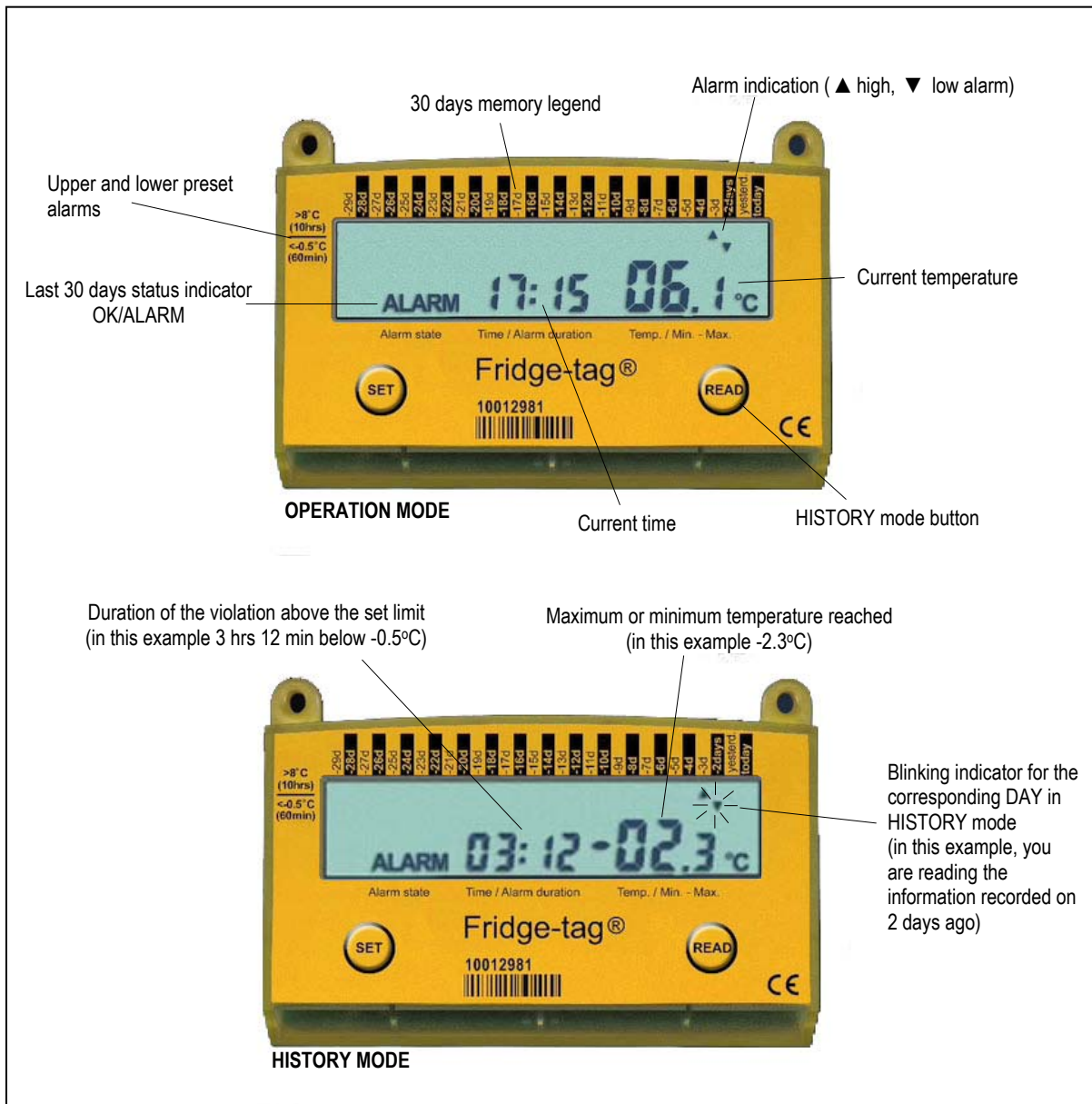
Yes. If a health worker only reads the current temperature and not the history, all other features of the Fridge-tag® will not be used. It is not correct to read the history function say once every week or in every 10 days. History has to be read every day. If there are any alarms and history is not read every day, when a health worker discovers a serious alarm in the weekly reading of history, it might be too late to act. In addition such cases would pose great risk of damaged vaccine being utilized. In all cases, Fridge-tag® history should be read every day, so health workers see the problems on time and can take informed decisions to correct them. For details of when and how to read the history see Annex IV.

What happens if there are device failures?

As in any electronic device, there could be some failures with the Fridge-tag® as well. However, the rate of such events are extremely rare. The following conditions are considered as failures. In such cases, devices should be sent back to the manufacturer (Berlinger & Co. AG). See Annex VI for "Fridge-tag® Quality Assurance, Quality Feedback Form" and instructions how to send back the devices.

When?	Description of the problem
During activation process <i>(Please note that if the device was in storage for more than one year following its production, the warranty is reduced and expected shelf life of the device is less than 2 years)</i>	LCD display remains blank despite three consecutive tries of activation
	Time and temperature cannot be adjusted correctly
During normal operation	LCD display failure
	No reaction to button pressing
	LOW BATT indication before 22 months of operation after maximum one year of storage

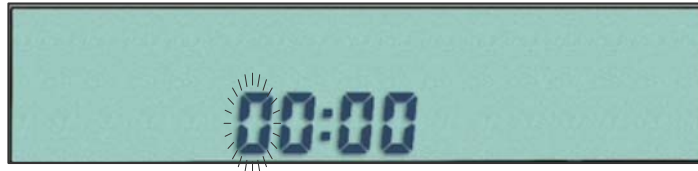
Annex I - Fridge-tag[®] functions



Annex II - How to activate and read the Fridge-tag®

How to activate the device

You receive the device in “**sleep mode**”. The LCD screen is blank. To activate the device press the **SET** and the **READ** buttons simultaneously for more than 2 seconds. Four zeros will appear on the screen. The first zero will flash.



Setting the time

Use the **READ** button to adjust the time. Each time you press the **READ** button, the number in the flashing digit will increase by 1. For example, if you want to set the time to 12:42 you have to perform the following steps:

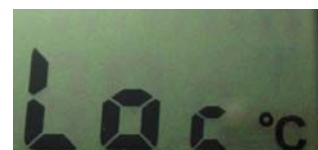
1. The first digit is flashing: Press **READ** once. “1” will appear as the first digit. Press **SET** to save.
2. The second digit will start flashing. Press **READ** two times, when “2” appears as the second digit press **SET** to save.
3. The third digit will start flashing. Press **READ** four times to set the digit as "4". Press **SET** to save.
4. The last digit will start flashing. Press **READ** two times to obtain “2”. Press **SET** to save.



If during this operation, you press **READ** more then you were supposed to, continue pressing the **READ** button until you obtain the desired number, then press **SET** button to save your settings.

Setting the temperature measurement unit

When you finish setting the time, the "°C" sign will appear and blink at the right bottom corner. If you would like to record and read temperatures in Celsius, press **SET**. This will complete your activation. The device starts recording. If you want to record in Fahrenheit, press **READ** once and the "°F" sign will appear. The display will now indicate the word **Loc** for 10 minutes for the Fridge-tag® not to record temperature for false readings. This allows for adaption to the changing environmental temperature when the device is placed in the refrigerator (within 10 minutes) before normal recordings starts. Place your device in the refrigerator now.



After 10 minutes of final activation, Loc will disappear and the following image with the "OK" sign and "current temperature reading" will appear on the screen.



Changing the time setting

If you made a mistake or wish to change the time setting, it can be readjusted. The number of possible time adjustments during a day is unlimited. But after any time adjustment and the next midnight date shift, the adjustment mode is locked for 24 hours following the midnight date shift. This is for security reasons. Thus, a new setting is possible only after the 2nd date shift again.

To adjust the time after the device is activated, you need to press and hold the **SET** button and then press the **READ** button shortly. Then you need to repeat the steps as described in "Setting the time". Additional time adjustments have no effect on the recording. Once the device is activated, it cannot be stopped. Adjustments can only be made for time setting and for changing the temperature measurement unit.

Violations

The Fridge-tag® has two temperature/time limits, a high and a low alarm. When a temperature/time violation occurs, the **OK** sign on the screen will be replaced by the **ALARM** sign. The low alarm appears if the device is exposed to temperatures lower than -0.5°C for 60 consecutive minutes in one go. The high alarm is set at more than +8°C for more than 10 hours. The high alarm appears if the device is exposed to temperatures above 8 degree Celsius for more than 10 consecutive hours in one go.

If the continuous exposure is less than the time limit, an alarm will NOT be triggered. For example, if the device is exposed to temperatures over +8°C for 9 hours, then the temperature returns to an acceptable range for 2 hours and then the temperature rises above +8°C for another 9 hours, this will NOT trigger an alarm since the time required for a high alarm has not been reached in one go. However, the cumulative exposure can always be seen in the history mode even when there has not been an alarm.

Days, recordings and screen display

On the top part of the device, you will see indication of 30-day display in columns. Whatever is recorded during the day the device is activated is shifted to **yesterday** column at midnight. Similarly, at midnight of the second day, first recordings will be shifted to **minus 2 day** while second day's recordings will be shifted to yesterday. Nonstop, this operation continues. On day 31, the very first day's recordings disappear both from the memory and the screen. Therefore after the first 30 days you will always see the last 30 days' recordings on the screen.



High alarm indicator in TODAY's column at 23:59



High alarm indicator moves to YESTERDAY's column at 00:00 (midnight)

If any violations occur, these will be marked with a up pointing arrow for high alarm, down pointing arrow for low alarm under the day column they occur. In the below example we see two high alarms occurred during yesterday, minus 2 days as well as a low alarm on the minus 5 days.



How to read the details of each day's recordings

For an effective temperature monitoring, Fridge-tag® should be checked at least twice a day, morning and afternoon. You must do this when you come to work in the morning and before you leave in the evening. First you should look at the current temperature displayed. You should record this on the new temperature monitoring chart. In this example, the temperature should be recorded as +4.1°C.



How to read the history

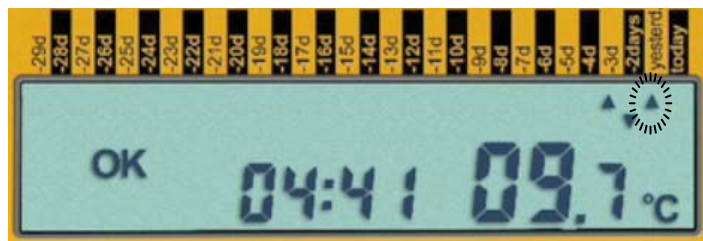
Pressing **READ** once displays the highest temperature reached and the cumulative time duration in hours and minutes that the temperature was above the given upper limit for the current day that is **today**. In this example the highest temperature reached during today is +6.1°C. Time shows 00:00 because the highest temperature reached today is lower than the upper alarm that is +8°C. During this operation a high arrow flash indicates the high temperature setting and the day it corresponds to. Since there is no alarm in this information, an **OK** indicator also appears on the screen.



If you press **READ** button once more, a low arrow flash indicates the low temperature setting and it displays the lowest temperature recorded during that day and the time period. In this example, lowest temperature recorded is +4.7°C. Since it is not lower than the set limit that is -0.5°C, time display will show 00:00 hours and minutes along with an **OK** sign.



When we press the **READ** button once more, the high arrow indicator under yesterday column will start flashing.



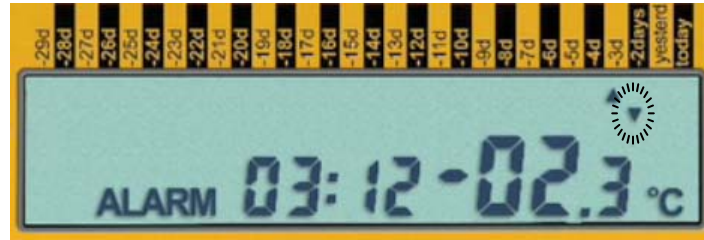
Yesterday, the highest temperature recorded was +9.7°C. Even this is higher than the set +8°C alarm condition, this is OK since the exposure was not longer than 4 hours and 41 minutes. It requires 10 hours continuously to trigger this alarm.



Yesterday, the lowest temperature recorded was +3.7°C, and this is indicated as okay.



Two days ago, the highest temperature was recorded as +6.4°C which is also okay.



Two days ago, there was a low alarm. The refrigerator was exposed to temperatures below -0.5°C for more than 60 minutes. Details can be read from the screen. The lowest temperature recorded was -2.3°C and the exposure below -0.5°C was for 3 hours 12 minutes.

Reading time of day's recordings differ from day to day. If you are in a work week, say Thursday, since you have read the device Wednesday late afternoon before you left the health centre, you need to read today's and yesterday's information. In today's information you see what has happened since the midnight. In yesterday's information you see what has happened until midnight. But if you are back in the centre on a Monday morning, you have to read today's, yesterday's, minus 2 days' and minus 3 days' information to see what has happened during the weekend since you left the centre on Friday late afternoon. This is illustrated in the below Table.

Tuesday			
Wednesday	◀	<i>In yesterday's information you see what has happened until midnight</i>	Thursday morning readings
Thursday	◀	<i>In today's information you see what has happened since midnight</i>	
Friday	◀	<i>In -3d information you will see what has happened until midnight on Friday</i>	Monday morning readings
Saturday	◀	<i>In -2days information you see what has happened on Saturday</i>	
Sunday	◀	<i>In yesterday's information you see what has happened on Sunday</i>	
Monday	◀	<i>In today's information you see what has happened since midnight</i>	
Tuesday			

During **read out** mode, the device stops recording temperatures in order to avoid incorrect data. During this operation, if you do not press the **READ** button for more than 30 seconds, the device locks itself automatically and the word **Loc** appears on the screen. Alternatively you can press **SET** button to cancel the **read out** mode (**Loc** function starts). This feature helps the device to condition to the refrigerator environment and not to record elevated temperatures reached during read out mode while holding the device in hand. Loc function disappears within 10 minutes. It is critical that following reading the device, you must place the device back in the refrigerator.

Please refer to Fridge-tag[®] temperature monitoring recording chart on how to record the readings (Annex X).

Important notes on Fridge-tag®

Read out mode

In order to avoid incorrect data, the Fridge-tag® does not collect any readings while in the read-out mode. However, if you do not press the **READ** button for more than 30 seconds, the device start recording data. Do not keep the device unnecessarily long outside the refrigerator.

Time adjustment

The number of possible time adjustments during a day is unlimited. But after any adjustment and the next midnight date shift the adjustment mode is blocked for 24hrs. This is for security reasons. Thus, a new setting is possible only after the 2nd date shift again.

Liability

The manufacturer shall not be held liable:

- a. If the device was used beyond the manufacturer's given limitations.
- b. For any claims due to the improper storage and use of the device.
- c. For any problems with the cooling unit.
- d. For the bad quality of the monitored goods, if any.
- e. For incorrect readings if the device was used with activated low battery sign for more than one month.

Battery

The Fridge-tag® does contain a CR Lithium battery, therefore please:

- a. Dispose or recycle the battery in accordance to your local regulations.
- b. Do not expose the device to extreme temperatures as it may lead to the destruction of the battery and may cause injuries.
- c. Keep out of reach of children.
- d. The end of the battery life is indicated by a LOW BATT sign. Make sure to replace the device within 30 days when the low battery sign appears.

Useful life

The operational life time of the unit is approximately 2 years after activation on the condition that:

- a. The device was not stored for over 1 year prior to activation.
- b. The read out mode is not excessively used i.e. several times a day.
- c. Storing & operating of the device remains inside the recommendations of the manufacturer, especially very low temperatures shall be avoided.

Annex III - Detailed session plan for training

NOTES FOR THE FACILITATORS

Reading Fridge-tag[®] requires some skills, therefore it is critical that this new device is not distributed without an initial hands-on training of staff who would use it.

In order to have good interaction between facilitators and participants and to respond all queries on site to make sure that all has learned the basic required skills, the number of participants should not exceed 25. For such a group preferably there should be minimum of two facilitators.

The session is arranged for half a day and includes video presentation as well as hands-on practices and question/answer session.

The physical space of the room should be big enough (approximately 100 m²), and there should not be any columns in the middle that would prevent anybody's vision.

The room can be arranged either in U-shaped or in small work-station style to accommodate 3-4 participants in one table.

Required materials

- Laptop and desktop computer
- Multimedia projector
- WHO Fridge-tag video file (in computer or in CD/DVD preferably in the language of training)
- White screen (for video and PowerPoint presentation)
- 2 flip charts
- 25 flip chart papers
- Cut-tip permanent markers in various colors (Black, Blue, Green, Red)
- 30 notepads
- 30 pens/pencils
- 10 Fridge-tag[®] devices activated and with some alarms (for hands-on practices)³
- Copies of the Fridge-tag[®] recording sheet (preferably 2 copies for each participant)
- Copies of the Fridge-tag[®] recording sheet for 12 months (12 pages per participant)
- Matching number of new Fridge-tag[®] devices for distribution to participants.
- Provisions for tea/coffee and snacks

Session objectives

At the end of this session, participants will be able to:

1. list the advantages of the Fridge-tag[®] devices in temperature monitoring
2. successfully activate the Fridge-tag[®] device
3. read correctly all functions of the Fridge-tag[®] device
4. explain what to do in the case of an alarm
5. record Fridge-tag[®] readings in the new recording form.

³ You have to activate these devices at least one week before the training. Place the devices in refrigerator for a couple of days, then move it to ambient temperature for less than 10 hours, move it to freezer compartment of the refrigerator for more than 1 hour (for alarm to appear), then leave it in ambient long enough (at least 10 hours) for high alarm to appear. Make sure that the device has both several high and low alarms for learning purposes.

Detailed timing

Activity	Name of the facilitator	Duration (minutes)	Time
Welcome, opening remarks		5	09:00 - 09:05
Introductory presentation - Why we are introducing Fridge-tag [®]		10	09:05 – 09:15
How does the Fridge-tag [®] work WHO video and hands-on practices		60	09:15 – 10:15
Coffee break		30	10:15 – 10:45
Recoding readings from the Fridge-tag [®] to new recording sheet		60	10:45 – 11:45
Activating Fridge-tag [®]		15	11:45 – 12:00
Question/Answer		30	12:00 – 12:30

Welcome and opening remarks (5 minutes)

One of the facilitators, or a senior staff from the national immunization programme welcomes the participants, makes a few opening remarks explaining the reason for this gathering and work modalities, flow of the half-day. Everybody should take turns introducing themselves briefly, by name and job position. This all and all should not take more than 5 minutes.

Introductory presentation - Why we are introducing Fridge-tag[®] (10 minutes)

One of the facilitators gives a presentation on explaining the main reasons for introducing the Fridge-tag[®] device. In this presentation, the facilitator should underline the following aspects:

- That "monitoring" is a continuous process which is not the case with thermometers
- In order to act promptly, health workers need to be equipped with tools providing necessary information so they can take informed decisions.
- Comparison of thermometer and Fridge-tag[®] (To demonstrate what is missed with thermometers, Albania study results can be used for this purpose)
- Features of the Fridge-tag[®] (as shown in Annex I)
- That the introduction of the Fridge-tag[®] will have impact on temperature recording sheets.

It is critical that the Fridge-tag[®] is not introduced as a supervisory tool. The facilitator should stress that this device is mainly for the health workers who manage vaccines in the field. Its supervisory feature should be explained that this would facilitate one-on-one discussions with health workers during the supervisory visit which facilitates better learning.

The facilitator could choose to use PowerPoint presentation (Annex IV) or use flipchart.

How does the Fridge-tag[®] work: WHO video and hands-on practices (60 minutes)

Before starting this session, make sure you have 10 Fridge-tag[®] devices already activated and with several alarms. Also set up the computer and multimedia projector to show the WHO video.

The facilitator explains the participants that they will now watch a training video, and following the video, they will have chance to work in groups with devices.

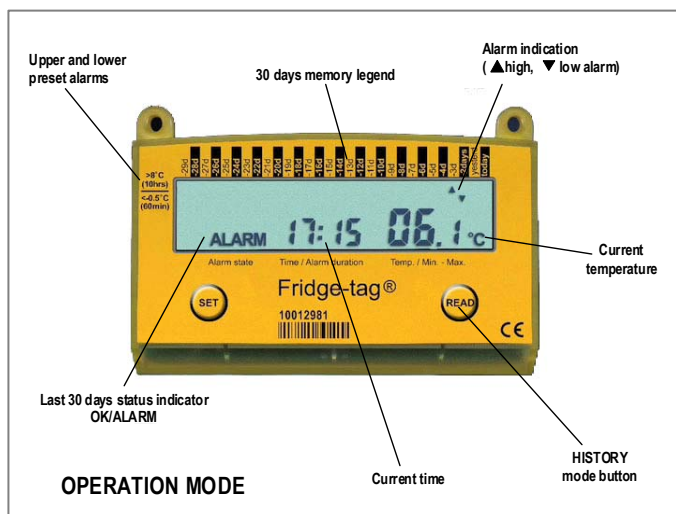
The video takes 14 minutes including the beginning and end credits.

The facilitator should split participants into groups of 3-4. If you have 25 participants, you should have 8 groups (7 groups of 3 participants and 1 group of 4 participants).

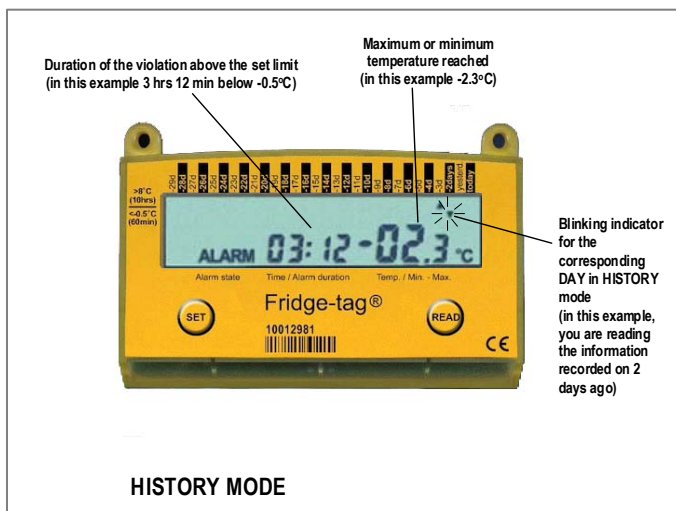
Distribute the activated Fridge-tag[®] devices with alarms to groups, and ask them to study the features of the device. First you can show the following slide (PowerPoint) to explain the features (file name Fridge-tag_features.ppt):

SLIDE 1 (cover slide)

SLIDE 2



SLIDE 3



Ask participants to work in groups to read the history of the distributed devices. Both facilitators should visit the groups to see all participants take turns to work with the device

and read the history correctly. Once the groups are done, switch the devices... Through this, everybody will have chance to work with 8 different devices.

Recoding readings from the Fridge-tag® to new recording sheet (60 minutes)

One of the facilitators present the new recording form and explains the reasons for such a change that current temperature monitoring charts are not enough to record all information gathered from the Fridge-tag® devices.

The ready PowerPoint presentation could be used for this purpose. This PowerPoint presentation is arranged in a way that the presenter should enter local data prior to the training in slide number 2. Animation of the text is fixed, settings should not be changed.

SLIDE #2 (Facilitator should change the BLUE ITALIC text to local context)

Fridge-tag® recording sheet											
District	<i>Name</i>			Health Facility	<i>Name</i>			Refrigerator No.	<i>number</i>		
Month/Year	<i>Month / Year</i>										
Equipment	<i>Name</i>										
Day	AM	PM	▲ °C	Alarm/OK	Duration	Initials	▼ °C	Alarm/OK	Duration	Initials	
1											
2											
3											
4											
5											
6											
7											
8											
9											
10											

All other slides are arranged with extensive animation to follow the reading and carrying these over to the recording form. Do not change any animation settings. It is strongly recommended that the facilitators should go over this presentation several times to familiarize themselves with the content as well as the animation.

Following the presentation, facilitator distributes 2 blank recording sheet to each participant and asks them to read the information from the devices they have and record the findings. Both facilitators should visit groups to check their performance and assist if necessary.

Day	AM	PM	▲ °C	Alarm/OK	Duration	Initials	▼ °C	Alarm/OK	Duration	Initials
1	4.3	5.7	<i>This reading belongs to Friday 1 October 2010</i>							
2			<i>This is Saturday and Sunday, this is why there are no readings recorded here</i>							
3										
4	5.2	6.1								
5										
6										
7										
8										
9										
10										

Activating Fridge-tag® (15 minutes)

Distribute Fridge-tag® devices to all participants and following the instructions provided in Annex II, activate all devices.

Once activated all participants should write the activation date on the sticker on the reverse side of the device.

Remind all participants that until they reach their facility, the device will be exposed to temperatures above 8 deg C, and in some cases could give an alarm depending on the exposure time. In all cases, they should also note the day and time they placed the Fridge-tag® in their refrigerators and should ignore the readings before this time.

Question/Answer (30 minutes)

Allow 30 minutes of period for participants to ask questions. Make sure that you answered all their questions.

Before all participants leave the place make sure that all of them receive at least 12 blank copies of the monthly Fridge-tag® recording sheet. Remind all participants that the dates 1, 2, 3 on this form are the calendar days, therefore if they start recording on 12 September, they should start from the line 12 and leave the previous ones blank.

Annex IV - Temperature monitoring chart for Fridge-tag®

The information you gather from a Fridge-tag® is different than a regular thermometer. Because of this, common temperature monitoring charts/graphs are not sufficient to record the data derived from the Fridge-tag®. It is required that the following temperature monitoring chart should be introduced along with the Fridge-tag® introduction.

All staff should be trained on how to fill in the information. It is important that the main difference between thermometer and Fridge-tag® is clearly explained in terms of recording the data. Although staff is encouraged to check temperatures morning and late afternoon twice a day with the Fridge-tag®, recording of the high and low temperatures reached to the chart is not instant. The below table illustrates what needs to be done for each time temperature is checked:

Morning (when you arrive to the facility)

1. Read the current temperature and record the value under AM column.
2. Check UNDER **today** whether there are any ▲ or ▼ signs. If there are no signs, this means since midnight there was no violation. If there is a sign, this means there was an alarm.
3. In all cases, start pressing the READ button. If there was an alarm today, read what was the highest and lowest temperature reached and the duration to understand the alarm.
4. Read the history mode for yesterday. Record the highest temperature under ▲ °C column, and recorder the status (Alarm/OK), duration of the exposure and put your initials.
5. If this is Monday morning, continue reading the information for Saturday (-2 days) and Friday (-3d) and enter this information to the monitoring chart to appropriate row.
6. Return the device back to the refrigerator
7. If there are any alarms, follow the defined procedures to address the issue (see Annex V).

Afternoon (before you leave the facility)

1. Read the current temperature and record the value under PM column.
2. Check UNDER **today** whether there are any ▲ or ▼ signs. If there are no signs, this means since midnight there was no violation. If there is a sign, this means there was an alarm.
3. If there was no alarm today, return the device to the refrigerator.
4. If there was an alarm today, press the READ button, read what was the highest and lowest temperature reached and the duration to understand the alarm.
5. Return the device back to the refrigerator.
6. If there are any alarms, follow the defined procedures to address the issue (see Annex V).

Fridge-tag[®] recording sheet

District		Health Facility		Refrigerator No.						
Month/Year										
Equipment										
Day	AM	PM	▲ °C	Alarm/OK	Duration	Initials	▼ °C	Alarm/OK	Duration	Initials
1										
2										
3										
4										
5										
6										
7										
8										
9										
10										
11										
12										
13										
14										
15										
16										
17										
18										
19										
20										
21										
22										
23										
24										
25										
26										
27										
28										
29										
30										
31										
Notes:										

Fridge-tag[®] recording sheet

District		Health Facility		Refrigerator No.						
Month/Year										
Equipment										
Day	AM	PM	▲ °C	Alarm/OK	Duration	Initials	▼ °C	Alarm/OK	Duration	Initials
1										
2										
3										
4										
5										
...										
28										
29										
30										
31										
Notes:										

How to fill in the recording sheet

District	Enter the name of the district
Health Centre	Enter the name of the health facility
Refrigerator No.	Enter the ID number of the refrigerator
Month/Year	Enter the month (full name, no numbers) and year (four digits)
Equipment	Write down the model and make of the refrigerator (including PIS/PQS code if exists)
AM	Enter the current temperature reading in the morning
PM	Enter the current temperature reading in the afternoon
▲ °C	Enter corresponding temperature reading from the HISTORY function
Alarm/OK	Indicate whether the reading is an ALARM or OK status
Duration	Enter corresponding time duration for the temperature reading in HH:MM format, such as 02:45
▼ °C	Enter corresponding temperature reading from the HISTORY function
Initials	Initials of the person who does the reading and enter data on this sheet, such as U.K.
Notes	Any action taken for ALARM status. Indicate date and explain the action.

Annex V - What to do in the case of alarms

In the case of alarms, the following points should be checked and corrective actions should be introduced.

HIGH ALARM (over 8 deg C for more than 10 hours continuous)

This alarm could only appear in the case of quite long electricity cuts or when the door of the refrigerator is left open. It may also occur with wrong thermostat settings. In principle, thermostat should be arranged in a way to obtain min 5 deg during the coldest time of the day (in the morning, when you arrive to the facility). WHO does not recommend manipulation of the thermostat and recommends all thermostats to be sealed.

1. Check the cable and make sure that the refrigerator is plugged
2. Check whether there is electricity
3. Check the door of the refrigerator, make sure it closes fully.

LOW ALARM (below -0.5 deg C for more than 1 hour continuous)

This alarm could appear in the case of wrong thermostat setting as well as when the ambient temperature is quite low (especially during the nights). In all cases you should conduct shake test for all freeze-sensitive vaccines in your refrigerator.

You should follow shake test guidelines published by the WHO (see Annex VII).

Fridge-tag Quality Assurance

Annex V

Quality Feedback Form



Vers. 1.3 / 05.03.2010

Author: Claude Hafner

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For any non-functioning Fridge-Tag, please mark the type of failure in the appropriate boxes. If the box is next to "**Return device**" please send the Fridge-tag with this completed form to the manufacturer. You will get a replacement if the device failed before the end of its guaranteed lifetime.

Address: Q-tag AG, Mitteldorfstr. 2, 9608 Ganterschwil, Switzerland.

Country office and contact _____

Fridge-tag Serial Number (8 digits) _____

Date of production (see device back) _____

Date of activation _____

Investigation path

In case of problems please examine your Fridge-tag according to the question paths below. Complete one of the two sections, depending if the device failed to activate at start up, or problems observed during its operation (before 2 years of operation and 3 years from production date as indicated on device back). Tick each box as per your findings and state any additional comments on the back of this form.

	Yes	No	Comment
Problems during activation process			
Device on stock since more than one year?	<input type="checkbox"/>	<input type="checkbox"/>	
Sufficient education and/or manual read education	<input type="checkbox"/>	<input type="checkbox"/>	if no: need for
More than 3 trials of activation completed?	<input type="checkbox"/>	<input type="checkbox"/>	if no: try again
Display blank?	<input type="checkbox"/>	<input type="checkbox"/>	if yes: Return device
Can time / temperature correctly be adjusted?	<input type="checkbox"/>	<input type="checkbox"/>	if no: Return device
Problems during operation			
Display failure?	<input type="checkbox"/>	<input type="checkbox"/>	before end of regular lifetime if yes: Return device
No reaction on button pressing?	<input type="checkbox"/>	<input type="checkbox"/>	if yes: Return device
LOW BATT indication before end of regular lifetime?	<input type="checkbox"/>	<input type="checkbox"/>	if yes: Return device , otherwise replace

You will help us to further optimize the high quality of this product. Thank you very much for your kind assistance.

Technical Director
Q-tag AG

How to do the "shake test"

The **shake test learning guide** provides the steps of accepted, standard and correct way of performing a shake test, evaluating the results and suggests on the correct action for different outcomes. It is a decision making tool to decide whether one suspected vaccine vial is damaged by freezing.

This learning guide is designed to be used during the demonstration and coaching sessions of a training program. The trainee (in this case health staff) is also encouraged to use it while practicing by her/himself.

Using the learning guide during demonstration

Teaching of a new skill should start with demonstration. A demonstration is basically showing how a skill is performed.

The study coordinator must first of all, make sure that s/he performs the skill precisely as outlined in the learning guide. All the steps are there for a reason, and none should be skipped or modified. The study coordinator must be proficient in performing the shake test. This issue cannot be overemphasized.

A demonstration should be as close to the real thing as possible. Therefore, having real vaccine vials (frozen for control, frozen for test, non-frozen for test) during the training is advised.

The study coordinator distributes the learning guides to health workers prior to demonstration and goes through each step making sure all is clear about the instructions. The study coordinator answers questions about the learning guide.

The next step is to show how to do the shake test. Following the proper demonstration guidelines, the study coordinator demonstrates the shake test by actually doing it. At this point, the participants should be following the study coordinator and their learning guides at the same time. They are free to ask questions at all times during demonstration and coaching.

Using the learning guide during coaching

Coaching is a one-to-one activity between a study coordinator and a health staff on learning to perform a specific skill. During this activity, the health staff performs the shake test, and the study coordinator watches the health staff to provide encouragement, support and feed-back. The health staff uses the learning guide during this session. The study coordinator should emphasize the importance of performing the shake test exactly as it is written on the learning guide.

Using the learning guide during self-practice

A health staff is encouraged to use the learning guide during self-practice. A partner may help the health staff, providing him/her with specific feed-back based on the steps of the learning guide. Self practice with or without a partner is a highly desirable situation which allows the health staff to pace his/her own learning experience, which in turn reduces the anxiety associated with learning a new skill, thus actually facilitating learning.

Using the learning guide during final assessment

This learning guide can be used to assess whether the health staff is in fact, competent to perform a shake test. Using the same tool for assessment and for learning, reduces performance anxiety on behalf of the health staff.

The structure of the learning guide

Performance assessment scale; The scale is used to mark whether each step is performed to a satisfactory level. We expect to see no "1"s to declare the health staff as "competent to perform the shake test" in the final assessment.

"Practice No." columns; Each numbered column indicates one practice session of the health staff. When practicing with a partner, the partner would write the appropriate number from the assessment scale to each cell in that column. It is assumed that three practices would be sufficient to learn to perform the shake test. If the health staff feels s/he should practice more, s/he should be provided with more blank learning guides.

Shake test learning guide

Name of health staff: _____

Performance assessment scale:			
1. Insufficient: Health staff performs the shake test incorrectly, or not in the right order or skips it altogether. 2. Competent: Health staff performs the shake test correctly and in the right order but either misses some points or needs to be reminded and encouraged by the study coordinator. 3. Proficient: Health staff performs the shake test correctly, in the right order, and without hesitating.			
NOTE: The test procedure described below should be repeated with each suspect batch. In the case of international arrivals, the shake test should be conducted on a random sample of vaccine. However, if there is more than one lot in the shipment, the random sample must include a vial taken from each and every lot.	Practice no.		
	1	2	3
1. Take a vial of vaccine of the same type and batch number as the vaccine you want to test, and made by the same manufacturer.			
2. Clearly write “FROZEN” on the label with a permanent marker. This is your control vial.			
3. Freeze the vial at -20°C overnight, until the contents are completely solid.			
4. Let it thaw. Do not heat it!			
5. Take a “ Test ” vial from the batch that you suspect has been frozen.			
6. Hold the “ Frozen ” vial and the “ Test ” vial together in one hand.			
7. Shake both vials vigorously for 10–15 seconds.			
8. Place both vials on a flat surface side-by-side and start continuous observation of the vials until the test is finished. Note: If the vials have large labels which conceal the vial contents, turn both vials upside down and observe sedimentation in the neck of the vial.			
9. Use an adequate source of light to compare the sedimentation rates between vials.			
Then:			
10. If sedimentation in the “ Test ” vial is <i>slower</i> than in the “ Frozen ” vial, <i>the vaccine has not been damaged.</i>	10. If sedimentation is <i>similar</i> in both vials, or If sedimentation in the “ Test ” vial is <i>faster</i> than in the “ Frozen ” vial <i>the vaccine has been damaged.</i>		
11. Use the vaccine batch – it is not damaged.	11. Discard all affected vaccine – it is damaged.		
	12. Notify your supervisor.		
	13. Fill in the <i>Loss/Adjustment Form</i> .		

The figure below displays the difference between frozen control and (non-frozen) test vial.

Seeing the difference in sedimentation rates during a shake test

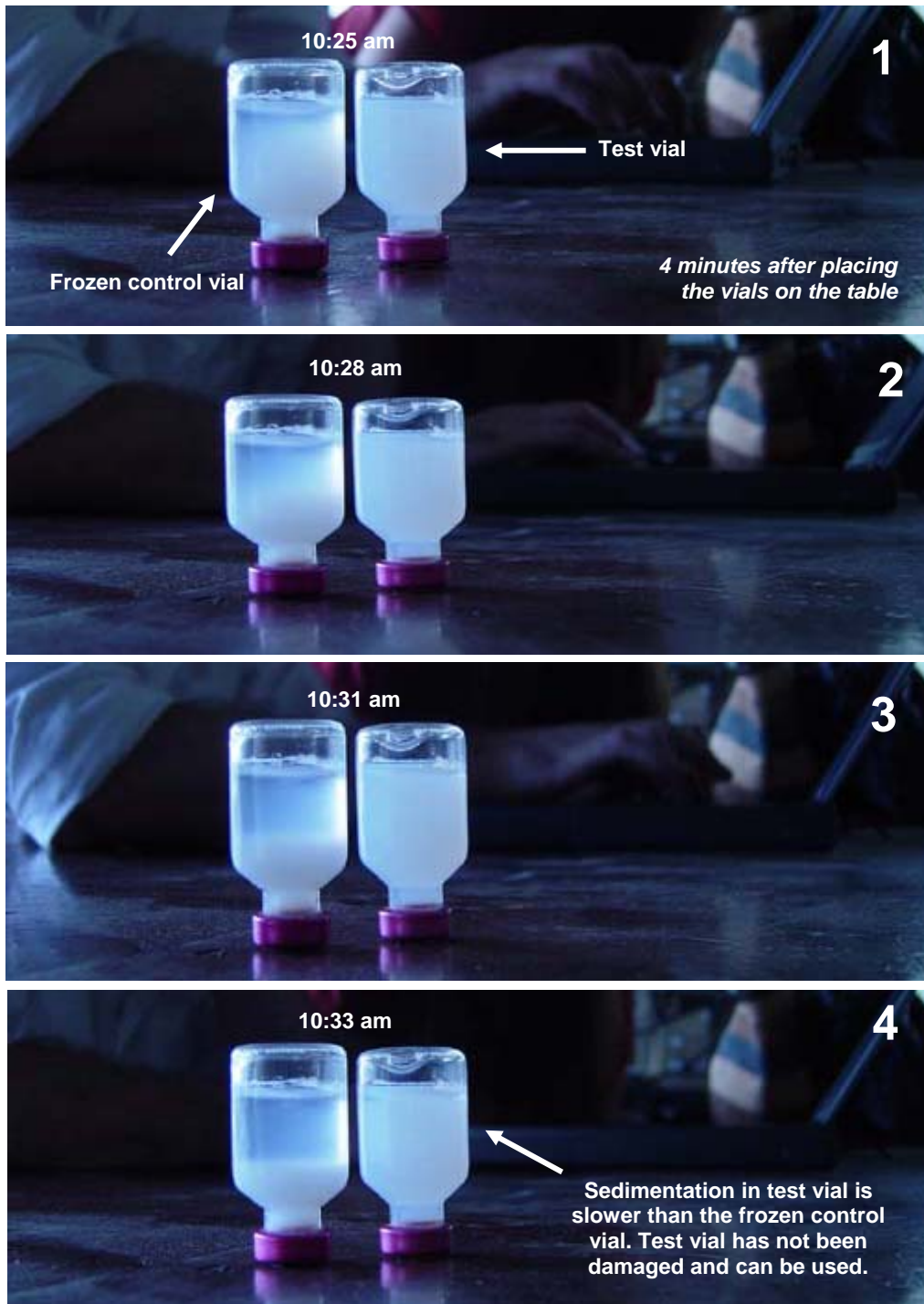


Photo: U. Kartoglu/WHO

Annex VII - Learning session on the shake test

NOTES FOR THE FACILITATORS

Shake test is a validated test with 100% specificity, 100% sensitivity and 100% positive predictive value to distinguish whether a freeze-sensitive vaccine has been affected (and damaged) by freezing (article here).

WHO has produced two videos on the shake test. The first one (Shake and Tell) is a visual article on the validation of the shake test and runs for 22 min and 17 seconds. This video is important for all facilitators to watch in order to understand fully the science behind the shake test and its validation against the phase contrast microscopy. The second video is an educational video (Step-by-step shake test) and is a must in all training sessions for the shake test. This video runtime is 10:07. Both videos can be accessed from the following links (On request, WHO can also provide DVD version of the videos):

Shake and tell (validation video for facilitators):

<http://vimeo.com/channels/worksforwho#8381355>

Step-by-step shake test (educational video):

<http://vimeo.com/channels/worksforwho#8389435>

In order to have good interaction between facilitators and participants and to respond all queries on site to make sure that all has learned the basic required skills, the number of participants should not exceed 25. For such a group preferably there should be minimum of two facilitators.

The session is arranged for an hour and half and includes video presentation as well as hands-on practices and question/answer session.

The physical space of the room should be big enough (approximately 100 m²), and there should not be any columns in the middle that would prevent anybody's vision.

The room can be arranged either in U-shaped or in small work-station style to accommodate 3-4 participants in one table.

Required materials

- Pre-prepared flip chart for session objectives
- Laptop and desktop computer
- Multimedia projector
- Internet connection (if you are going to use vimeo link to show the videos)
- WHO Shake test DVD
- White screen (for video and PowerPoint presentation)
- 28 vials of a freeze-sensitive vaccine (from the same manufacturer and with the same batch number)
- Shake test learning guide (one for each participant)

The number of vials indicated above is required for a session for 25 participants. In principle, one vial of vaccine is needed for each participant. In the case of having less participants than 25, you can reduce the number of vials (always add three additional vials to the total number required).

In terms of preparations, the following temperature treatment should be done to the vials:

1. Let's prepare vials for 20 participants.
2. For demonstration purposes you need one frozen control vial. You also need to prepare one frozen control vial for every two participants. For example, if you have 20 participants, you need a total of 11 frozen control vials, one frozen control vial for demonstration and 10 frozen control vials for participants,
3. Mark these vials with a permanent marker as FROZEN.
4. As for test vials, you need some frozen and some unfrozen vials. You can prepare half of the vials needed for this purpose as frozen - for participants you need to prepare 5 frozen test vials and 5 unfrozen test vials. For yourself to use during the demonstration, you also need one frozen and one unfrozen vial. This requires you to freeze six vials and prepare six unfrozen vials. All test vials should be marked with a permanent marker in a sequential order such as A, B, C or 1, 2, 3 and so on. You have to keep a log for these codes.
5. Frozen test vials could be prepared together with control vials.
6. In summary the below table illustrates the number of vials you need to prepare:

Number of vials	Purpose	Markings	Temperature treatment	To be used by
1	Frozen control vial	FROZEN	- 20°C	Facilitator during demonstration
10	Frozen control vial	FROZEN	- 20°C	Participants
1	Frozen test vial	A or 1	- 20°C	Facilitator during demonstration
5	Frozen test vial	B,C,D,E,F or 2,3,4,5,6	- 20°C	Participants
1	Unfrozen test vial	G or 7	+2°C to +8°C	Facilitator during demonstration
5	Unfrozen test vial	H,I,J,K,L or 8,9,10,11,12	+2°C to +8°C	Participants

7. Mark all the vials as required.
8. You can place the vials in small nylon bags in groups.
9. You should freeze your frozen control vials and frozen test vials in freezer for overnight. Make sure that before you take them out of the freezer, all vials are in solid frozen state.
10. Do not heat the frozen vials, you should let them thaw themselves.
11. Before demonstrating to the participants, it is highly advised that facilitators should try all the vials to make sure that all work as they should.

Session objectives

At the end of this session, participants will be able to:

1. Explain when to conduct the shake
2. Explain how the shake test works

3. Perform correctly the shake test for given five test vials
4. Based on the results of the shake test conducted, decide whether vaccine could be used or not.

Detailed timing

Activity	Name of the facilitator	Duration (minutes)	Time
Introduction		5	13:30-13:35
Illustrated lecture		15	13:35-13:50
Demonstration		10	13:50-14:00
Grouping and distribution of vials		10	14:00-14:10
Shake test by participants (and coaching)		30	14:10-14:40
Questions and answers		10	14:40-14:50
Summary		10	14:50-15:00

Introduction (5 minutes)

One of the facilitators explain the session objectives to participants on a prepared flip chart:

At the end of this session, participants will be able to:

1. Explain when to conduct the shake
2. Explain how the shake test works
3. Perform correctly the shake test for given five test vials
4. Based on the results of the shake test conducted, decide whether vaccine could be used or not.

Illustrated lecture (15 minutes)

One of the facilitators explain the group that you will be watching an educational video that explains when to conduct the shake test, its mechanism and how to conduct it.

Demonstration (10 minutes)

The demonstration should be done in a place with good lighting so the sedimentation could be observed easily. This could be next to a window (additional boxes or books may be required to prepare a higher level surface for easy observation).

Distribute shake test learning guide to all participants.

Show the frozen control vial to participants, explaining that this has been frozen over night and it was solid frozen, but now thawed. Explain that you have two vials for testing.

Tell participants that you will start from the Step 6 in the learning guide since all previous steps have been done by you earlier.

Ask one participant to read the step 6 (and other steps as you progress) - in this case, you take all 3 vials in one hand (your frozen control sample and you're A or 1 marked frozen test vial and G or 7 marked unfrozen vial).

Shake all three vials vigorously for 10–15 seconds.

Place all three vials on a flat surface side-by-side and start continuous observation of the vials until the test is finished. Ask participants to come closer to see the difference in sedimentation rate.

Once the test is completed, explain to the participants which test vial is considered as frozen therefore damaged and which one unfrozen and not damaged.

Grouping and distribution of vials to participants (10 minutes)

Put all the participants in groups of two. In the case of an even number of participants, one of the facilitators should pair with the last participant.

Give one frozen control vial to each group (marked as FROZEN).

Give one of the test vials to each group (marked as H,I,J,K,L or 8,9,10,11,12).

Ask participants to find a good place with light and start the test following the learning guide step 6.

Shake test by participants and coaching (30 minutes)

During the test by participants, visit all the groups and discuss the process they follow as well the results (make sure you have your corresponding codes with you for the test vials).

Once participants successfully complete the first test, switch the test vials between groups. By doing this each group will test a total of five vials.

Questions and answers (10 minutes)

Ask participants whether they have any questions.

Summary (10 minutes)

Summarize the session, by explaining the rules of when to make the shake test and steps involved in preparing the frozen control and the decisions to be taken based on the results.