Effective Vaccine Management

EVM Good Practice

E2 Temperature management

E7 Distribution of vaccines and dry goods

C2 Equipment

C4 Human Resources

How to temperature map cold chain equipment and storage areas

Second edition

World Health Organization

How to temperature map cold chain equipment and storage areas

Second edition

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Abbreviations

2D	two-dimensional
3D	three-dimensional
EPI	Expanded Programme on Immunization
EVM	effective vaccine management
LED	light-emitting diodes
MKT	mean kinetic temperature
MS	Microsoft
PAHO	Pan American Health Organization
PDF	portable document format
PQS	performance, quality and safety
SD	standard deviation
TM	temperature mapping
UNICEF	United Nations Children's Fund
ULT	ultra-low temperature
USB	universal serial bus
WHO	World Health Organization

1. Background

The central-level cold room of any country may hold millions of dollars' worth of vaccines.[1] In highly populated countries this may also be the case for provincial- and even district-level cold rooms. The WHO effective vaccine management (EVM) initiative sets standards for safe vaccine handling and storage to ensure that heat and freezing temperatures do not damage vaccines.[2]

The standards require all vaccine cold and freezer rooms to be temperature mapped routinely every 2 years. This document provides guidance for undertaking the process. The first temperature mapping should take place at the time of the storage unit's commissioning, and then should be performed when the cold and freezer rooms, as well as associated storage units (refrigerators and freezers), undergo any modifications or major repairs. Annex 1 provides further information on conducting temperature mapping after modifications or major repairs.

Temperature mapping is not limited to vaccine cold and freezer rooms. Temperatures in refrigerators, freezers and dry stores – where diluents, injection equipment and other pharmaceuticals are kept – should also be temperature mapped.

1.1 The problem

The high cost of vaccines justifies the routine temperature mapping of all vaccine cold and freezer rooms and vaccine storage units. That said, EVM assessments completed to date by national immunization programmes have not shown thorough documentation of effective temperature distribution within cold rooms. There are several reasons for this, including:

» lack of trained immunization programme managers and store managers, and the lack of a simple tool to facilitate carrying out a temperature mapping exercise;
» cost of hiring external consultants to carry out these studies; and
» cost of compliance with the technical requirements and standards for temperature mapping. For example, temperature mapping requires at least 48 hours of continuous temperature recording with an appropriate number of temperature sensors (pre-qualified by WHO) placed accurately within empty and fully stocked storage units.

1.2 The solution

One practical solution is to empower and equip field-level Expanded Programme on Immunization (EPI) programme staff, especially store managers, to conduct temperature mapping. This can be achieved through several simple, well-defined, clearly explained and step-by-step actions, assisted by an open-access, user-friendly, computer-based application.

In response to this need, WHO has developed the Temperature Mapping tool which aids the process of mapping temperatures in various types of cold chain equipment and dry stores. The Temperature Mapping tool is a computer-based application in Microsoft (MS) Excel® available in official United Nations languages. The tool and this guidance are downloadable from the WHO Vaccine Management and Logistic Support website.

[1] A 40 m^3 cold room may house approximately US$ 2.5 million worth of vaccines when fully loaded.

[2] WHO (2016). WHO/UNICEF Joint Statement. *Achieving immunization targets with the comprehensive effective vaccine management (EVM) framework*. 10 March 2016. WHO Reference WHO/IVB/16.09 (http://apps.who.int/iris/bitstream/10665/254717/1/WHO-IVB-16.09-eng.pdf?ua=1, accessed 5 March 2021).

1.3 The importance of temperature mapping

Temperature mapping is the process of recording and mapping temperatures within three-dimensional (3D) spaces, such as cold and freezer rooms, dry storage areas, and refrigerator and freezer units. Temperatures will not be the same everywhere within the storage area. Whether in a small refrigerator, a well-designed cold or freezer room, or, particularly, in a large warehouse, temperatures can vary by as much as 10 °C from one location to another within the same unit. Temperatures in the corners will most likely be different from those measured in the centre or close to cooling units. In dry stores, the temperatures close to the ceiling tend to be higher than those close to the floor. There are also specific areas within the cold rooms where the temperature will differ. For example, temperature will be coldest next to the cooling fans and likely to be warmest close to the doors.

Temperature mapping and temperature monitoring are integral to the appropriate storage conditions for pharmaceuticals. Good manufacturing practice for pharmaceutical products recommends regular temperature mapping in all types of warehouses.[1]

[1] See Clause 3.19 of Pharmaceutical Inspection Co-operation Scheme (PIC/s) (2017). *Guide to good manufacturing practice for medicinal products* (https://www.picscheme.org/en/publications?tri=gmp, accessed 5 March 2021).

2. The temperature mapping process

Temperature mapping consists of several key steps.

1) Decide when to perform temperature mapping.
2) Place an appropriate number of sensors in different areas, particularly areas that might go above or below specified safe temperature ranges. Generally, 20 sensors are used to temperature map a medium-sized cold storage unit, with an additional sensor to measure the ambient temperature. Temperatures need to be recorded at specified regular intervals, continuously, for at least 48 hours.
3) Read and transfer recorded temperatures (minimum, maximum, mean and mean kinetic[1]) to a 3D sketch of the storage vessel to be temperature mapped. This can include cold and freezer rooms, dry storage areas, and equipment such as refrigerators and freezers.
4) Identify areas where vaccines and thermo-sensitive pharmaceutical products should NOT be stored.
5) Implement actions to prevent and reduce the exposure of vaccines and pharmaceuticals to incorrect temperatures.

2.1 A simplified process

The Temperature Mapping tool automatically develops a simple 3D sketch of a storage area based on data input on the actual dimensions of the equipment to be mapped, be it a cold room, freezer room, refrigerator/freezer or a dry store. It requires specifying the unit's length, width and height, as well as:

» number, location and dimensions of door(s), evaporators and shelves; and
» number and location of sensors.

This information is entered into the application, which includes a Measurement Form designed for recording the temperature data. Using this form simplifies taking measurements and transferring them to the application.

The process calls for the placement of an appropriate number of sensors in pre-specified locations within the 3D sketch, which provides a guide for placing the sensors in the correct spots within the storage area or unit to be mapped. The application guides the placement of 12 required sensors in pre-specified positions, beginning with three sensors in each of the four corners of the unit to be temperature mapped. There is also the option of positioning an additional 28 sensors in places that might be considered risky areas for storing specific items such as vaccines.

After completing the temperature recording over a period of at least 48 – but up to 72 – hours, the application imports temperature records (converted to Excel®). It ascribes the temperature readings to the location of the sensors, and colour codes the areas where temperatures fall outside the desired range using the 3D diagram.

The application produces a report based on the summarized temperature recording data that includes a summary of key findings. A standard template is provided to facilitate the preparation of reports. Users need to use their judgment to:

» decide whether the storage room or equipment tested is adequate for storing specific items (vaccines and other pharmaceutical products); and
» identify safe and risky areas within the unit.

[1] Mean kinetic temperature (MKT) is a simplified way of expressing the overall effect of temperature fluctuations during storage or transit of perishable goods. The MKT is widely used in the pharmaceutical industry.

The application takes care of the most complicated part – by creating a sketch of the unit scaled to fit an A4 sheet for printing. The most critical part of the mapping calls for taking accurate 3D measurements of a minimum of eight places in the unit.[1] This task is explained in detail with pictorial aids in Section B.

[1] The number of measurements to be recorded depends on the size of the unit, number of cooling units, the number of doors and the number of shelves.

3. How to use this guide

This guide provides a step-by-step approach to temperature mapping of storage areas or equipment. The application it presents can be used for temperature mapping of cold and freezer rooms, refrigerators and freezers, and dry stores. Systematic follow-up of the steps provided in this guide is essential for successful temperature mapping. Once you have completed the initial exercise, you will have learned how to perform temperature mapping.

The instructions provided in this guide have been developed for those with limited computer knowledge. Users familiar with MS Excel® and other computer programmes will learn the temperature mapping method faster.

Note: *Users should save this guide for future reference.*

3.1 Equipment and material required for temperature mapping

Hardware requirements

The following items are required for temperature mapping, using this application:

» minimum of 21 temperature monitoring sensors (temperature data loggers);
» computer with Windows® and MS Excel® installed;
» tape measure;
» clipboard for recording information on the Measurement Form;
» warm clothes for working in the cold and freezer rooms.

Three brands of temperature-monitoring devices – tested and approved by WHO – are compatible with the current version of the temperature mapping application: LogTag®; Q-tag®; and Libero®.

Table 1. WHO pre-qualified temperature-monitoring devices compatible with the Temperature Mapping tool

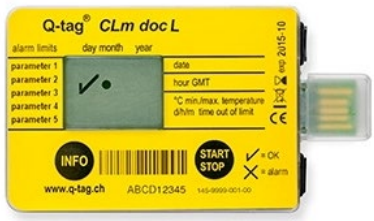
Brand name	Model	PQS number	Software requirement for the device	User interface	Working temperature range (°C)
LogTag®	TRIX-8	E06/006	LogTag® Analyzer_24r4	LogTag® interface	-40 to +85
Q-tag®	CLm doc LR	E06/016	None	USB	-5 to +60
Libero®	Ti1-L	E06/024	ElproVIEWER	USB	-35 to +70

The application does not appy to temperature mapping of ultra-low temperature (ULT) freezers. Currently, there are available temperature recorder models used for monitoring ultra-low temperatures but they are neither WHO pre-qualified nor validated for use in mapping temperature of ULT freezers.[1]

[1] Operational guidance on establishing ultra-cold chain system in support of Pfizer-BioNTech COVID-19 Vaccine roll out. COVID-19 vaccine introduction toolkit (who.int)

Fig. 1. Temperature monitoring devices (sensors)

LogTag® (TRIX-8) with interface



Q-tag® (CLm doc LR)

Libero® (Ti1-L)

Requirements specific to the three WHO-pre-qualified temperature monitoring devices

LogTag®: This sensor needs at least one interface for configuring the sensors and for transferring data from the sensors (loggers) to the computer. See Annex 2: LogTag® temperature data logger for compatibility between the temperature data logger LogTag® (TRIX-8) and your computer's operating system.

Q-tag® and Libero®: These sensors are equipped with a universal serial bus (USB) interface. This device might not be appropriate for temperature mapping freezer rooms and deep freezers since the lowest working temperature is only at -5 °C. Therefore, an appropriate device for recording ultra-low temperature must be used.

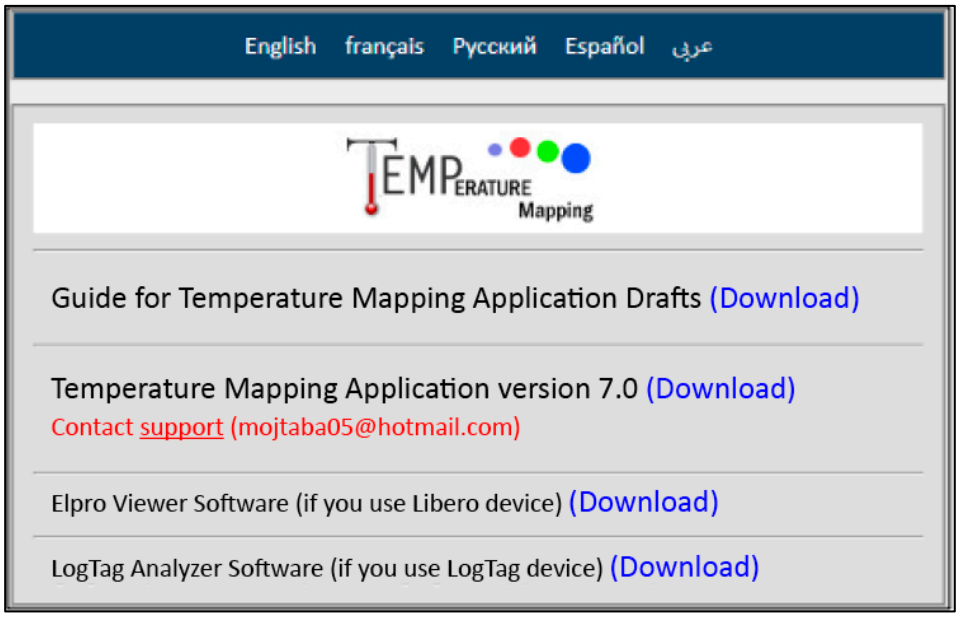
***Note:** The LogTag® and Libero® sensors require specific software, whereas the Q-tag® sensor has no software requirement.*

Software requirements

The required software application is downloadable from the WHO vaccine supply chain and logistics support website (https://www.who.int/teams/immunization-vaccines-and-biologicals/essential-programme-on-immunization/supply-chain/).

The site, as shown in Fig. 2, also includes links to the following relevant document and applications:

» electronic copy of this guideline;
» ElproVIEWER software application;
» LogTag® Analyzer software application.

Fig. 2. Temperature Mapping tool: downloading page	

Note: *The actual appearance of the Temperature Mapping tool main page may be different from the above image due to version upgrade or migration of the resources to a new website.*

Before downloading the temperature mapping application, create a folder that will serve as your “main folder” in one of the computer’s drives. All the files and subfolders that are automatically created by the application will be saved in this “main folder”.

Then, download the "Temperature Mapping Source” zip folder, and unzip the contained files into the “main folder”.

Note: *To ensure smooth execution, it is recommended to download the application to one of the computer drives, not to the desktop.*

Additionally, if you are using LogTag®, download the “LogTag® Analyzer” software"; if you are using Libero®, download the “ElproVIEWER” software.

You do not need to download anything if you are using Q-tag® devices.

Once downloading is complete, you should have the files and subfolders in the “Temperature Mapping Source” as listed in Table 2.

Table 2. Temperature Mapping Source: main and subfolders

	Common files		EnablingMacros.docx	
			MeasurementForm.xlsx	
			Profile_LogTag® .ltp	
			Option_LogTag® .asxml	
	Source		Device outputs	Ambient
				Sensor 1
				Sensor 2
				Sensor 3
				Sensor 4
				Sensor 5
				Sensor 6
				Sensor 7
				Sensor 8
				Sensor 9
				Sensor 9
				Sensor 10
				Sensor 11
				Sensor 12
				Sensor 13
				Sensor 14
				Sensor 15
				Sensor 16
				Sensor 16
				Sensor 17
				Sensor 18
				Sensor 19
				Sensor 20 …….. Sensor 40
			Logo images	3 logo files
			Source.xlsm	
	TM Manager.xlsm			

4. How to use the Temperature Mapping tool

This guide contains 13 sections (A to M), with each section divided into several steps (see Table 3).

Table 3. List of temperature mapping activity sections

Sections	Descriptions
A	File management
B	Measuring the storage unit to be temperature mapped
C	Preparing the temperature mapping application
D	Transferring data from the Measurement Form to the temperature mapping application
E	Guide on placing and configuring three different types of sensors • LogTag® • Q-tag® • Libero®
F	Positioning the sensors
G	Removing sensors and downloading temperature readings to the temperature mapping application • LogTag® • Q-tag® • Libero®
H	Obtaining the temperature mapping report
I	Making decisions and taking action
J	Managing logos
K	Repeating temperature mapping for the same equipment or identical equipment • Repeating temperature mapping of the same storage units • Temperature mapping for identical equipment
L	Estimating hold-over time of the storage unit (optional)
M	Separate testing of cooling units (optional)

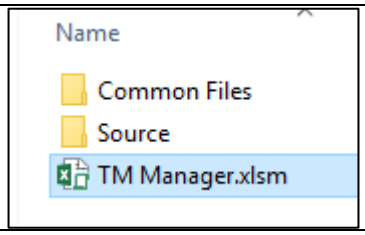
Section A. File management

This section describes how to configure the software and prepare the materials needed to start temperature mapping. It outlines three simple steps to use <TM Manager.xlsm> for the different sensors and for mapping various storage units. It also provides important information about what to do – and what not to do – with the application's files.

Step A.1

Check if the application has been installed correctly. Once the Temperature Mapping Source application has been copied or downloaded into the computer, you will have the files and folders listed in Fig. 3.

Fig. 3. Temperature Mapping Source: main folder



Click on <TM Manager.xlsm> to open the temperature mapping application. When using this application for the first time, you may see this warning message.

If you see this message, it means that macros are disabled!

You must enable macros before using this application.

For more information and to enable macros please refer to the “Enable Macros” document in the main folder or click on the following link:

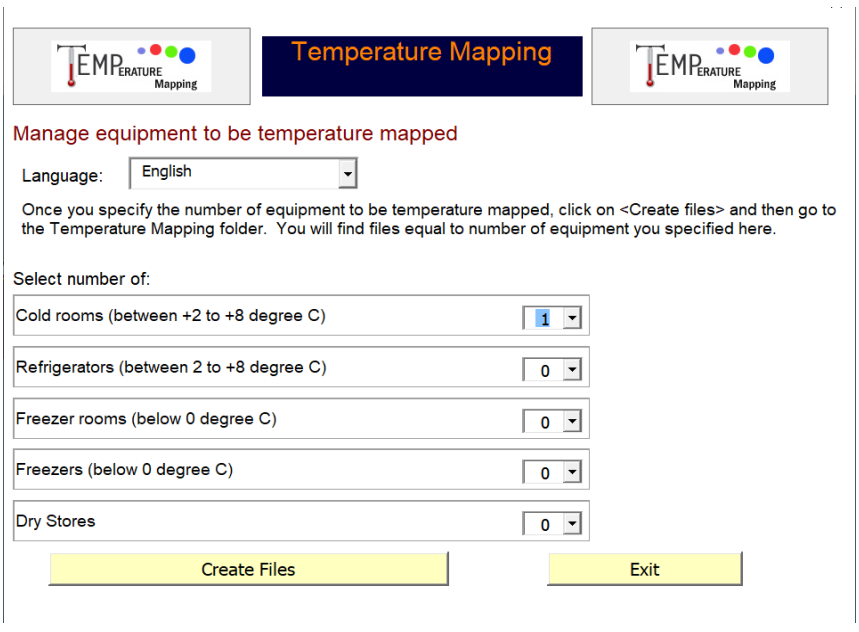
Enabling Macros Help Document.

The warning message means that you should enable macros in the computer before starting to use the application. As the method to enable macros differs across operating systems, instructions to enable macros are provided in detail in several languages in the file <EnableMacros>, which is found in the “Common Files” subfolder of the Temperature Mapping Source main folder.

Step A.2

Select the number of units to be mapped for each type of cold chain equipment and dry store using the drop-down menu, as illustrated in Fig. 4.

Fig. 4. Type and number of equipment to be temperature mapped

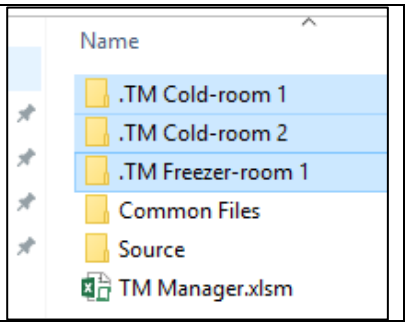


The application will generate a source file for each equipment and storage space indicated. The file names of these newly generated folders start with a ".TM" and include a number that corresponds to the quantity of the same-type equipment to be temperature mapped.

You should, therefore, assign a number for each piece of equipment and storage space to be temperature mapped to ensure the input data are entered to the corresponding Temperature Mapping tool, which will be auto-generated by the application. This will be further discussed in Section C.

For example, if you select two cold rooms and one freezer room, three folders will be added automatically in the "main folder" as illustrated in Fig. 5.

Fig. 5. Sample of equipment-specific Temperature Mapping tool "source" folders

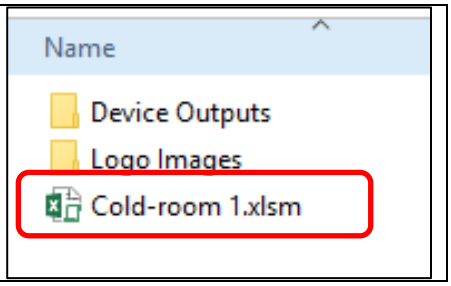


Note: *You should NOT move, open or use files outside of their designated folders. This is very important!*

Step A.3

Click on the first unit (e.g. either equipment or dry store) to be temperature mapped. Using the example given in Fig. 5, click on ".TM Cold-room 1". A folder consisting two subfolders and one Excel® file will appear as follows:

Fig. 6. Sample of an auto-generated, equipment-specific Temperature Mapping tool



Section B. Measuring the storage unit to be temperature mapped

This section presents the eight steps required for completing the temperature mapping Measurement Form. It explains what data should be entered for all the required dimensions within the unit that is being temperature mapped. Once complete, this form will be used to transfer the measurements to the equipment-specific Temperature Mapping tool (which is further illustrated in Section D).

Step B.1

Print the Measurement Form <TM MeasurementForm.xlsx> found in the "Common Files" subfolder.

Note: *Make sure to bring the hard copy of the Measurement Form with you when you go to the area to be mapped.*

Step B.2

Insert the specifications, codes and essential measurements in Table 1 of the General Information section located in the upper part of the Measurement Form. Fig. 7 presents an example of a completed Table 1 of the form.

Fig. 7. Table 1 of the Measurement Form: general information

A. General Information

Table 1. Codes and General Information

Location	**Central vaccine store**	
Code	**CVS-CR1**	
Manufacturer	Not known	
Model	Not known	
Type	*Cold-room* *Freezer-room* *Dry Store*	*(Circle one)*

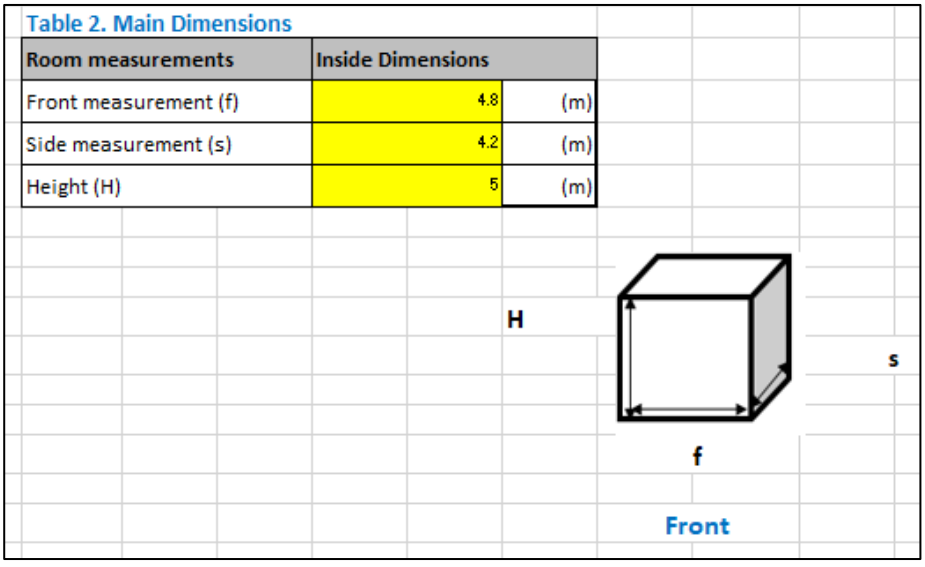
Step B.3

Take the unit's internal measurements for length (L), width (W) and height (H). Begin with the unit's front side, where the entrance door is located. Then, measure the internal dimensions of the unit's other sides. Fill in Table 2 of the Measurement Form accordingly, as shown in Fig. 8.

Fig. 8. Table 2 of the Measurement Form: internal dimensions

Table 2. Main Dimensions

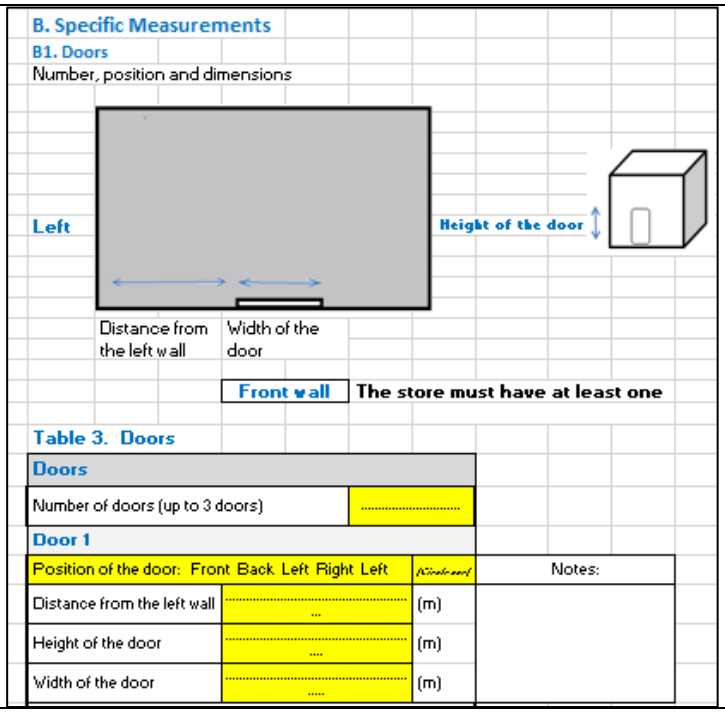
Room measurements	Inside Dimensions	
Front measurement (f)	4.8	(m)
Side measurement (s)	4.2	(m)
Height (H)	5	(m)



Step B.4

Go to the Specific Measurements section of the Measurement Form. Specify the number of doors, their positions and their dimensions as shown in Fig. 9. If the unit to be measured has only one door, which is the normal case, complete only one of the tables.

Fig. 9. Table 3 of the Measurement Form: doors



Step B.5

Specify the number and the position of evaporators inside the equipment. Bigger cold rooms may have several evaporators. Measure the dimensions of each evaporator and enter them in Table 4 of the Measurement Form, as illustrated in Fig. 10.

***Note:** If you are temperature mapping a refrigerator, freezer or dry store, skip Step B.5 and proceed to Step B.6.*

Fig.10. Table 4 of the Measurement Form: evaporators

B2. Evaporator

Number, Dimensions and Positions

This part should be ignored when you temperature map a Dry Store

Page 6

Table 4. Evaporators — In the case of Dry Store, ignore Table 4.

Table 4. Evaporators	Number of evaporators: (Up to 8 evaporators)	------	
Evaporator 1			
Position of Evaporator	Front/Back/Right/left	(Circle one)	Notes:
Distance from the left wall	.....	(m)	
Distance from the front wall	.....	(m)	
Distance from the floor	.....	(m)	
Height (H)	.....	(m)	
Length (L)	.....	(m)	
Width (W)	.....	(m)	
Related to group 1 or 2 of colling units	1 or 2 (Circle one)		

Measurement Sheet | Language

Accessibility: Investigate

Step B.6

Specify the number and the position of shelves inside the unit to be temperature mapped. Use the instructions provided in Fig. 11, which are also found in the Measurement Form. Then, complete Table 5 accordingly, as illustrated in Fig. 12.

Ignore this step if shelves are not relevant for this exercise or if the unit does not have any shelves. If the distances between shelves are not equal, calculate and use the average of the distance between shelves.

Fig. 11. Guide to measuring storage shelves

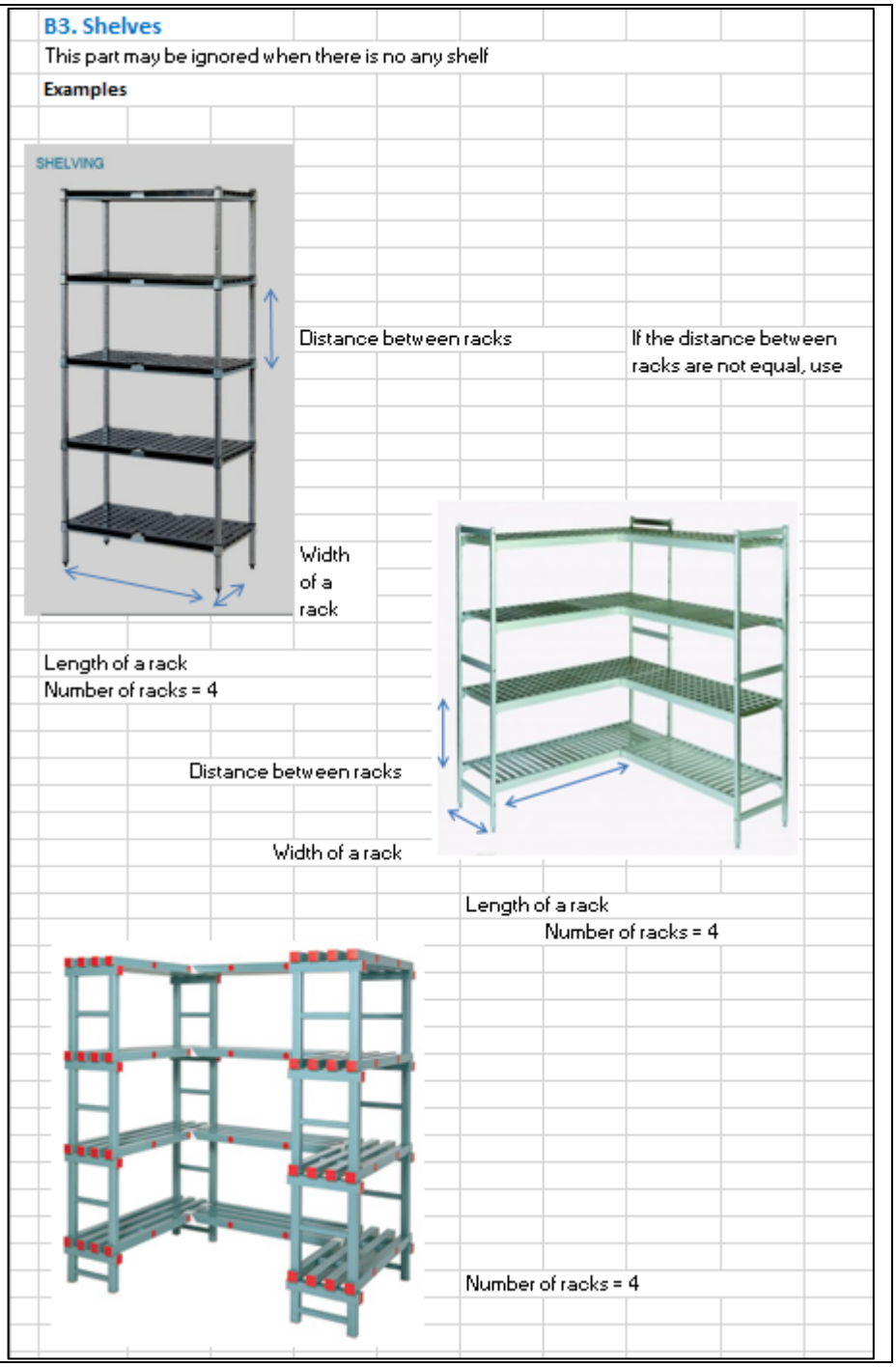


Fig. 12. Table 5 of the Measurement Form: shelves

Table 5. Shelves

Shelves	Number of shelves: (Up to 6 shelves)	.....
Shelf 1		
Position	Front/Back/Right/left	(Circle one)
Distance from the left wall	.....	(m)
Distance from the front wall	.....	(m)
Distance from the floor	.....	(m)
Number of racks	.....	(m)
Distance between racks	.....	(m)
Length of a rack	.....	(m)
Width of a rack	.....	(m)

Step B.7

Determine the number of optional sensors to be used per each unit of equipment to be temperature mapped. Section B4 of the Measurement Form only requires information on the position of optional sensors. Recommended positions for fixed sensors are discussed separately in Section F.

The total number of sensors to be used in recording the internal temperatures depends on the size of the cold chain equipment or dry store to be measured. However, 12 sensors are mandatory for temperature mapping all types of cold chain equipment and dry stores.

Note: *Do not reduce the number of mandatory sensors in fixed locations or change their positions.*

The optional sensors may not be required to temperature map refrigerators or freezers. When temperature mapping cold rooms and freezer rooms, WHO recommends using 20 compulsory sensors.[1] In this case, 12 mandatory sensors are placed in 12 fixed positions and 8 optional sensors are placed in 8 additional positions. Section F of this document provides specific guidelines on the placement of both the mandatory and optional sensors. Section B4 of the Measurement Form provides further guidance for taking correct measurements.

Up to 28 optional sensors can be placed in positions of your choice. Position the optional sensors where you think it is important to record temperatures or you suspect the temperature is outside of the safe range (also referred to as “risk zones”). In other words, you should place the optional sensors in critical locations. Temperature mapping a very large or drive-in cold room, or very large dry stores will require 40 sensors.[2]

Once the number of optional sensors and their desired locations in the equipment or dry store are identified, take the coordinates of each of the sensors based on instructions given in the Measurement Form. Then complete Table 6 of the Measurement Form, as shown in Fig. 13.

[1] More information about WHO’s recommendations, see WHO/PQS/E01/CR-FR01-VP1.2 (2009) (https://www.who.int/immunization_standards/vaccine_quality/pqs_e01_cr_fr01_vp1_2.pdf, accessed 5 March 2021).

[2] More information about WHO’s recommendations, see Supplement 8, technical supplement to *Temperature mapping of storage areas*. WHO Technical Report Series No. 961, 2011, Annex 9 (2015). (https://www.who.int/medicines/areas/quality_safety/quality_assurance/TS-mapping-storage-areas-final-sign-off-a.pdf, accessed 5 March 2021).

Fig. 13. Table 6 of the Measurement Form: sensors

Table 6. Sensors

Sensors	Number of sensors:	.....	
	Up to 8 optional sensors		
Sensor 13			Notes:
Distance from the left wall	.....	(m)	
Distance from the front wall	.....	(m)	
Distance from the floor	.....	(m)	
Sensor 14			Notes:
Distance from the left wall	.....	(m)	
Distance from the front wall	.....	(m)	
Distance from the floor	.....	(m)	
Sensor 15			Notes:

Step B.8

Check the completed Measurement Form to determine whether any item or measurement has been left out. Once you are satisfied that all the information has been collected and the related tables are completed, proceed to Section C.

Section C. Preparing the temperature mapping application

In Section A, you were asked to indicate the number and types of equipment and storage spaces that will be temperature mapped. This action will have generated new subfolders for each type of equipment in the Temperature Mapping "main folder", as shown in Fig. 5.

Each subfolder contains an Excel® file (see example shown in Fig. 6) with a label bearing the type of equipment and a number representing the quantity. Even if there are identical pieces of equipment to be mapped, the tool can only be used for the specified equipment.

This section explains how to complete – in two simple steps – the information required in the Excel® sheet labelled "Room", which is one of the worksheets in the equipment-specific tool.

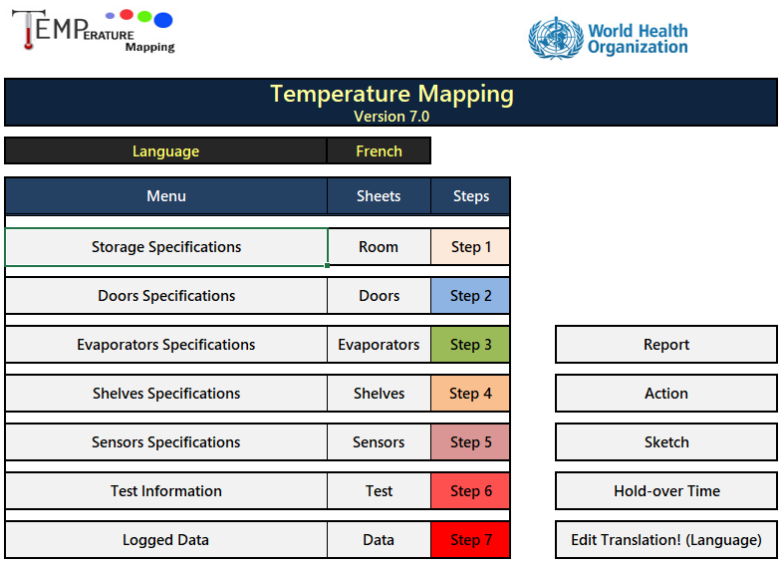
Step C.1

Open the Temperature Mapping "main folder". Then, open the folder <.TM Cold-room 1> to find the Excel® workbook <Cold-room 1.xlsm>, which is specific for this location.

Step C.2

Click on <Cold-room 1.xlsm> to open the equipment-specific Temperature Mapping tool, which is illustrated in Fig. 14.

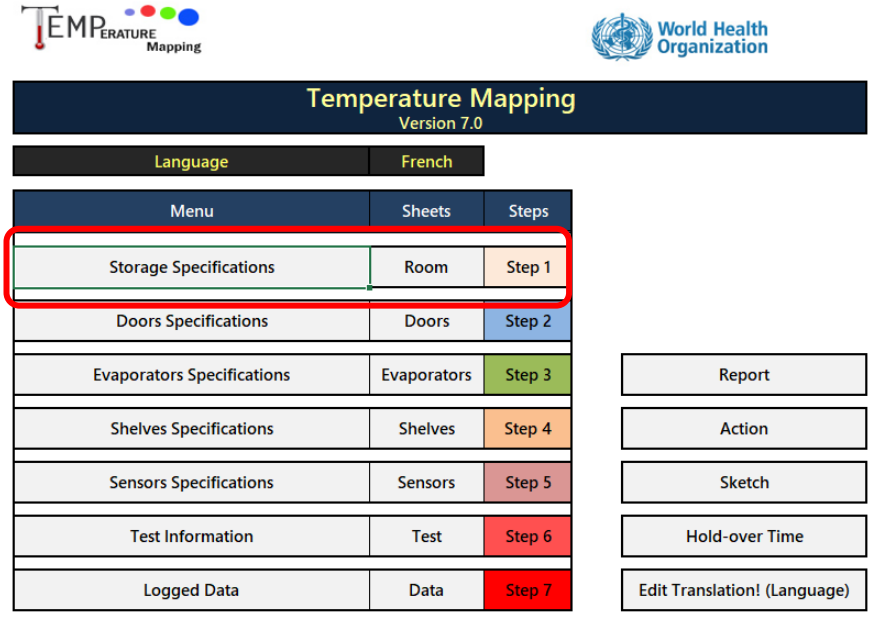
Fig. 14. Main menu of the temperature mapping application



Section D. Transferring data from the Measurement Form to the temperature mapping application

In Sections B and C, respectively, you calculated and added the dimensions and measurements of the unit being temperature mapped to the Measurement Form. Now, in Section D, you transfer that information to the application.

Fig. 15. Selecting worksheet for storage specifications



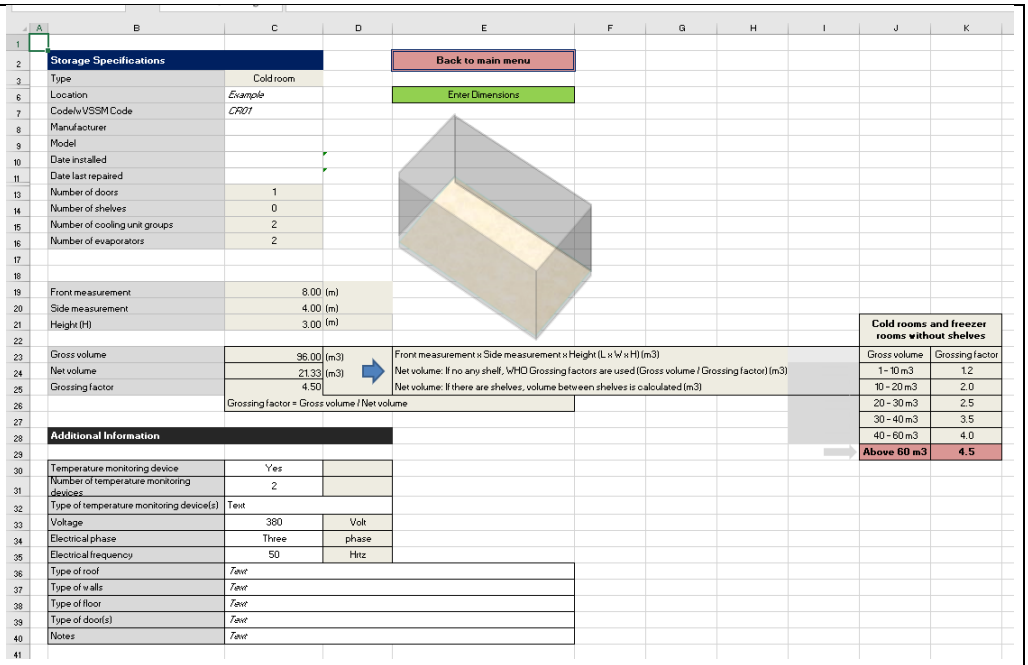
Step D.1

Once the application is opened, click on <Storage Specifications> from the “main menu” (see Fig. 15).

Fill in the “storage specification” table, as shown in the example in Fig. 16. Start by completing the information in cells C3 and D3, using the dropdown menus.

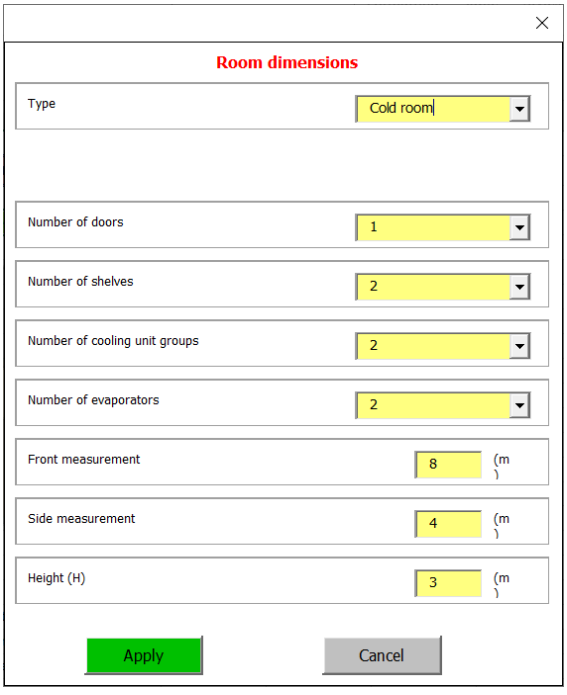
Note: *Cells in the tables with a yellow background are mandatory fields that should be completed. The cells with a white backgrounds are optional. Cells with a grey background are protected and you cannot type anything in them.*

Fig. 16. Sample of a completed storage specification worksheet ("room" worksheet)



In version 7.0 of the application the data entry is different from earlier versions. You should click the "**Enter dimensions**" key. A window similar to that shown in Fig. 17 will open and the data entry is in this window. Once you finish completing data entry, click on "**Apply**". The window will fade away and the data will appear in their right cells.

Fig. 17. Sample of data entry form ("room" worksheet)



STEP D1.1 SELECTING TYPE OF STORAGE OR EQUIPMENT

Select the type of storage equipment in the box in front of “Type” (Fig. 17).

STEP D1.2 INDICATING INSTALLATION DATE

Indicate the installation date of the equipment in cell C10. If you do not know the installation date, type “not known”.

Step D.2

In the “Room dimensions” window (Fig. 17) fill in dimensions of the equipment to be temperature mapped based on the room dimension recorded in Table 2 of the Measurement Form. The unit of measurement is in metres.

Similarly, specify the number of doors, number of shelves, number of cooling unit groups and number of cooling units (evaporators) in the right cells in the data entry window. The tool allows you to specify up to 3 doors, 6 sets of shelves, 2 cooling groups and 8 cooling units (evaporators).

If the storage unit is a dry store (ambient temperatures), the drop-down menus for the number of cooling unit groups and number of cooling units will be disabled and you will see 0 in these boxes.

Let’s now see the differences between cooling unit groups and cooling units (evaporators). If you have a large cold room or freezer room (it does not apply to refrigerators, freezers and dry stores) you may wish to divide the cooling units into two groups and test them separately. In this case you specify the number of cooling unit groups as 2 in the data entry form and consequently cell C15 will be filled with 2. If you select 1, the test will be similar to the earlier versions of the application and you will have one report for all of the cooling units together. If you select 2, you will have to divide the total test time between two groups of cooling units and consequently you will have two data sets and two reports separately.

Cells C23 to C25 are automatically filled in, based on the data in cells C19 to C21.

» Cell C23 presents the gross volume. This is the product of the multiplication of the three dimensions in cells C19, C20 and C21.
» Cell C24 is the net volume. The volume indicated will depend on the number of shelves, the distance between them and their dimensions (length and width).These dimensions are specified in the “shelves” worksheet.
» Cell C25 represents the grossing factor. If “0” (meaning no shelves) is the value in cell C14, the net volume will be estimated using grossing factors, which are based on WHO recommendations. The grossing factor increases with the size of the equipment.

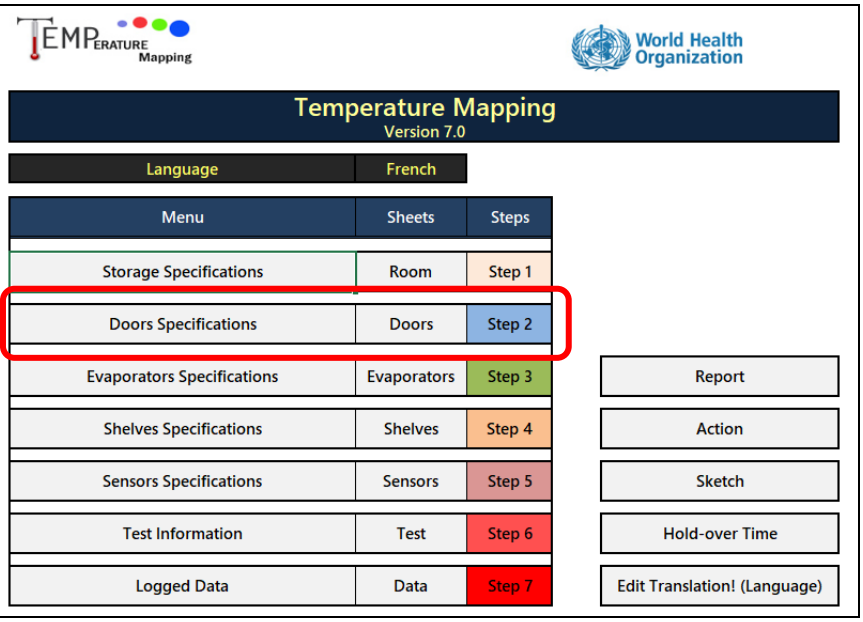
ADDITIONAL INFORMATION

From cell C30 to C40 there are spaces for optional additional information. The information, such as type and number of built-in temperature monitoring devices, electrical phase of the equipment and other information in this section are not required and are considered as optional. The data in this section will NOT affect the temperature mapping test.

Step D.3

Go back to the “main menu” and select <Doors specifications> as shown in Fig. 18.

Fig. 18. Selecting worksheet for door specification



STEP D.3.1 CREATING THE DIAGRAM TO SHOW EXACT LOCATION AND DIMENSION OF DOORS

In the “Doors” worksheet, the number of door specification options depends on the information indicated in cell C3. The digit in C3 comes from <Room> C13. If you want to change the number of doors, you should go back to <Room> and replace the digit there. Here again you should click on **Enter dimensions** and fill in the right boxes from the data on door dimensions recorded in Table 3 of the Measurement Form (see example in Fig. 19).

Each door requires data input on its position, distance from the left wall, height and width. After indicating all the information in this window, click on Apply and a diagram will show the door in its corresponding position in both the two-dimensional (2D) or horizontal diagram and the 3D diagram. This is illustrated in Fig. 20.

Fig. 19. Example of door data entry

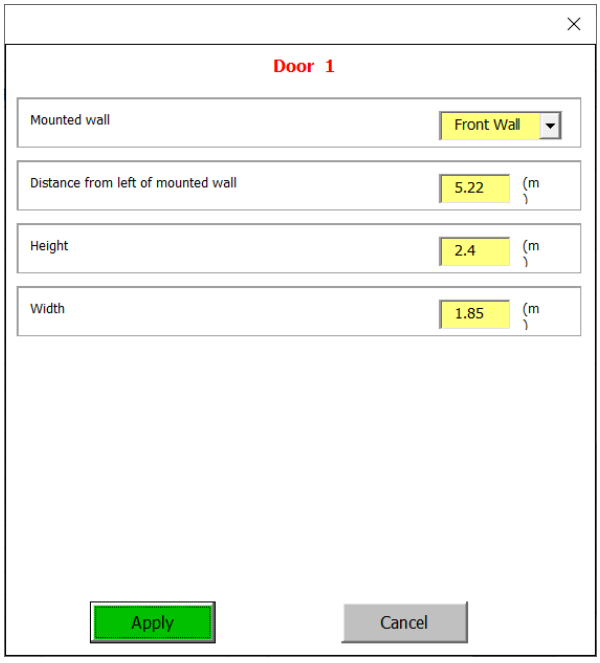
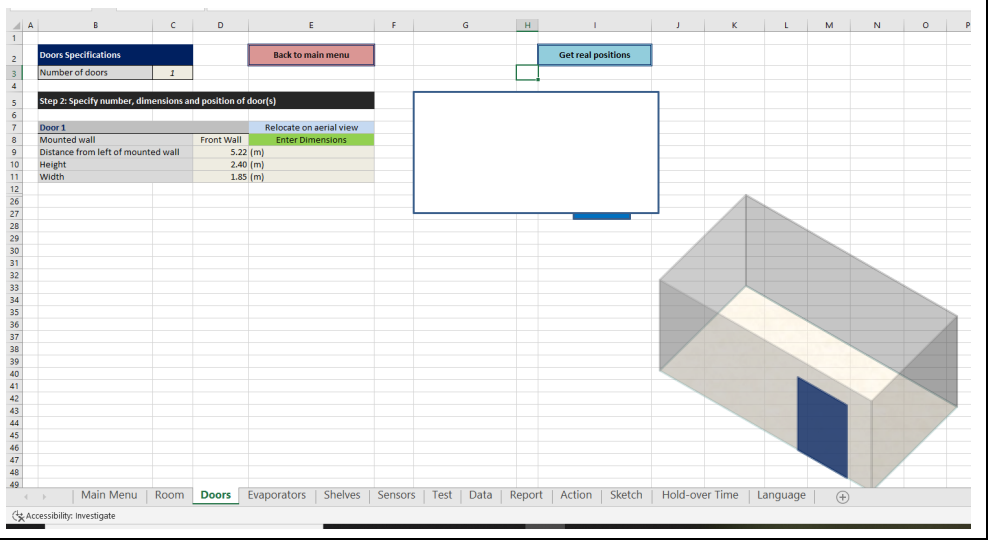


Fig. 20. Sample of a completed door specification worksheet

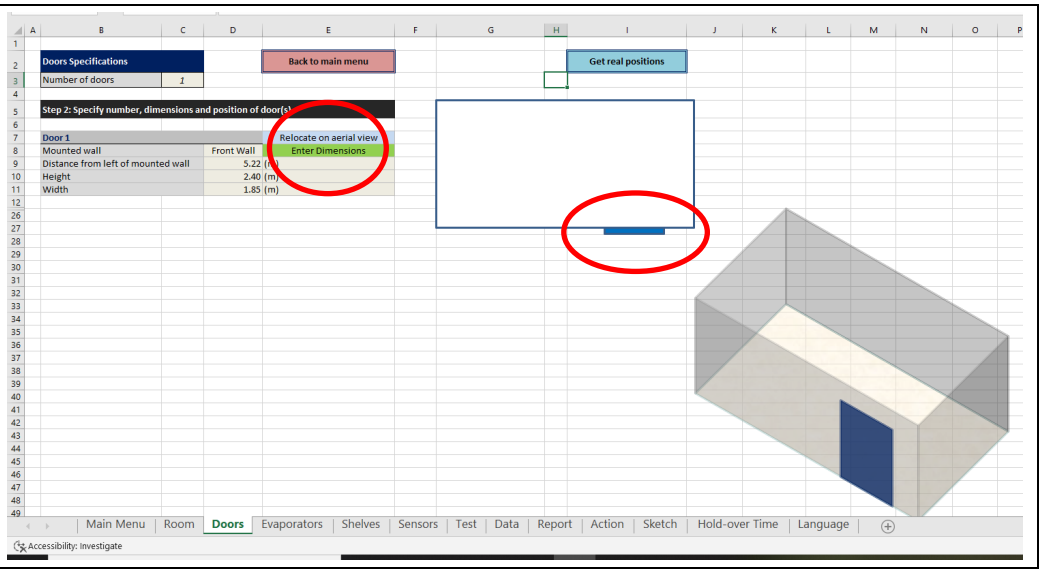


STEP D.3.2 USING THE "GET REAL POSITION" FEATURE OF THE TOOL

This feature of the tool enables manual relocation of the position of the door. This is optional and used only when the auto-generated 2D and 3D diagrams do not properly reflect the door's correct position.

The process involves clicking on the <Relocate on plan> in column E next to the door that requires a position correction. When you click on <Relocate on plan>, the door on the 2D diagram will be highlighted, and it can then be moved to the left or to the right and its width can be adjusted (see Fig. 21). Once the desired location is determined, click on <Get real positions>.

Fig. 21. Manual specification of door location



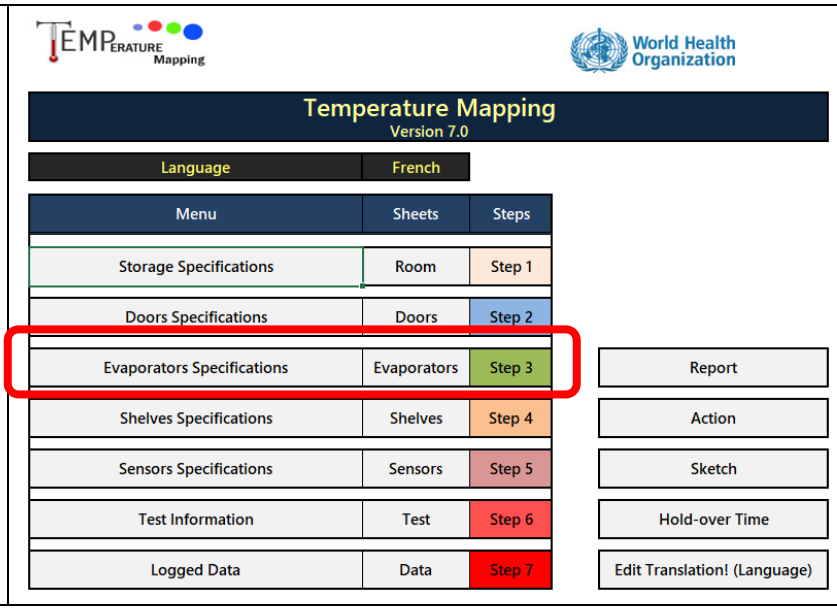
By clicking on <Get real positions>, a message will appear showing the measurement of the location (distance from the left wall) and width of the selected door. If you click on <Yes> in the message box, the 3D diagram will be updated to reflect the door location.

Once the data for all doors is entered, click on <Back to Main Menu>.

Step D.4

Click on <Evaporators Specifications> in the “main menu” (Fig. 22).

Fig. 22. Selecting worksheet for evaporators specifications



The number of evaporators or cooling units is automatically indicated in cell C3 of the “Evaporators” worksheet. The number of options for the location and dimensions of the evaporators is equal to the number specified in cell C16 in the “Room” worksheet (see example in Fig. 24).

Transfer the data on the location and dimension of each evaporator from Table 4 of the Measurement Form to the corresponding boxes when you click on **Enter dimensions** in “Evaporators” worksheet.

Fig. 23. Example of data entry form for position and dimensions of the cooling units (evaporators)

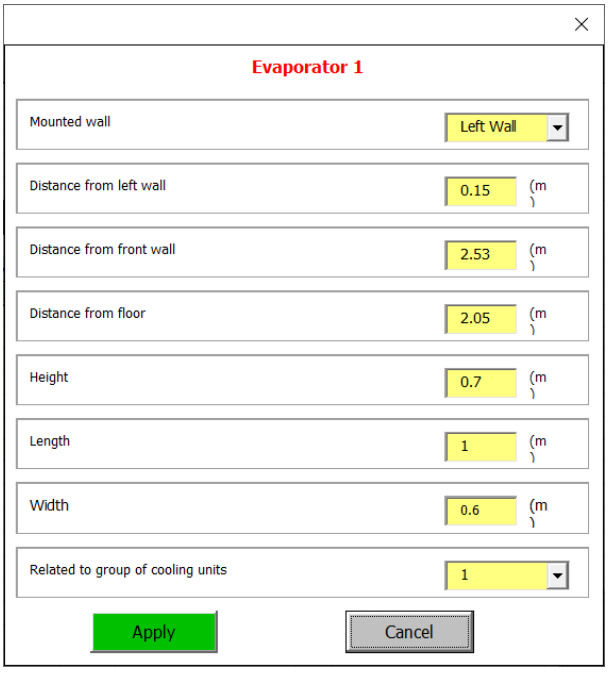
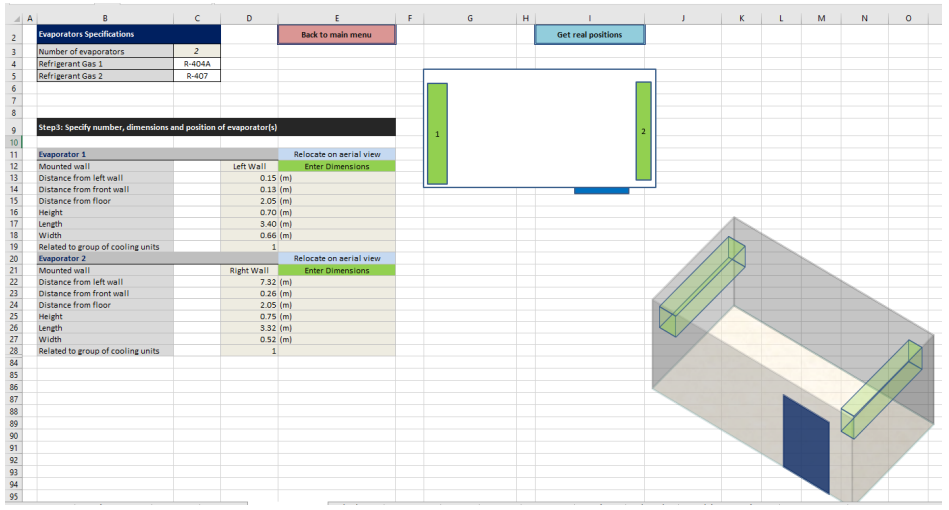


Fig. 24. Sample of a completed evaporators specification worksheet



If the location of the evaporators is not correctly reflected in the 2D and 3D diagrams, you can reflect their proper locations in the diagrams using the <Relocate on plan> option. Follow the same procedures as described in Step D.3.2 for door size and location.

“Related to group of cooling units” (D19, D28 and so on) will be disabled when you only make one test and you do not differentiate between two groups of cooling units. In other words, “Related to group of cooling units” will be disabled when:

» <Room> C15 = 0 or 1
» <Test> C23 = “No” and
» <Test> C24 = 0.

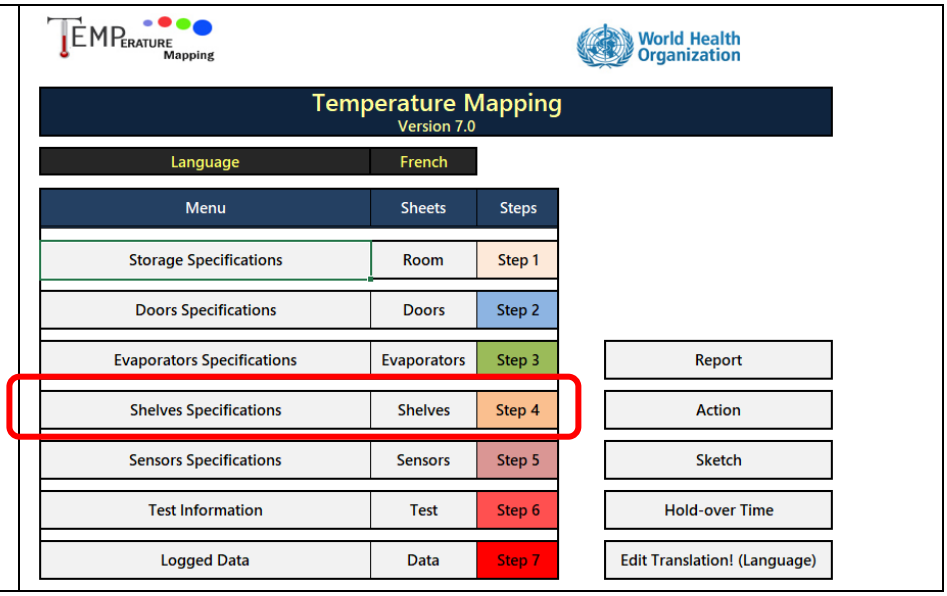
The default is for testing with one group of cooling units unless you decide to have a more stringent test and see how the temperature map is when only one of the two groups of cooling units are functioning. If you have only two evaporators, you may test with one of them only. In this way you map the equipment for only one of the cooling units. If you have several evaporators, you can divide them into two groups and test one group first and then test the other group second.

Once the data transfer is completed, click <Back to Main Menu>.

Step D.5

Click on <Shelves Specifications> sheet as shown in Fig. 25.

Fig. 25. Selecting worksheet for shelves specification

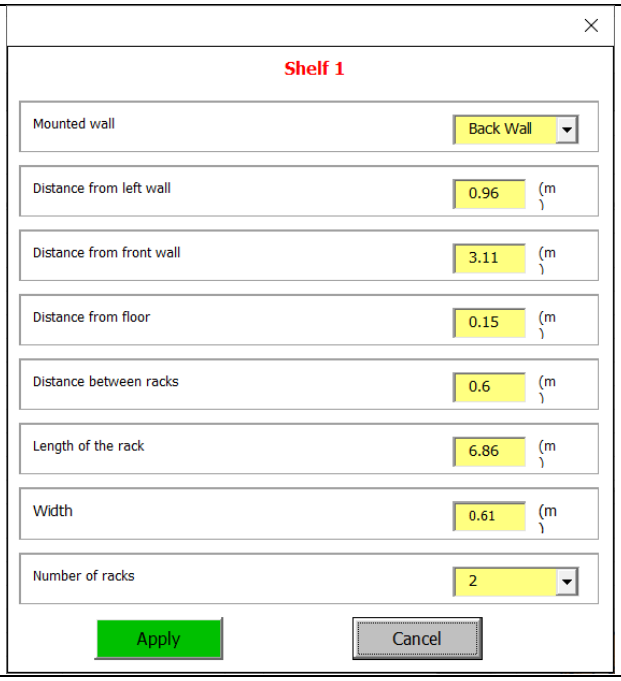


Examine Section B3 and Table 5 of the Measurement Form for the way shelves are numbered.

***Note:** The number of options for locations and dimensions of shelves is equal to the number specified in cell C14 on the "Room" worksheet.*

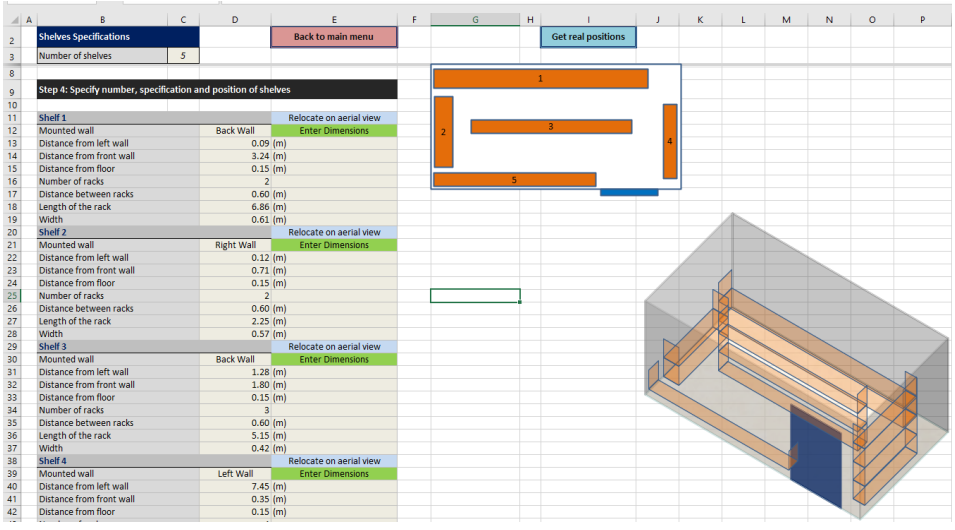
Transfer the data on shelves' locations and specifications recorded in Table 5 of the Measurement Form to the right boxes in the data entry windows in this worksheet. The procedures are similar to those as explained for doors and evaporators (see Fig. 26).

Fig. 26. Example of data entry for position and dimensions of the shelves



See the example in Fig. 27.

Fig. 27. Sample of a completed shelves specification worksheet



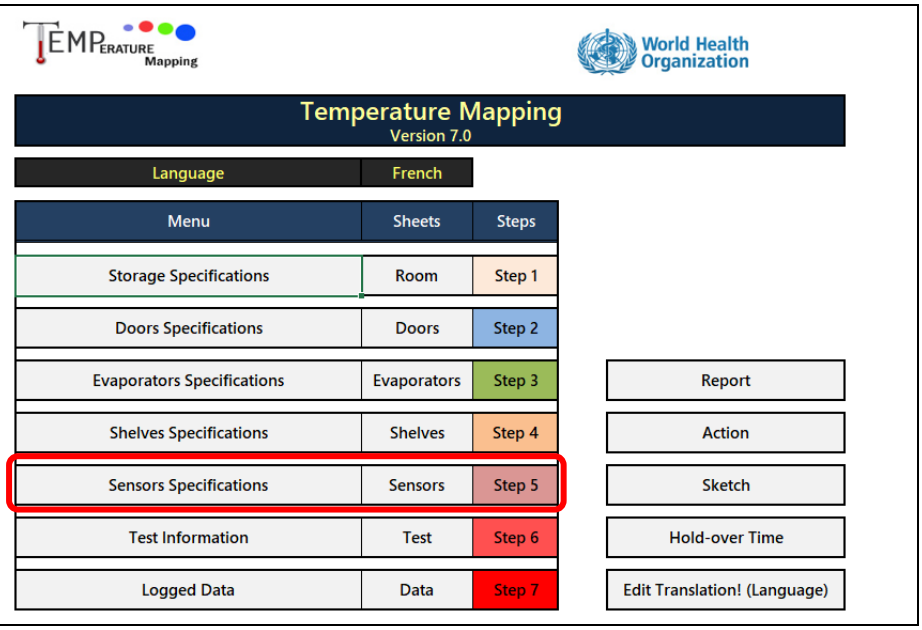
If the location of the shelves is not correctly reflected in the 2D and 3D diagrams, you can reflect their proper location in the diagrams using the <Relocate on plan> option. Follow the same procedures as described in Step D.3.2 for door size and location.

Once the data transfer is completed, click <Back to Main Menu>.

Step D.6

For specifying the number of sensors to be used you should firstly open the ”Test” worksheet and, in cell C16, specify the total number of sensors that will be used for temperature mapping of this particular equipment or storage area. Remember, one extra sensor for recording the ambient temperatures during the test is not included in the number of sensors put in C16.

Fig. 28. Completing “Test” worksheets



As explained in Step B.7, the Temperature Mapping tool calls for 12 mandatory sensors with an addition of up to 28 optional sensors. Sensors numbered 1 to 12 are fixed at three specific levels in each of the four corners of the storage unit to be mapped.

Selecting “12” indicates that you do not require any sensors other than the minimum mandatory sensors placed in fixed positions. If you wish to use optional sensors, then the value to be indicated in cell C16 in the “Test” worksheet should be the sum of the 12 mandatory sensors plus the optional sensors. The maximum number allowed by the tool is 40 sensors.

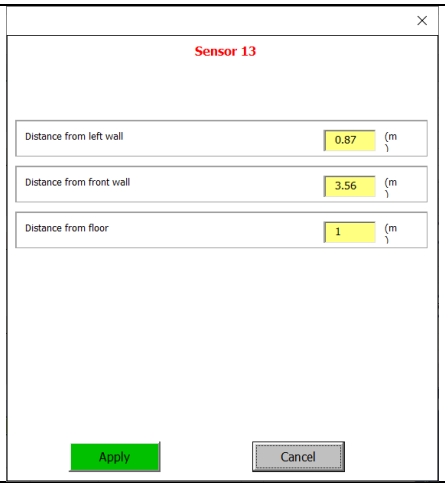
The guidance for identifying the correct number of optional sensors to be used for different types of equipment is found in Step B.7. Correctly identifying the number of sensors helps improve accuracy of temperature mapping. However, regardless of the number of optional sensors placed, the location of the first 12 mandatory sensors should not be altered.

After indicating the total number of sensors, click on <Back to Main Menu>, and then click on the <Sensor Specifications> option (see Fig. 28).

Step D.7

Scroll down to reach sensor number 13. On sensor number 13, click on **Enter dimensions** (see Fig. 29). Record the specific positions (coordinates) of additional sensors that will be placed within the storage unit to the corresponding boxes. The data on additional sensors coordinates is found in Table 6 of the Measurement Form.

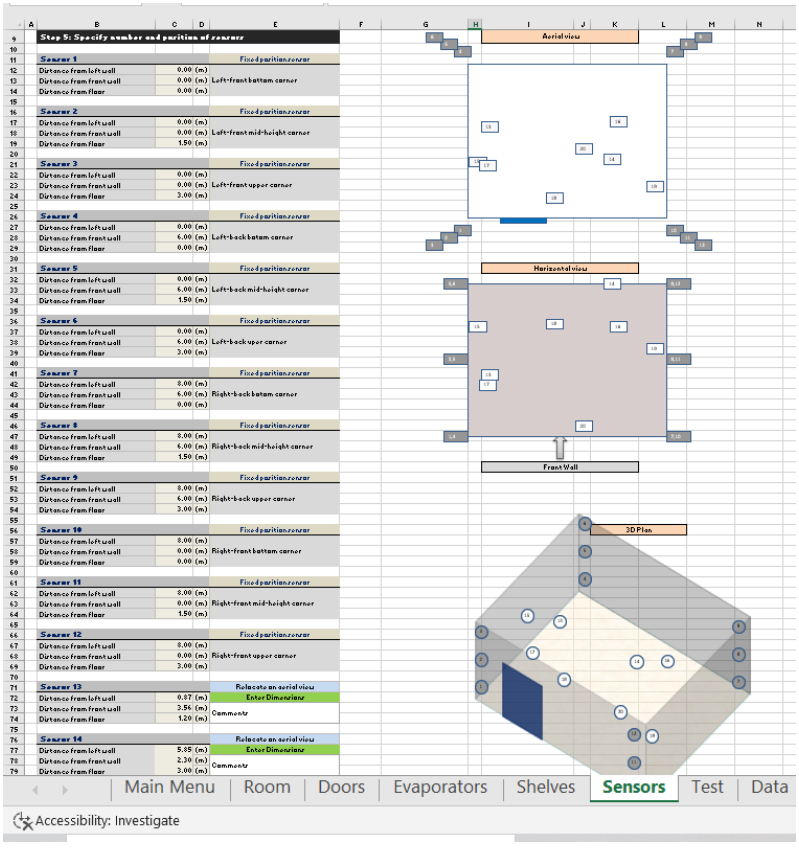
Fig. 29. Example of data entry for position (coordinates) of one of the sensors



The position of the optional sensors can be freely moved on all three plans: horizontal, vertical and 3D (see Fig. 30).

If the desired location of the sensors is not correctly reflected in the 2D and 3D diagrams, you can adjust their location in the diagrams using the <Relocate on plan> option. Follow the same procedures as described in Step D.3.2 for the door position.

Fig. 30. "Sensors specification" worksheet

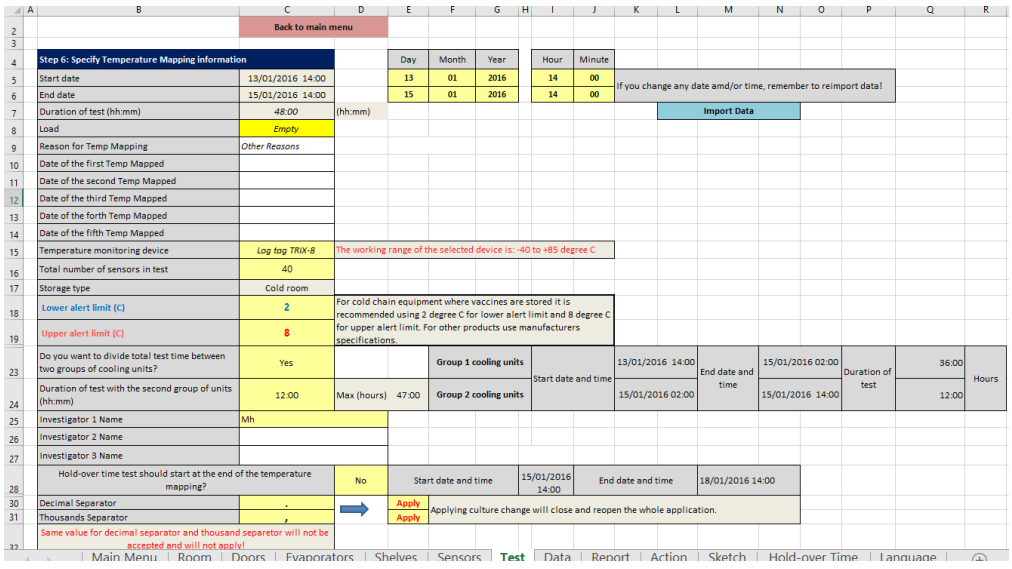


Once the "Sensors" worksheet is completed, click on <Back to Main Menu>.

Step D.8

Go back to the “Test” worksheet and specify in cells E5, F5, G5, I5 and J5 the start date and time of the temperature mapping test. Then, complete cells E6, F6, G6, I6 and J6 with the end date and the time of the test as shown in Fig. 31. You can always go back to this worksheet to modify both the start and end dates in case of delay in the implementation. Note that any change in date and/or time requires that you re-import data either from the “Data” sheet or by clicking on cell L7.

Fig. 31. Sample of a completed test worksheet



The accurate specification of start and end dates and times is very important – and should match the exact dates and times of the reading of the sensors.

Note: *You can postpone this step and fill in only the required start and end dates and times once the sensors are removed from the storage unit and temperature records have been downloaded to “Device Output”. This is further detailed in Section G.*

Complete the rest of the information from cells C8 to C16 and cells C18 and C19. Note that C17 is already filled in since you selected the storage type in “Room” worksheet C3.

In this version both lower alert and upper alert limits (C18 and C19) can be from -50 °C to +55 °C. However, “Upper alert limit (C19)” cannot be less than or equal to “Lower alert limit (C18)”. It must always be higher than that of the lower alert limit. If the cold room or the refrigerator to be tested is for vaccines, usually you should select 2 °C and 8 °C for lower and upper alert limits, respectively. For products other than vaccines you should consult the manufacturers of the products to be stored in this equipment or storage area.

Section E. Guide on placing and configuring three different types of sensors

This section describes how to prepare and configure the temperature recording sensors required for recording internal temperatures of different areas inside the equipment or storage unit for a minimum of 48 and up to 72 hours. The number of steps required to complete this depends on the type of the temperature recording sensor used. Using LogTag® devices require more steps compared with using Q-tag® and Libero® devices.

Note: *It is not necessary to read the steps for all three types of temperature recording devices. Read only the steps related to the device you are using for temperature mapping.*

Make sure you prepare one extra sensor, which will be used to measure ambient temperatures surrounding the equipment. For example, if 20 sensors are indicated, the total number of sensors to prepare should be 21.

Step E.1 Labelling the temperature recording sensors

When using the sensors for the first time, number each one from 1 to 20, or a higher number up to 40. Then, mark the extra sensor that will be used for ambient temperature monitoring with the last number. Use a felt pen with permanent ink. Fig. 32 is an example of marked LogTag® sensors. Q-tag® or Libero® sensors are marked in the same way.

Note: *These sensors can be re-used a few times. For temperature mapping requiring additional sensors, just continue marking new sensors from the last number of the old ones.*

Fig. 32. Numbering sensors

If you are mapping temperature in very large cold rooms (e.g. drive-in cold rooms) up to 40 sensors are required. Do not forget the extra sensor for recording ambient temperature.

Step E.2 Preparing and configuring temperature sensors

In this step you are preparing or configuring the sensors for the temperature mapping test.

STEP E.2.1 PREPARING AND CONFIGURING THE LOGTAG® SENSORS

Download and install the LogTag® Analyzer software from the Temperature Mapping tool main page (see Fig. 2).

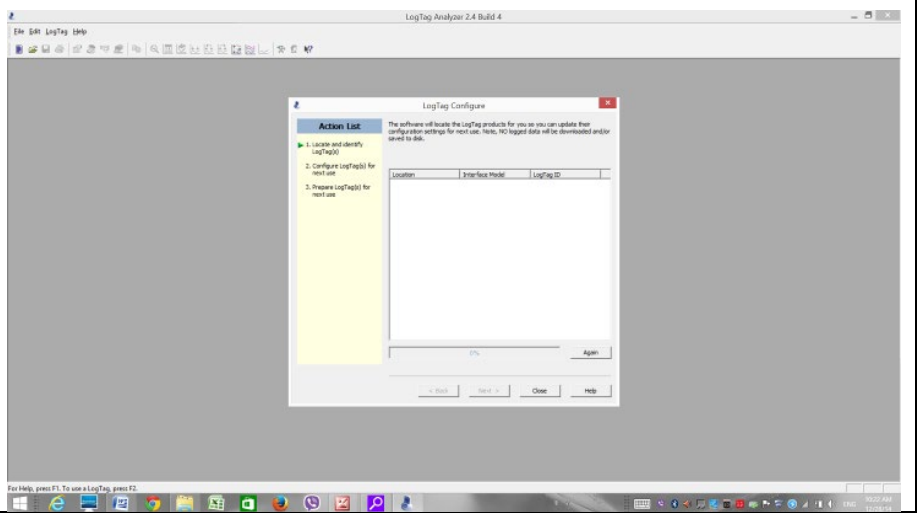
Note: *For smooth execution, the software should be installed at <C:\Program Files \LogTag® Recorders\LogTag® Analyzer\>.*

Step E.2.1a

Go to <C:\Program Files \LogTag® Recorders\LogTag® Analyzer> to open the program and click on <LogTag® Analyzer.exe>. The LogTag® Analyzer main window will appear as shown in Fig. 33.

A shortcut icon may be placed on the computer desktop or pinned in the task bar for easy access.

Fig. 33. LogTag® Analyzer main window



Step E.2.1b

Connect the LogTag® interface (Fig. 34) to the computer where the LogTag® Analyzer application was installed.

Fig. 34. LogTag® interface connected to a computer

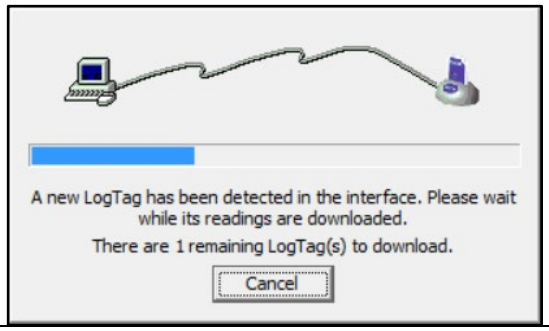
Step E.2.1c

Insert sensor number 1 into the LogTag® interface, as shown in Fig. 34. Ensure that the three connection circles are in contact with the three connection spheres inside the groove of the interface (see Fig. 35).

Fig. 35. Connection points for LogTag® interface and sensor

A window with a message indicating recognition of sensor 1 will appear (Fig. 36). Allow the application to complete reading and connecting to sensor 1.

Fig. 36. Recognition of a sensor in the LogTag® Analyzer



Step E.2.1d

Open the <Configuration Profiles> window by clicking on the <LogTag®> option, as shown in Fig. 37, and select <Profile>. If this is the first time the LogTag® Analyzer has been used, the "configuration profile" window may be empty as shown in Fig. 38.

Fig. 37. Setting sensor's profile in the LogTag® Analyzer

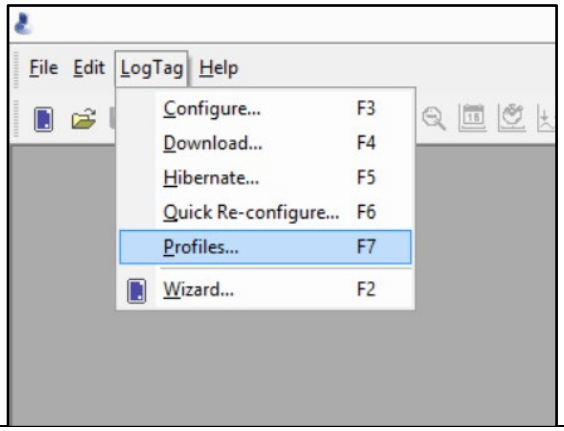
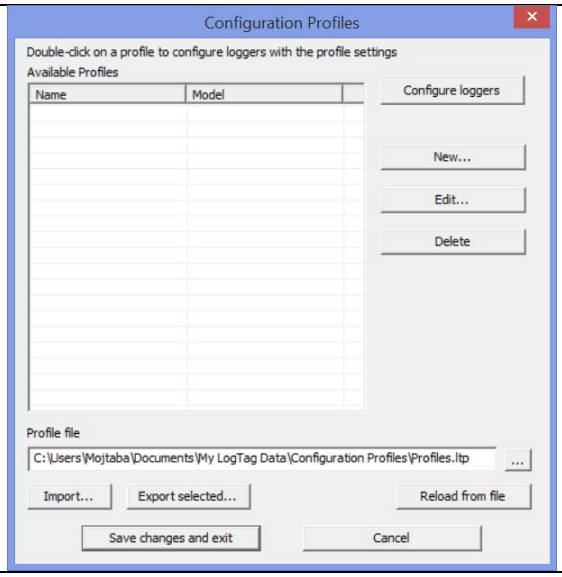


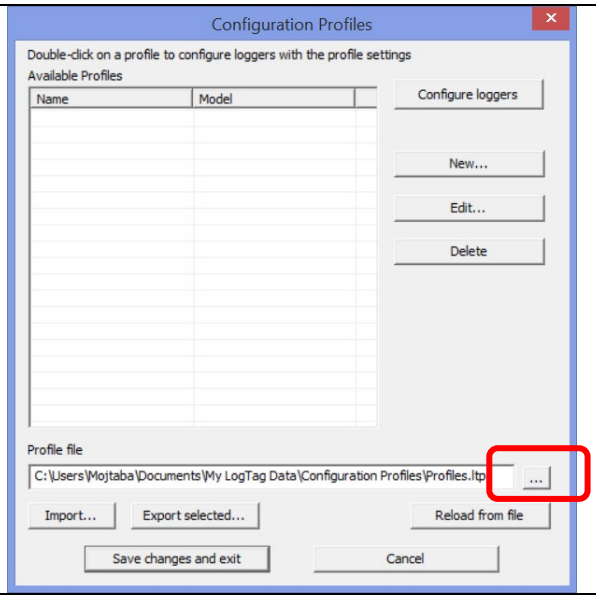
Fig. 38. LogTag® Analyzer window for configuring sensor profile



Step E.2.1e

Select the correct file containing the LogTag® profile by clicking on browse key < … > located in the lower right corner of the “Configuration Profile” window (see Fig. 39).

Fig. 39. Browser for selecting the correct profile for the configuration process



***Note:** The LogTag® profiles are found in the “Common Files” subfolder.*

Step E.2.1f

Go to the “Common Files” subfolder and select <Profile_LogTag®.ltp>, then click on <Open> (see Fig. 37). This will allow the profile to be added to the list of available LogTag® configuration profiles as shown in Fig. 40.

Fig. 40. ”LogTag® profile” to be added to the LogTag® Analyzer program, located in the Temperature Mapping “Common files” subfolder

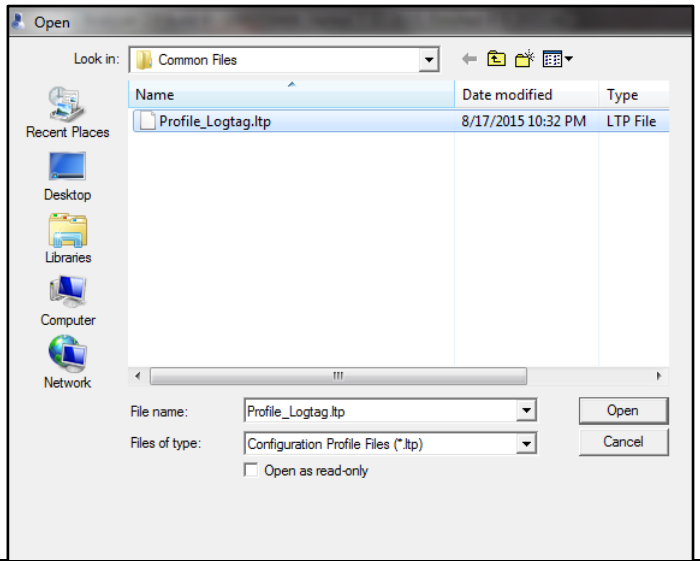
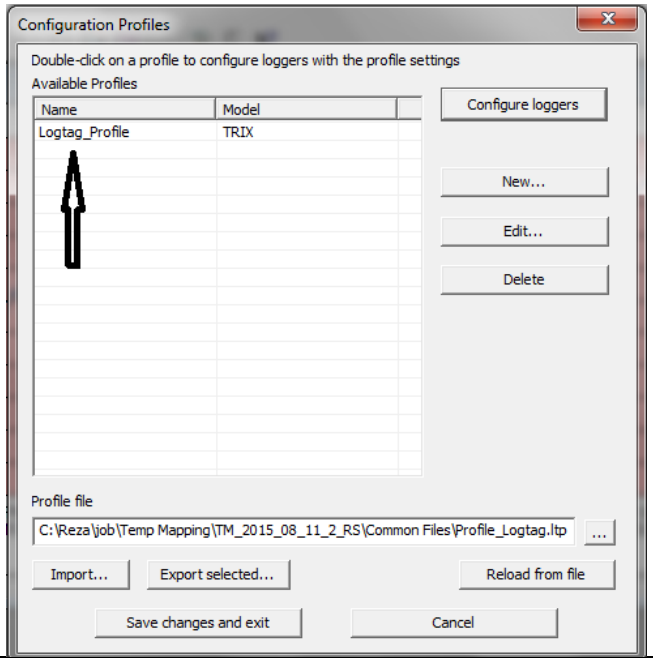


Fig. 41. LogTag® sensor profile added into the LogTag® Analyzer's sensor "Configuration profiles"



Step E.2.1g

Select this LogTag® profile from the list and click on <Configure loggers>. This step will complete the configuration process for LogTag® sensor 1.

Remove sensor 1 from the interface. It will begin to record temperatures 20 minutes after the sensor's start button is pushed.

The configuration is successfully completed and the sensor is ready for use once the two light-emitting diodes (LEDs) on the sensor blink. Although the sensor is ready for use, it will not detect and record temperatures until the sensor's start button has been pushed. See Step F.4.

This profile will configure the sensor for the following specifications:

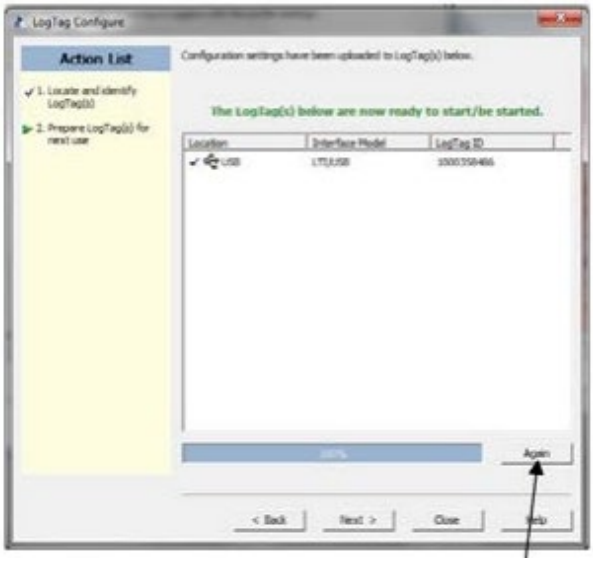
» The sensor will not record temperatures until 20 minutes after the start button is pushed.
» The sensor records temperatures at regular 10-minute intervals.
» The temperature is recorded for a maximum of 4 days (96 hours), which provides a maximum of 576 readings.

Note: *You should only use the profile provided for this application! Do not change the profile! Any change to the profile may disrupt the application's functionality and you may not be able to obtain a report, or a correct and accurate result.*

Step E.2.1h

To configure sensor number 2, insert the sensor to the LogTag® interface and repeat Step E.2.1g by clicking on the <Again> key as shown in Fig. 42. You do not have to repeat E2.1a, E2.1b, E.2.1d, E2.1e and E.2.1f.

Repeat the actions done for sensor 2 to configure all the remaining sensors, including the one for measuring and recording the ambient temperature.

Fig. 42. Using the <again> button for configuring remaining sensors	

Step E.2.1i

After you finish configuring all the sensors, stack them as shown in Fig. 43, with the first 12 sensors in 4 stacks of 3 sensors each, as follows:

» sensors 1 to 3 together
» sensors 4 to 6 together
» sensors 7 to 9 together
» sensors 10 to 12 together.

Then, stack additional sensors 13 to 20 or more. When additional sensors are used, they should be stacked all together, up to 40.

One extra sensor is needed for recording ambient temperatures. Keep it separate from the other sensors but make sure it has been configured like the other sensors.

Fig. 43. Proper way of stacking sensors	

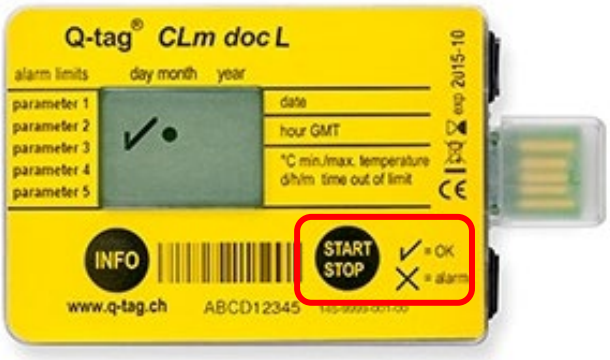
STEP E.2.2 PREPARING AND CONFIGURING THE Q-TAG® SENSORS

Step E.2.2a

Enumerate the sensors as explained in Step E.1 for the LogTag® sensors.

Step E.2.2b

Press and hold the <START/STOP> button for 5 seconds (see Fig. 44). The number *00:30* will start to blink and will count down. Once it reaches *00:00,* the device is ready to record temperatures. This delay provides time to place the sensors inside the equipment or storage area to be temperature mapped.

Fig. 44. Location of start/stop button of Q-tag® sensor	

Note: *Contrary to LogTag®, Q-tag® does not require any configuration or lengthy preparation.*

Step E.2.2c

Repeat Step E.2.2b for all Q-tag® sensors.

Step E.2.2d

After configuring all of the Q-tag® sensors, stack them as explained in Step E.2.1i.

STEP E.2.3 PREPARING AND CONFIGURING THE LIBERO® SENSORS

Step E.2.3a

Enumerate the sensors as explained in Step E.1 for the LogTag® sensor.

Step E. 2.3b

Press and hold the <START Transit> button for 3 seconds (see Fig. 45). The word "Transit" will appear and "Logging" will blink on the unit's digital screen. This means the sensor is ready and can be positioned for temperature mapping.

Fig. 45. Location of start button of Libero® sensor	

Step E.2.3c

Repeat Step E.2.3b for all Libero® sensors.

Step E.2.3d

After configuring all of the Libero® sensors, stack them as explained in Step E.2.1i.

Section F. Positioning the sensors

This section explains how to position the sensors in the correct locations inside the storage unit to be temperature mapped. This is done once all the sensors have been numbered and configured according to the directions in Section E.

Once the sensors and the application are prepared, the sensors can be positioned in their assigned place inside the storage unit that is to be temperature mapped.

Recall that there should be:

» 12 sensors in fixed positions;
» up to 28 optional sensors which can be placed in critical areas inside the storage unit; and
» 1 sensor for measuring and recording ambient temperatures.

Step F.1 Positioning the 12 mandatory sensors

STEP F.1.1

Bring the 12 mandatory sensors to the storage unit that is to be temperature mapped.

STEP F.1.2

Refer to the Measurement Form specific to the storage unit that is to be temperature mapped (see Step B.3). Note the height of the storage unit as listed in Table 2 in the temperature mapping Measurement Form. Divide the height by two (h/2) and note the result. For example, if the height is 2.2 m, the result will be 1.1 m.

STEP F.1.3

Begin by correctly placing sensor 2 (see Fig. 46a) which will serve as the point of reference for placing the rest of the 12 mandatory sensors. Figs 46b–f illustrate the sequential recommended placement of the mandatory sensors.

» Place **sensor 2** in the front left corner attached to the wall at mid-height of the storage unit.
» Place **sensor 1** directly below sensor 2 in the front left corner on the floor or attached to the wall close to the floor.

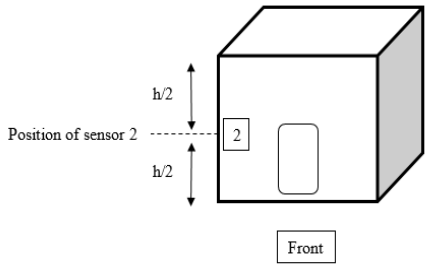
» Place **sensor 3** in the front left corner, attached to the wall close to the ceiling.
» Place **sensor 4** in the rear left corner on the floor or attached to the wall close to the floor.
» Place **sensor 5** at mid-height in the rear left corner, at the same level as sensor 2.
» Place **sensor 6** in the rear left corner, attached to the wall close to the ceiling.
» Place **sensor 7** in the rear right corner on the floor or attached to the wall close to the floor.
» Place sen**sor 8** at mid-height in the rear right corner, at the same level as sensors 2 and 5.
» Place **sensor 9** in the rear right corner, attached to the wall close to the ceiling.
» Place **sensor 10** in the front right corner on the floor or attached to the wall close to the floor.
» Place **sensor 11** at mid-height in the front right corner, at the same level as sensors 2, 5 and 8.
» Place **sensor 12** in the front right corner, attached to the wall close to ceiling.

After placement of all 12 mandatory sensors, place the sensor designated to measure ambient temperature just outside of the cold chain equipment, at a mid-height of the equipment.

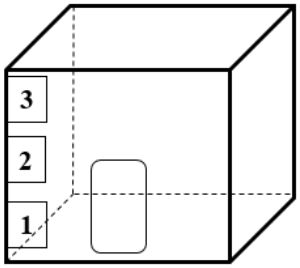
A summary of recommended sensors location is presented in Table 4.

Note: *It is very important that the 12 fixed sensors are in their correct positions in the unit's four corners at the correct level (floor, mid-height and ceiling).*

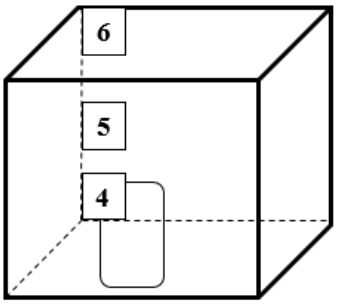
Fig. 46a–f. Correct positioning of the 12 mandatory sensors in a cold chain equipment or dry store



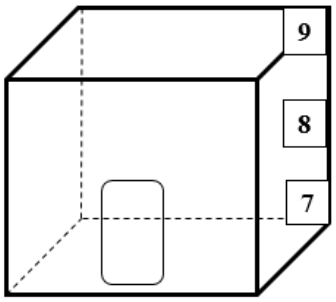
a. Correct placement of sensor 2



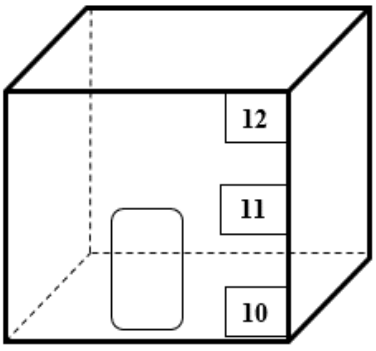
b. Position of sensors 1, 2 and 3



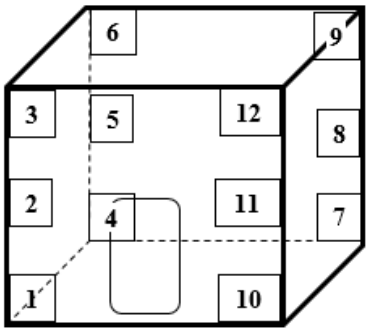
c. Position of sensors 4, 5 and 6



d. Position of sensors 7, 8 and 9



e. Position of sensors 10, 11 and 12



f. Properly placed mandatory sensors

Table 4. Quick reference guide for placement of 12 mandatory sensors

Sensor number	Position of fixed sensors			
	Side	Corner	Level	
1	Front	Left	Close to floor	Fixed sensors
2	Front	Left	Mid-height	
3	Front	Left	Close to ceiling	
4	Rear	Left	Close to floor	
5	Rear	Left	Mid-height	
6	Rear	Left	Close to ceiling	
7	Rear	Right	Close to floor	
8	Rear	Right	Mid-height	
9	Rear	Right	Close to ceiling	
10	Front	Right	Close to floor	
11	Front	Right	Mid-height	
12	Front	Right	Close to ceiling	
21 *(or whichever number is the last)*	Immediately outside of the cold chain equipment at a mid-height of the equipment			Ambient

Step F.2 Identifying risk zones for placement of optional sensors

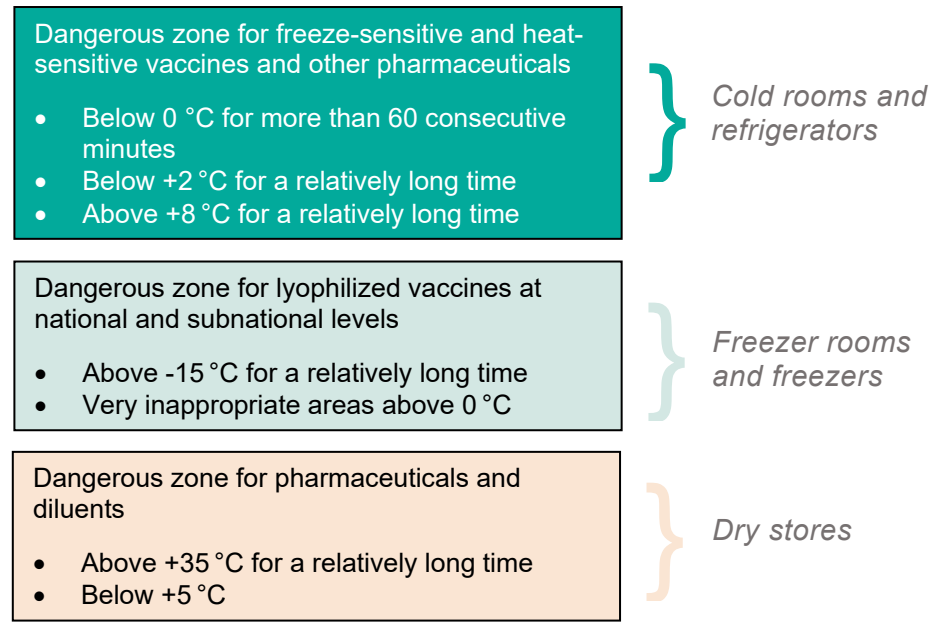
Identify the risk zones for each piece of cold chain equipment or store room to be temperature mapped (Fig. 47). The presence of risk zones determines the ideal placement of the optional sensors.

CONSIDERATIONS FOR IDENTIFYING RISK ZONES

The definition of *risk zones* varies depending on the type of storage unit and the nature of the items to be stored in the storage unit.

» If temperature mapping a cold room for storing freeze-sensitive vaccines, the risk zones are areas where the temperatures are below +2 °C or above +8 °C.
» If the equipment is a freezer, the risk areas are where temperatures are above -10 °C.
» For the dry stores, all areas where the temperature is below +5 °C and above +35 °C are inappropriate areas for storing pharmaceutical items and diluents.

Fig. 47. Quick guide for identifying risk zones



Step F.3 Positioning the additional sensors

Place the remaining sensors (sensor 13 onwards) on the shelves (if any) or in identified/ suspected risk zones inside the equipment or store room.

STEP F.3.1 POSITIONING THE OPTIONAL SENSORS IN THE COLD ROOMS

Place the optional sensors anywhere inside the cold room where you think the temperatures may be outside the range of +2 °C to +8 °C. It is advisable to place one sensor close to the door. Table 5 describes the suggested positions for the optional sensors inside a cold room.

Table 5. Guide for placement of optional sensors in cold rooms

Sensor number	Position of optional sensors	
13	Up to 10 cm from the front of evaporator 1 at the same level of the air flow or on the top shelves	Optional sensors
14	Up to 10 cm from the front of evaporator 2 at the same level of the air flow or on the top shelves	
15	In the middle of the lowest shelf in front of evaporators	
16	On shelf close to the door	
17–40	Wherever there might be a risk area for freeze- and heat-sensitive products	

STEP F.3.2 POSITIONING THE OPTIONAL SENSORS IN FREEZER ROOMS

Place the optional sensors anywhere inside the freezer room where you think the temperatures may be above -15 °C or the warmest area inside the unit to be temperature mapped. It is advisable to place one sensor close to the door. Table 6 shows the suggested positions for the optional sensors inside a freezer room.

Table 6. Guide for placement of optional sensors in freezer rooms

Sensor number	Position of optional sensors	Remarks
13	At the centre of the unit close to the ceiling	Optional sensors
14	Close to the ceiling and near the door	
15	On the shelf close to the door's higher level	
16	On the shelf close to the door's lower level	
17	Wherever there might be a risk that the temperature might be above freezing point	
18		
19		
20		
….		
….		
40		

STEP F.3.3 POSITIONING THE OPTIONAL SENSORS IN DRY STORES

Place the optional sensors anywhere inside the dry store where the temperature might be above +35 °C, or the warmest area inside the store room. It is advisable to place one sensor inside the unit, close to the door. Table 7 shows the suggested positions for 8 optional sensors inside a dry store.

Table 7. Guide for placement of optional sensors in dry stores

Sensor number	Position of fixed sensors	Remarks
13	At the centre of the store close to the ceiling	Optional sensors
14	Close to the ceiling and near the door	
15	Close to the ceiling and near the door	
16	On shelf close to the door higher level	
17	Wherever there might be a risk that the temperature may be outside the acceptable range	
18		
19		
20		
….		
….		
40		

Note: *While the number of mandatory sensors cannot be changed, the number of optional sensors can be reduced for smaller storage rooms and equipment.*

Step F.4 Activating LogTag® sensors

Once all LogTag® sensors are in their correct positions, activate them by pushing and holding for a few seconds the <Start> button on each sensor (see Fig. 48). This is an important step and can easily be forgotten. This process does not apply to Q-tag® and Libero® sensors.

Fig. 48. Start button to be pushed to activate the LogTag® sensors	

Step F.5

Close the storage unit's door(s) and leave the sensors there for 48–96 hours without opening the unit in between. The minimum period for temperature mapping is 48 hours and the maximum is 96 hours.

Very important: *Put a highly visible sign in appropriate language(s) on the door to warn that there is a temperature mapping in progress. A sample sign, which warns to NOT open the door, touch the thermostat or turn off the machine, is available in Annex 3.*

Step F.6

Place the last sensor – prepared for recording the ambient temperatures – just outside the unit to be temperature mapped. See Table 4 for sensors' recommended placement.

Section G. Removing sensors and downloading temperature readings to the temperature mapping application

This section explains how to remove the sensors positioned inside the store room or equipment after the pre-determined period of time, and how to transfer the recorded temperature information to the equipment-specific Temperature Mapping tool.

If several storage units have been temperature mapped, make sure data are entered into each unit's corresponding Temperature Mapping tool.

Step G.1

Remove all the sensors from the storage equipment or storage room and stack them in order, from the first to the last sensor.

Keep the ambient temperatures sensor separate from the other sensors.

Step G.2

Download and save the recorded temperature data from the sensors. The following steps (G.2.1 G.2.2, and G.2.3) present the steps for recording data from the three types of sensors. It is not necessary to

read the steps for all three types. Read only the steps related to the device you are using for temperature mapping.

STEP G.2.1 DOWNLOADING RECORDED DATA FROM LOGTAG® SENSORS

Download and save the recorded temperature data from LogTag® sensors.

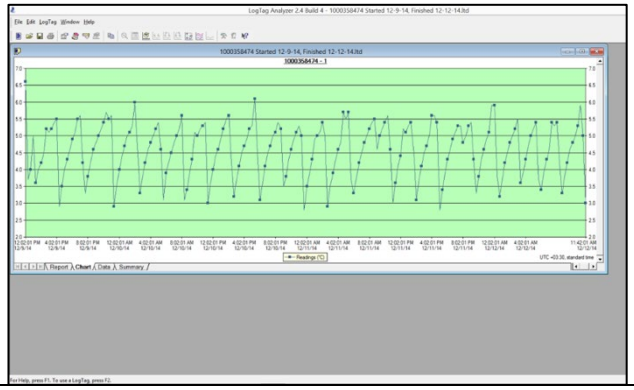
Open the <Common files> subfolder of the Temperature Mapping Source folder. Double click on the <Option_LogTag®.asxml> file to download the recorded temperature data from the LogTag® sensors.

Step G.2.1a

Connect the LogTag® interface to the computer where the LogTag® Analyzer is downloaded (see Step E.2.1 Preparing and configuring the LogTag® sensors). Then, open the LogTag® Analyzer application (see Step E.2.1a).

Step G.2.1b

Insert sensor 1 in the LogTag® interface (see Step E.2.1c). Allow the application to complete reading and connecting to sensor 1 (Figs 34 and 35). A graph of the temperature reading will then appear on the screen as shown in Fig. 49.

Fig. 49. Sample of graphed temperature readings	

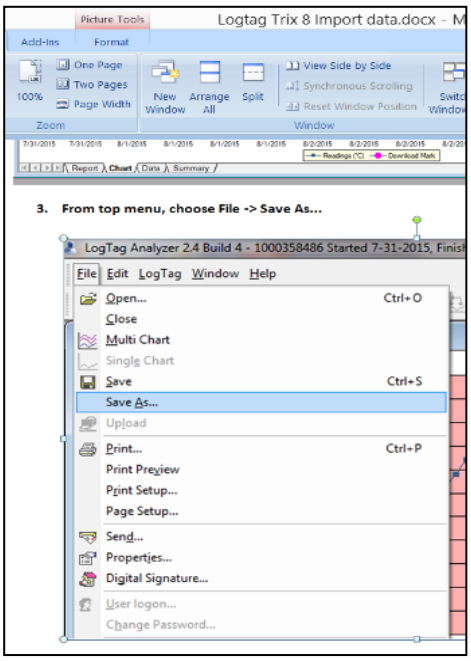
Step G.2.1c

Save the temperature data recorded in the sensors to the LogTag® Analyzer.

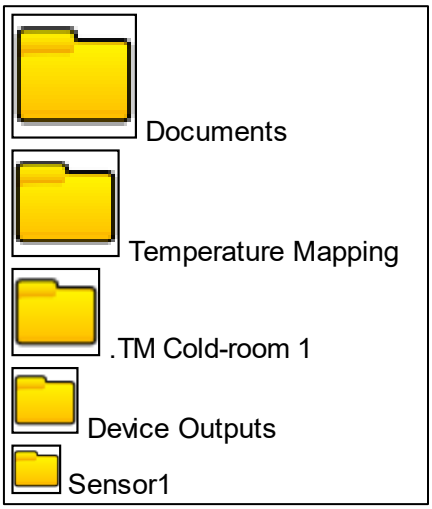
To describe the necessary actions for correctly saving the recorded temperature data in the sensors, use “sensor 1” which contains temperature data take in “cold room 1”. The following set of procedures is illustrated in Fig. 50.

a) First, go to <File> and select <Save as>.
b) When the <Save as> window opens, click on the following folders in a sequential manner: <Documents>; <Temperature Mapping>; <.TM Cold-room 1>; <Device Outputs>; and <sensor 1>.
c) Then, within the “save as” window, just below the <File name>, check the options for “save as type” from the drop-down list. Select <Text (tab delineated)>. This procedure is very important.
d) Check the <Include Summary> tick box.
e) Finally, click on <save>.

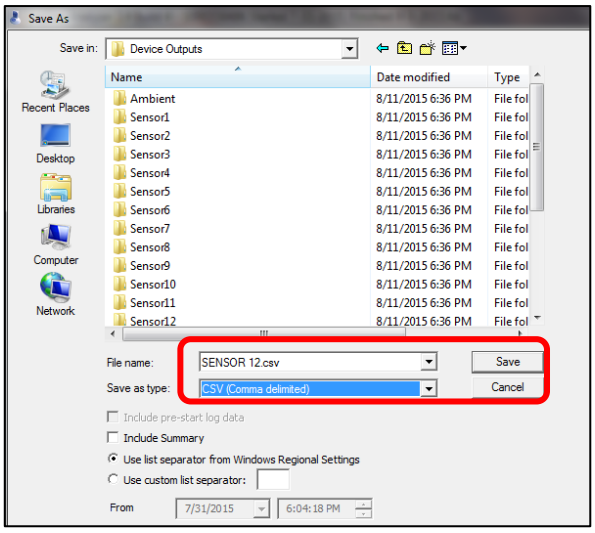
Fig. 50a–d. How to save temperature data from the LogTag® sensor to the LogTag® Analyzer



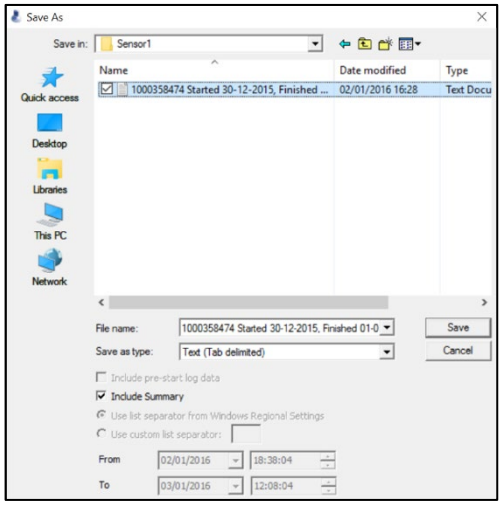
a. "save as" must be used



b. Sequential actions to save data to the right "sensor" folder



c. Choosing the correct sensor folder to save data



d. Saving data to the LogTag® Analyzer

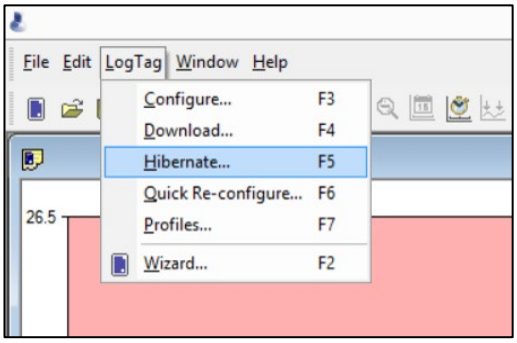
Note: *<.TM Cold-room 1> in Figure 50b is used only as an example. This could be any storage room or equipment.*

Step G.2.1d

Once the file is saved, click on <LogTag® > and select <Hibernate ... F5> as shown in Fig. 51. This turns off the sensor and deletes all temperature readings.

***Note:** Perform Step G.2.1d only when you are certain the recorded temperature data is saved on the LogTag® Analyzer, because you will NOT be able to retrieve the data if they are not saved.*

Fig. 51. Clicking <Hibernate… F5> will delete all temperature data from the sensor



Step G.2.1e

Repeat steps G.2.1b to G.2.1d, including all of their sub-steps, for each sensor used in mapping temperature of a specific storage room or equipment, including the sensor for measuring and recording ambient temperature.

For example, if there were 20 sensors inside the storage room/equipment and one sensor for recoding ambient temperatures, you must repeat steps G.2.1b to G.2.1d 20 more times.

STEP G.2.2 DOWNLOADING RECORDED DATA FROM Q-TAG® SENSORS

Download and save the recorded temperature data from Q-tag® sensors.

The steps described below are specific only for Q-tag® sensors.

Step G.2.2a

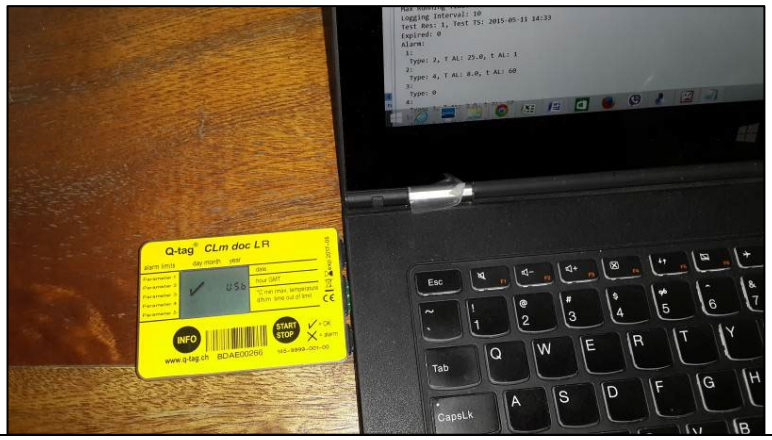
Hold the <START/STOP> button (see Fig. 52) until the word “OFF” appears in the corner of the screen of the Q-tag® sensor. This stops it from recording temperature readings.

***Note:** If you do not stop the recording, the computer cannot retrieve the data from the device.*

Fig. 52. Stopping the Q-tag® sensor from recording temperatures

Step G.2.2b

Connect the Q-tag® sensor to the computer's USB port. If the device is connected properly to the computer, a check symbol (✓) and the letters "USB" will appear on the card's display as shown in Fig. 53.

Fig. 53. Check mark appears on Q-tag® sensor when successfully connected to a computer	

A virtual drive will be created automatically in the computer. The drive's name is <CLM DOC>.

Step G.2.2c

Go to the computer's main drive <Computer> and choose the virtual drive <CLM DOC>.

Open the drive, which will access a list of files. One of the files has a text extension (.txt) (see example in Fig. 54).

Fig. 54. Sample of an automatically created file with a ".txt" extension	<BDAE00266_10_201509060817.txt> (example)

The following describes the necessary actions to save the recorded temperature data from the sensor to the computer. For this exercise, we use "sensor 1", which contains temperature data taken in "cold room 1", as an example.

a) First, select and copy the text file created in the <CLM DOC> virtual drive. Example: "BDAE00266_10_201509060817.txt'.
b) Copy this text file to the sensor folder with a name corresponding to the sensor number.
c) Locate the sensor 1 folder by opening the following folders in a sequential manner: <Documents>; <Temperature Mapping>; <.TM Cold-room 1>; <Device Outputs>; and < sensor 1>.
d) Then, paste the text file (e.g. "BDAE00266_10_201509060817.txt" in "sensor 1" folder. This saves the data from sensor 1 to the computer.

Step G.2.2d

Remove the device from the computer. There is no need to push the <START/STOP> button as the device has already been deactivated in Step G.2.2a.

Step G.2.2e

Repeat steps G.2.2a to G.2.2d for all other Q-tag® sensors.

STEP G.2.3 DOWNLOADING RECORDED DATA FROM LIBERO® SENSORS

Download and save the recorded temperature data from Libero® sensors.

If you use the Libero® model Ti1-L sensor, you will have already downloaded the software "ElproVIEWER". This software usually is in the folder "Program Files". Install the software and a shortcut icon will appear on the computer's desktop.

The steps described below are specific only for Libero® sensors.

Step G.2.3a

Press the <STOP Arrived> button on the Libero® sensor.

Step G.2.3b

Click on <ElproVIEWER> desktop shortcut to run the application.

***Note:** You will need to type in a serial number code the first time you run this software. Use this generic code: <N865C-EBBJG-2GRMQ-U7GMG-AJCCS-9>.*

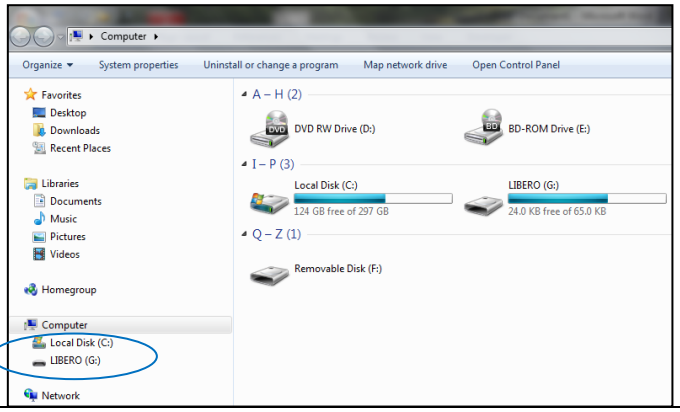
Step G.2.3c

Connect Libero® sensor device to the computer's USB port as shown in Fig. 55. A virtual drive – labelled "Libero" – will be created automatically.

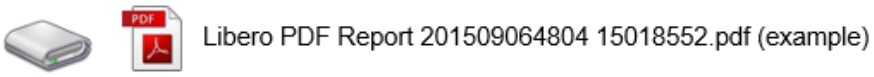
Fig. 55. Connecting the Libero® sensor to the computer	

Step G.2.3d

Go to the computer's main drive and click on <Computer>, then select the <Libero> virtual drive as indicated in Fig. 56.

Fig. 56. Selecting the "Libero" virtual drive in the computer	

Open the drive and you will see a file in a portable document format (PDF), represented with a ".pdf" extension (see sample shown in Fig. 57).

Fig. 57. Sample of a file in ".pdf" format generated by "Libero", which contains recorded temperature data	

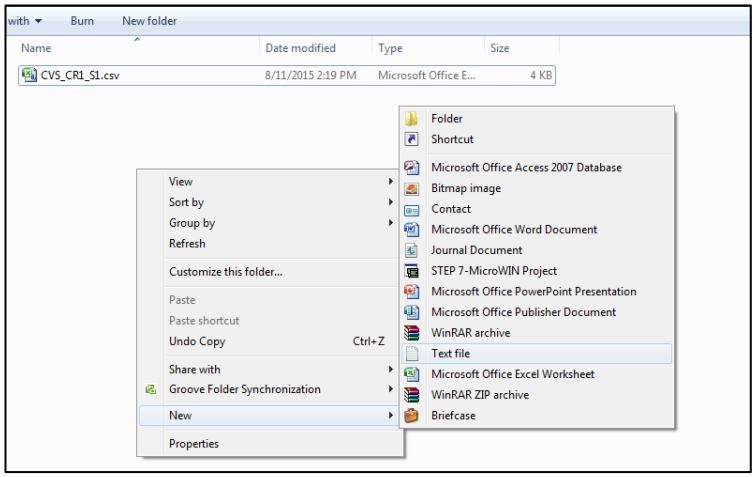
The following describes the necessary actions to save the recorded temperature data from the sensor to the computer. For this exercise, we use "sensor 1", which contains temperature data taken in "cold room 1" as an example.

a) Select and copy the text file created in the <Libero> virtual drive. Example: "Libero PDF report 201509064804 15019552.pdf".
b) Copy this text file to the sensor folder with a name corresponding to the sensor number.
c) Locate the sensor 1 folder by opening the following folders in a sequential manner: <Documents>, <Temperature Mapping>, <.TM Cold-room 1>, <Device Outputs> and < sensor 1>.
d) Paste the text file (e.g. "BDAE00266_10_201509060817.txt" in "sensor 1" folder. This saves the data from sensor 1 to the computer.

Step G.2.3e

Create a text file in the sensor folder by performing the following actions (see Fig. 58).

a) Right click the white part of the screen and a menu will open.
b) Select <NEW>.
c) Select <Text file>.
d) Give the new text file an easily recognizable name. Example: "Libero 1.txt".

Fig. 58. Creating a new text file within the sensor folder	

Step G.2.3f

Open the sensor data file using the "ElproVIEWER" application by performing the following actions.

a) Go to <ElproVIEWER> software.
b) Click on <Add File(s)> from the top menu (see Fig. 59).
c) Browse to find the relevant sensor folder in which the ".pdf" file was copied in Step G.2.3d.

d) Select the file and then click open. In this example, the path is <Documents/Temperature Mapping/.TM Cold-room 1/Device Outputs/Sensor1>.
e) When the ".pdf" file opens, click on the <Table> tab at the bottom of the window (see Fig. 60).
f) Then, click the box in the upper left corner of the table.
g) Right click on the same point (e.g. the box in the upper left corner of the table) and a new box <Copy selected rows to clipboard> will open.
h) Click on the newly opened box <Copy selected rows to clipboard> and wait until data retrieval is completed.

Fig. 59. Location of "add file(s)" in the ElproVIEWER application

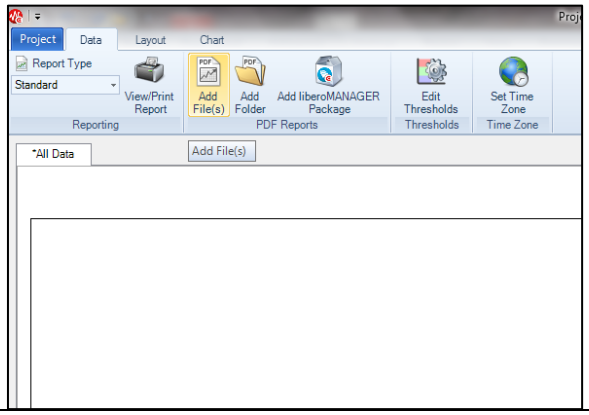
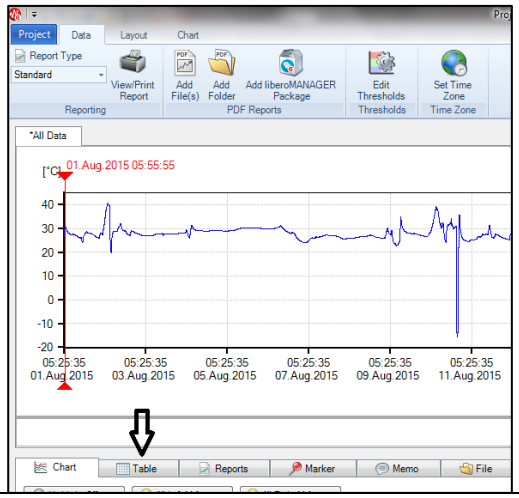


Fig. 60. Window showing retrieved temperature data from the data table



Step G.2.3g

a) Go back to the relevant sensor folder. In the example used, the path is <Documents/Temperature Mapping/.TM Cold-room 1/Device Outputs/Sensor1>.
b) Open the text file created in this folder in Step G.2.3e. In this example, the text file was named <Libero 1.txt>.
c) Copy the data in this text (its name has a ".txt" extension) file. This action will allow all data rows to be pasted into this text file.
d) Click <Save> and close the text file.

Step G.2.3h

Close "ElproVIEWER" software.

Step G.2.3i

Repeat steps G.2.3a to G.2.3h for all the Libero® sensors.

***Note:** Do NOT change the name of the <Device Outputs> folder!*

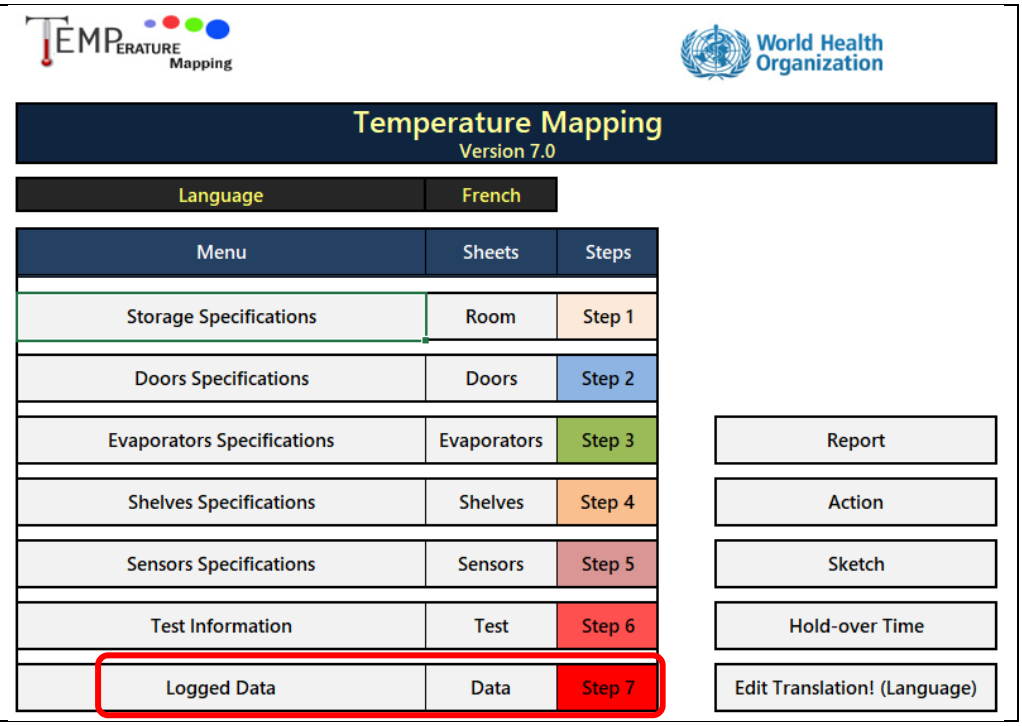
From this point forward, the steps shown apply to all three types of devices.

Step G.3 Importing the temperature data to the main Temperature Mapping tool

Open the equipment-specific Temperature Mapping tool. For this exercise, we use “Cold Room 1” as an example.

a) Open the Excel® file <Cold-room 1.xlsm> located in the “.TM Cold-room 1” subfolder of the Temperature Mapping main folder (see Figs 5 and 6).
b) Click on the <Logged Data> tab as shown in Fig. 61. This will take you to the “Data” worksheet of the tool.
c) Click on <Import Data> (Fig. 62).

Fig. 61. Location of the “logged data” worksheet for importing temperature data in the equipment-specific Temperature Mapping tool



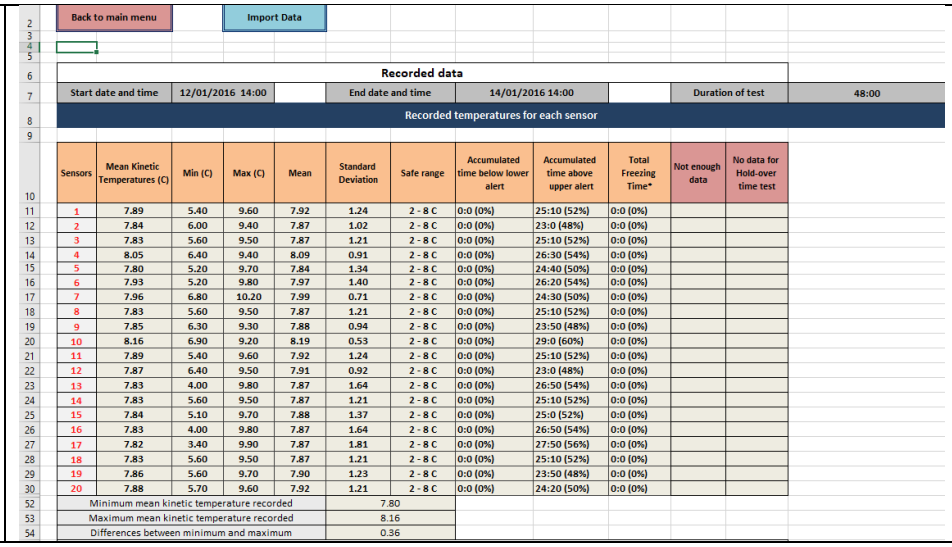
The table in the “Data” worksheet will automatically be filled with the required information from recorded temperatures. All the information is automatically extracted from all sensor files in the “Device Outputs” folder. DO NOT CHANGE this folder's name.

You may see “X” in some of the cell in column L (from cells L11 to L50). This means there is something wrong in relation to the data for that particular sensors.

The information in the table within the “Data” worksheet is very important since this will be imported to the “Report” worksheet, which will become the basis for decision-making.

> ***Important!*** *Anytime you change the “start date and time” and/or “end date and time” on the ”Test” worksheet, the data should be re-imported.*

Fig. 62. Sample of data table auto-filled with temperature recording information from the sensors



Back to main menu | Import Data

Recorded data

Start date and time	12/01/2016 14:00		End date and time	14/01/2016 14:00		Duration of test	48:00

Recorded temperatures for each sensor

Sensors	Mean Kinetic Temperatures (C)	Min (C)	Max (C)	Mean	Standard Deviation	Safe range	Accumulated time below lower alert	Accumulated time above upper alert	Total Freezing Time*	Not enough data	No data for Hold-over time test
1	7.89	5.40	9.60	7.92	1.24	2 - 8 C	0:0 (0%)	25:10 (52%)	0:0 (0%)		
2	7.84	6.00	9.40	7.87	1.02	2 - 8 C	0:0 (0%)	23:0 (48%)	0:0 (0%)		
3	7.83	5.60	9.50	7.87	1.21	2 - 8 C	0:0 (0%)	25:10 (52%)	0:0 (0%)		
4	8.05	6.40	9.40	8.09	0.91	2 - 8 C	0:0 (0%)	26:30 (54%)	0:0 (0%)		
5	7.80	5.20	9.70	7.84	1.34	2 - 8 C	0:0 (0%)	24:40 (50%)	0:0 (0%)		
6	7.93	5.20	9.80	7.97	1.40	2 - 8 C	0:0 (0%)	26:20 (54%)	0:0 (0%)		
7	7.96	6.80	10.20	7.99	0.71	2 - 8 C	0:0 (0%)	24:30 (50%)	0:0 (0%)		
8	7.83	5.60	9.50	7.87	1.21	2 - 8 C	0:0 (0%)	25:10 (52%)	0:0 (0%)		
9	7.85	6.30	9.30	7.88	0.94	2 - 8 C	0:0 (0%)	23:50 (48%)	0:0 (0%)		
10	8.16	6.90	9.20	8.19	0.53	2 - 8 C	0:0 (0%)	29:0 (60%)	0:0 (0%)		
11	7.89	5.40	9.60	7.92	1.24	2 - 8 C	0:0 (0%)	25:10 (52%)	0:0 (0%)		
12	7.87	6.40	9.50	7.91	0.92	2 - 8 C	0:0 (0%)	23:0 (48%)	0:0 (0%)		
13	7.83	4.00	9.80	7.87	1.64	2 - 8 C	0:0 (0%)	26:50 (54%)	0:0 (0%)		
14	7.83	5.60	9.50	7.87	1.21	2 - 8 C	0:0 (0%)	25:10 (52%)	0:0 (0%)		
15	7.84	5.10	9.70	7.88	1.37	2 - 8 C	0:0 (0%)	25:0 (52%)	0:0 (0%)		
16	7.83	4.00	9.80	7.87	1.64	2 - 8 C	0:0 (0%)	26:50 (54%)	0:0 (0%)		
17	7.82	3.40	9.90	7.87	1.81	2 - 8 C	0:0 (0%)	27:50 (56%)	0:0 (0%)		
18	7.83	5.60	9.50	7.87	1.21	2 - 8 C	0:0 (0%)	25:10 (52%)	0:0 (0%)		
19	7.86	5.60	9.70	7.90	1.23	2 - 8 C	0:0 (0%)	23:50 (48%)	0:0 (0%)		
20	7.88	5.70	9.60	7.92	1.21	2 - 8 C	0:0 (0%)	24:20 (50%)	0:0 (0%)		

Minimum mean kinetic temperature recorded	7.80
Maximum mean kinetic temperature recorded	8.16
Differences between minimum and maximum	0.36

The variables for plotting sensor-recorded temperature data, shown in Fig. 62 are further described in Table 8.

Table 8. Description of the variables in the "Data" table of Temperature Mapping tool

Column	Column title	Descriptions
(1)	Sensors	The numbers are those assigned to the sensors as per the instructions in Step E.1 of Section E.
(2)	Mean kinetic temperature (°C)	Mean kinetic temperature (MKT) is the calculated average temperature for each sensor from all temperature readings recorded during the test's duration.
(3)	Min. (°C)	The lowest temperature recorded for each sensor based on all temperature readings.
(4)	Max. (°C)	The highest temperature recorded for each sensor based on all temperature readings.
(5)	Mean (°C)	This is the absolute average temperature, being the sum of all temperatures recorded in all sensors from the beginning to the end of the temperature readings divided by the total number of readings. The mean temperature may not be the same as the recorded MKT.
(6)	Standard deviation	Standard deviation (SD), represented by the Greek letter σ (sigma), is the quantitative measurement of the amount of variation across a set of data values. A small SD means that most of the readings are similar, while a large SD indicates a large variation across the sensor readings. When SD is equal to zero, it means that all temperature readings are exactly the same.
(7)	Safe range	Also called "non-alert temperatures range". The safe temperature range is chosen as per the instructions found in Step D.8 in Section D. For example, safe temperature ranges for vaccine storage: • cold rooms and refrigerators: +2 °C to +8 °C • freezer rooms and freezers: -5 °C to -15 °C • dry stores: +5 °C to +35 °C.
(8)	Accumulated time below lower alert	Accumulated total time in which each sensor's temperature reading was below the safe temperature range.
(9)	Accumulated time above upper alert	Accumulated total time in which each sensor temperature reading was above the safe temperature range.

Column	Column title	Descriptions
(10)	Total freezing time	Number of times each sensor was continuously exposed to temperature equal to or less than 0 °C for 60 minutes. This criterion is based on the performance of a FreezeTag® device, which is used to monitor freeze-sensitive vaccines during storage and transportation time.
(11)	Not enough data for the duration of the test!	There might be a cross in red (**X**) in one or more rows. This means that this particular sensor either did not work at all and did not record temperature data or at a certain time during the test period stopped recording.
(12)	Not enough data for the “hold-over time” test!	There might be a cross in red (**X**) in one or more rows. This means that this particular sensor either: a) did not work at all and did not record temperature data; or b) at a certain time during the test period, it stopped recording after the temperature mapping test was completed and the hold-over time test started. This function works only when you activate the hold-over time in cell D28 of the ”Test“ worksheet.

Step G.4

Once you are satisfied with the data imported into the table, open the <Sketch> worksheet as shown in Fig. 63.

This worksheet provides a graphical representation of the temperature mapped storage equipment or storage area, including its dimensions, evaporators, shelves and sensors locations, and the status of the recorded MKT. It also has a colour-coded legend for temperature alert levels.

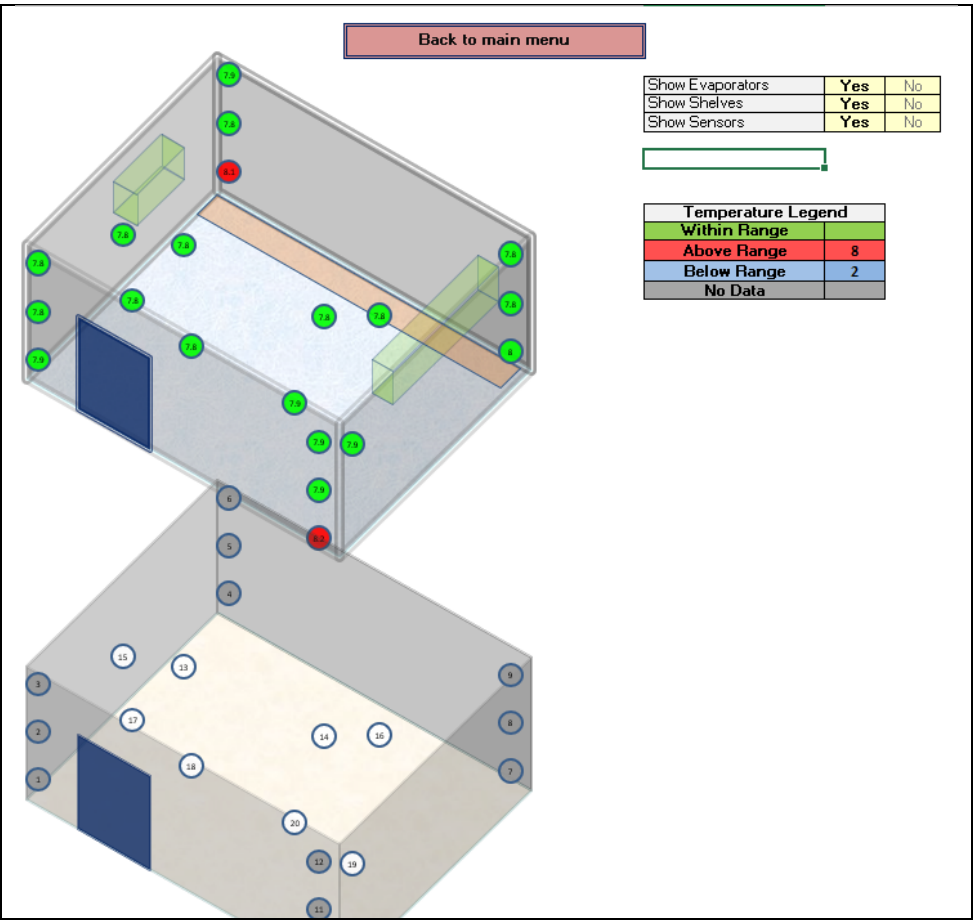


Fig. 63. Sample of a “Sketch” worksheet showing sensor detecting fluctuations in temperature reading within a cold room

As shown in the example in Fig. 63, if any of the sensors recorded MKTs above the higher defined limit, the colour will turn to red. If any of the sensors recorded MKTs below the lower defined limit, the colour will turn to blue. Green means the temperatures stayed within the defined safe limit.

Section H. Obtaining the temperature mapping report

You are almost done. It is now time to review the temperature mapping report.

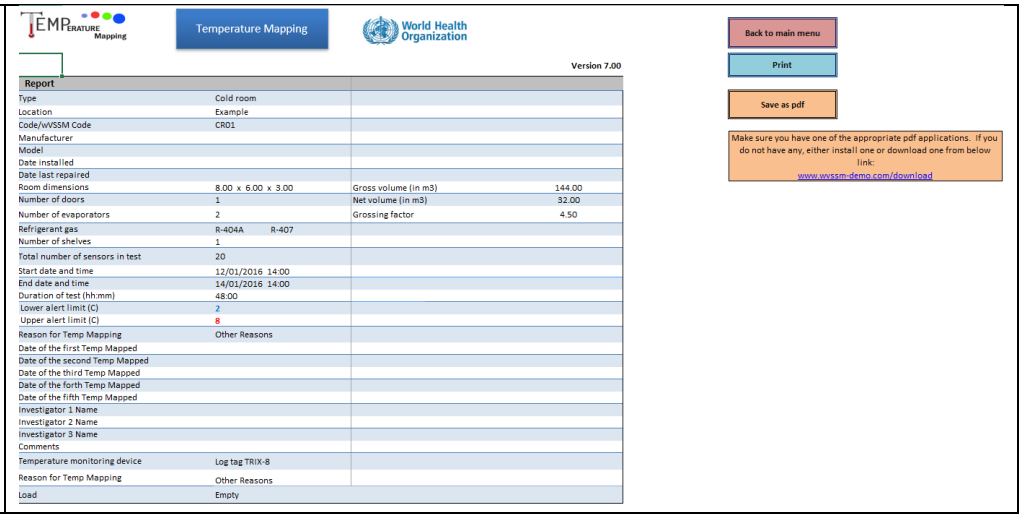
All information about the cold chain equipment or dry store is summarized in the “Report” worksheet of the Temperature Mapping tool. This worksheet is write-protected since all information has been extracted from the data generated by the previous steps.

Step H.1

Open the “Report” worksheet as shown in Fig. 64. Carefully review the information provided, such as graphs, pictures and tables to make sure everything is in order.

***Note:** It is important to examine all the information in this worksheet and take note of any problematic findings before printing/sharing the report.*

Fig. 64. Sample of the “Report” worksheet in the Temperature Mapping tool



Report			
Type	Cold room		
Location	Example		
Code/WVSSM Code	CR01		
Manufacturer			
Model			
Date installed			
Date last repaired			
Room dimensions	8.00 x 6.00 x 3.00	Gross volume (in m3)	144.00
Number of doors	1	Net volume (in m3)	32.00
Number of evaporators	2	Grossing factor	4.50
Refrigerant gas	R-404A R-407		
Number of shelves	1		
Total number of sensors in test	20		
Start date and time	12/01/2016 14:00		
End date and time	14/01/2016 14:00		
Duration of test (hh:mm)	48:00		
Lower alert limit (C)	2		
Upper alert limit (C)	8		
Reason for Temp Mapping	Other Reasons		
Date of the first Temp Mapped			
Date of the second Temp Mapped			
Date of the third Temp Mapped			
Date of the forth Temp Mapped			
Date of the fifth Temp Mapped			
Investigator 1 Name			
Investigator 2 Name			
Investigator 3 Name			
Comments			
Temperature monitoring device	Log tag TRIX-8		
Reason for Temp Mapping	Other Reasons		
Load	Empty		

Section I. Making decisions and taking action

It is now time to make decisions about how to use the gathered data to improve the store room and equipment that were temperature mapped.

You should determine whether the store room or equipment is:

1. **Fully suitable:** Can items be stored safely throughout the area or in the equipment?
2. **Partially suitable:** Are there some areas inside the equipment or storage area not suitable for storing the items?
3. **Not at all suitable:** Is the equipment or storage area mapped not at all suitable for storing the items?

In the case of condition 2 or 3, based on the analysis of the information collected from the mapping exercise, identify the source(s) of the problem and provide appropriate recommendations to improve the temperature stability of the cold chain equipment or storage area.

The date for the next scheduled or ad hoc temperature mapping should be determined and recorded.

Use the decision-tree matrix (Fig. 65) provided in Step I.2 to guide you in making decisions on appropriate action points.

Step I.1

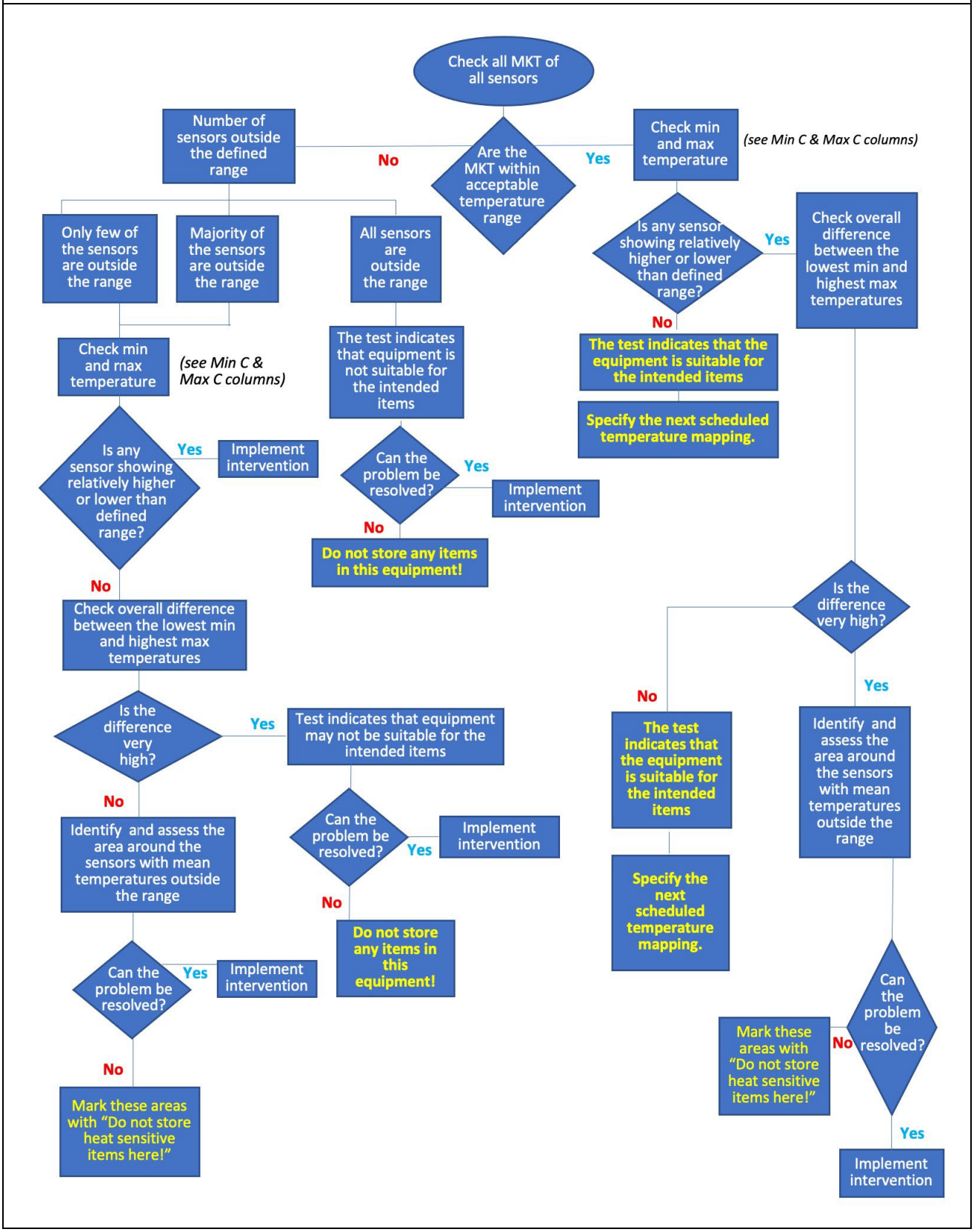
Review the MKT recorded for each sensor. Specifically, this information is found in cells C39 onwards in the summary table of the “Report” worksheet.

Pay close attention to the temperature data highlighted in red, as these are the areas that require problem-solving.

Step I.2

Based on the calculated MKT presented in the summary report table of the “Report” worksheet, determine the recommended action points by following the matrix in Fig. 65.

Fig. 65. Flow chart (decision-tree matrix) to guide decision-making and actions



Step I.3

Open the <Actions> worksheet of the equipment-specific Temperature Mapping tool and fill in the table by following the instructions below.

For this exercise, we will use “cold room 1” with a defined safe temperature range of +2 °C to +8 °C.

> ***Note:***
>
> *For section A, B and C of the table, all cells in the "Acceptable” column have a yellow background. This means that indicating either “Yes” or “No” using the drop-down menu is mandatory.*
>
> *If "No" is selected, the colour of the adjacent cell in the column "Actions to be taken" will change to yellow. This means that you should indicate the appropriate action to address the situation (see Fig. 66).*

STEP I.3.1

Complete section A. Actions should be based on sensors’ detailed recorded information, as shown in the example given in Fig. 66.

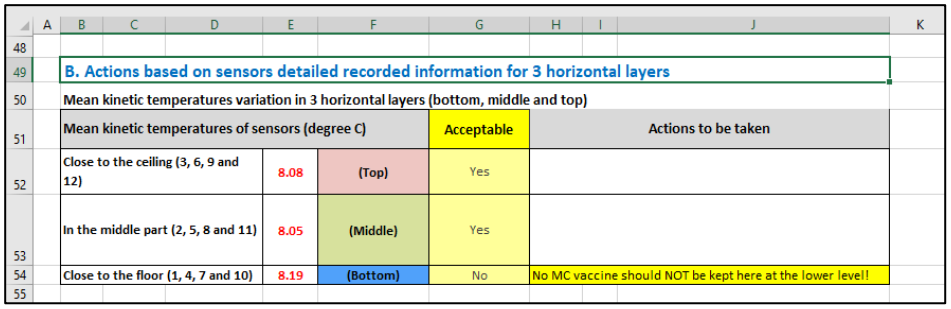
Fig. 66. Sample of filled in section A of the table: actions should be based on detailed recorded information

									Back to main menu
					Lower alert limit (C)				2
					Upper alert limit (C)				8
			Actions to be taken based on temperature mapping test results						
			Ambient mean kinetic temperatures (C)		7.86				
			A. Actions based on sensors detailed recorded information						
			Recorded temperatures for each sensor						
	Sensors	Mean Kinetic Temperatures (C)	Min (C)	Max (C)	Accumulated time below lower alert	Accumulated time above upper alert	Total Freezing Time*	Acceptable	Actions to be taken
	1	7.89	5.40	9.60	0:0 (0%)	25:10 (52%)	0:0 (0%)	Yes	
	2	7.84	6.00	9.40	0:0 (0%)	23:0 (48%)	0:0 (0%)	Yes	
	3	7.83	5.60	9.50	0:0 (0%)	25:10 (52%)	0:0 (0%)	Yes	
	4	8.05	6.40	9.40	0:0 (0%)	26:30 (54%)	0:0 (0%)	Yes	
	5	7.80	5.20	9.70	0:0 (0%)	24:40 (50%)	0:0 (0%)	Yes	
	6	7.93	5.20	9.80	0:0 (0%)	26:20 (54%)	0:0 (0%)	Yes	

STEP I.3.2

Complete section B. Actions should be based on sensors' detailed recorded information for three horizontal layers, as shown in the example given in Fig. 67.

Fig. 67. Sample of filled in section B of the table: actions should be based on detailed recorded information for three horizontal layers

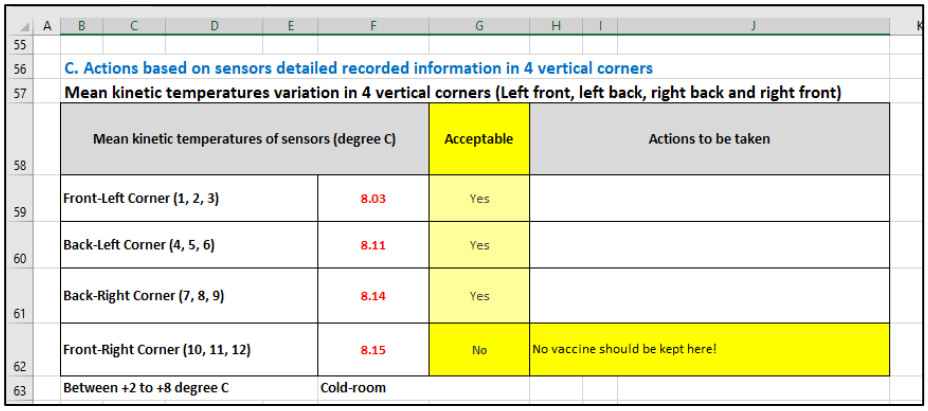


B. Actions based on sensors detailed recorded information for 3 horizontal layers				
Mean kinetic temperatures variation in 3 horizontal layers (bottom, middle and top)				
Mean kinetic temperatures of sensors (degree C)			Acceptable	Actions to be taken
Close to the ceiling (3, 6, 9 and 12)	8.08	(Top)	Yes	
In the middle part (2, 5, 8 and 11)	8.05	(Middle)	Yes	
Close to the floor (1, 4, 7 and 10)	8.19	(Bottom)	No	No MC vaccine should NOT be kept here at the lower level!

STEP I.3.3

Complete section C. Actions should be based on sensors' detailed recorded information in four vertical corners, as shown in the example given in Fig. 68.

Fig. 68. Sample of filled in section C of the table: actions should be based on detailed recorded information for four vertical corners



C. Actions based on sensors detailed recorded information in 4 vertical corners			
Mean kinetic temperatures variation in 4 vertical corners (Left front, left back, right back and right front)			
Mean kinetic temperatures of sensors (degree C)		Acceptable	Actions to be taken
Front-Left Corner (1, 2, 3)	8.03	Yes	
Back-Left Corner (4, 5, 6)	8.11	Yes	
Back-Right Corner (7, 8, 9)	8.14	Yes	
Front-Right Corner (10, 11, 12)	8.15	No	No vaccine should be kept here!
Between +2 to +8 degree C	Cold-room		

STEP I.3.4

Complete section D by indicating your recommendation for the use of the particular cold chain equipment or dry store. The list of options, presented in Table 9, is dependent on the type of equipment or storage unit temperature mapped.

Then, complete section E of the "Action" worksheet with your general comments elaborating the rationale for your recommendation and other relevant remarks. In this part is you are able to type in what you wish – using alphanumeric characters and symbols**.**

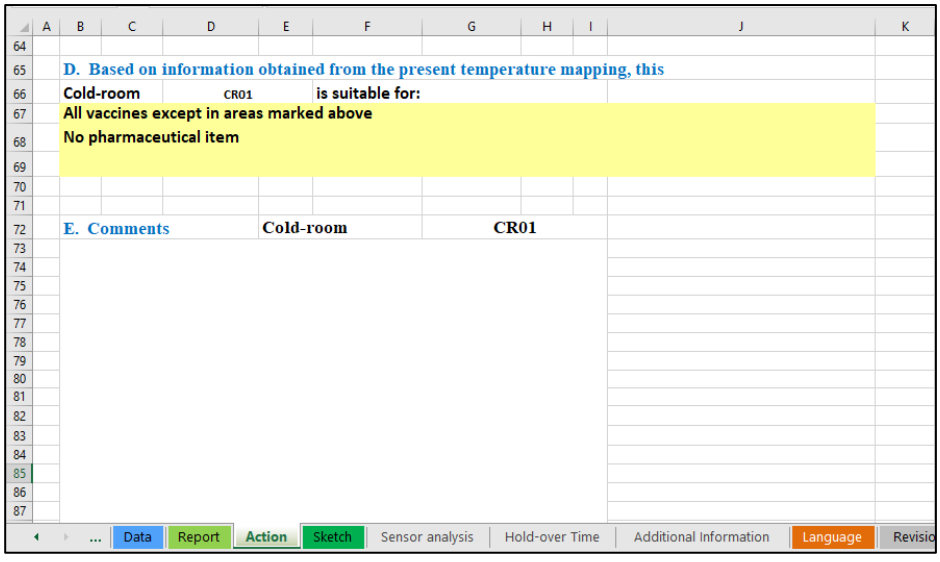
Fig. 69 presents an example of a completed section D and the "comments" box in section E of the "Action" worksheet.

Note: *The options in the drop-down menu change based on the type of equipment being temperature mapped.*

Table 9. List of options for recommended actions on the use of the mapped equipment (cold rooms and refrigerators, freezer rooms and freezers and dry stores)

List for cold rooms and refrigerators
All solid vaccines
All vaccines except in areas marked above
Only solid vaccines
Only solid vaccines except in areas marked above
Only liquid vaccines
Only liquid vaccines except in areas marked above
Only pharmaceutical items and no vaccines
Only pharmaceutical items (no vaccines) except in areas marked above
All items except pharmaceuticals and vaccines
Others (specify in section E)
List for freezer rooms and freezers
All solid vaccines
All solid vaccines except areas marked above
No vaccines
No pharmaceutical items
All items except pharmaceuticals and vaccines
Others (specify in section E)
List for ambient temperatures (dry stores)
All pharmaceutical items (no vaccine)
All pharmaceutical items (no vaccine) except areas marked above
No pharmaceutical items
All items except pharmaceuticals and vaccines
Others (specify in section E)

Fig. 69. Sample of sections D and E of the table, indicating recommendations and comments based on the results of the temperature mapping



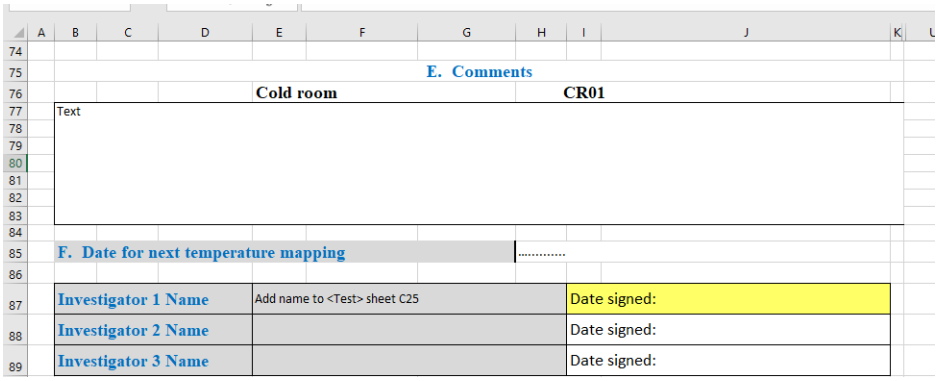
STEP I.3.5

Specify the date for the next temperature mapping of the same equipment in cell H85 of the “Action” worksheet (see Fig. 70). The next schedule should be based on the actions recorded in the preceding steps.

The conditions for setting the next temperature mapping date include the following:

1. If the equipment is suitable for the intended items to be stored, then the next temperature mapping should be done 2 years after, and the succeeding schedules will be every 2 years henceforth.
2. If some major repairs and modifications are recommended, the next temperature mapping should be done immediately after the repairs/modifications are conducted and the initial functionality tests are performed.

Fig. 70. The date of next temperature mapping: indicated in “cell H85”



Step I.4

Printing of the temperature mapping report:

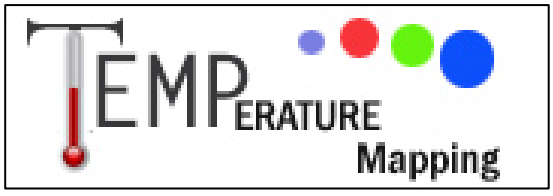
a) Go back to the <Report> worksheet.
b) Click on <Print>.
c) Make sure the report is duly signed by the responsible staff.
d) Keep and file the hard copy of the report in a safe place.

Section J. Managing logos

The temperature mapping logo (filename: TM_Logo.jpg) can be found in the subfolder “Source”, which is shown in Fig. 3. To access the logo, click on the <logo Images> folder within the “Source” folder. You can also import your agency’s logo or any other logos to this folder.

Fig. 71 shows an image of the temperature mapping logo, which can be used in your report or PowerPoint presentations.

Fig. 71. Temperature Mapping logo



An error message might appear if the above-mentioned folder is not in the correct place. Usually Error 1004 relates to this issue. See Annex 4 for the list of possible error messages.

Note: *You should NOT move, open or use files out of their designated folders. This is very important!*

Section K. Repeating temperature mapping for the same equipment or identical equipment

This section provides instructions for subsequent temperature mapping of the same or identical equipment. You do not need to repeat all the instructions in this guideline. There are some possible shortcuts when temperature mapping identical equipment.

Step K.1 Repeating temperature mapping of the same storage units

Once the initial temperature mapping has been completed, all the steps in this guideline do not have to be followed for subsequent temperature mappings. Only these short steps need to be implemented. They are based on the assumption that the same type and number of sensors will be used, and that they will be positioned in the same places as before.

STEP K.1.1

Copy the Temperature Mapping file from the initial mapping, and assign it a different filename.

STEP K.1.2

Repeat Step E.2.1f of Section E and specify the current date and time.

STEP K.1.3

Perform all the steps in Sections F, G, H and I.

STEP K.1.4

Compare the results with those of previous temperature mapping reports and perform any necessary actions to resolve any issues.

Step K.2 Repeating temperature mapping for identical equipment

This step describes the shortcuts to temperature mapping identical equipment. These shorter steps are based on the assumption that the additional equipment is exactly identical in terms of: dimension, position and size of the door(s); number and position of evaporators; and the number, shape, size and position of shelves, and all other specifications. The other assumption is that the same type and number of sensors are used, and placed in the same positions as before.

STEP K.2.1

Copy the Temperature Mapping file from the initial mapping, and assign it a different filename.

STEP K.2.2

Repeat step E.2.1f of Section E and specify the current date and time.

STEP K.2.3

Perform all the steps in Sections F, G, H and I.

Section L. Estimating hold-over time of the storage unit (optional)

Let's firstly look at the definition of "hold-over time". Hold-over time in the context of this application and this guide means when an active cold chain equipment (cold or freezer room, refrigerator and freezer) is:

» at the ideal temperature range (for vaccines between +2 °C to +8 °C);
» in a fixed ambient temperature;
» and the power is disconnected;

and the door remains closed, how long it takes for the internal temperature of the equipment to reach a certain defined degree. For vaccines this temperature is defined as 10 °C.

The longer the hold-over time the better the equipment. The range of 2 °C to 8 °C and 10 °C are for vaccines. These numbers may will not be the same for other products.

Hold-over time is specific to a fixed ambient temperature. WHO/UNICEF PQS/PIS specifies hold-over time at 32 °C and 43 °C fixed ambient temperatures. Tests are made in laboratories where the ambient

temperatures can be controlled and kept stable. Since we do not temperature map equipment in any fixed ambient temperatures, we call it “estimation” of the hold-over time at an existing ambient temperature. The result of this estimation may not be valid for other ambient temperatures. It is just an estimation to help us to see how long we have time to take action when the equipment does not function or there is no power available.

For instance, if a hold-over time of a vaccine refrigerator at 32 °C is estimated to be 22 hours, it means that when there is no electricity at this ambient temperature, the vaccines are safe inside the refrigerator for 22 hours provided the refrigerator door is not opened during this period. If the ambient temperature is higher than 32 °C, the hold-over time is shorter than 22 hours in this example. Similarly, if the ambient temperature is lower than 32 °C, we can imagine that the hold-over time can be longer than 22 hours.

With the above definition in mind, the procedures here in this application for estimation of hold-over time are as follows:

1. The equipment must be empty. If we specify in C8 “Test” worksheet “half loaded” or “fully loaded”, the hold-over time estimation option will disappear and you no longer will be able to estimate the hold-over time.
2. The estimation is at the end of the temperature mapping test. This means that when you wish to estimate the hold-over time in the present ambient temperatures, you should:
    a) firstly, turn off the power of all cooling units at the end of the time of the temperature mapping; and
    b) not remove the sensors (leave them where they are) for another 72 hours after the end time of the temperature mapping test.

In other words, this means you cannot estimate only hold-over time. You have to run the temperature mapping test and at the end estimate the hold-over time.

Collect the sensors and download data as described in Section G (Removing sensors and downloading temperature readings to the temperature mapping application).

There will be a chart of time and temperatures for all sensors starting from the end of the temperature mapping up to 72 hours.

When the first sensor reaches the limit of the hold-over time (for vaccines it is specified by WHO to be at 10 °C) the chart related to that particular sensor becomes red and the time will be noted by the application. **This duration of time indicates to the estimation of the hold-over time in a specific mean ambient temperature.**

In the earlier versions of this application, 10 °C was fixed and users could not estimate the hold-over time for any other temperature limits except 10 °C. In this version you have the option of specifying the temperature limit from -40 °C to +45 °C.

If no sensor reaches the limit (10 °C for vaccines cold rooms) within 72 hours, which is the usual length of a long weekend, you may conclude that the hold-over time for this specific equipment is 72 hours or more at this very specific ambient temperature.

The Temperature Mapping tool allows you to specify whether or not you would like to estimate the “hold-over time”. The default is NO. If you decide to collect the information on estimation of “hold-over time” of a specific cold chain equipment, you should follow these steps.

Step L.1

Make sure in “Room” worksheet you select an active cold chain equipment (cold or freezer room, refrigerator or freezer, not a dry store). See “Room” cell C7. This test does not work for dry storage areas.

Step L.2

Make sure the equipment is empty. Check “Test” worksheet C8.

Step L.3

Make sure that the internal temperature of the equipment reached the desire range and it is stable for some period of time. For vaccines the range is 2 °C to 8 °C.

Step L.4

In “Test” worksheet select “Yes” from the drop-down menu in cell D28. This means you would like to estimate the “hold-over time” of the equipment.

Step L.5

Specify the desired safe temperature for the product intended to be in this active cold chain equipment in “Test” sheet cell C29 in °C. WHO specifies this limit at 10 °C for equipment storing vaccines.

Step L.6

Then, perform the temperature mapping test as usual and as it is described in this guide.

Step L.7

Switch off or disconnect the cooling units from their power supply after completing temperature mapping per required duration (e.g. minimum of 48 hours – or any duration from 48 to 96 hours). The start date and time for the hold-over time test is automatically specified in cells H28 and M28.

Step L.8

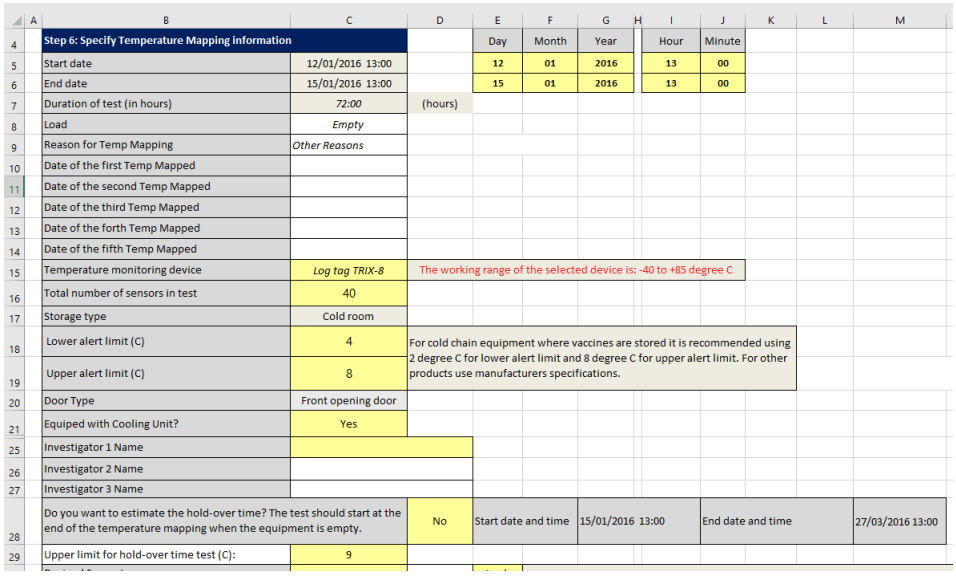
Leave the sensors inside the storage unit for an additional 72 hours, without opening the door(s).

Step L.9

At the end of the 72-hour period, remove the sensors from the storage unit and follow all the steps in Sections G, H and I.

See Fig. 72 for an example on how to complete the information for estimation of hold-over time.

Fig. 72. Procedures for testing hold-over time



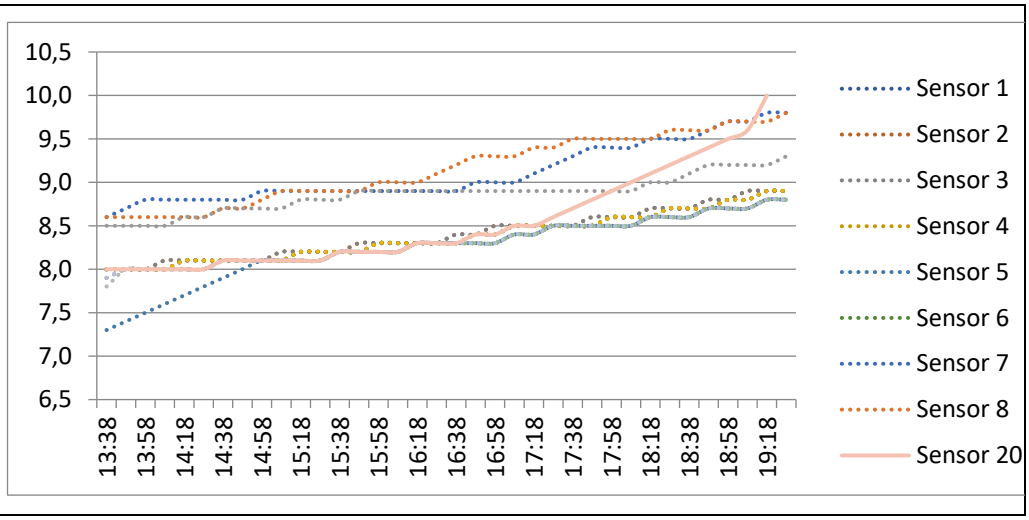
	B	C	D	E	F	G	H	I	J	K	L	M
4	**Step 6: Specify Temperature Mapping information**			Day	Month	Year		Hour	Minute			
5	Start date	12/01/2016 13:00		12	01	2016		13	00			
6	End date	15/01/2016 13:00		15	01	2016		13	00			
7	Duration of test (in hours)	*72:00*	(hours)									
8	Load	*Empty*										
9	Reason for Temp Mapping	*Other Reasons*										
10	Date of the first Temp Mapped											
11	Date of the second Temp Mapped											
12	Date of the third Temp Mapped											
13	Date of the forth Temp Mapped											
14	Date of the fifth Temp Mapped											
15	Temperature monitoring device	*Log tag TRIX-8*	The working range of the selected device is: -40 to +85 degree C									
16	Total number of sensors in test	40										
17	Storage type	Cold room										
18	Lower alert limit (C)	4	For cold chain equipment where vaccines are stored it is recommended using 2 degree C for lower alert limit and 8 degree C for upper alert limit. For other products use manufacturers specifications.									
19	Upper alert limit (C)	8										
20	Door Type	Front opening door										
21	Equiped with Cooling Unit?	Yes										
25	Investigator 1 Name											
26	Investigator 2 Name											
27	Investigator 3 Name											
28	Do you want to estimate the hold-over time? The test should start at the end of the temperature mapping when the equipment is empty.		No	Start date and time	15/01/2016 13:00			End date and time		27/03/2016 13:00		
29	Upper limit for hold-over time test (C):	9										

The temperature mapping application will provide you with a report of the temperatures of all sensors inside the storage unit from the time the cooling units are turned off until the first sensor reaches the specified safe temperature. This will be an estimation of the hold-over time of the cold chain equipment at the recorded mean outside ambient temperature.

If none of the sensors reach the specified temperature within 72 hours, this means the hold-over time of this equipment is equal to or greater than 72 hours after being exposed to the particular ambient temperature.

Fig. 73 shows a sample of the curves provided by the application after completing the estimation of the hold-over time. In this example, it can be seen that sensor number 20 is the first one that reached 10 °C at 19:18 hours and therefore the hold-over time of this equipment at this specific mean ambient temperature is estimated to be 5:40 (5 hours and 40 minutes).

Fig. 73. Sample of the curves provided by the application for estimation of hold-over time



Section M. Separate testing of cooling units (optional)

In versions 6 and 7 a new function was added to the application in which you can separately test the equipment with different cooling units. In other words, this means that you can temperature map the equipment once with the first group of cooling units and then with the second group of cooling units. In this way you can compare the performance of the cooling units. This also allows you to see which of the group of cooling units has a problem and which one is working with no problem. In earlier versions of this application this option did not exist.

The default setting of this version (7.0) is similar to version 5.0 and earlier versions. This means that you do not see this option unless you decide to temperature map any cold or freezer room separately for two groups of cooling units. In case you decide to temperature map the cold or freezer room in two tests: first for one group of cooling units and then for the second group, then you should follow instructions for changing some settings in “Room” and “Test” worksheets.

The default setting is based on the assumptions that you are temperature mapping the equipment no matter which cooling unit is working. Modern cold and freezer rooms and WHO standard is that all cold and freezer rooms should have at least two separate cooling units. Each cooling unit works for a certain period of time and there will be a changeover switch to bring the second cooling unit up and turn the first one off. This is to make sure that both groups of cooling units are wearing out equally. Normally, when ambient temperatures are high, and in some other exceptional conditions, both cooling units may work at the same time. Therefore, the default setting of the application is adequate and there is no need for separately testing different cooling units.

Before you start the procedure, carefully consider the following notes:

Notes:

» This option exists only for active cold chain equipment (cold and freezer rooms, refrigerators and freezers). This option does not apply to dry storage areas.
» Active cold chain equipment must have more than one cooling unit.
» If there are more than two cooling units, cooling units should be divided into two groups.
» Each group of cooling units may have one or more evaporators.

If the above conditions apply to the cold chain equipment you would like to temperature map and you would like to test it in two separate groups, follow the following steps:

Step M.1

In “Room” worksheet cell C15 select 2 (default is 1). This means that you have two separate cooling units and each of the cooling units may have one or more evaporators.

Step M.2

In “Test” worksheet cell C23 (divide test time between two cooling units?) select “Yes” (default is No). This means you decided to test cooling units separately.

Note: If cell C15 in “Room” sheet is 1, rows 23 and 24 in “Test” sheet are hidden.

Step M.3

In “Test” worksheet cell C24 type the number of hours you wish to test the second group of cooling units. You can enter a time period that should be at least 1 hour less than the total test hours indicated in cell C7. Cell E24 shows you the maximum hours allowed for this test. Note that the format of typing is very important here. You should type in hours (two digits) colons (:) then minutes (two digits) hh:mm. For instance, 07:30 which means 7 hours and 30 minutes.

Step M.4

Once you have specified the period in which you would like to test the second group of cooling units, the date and the time for the start and the end of the test will appear for each of two groups in cells K23 to Q24 of the “Test” sheet.

Step M.5

Go to the equipment to be temperature mapped. When you start the test (based on information in cell K23), turn the second group of cooling units off. Make sure the automatic changeover switch is forced off if there is one.

Step M.6

When the period of time for the test of the first group of cooling units is over (based on information in cells N23 and N24), go to the equipment. Turn the first group of cooling units off. Make sure the automatic changeover switch is forced off if there is one.

Step M.7

Immediately turn on the second group of cooling units. Check the date and time for the start of the test for the second group of cooling units in cell K24 in “Test” sheet. If you are late or early for this action, adjust the "Duration of test with second group of cooling units” in cell C24 of the “Test” sheet (see Step M.3).

At this stage go to Section E (Guide on placing and configuring three different types of sensors) and continue the other steps.

Example: See Figs 74 and 75:

- The equipment to be temperature mapped is a cold room.
- C15 in “Room” worksheet is set to 2 which means there are two groups of cooling units in this cold room.
- The total test time is set to 48 hours (cell C7 of “Test” worksheet) in this example.
- The total test hour for the second group of cooling units is 12 hours and therefore the period of test for the first group of cooling units is 36 hours (see Fig. 75).
- After completing the other steps and testing the cold room for a total of 48 hours, you will see two reports separately following each other for each of the two groups of cooling units (see Data and Report worksheets) at the end of the test after downloading the recorded temperatures of the sensors.

Fig. 74. Example of changing setting for testing cooling unit groups separately ("Room" sheet)

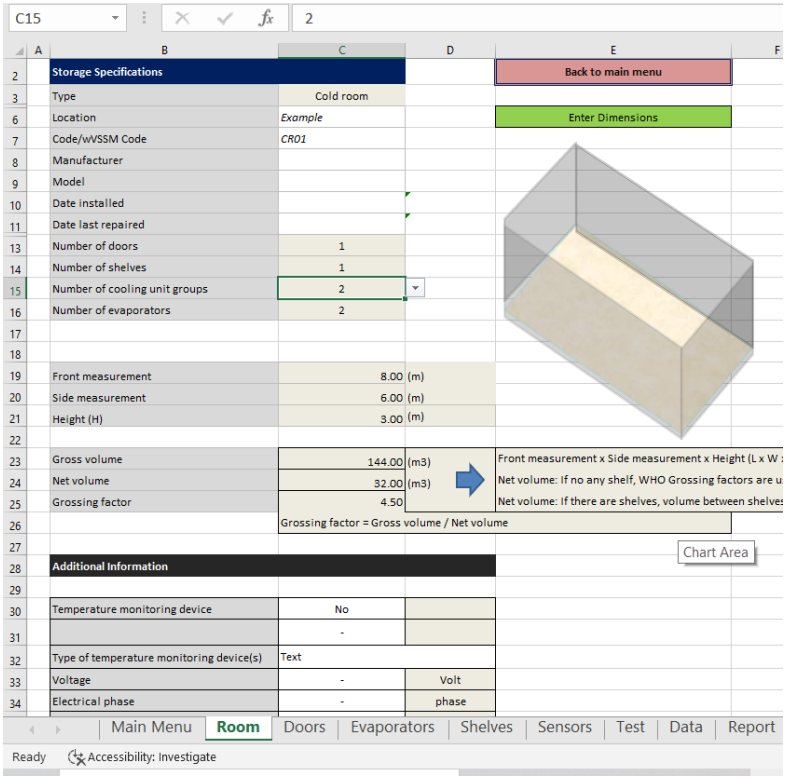
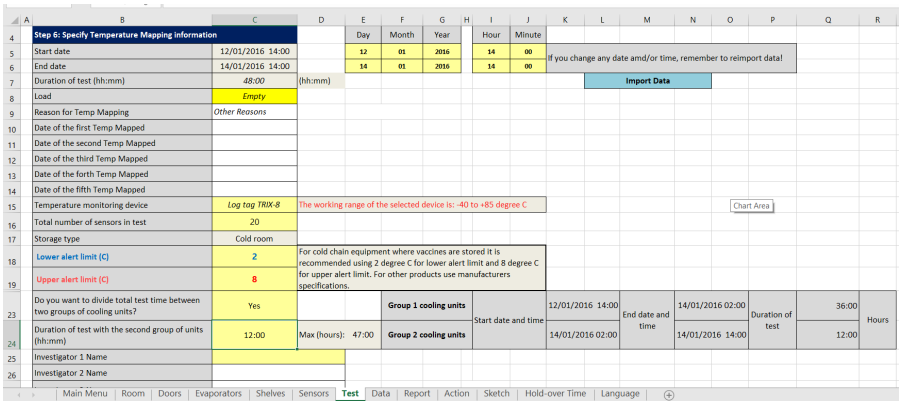


Fig. 75. Example of changing setting for testing cooling unit groups separately ("Test" sheet)



Annex 1: When to conduct temperature mapping after modifications or major repairs

This list is not exhaustive and any additional repairs not listed must be discussed between departmental manager, QA manager and engineers/technicians to deduce the risk and to decide on whether mapping is required or not.

- ❑ Full refurbishment of walk-in fridge/freezer.
- ❑ Change of compressor on walk-in fridge freezer, upright fridge, freezer or incubator.
- ❑ Re-gassing of compressor – may be a top-up of gas or full re-gas. Implications must be discussed with engineer and decision taken locally on whether to re-map or not.
- ❑ Change of fan motor or fan motor bearings for evaporator or condenser.
- ❑ Change driving and non-driving end bearings followed by lubrication with correct grade of motor bearing lubricant.
- ❑ Circulation fan motor changed.
- ❑ Door catches, locks and hinges changed (external doors).
- ❑ Door seal replaced due to significant irreparable damage or door seal to be replaced before significant damage.
- ❑ Pipework and pipe insulation replacement or repair.
- ❑ Replacement of any badly worn fixed and moving contacts.
- ❑ Replacement or adjustment of thermostat.
- ❑ Total freezer defrosts and maintenance (for walk-in freezer only). Defrost only may not require re-mapping but will need to be discussed with engineer to consider risks.
- ❑ Replacement of system valves.
- ❑ Shut down of control panel where associated plant items will also be shut down. In many cases there will be separate plant to run the cold rooms but in cases of only one system then this will require re-mapping.
- ❑ Check each stage and function of multistage relay (step controller) in accordance with its associated controller output and ensure correct operation.
- ❑ For cold stores using DX air conditioning units to maintain temperature:

    - Check condensate pump replace if necessary. Examples of minor repairs/maintenance which should not routinely result in a requirement to remapping a facility.
    - Replacement of electrical wiring mains lead; mains plug and plug wiring.
    - Adjustment of door catches locks and hinge operation.
    - System valves checked.
    - Fans checked for alignment and adjustment as required.
    - Operational test of condenser unit.
    - Inspection of drive pulleys and impellers for wear and adjustment as necessary.
    - Checking of chassis and drain tray for condensate leaks and drain tube for free flow.
    - Cleaning of air-cooled refrigeration condenser filter and condenser.
    - Checking of all pipe connections for leaks.
    - Check set cut out points for general calibration and wear.
    - Check control thermostats for correct temperature sets and operation.
    - Removal of build-up of ice on doors and seals.
    - Capillary defrost system.
    - Forced defrost timer/system check.
    - Verification of defrost heater function.
    - Checking of freezer centre temperature with digital thermometer and record instrument delay.
    - Lubrication of driving and non-driving end bearings with correct grade of motor bearing lubricant.
    - Carry out insulation test of motor and record motor running current.
    - Check fixed and moving contacts for wear and replace any badly worn contacts.

- Electric motors – check that the commutations of open type machines is satisfactory, i.e. slip rings or commutators appear to be satisfactory and brushes do not require renewal. Check slip rings or commutator enclosure for carbon or metal deposits and that slip rings are not worn or grooved.
- Check operation of condensate pump.
- Sterilize clean and flush if necessary.
- Ensure cable terminals to be checked.
- Pipework and seals to be checked.
- Check on correct condensate discharge into drain.

Annex 2: LogTag® temperature data logger

System requirements

The following minimum specifications are required:

- a computer capable of running Windows® XP SP2 or later, or Windows® 2003 Server or later
- 60 MB free disk space
- Internet Explorer 5.0 or later
- 1 available serial port and/or 1 available USB port, depending on purchased interface
- 1024 x 768, or higher, screen resolution
- 256 screen colours.

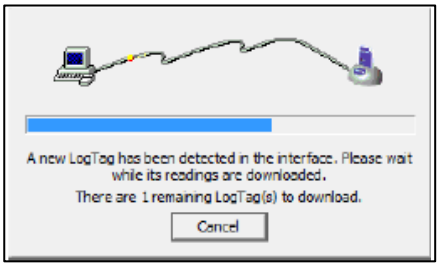
The recommended specifications are:

- processor equivalent to Pentium IV or later
- 512 MB of available RAM
- Internet Explorer 6.0 or later
- 65535 (16 bit) or more, screen colours.

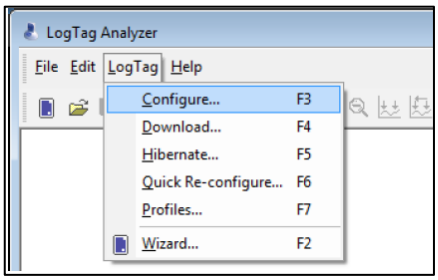
Using the LogTag® with the interface

LogTag® uses the standard interface cradle, wherein it is inserted into the slot from the top to enable communication. The contact pins inside the slot should connect with the matching contact pads on the LogTag®.

LogTag® Analyzer will automatically download and display any readings or statistics stored inside the LogTag®.



Getting a LogTag® ready for use



Once a LogTag® has been re-configured for its next use, any readings previously recorded will no longer be available for retrieval.

Click the "Configure..." menu item located in the LogTag® menu.

The values initially presented are the configuration parameters that were used when this recorder was last configured.

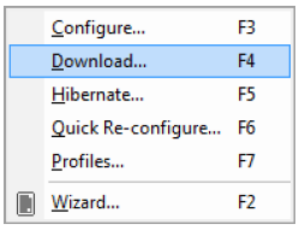
When the details have been entered and the settings adjusted as desired, click on the “Next” button to send the configuration information to the LogTag®(s):

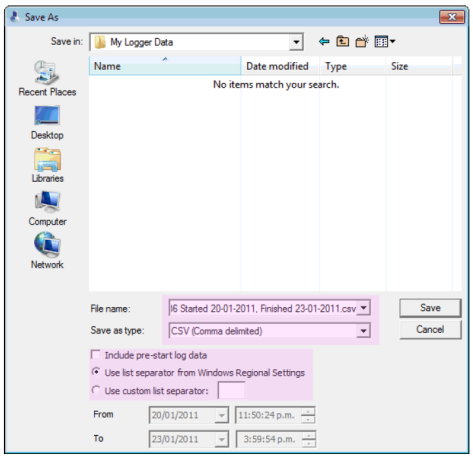
» Enter the number of sensor in “User ID” box.
» Choose period of 20 minutes for “Record a reading every” option.
» Enable alert for cold rooms between 2 °C to 8 °C.
» Enable alert for freezer rooms between -20 °C to -10 °C.
» Enable alert for dry stores between 0 °C to 35 °C.
» Configure it to alert should one continuous reading be out of range.

Another way is to load the pre-saved configuration profile.

Getting results from LogTag®

Click **Download...** from the **LogTag®** menu.





Annex 3: Sample door sign for temperature mapping

Temperature Mapping in Progress

Do not open door!

Do not touch thermostat!

Do not turn off the machine!

Start date and time:

01 July 2021, time: 08:00:00

Expected end date and time:

03 July 2021, time: 10:00:00

Annex 4: Error messages

Error # 1004

This error message may appear when you open the source file. This error message indicates that one of the required files for this application is missing in the Temperature Mapping folder. There are two folders that may be missing and causing this error message:

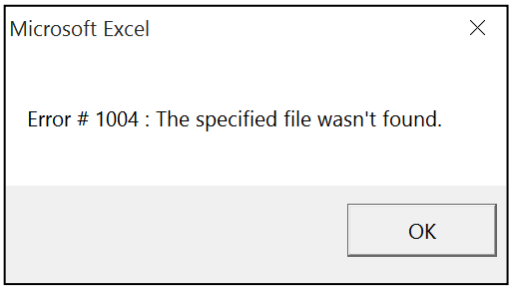
» Logo Images
» Device Output.

This message may appear three times as there are two separate files in Logo Images and the application is searching for these files twice and as well for the Device Output file.

If you click on OK, the application may open but:

» You may not have logos in your reports.
» You will have problems with transferring data from the temperature readings recorded by the sensors.

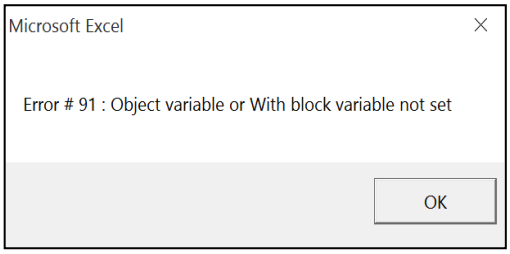
Therefore, it is better to resolve the problem beforehand, making sure that all related and required folders and files are present and in the correct order.



Error # 91

This message will appear when you try to transfer recorded temperatures from the <Device Outputs> and the folder is not in the correct location. This usually appears when you click on cell J6 in the Data sheet.

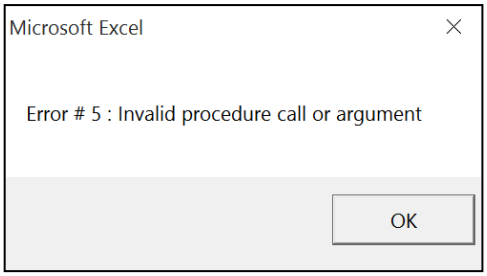
Click on OK and then make sure the related and the correct <Device Outputs> folder is in the Temperature Mapping folder.



Error # 5

This error message may appear in the Data sheet when you click on cell J6. This means that the Device Output folder is present in the correct place but the data recorded for one or more sensors do not correspond to the start date and/or the end date in cells C36 and C37 on the Main Page. If you click on OK, the first sensor file with a problem will open. In this case, either correct the dates in cells C36 and C37 in the Main Page or replace the sensor data file in the “Device Outputs” folder.

These error messages and others will appear if the instructions in this guideline are not followed step by step and if the files and their order are changed.



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