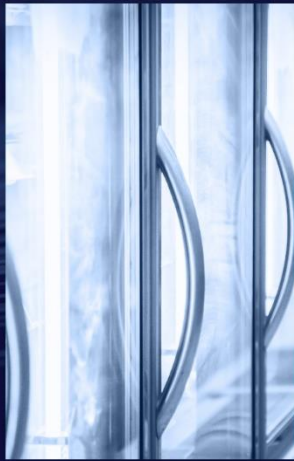




Sense
Anywhere
SIMPLY SMARTER

Temperature Mapping

Version 1.2



SenseAnywhere B.V.

Bergrand 218
4707 AT Roosendaal
The Netherlands

+31 165 796 210

info@senseanywhere.com
www.senseanywhere.com

Temperature Mapping

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Revision History

Table 1 Revision History

Version	Date	By	Reason
1.0	20180901	N. Segers	Initial version
1.1	20190917	N. Segers	<ul style="list-style-type: none"> • Added Table of Contents • Added deactivated loggers
1.2	20210121	N. Segers	<ul style="list-style-type: none"> • Added Guidance on warehouse mapping sensor placement • Added Magnetic Holders

Definitions and abbreviations

Table 2 Definitions and abbreviations

Definition / Abbreviation	Explanation
EDLM	Electronic data logging monitor
TTSP	Time- and temperature-sensitive pharmaceutical product

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What is Mapping?

Mapping is a documented measurement of the temperature and/or relative humidity distribution within a storage area, including identification of hot and cold spots. The purpose of a temperature mapping study is to document and control the temperature distribution within a storage area. All mapping exercises should be fully documented in order to demonstrate compliance to management, clients and the regulatory authorities.

All new temperature-controlled storage areas must be temperature-mapped as part of a fully documented verification process, before the installation is commissioned and handed over by the installer. Until this has been done, it is not safe to store time- and temperature-sensitive pharmaceutical products in such areas.

A Mapping Exercise results in the identification of hot and cold spots. Cold spot refers to the lowest temperature(s) recorded in the space over the study period. A hot spot refers to the highest temperature(s) recorded in the area studied over the study period. The purpose of determining hot and cold spots is to identify the locations where the monitoring system sensors should preferentially be located. Average values can be useful to help confirm true hot and cold spots.

The SenseAnywhere Temperature Mapping is an extremely efficient and economical mapping process with a minimum of time and resources, which quickly and clearly discovers possible resist areas. Based on the generated Mapping Report in SAClient, users can make recommendations about the optimum storage locations for highly sensitive products, and those that are less sensitive.

Mapping Costs

- Mapping is paid with Credits. Normally, the registration of a device cost 1 to 2 Credits per year. After payment, the license runs for one year. However, a SenseAnywhere Mapping subscription is paid monthly. It costs 0.125 Credit for a one-month subscription. This way it is possible to temporarily register loggers to do a mapping without having to pay for a whole year's subscription.
- The price for a mapping report is 0.2 Credit per logger in the report. A report is a fixed period (start until stop) and a fixed set of loggers. If the start and stop date time and the loggers are not changed, it is possible to change anything else and recreate the report without having to pay for the updated report. This way draft reports can be made.
- If after a Mapping the loggers will not be used for a longer period of time (weeks) you can stop the logger (and the license). Deactivate the loggers (they stay in the account, but do not send data anymore and do not consume Credits).
 - When loggers are deactivated or deregistered you can create a report based on the historical data.
 - When the sensors are deactivated, you can add them by re-registering them (Management > Register Device). This can be done until the report is created. After generating, it's locked.
- When you need the loggers again, you need to go through the normal registration process and monthly subscription starts running again.

Carry out the Mapping Exercise

1. Login under your mapping account. Go to [Management > Mapping](#).
2. **Create a new Mapping Template.**
A Mapping Template defines which chapters are included in the Mapping Report. If there is no Mapping Template created yet, see the 'Generate a Mapping Template' section. Else continue to step 3.
3. **Create a Mapping Profile: Click + New Mapping**
 - a. Fill out the *Name* of the Mapping.
 - b. Select the *Company*. By clicking *Manage Addresses* it's possible to select an address or to add a new address (+ *New Address*).
 - c. Select the *Customer*.
 - d. Determine the temperature range by filling out a *Lower Acceptance Criteria* (°C) and an *Upper Acceptance Criteria* (°C). This means that the temperature may not exceed the lowest value and neither the highest value.
 - e. Select the *Loggers*.
 - f. Choose the *Start Date* and *End Date* of the Mapping.
 - g. Choose a *Timezone*. Once saved, a new Mapping is created.

The 'Mapping Settings' screen appears and from here it's possible to edit settings, manage loggers, set signature, view chart or copy the mapping. These settings are described below. By clicking *Edit Settings* it is possible to change the previous entered settings.

4. **Click *Manage Loggers*.**
 - a. It is possible to edit the name of the loggers, by clicking *Edit*. Changing the name of the logger only has effect for this Mapping. Please note that the Logger Name must correspond with the name on the Floorplan.
 - b. It is possible to check the 'Outside' box to indicate which loggers are located outside.
 - c. It is also possible to change the T/RH (Temperature / Relative Humidity) Interval, for instance to 1 min, 5 min, 15 min or 1 hour. Once the loggers are correctly set, click *Save* and go *Back*.
5. **Click *Signature Settings* on the 'Mapping Settings' page.**
Set a *Signature*. Click *Set*. It's possible to *Add* a Name and Title. Once saved, go *Back*.
6. **Scroll down on the 'Mapping Settings' page. On the 'Report Content' section a Floorplan can be added.**
 - a. Click + *Add Image*
 - b. *Click+ New Image*. A *Title* and *Description* can be entered. Then the image can be uploaded. Please note that only png, jpg or jpeg files are allowed. After submitting, the file will be uploaded and available for selection.
 - c. Select an uploaded Floorplan by using the 'Add' button.
 - d. Multiple images can be uploaded.
7. **Scroll down on the 'Mapping Settings' page and go to 'Properties'.**

On the 'Properties' section the *Name* of the Mapping Technician can be filled out, by clicking the pen on the right side. Once saved, the properties are correctly set.

8. Scroll down on the 'Mapping Settings' page and go to 'Contents'.

On the 'Contents' section the *Introduction*, *Summary*, *Recommendations* and *Conclusion* of the Mapping Report can be written. Go to all parts one at a time by clicking the pen on the right side. The items that could be covered can be found in each text per section. This is the most important part where you as the mapping expert explain what has been mapped and what the outcome of the mapping exercise is. Once finished, check the box 'Show in report' and Save. Do this for all four parts.

Generate a Mapping Report

- Go back to the 'Mapping Settings' and scroll down.
- Please note that after clicking 'Unlock Reports' it will not be possible to edit:
 - a. The selection of loggers and
 - b. The start/end time of the mapping anymore!
- Use the 'Chart' button to confirm that the Mapping results are as expected.
- The Mapping Report cost 0,2 Credits per logger. So, the total number of selected loggers x 0,2 = the amount of Credits that will be deducted.
- If everything is correctly set, click the 'Unlock Reports' button. After unlocking you are allowed to create an unlimited amount of Reports for this Mapping.
- Click + *New Report*.
 - Select the correct *Template*.
 - Fill out the *Reference* (for instance: Version 1.0).
 - If a 'Draft' Watermark is preferred, select this checkbox.
 - Once *Created*, the Mapping Report will be generated. When finished, it can be downloaded. Please note that it can take a few minutes before the Mapping Report is generated.
- To verify if the digital copy of this document has been modified after it has been generated by SenseAnywhere visit <https://www.saclient.com/genuine> and upload the Mapping Report. The portal will check the document against internal records and respond with 'Genuine' if the document has not been modified in any way. The uploaded copy will not be stored.

Generate a Mapping Template

1. Click *Manage Templates*.
2. Click + *New Template* to create a new template.
3. Fill out the *Template Name* and *Description*.
4. A company *Logo* can be added.
5. Select the options (chapters) that are preferred in the Mapping Report.
 - a. If the Mapping Report should include Hot Spots, select this option.
 - b. If the Mapping Report should include Cold Spots, select this option.
 - c. If the Mapping Report should include Stability Spots, select this option. The Report will show the loggers (data and charts) with the lowest stability (highest spread) and highest stability (lowest spread).
 - d. The amount of Top Spots (if included) can be entered. For instance: if a top 3 of Hot and Cold Spots is preferred, fill out '3'.
 - e. If the Mapping Report should include a Certificate Overview, select this option. A Certificate Overview is a table with the Logger Names, Serial numbers, Certificate Type, Date of Calibration, Date of Recalibration and related temperatures.
 - f. If the Mapping Report should include Certificate Details, select this option. Certificate Details will include a copy of the original Certificates.
 - g. If the Mapping Report should include Logger Analysis, select this option. The Logger Analysis shows a Chart, Minimum temperature (°C), Maximum temperature (°C), Average temperature (°C), Spread (°C), Std (°C) and MKT (°C) for each logger.
 - h. If the Mapping Report should include raw data for loggers, select this option. The Report will show a table with all measurements of the Mapping for each logger.
 - i. If the Mapping Report should include a Genuine Chapter (validation that the Report is real and authentic), select this option.
6. When the preferred options are selected, the template can be created.

Guidance on warehouse mapping sensor placement

- Source: Temperature mapping of storage areas. Technical supplement to WHO Technical Report Series, No. 961, 2011.

Warehouse mapping

Sometimes it is unclear where sensors should be placed when performing warehouse mapping. It is important to distribute sensors evenly and geometrically throughout the warehouse covering the entire space. 'USP Chapter 1079 Good Distribution Practices' states that sensors should be placed in three planes in three dimensions.

Determine EDLM locations

The 'Temperature mapping of storage areas, Technical supplement to WHO Technical Report Series, No. 961, 2011' states to use the site survey to mark the required locations of the EDLMs. A risk-based approach can be applied to define these locations. However, the following guidelines will help determine the number and location of the EDLMs required.

Length and width: EDLMs should be arranged in a grid fashion along the width and length of the area so that the area is reasonably covered, with EDLMs located every 5–10 metres. The chosen sensor grid should take account of:

- the layout of the area (e.g. whether it is square or includes alcoves);
- the degree to which shelving and products may affect airflow;
- where products are placed. The positions of EDLMs should coincide with locations where TTSPs are actually stored or planned to be stored. For example, it may be unnecessary to fit EDLMs in areas such as the upper part of high loading bays;
- other considerations that may warrant more or fewer EDLMs.

Height: At each point on the grid, arrange EDLMs vertically as follows:

- If the ceiling height is 3.6 metres or less, position EDLMs directly above one another at high, medium and low level (e.g. one EDLM at floor level, one at 1.2 metres and one EDLM at 3.0 metres).
- If the ceiling height is greater than 3.6 metres, EDLMs can be arranged in vertical arrays at the bottom, middle (multiple) and top of the space. For instance, for a storage area 6 metres in height, EDLMs can be positioned in each grid location at heights of 0.3 metres, 1.8 metres, 3.6 metres and 5.4 metres.

Give each logger location a unique ID. It may be helpful to use a generic floor plan or diagram to decide where each logger should be positioned – see Figures 1 and 2. Figure 1 shows part of a pallet racking cold room with an adjoining temperature-controlled packing area. Figure 2 shows a small walk-in cold room with products stored on shelves – the shelves (on which the EDLMs should be placed) have been omitted for clarity. If products are also stored on pallets in the centre of the room, additional EDLMs should be placed in this location.

Figure 1
Typical location of data loggers in a pallet racking storage area

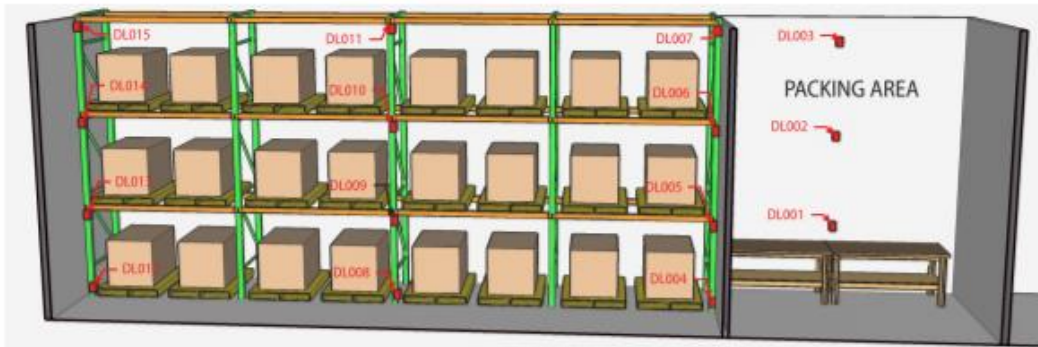
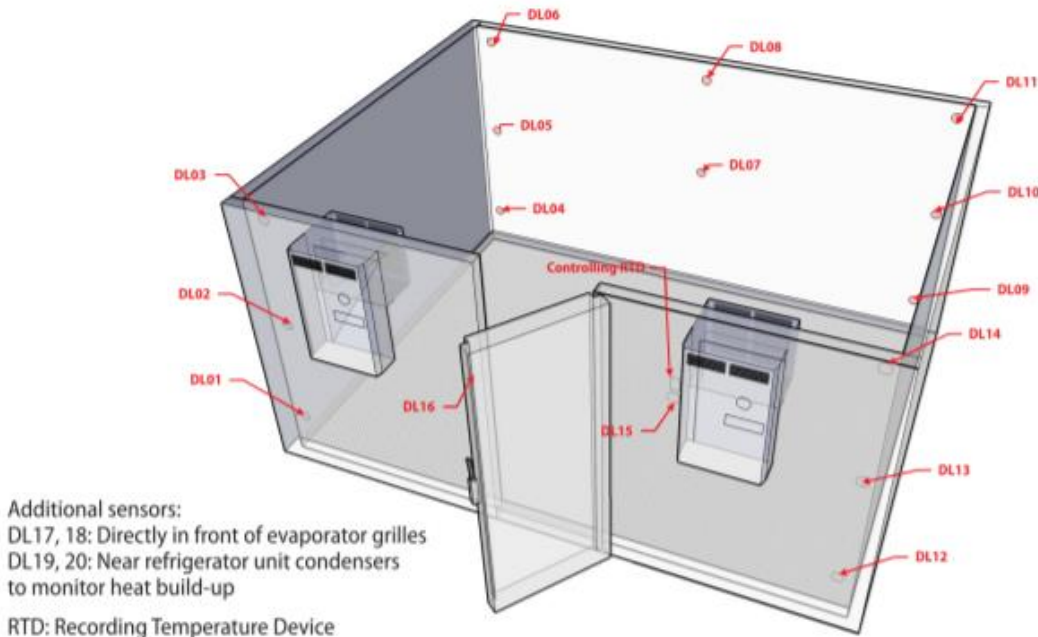


Figure 2
Typical location of data loggers in a walk-in cold room



Recommendation

Stacks of three are generally recommended for a warehouse. If the ceiling is low, for example less than 2.5 metres, place the sensors in stacks of two.

Magnetic Holders

SenseAnywhere offers magnetic holders to easily hang loggers during Mapping. They are strong magnets with thermal insulation. The logger hangs a bit away from the wall, so the magnetic holder has no influence on the temperature. The magnets can also be attached to a Mobile AccessPoint, making them easy to hang up in a warehouse.

