

DYNATHAW-V



User manual



WARNING

Please read the present document carefully and follow the instructions specified herein prior to working with the instrument.



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Area of application – Purpose of use

refer to the table of contents

About this user manual

This user manual contains:

- General information
- Installing the instrument
- Operating the instrument
- Cleaning and maintenance procedure

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History of changes

Revision	Date	Change
0	04.02.2019	First edition for prototypes of the instrument
1	25.06.2019	Changes related to DynaThaw software 1.2.0.0 version.
2	07.11.2019	CE IVD correction
3	22.11.2019	Technical specification correction, chapter 2.5 – new power supply
4	13.03.2020	Modification of CE-IVD data

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Warning, attention, and notes

The following types of notices and highlighting important information or user warnings about potentially hazardous situations are used in the present document:



NOTE

Contains useful information.



ATTENTION

Indicates potential damage to instrument or data loss unless the instructions are followed.



WARNING

Points out to potential injury, death, or damage to instrument unless the instructions are followed.



INSTRUCTIONS

Tasks to be performed.



WARNING

This symbol indicates potential presence of a biologically hazardous material. Proper safety measures for working at laboratories must be observed.



ATTENTION

Negative environmental impacts associated with handling of waste. Electric and electronic instruments do not belong to unsorted household waste. Collect electric and electronic waste separately.



WARNING

Fire and explosion hazard!
Some disinfecting agents may be flammable and may result in explosion when used improperly. Proper safety measures for working at laboratories must be observed.



WARNING

Chemical and biological waste may be associated with the waste material from DBH processes. Handle the substances and disposable aids, such as vessels, liquid system, etc. in compliance with the best laboratory practice. Get information about proper collection points and approved disposal methods in your country, state, or region.

Symbols used

	Manufacturer
	Date of production
	Catalogue number
	Serial number
	indicates potential presence of a biologically hazardous material
	Conformité Européenne
	Toxic
	Hot surface
	Use by date
	Disposable use
	USB
	Refer to manual
	Warning
	Instructions

1 Safety

1.1 Instrument safety

- A responsible entity must make sure that adequate decontamination is conducted in the event that hazardous substances leak into the instrument. Refer to Instrument disinfection.

- A responsible entity must make sure that the manufacturer or a representative thereof is consulted in case of doubts about decontamination or cleaning products with the instrument parts, or material contained therein.
- The instrument must not be used in a hazardous environment or in conjunction with hazardous substances for which it is not intended.
- Safety and protection guaranteed in use of the instrument may be compromised if the instrument is used with accessories not provided or recommended by the manufacturer, when solutions incompatible with the instrument are used, or if the instrument is used in a manner not specified by the manufacturer.



WARNING

Should any unauthorized modification of a DYNATHaw instrument or firmware thereof occur, their function and performance may be negatively influenced. In such a case, the warranty becomes void, and no CE shall apply to the instrument.



WARNING

The present instrument complies with the radiation and resistance requirements according to ČSN EN 61326-2-6; however, the electromagnetic environment should be evaluated before turning the machine on.

The operator's liability is to make sure the electromagnetic environment compatible for the instrument operation is maintained so that the instrument's function complies with the intended use.

Do not use the instrument near strong electromagnetic radiation (e.g. unshielded RF source) as proper function of the instrument may be compromised, and the results may be incorrect.

2 General

2.1 Introduction

DYNATHaw is an instrument for thawing cell preparations placed in cryogenic test tubes. The thawing process is standardized in the cryoconservation workflow.

Prior to using the DYNATHaw, the user must validate the thawing process parameters (hereinafter referred to only as *profiles*) in combination with the system according to the best laboratory practice and local laws.

Only qualified and trained users may operate the instrument.



IMPORTANT

Failure to properly comply with the operation instructions in this user manual may result in damage to the instrument or in incorrect execution of procedure; the safety of the operator may not be guaranteed in this case.

2.2 Area of application

DYNATHaw is an instrument for use in consulting rooms or laboratories. It automates and standardizes the process of thawing the preparations placed in the cryogenic test tubes.

2.3 User profile

2.3.1 Professional user – administrator level

The administrator is an adequately professionally trained person who possesses the corresponding abilities and experience. If the product is used in conformity with the intended use, the administrator can distinguish and avoid hazards.

The administrator holds vast knowledge and can instruct an end user or common user in the assay protocols within the intended use.

Computer application skills are required.

2.3.2 End or common user

An end or common user is a person who is adequately professionally trained and who possesses the corresponding capabilities and experience. If the product is used in conformity with the intended use, the end or common user can distinguish and avoid hazards.

Computer application skills are required, as are good language skills of English and of the relevant national language at the place of installation.

2.3.3 Service technician

A service technician is a person who is adequately professionally trained and who possesses the corresponding capabilities and experience. If the instrument requires service or maintenance, the service technician is able to distinguish a hazard during these operations and avoid it.

Computer application skills are required.

2.4 Validation

DYNATHaw has been validated in compliance with European regulations.



INSTRUCTIONS

If bespoke protocols and/or accessories are used, the user is obliged to validate the test settings.



NOTE

Should either DYNATHaw software or firmware be modified in an unauthorized manner, the warranty becomes void, and the instrument becomes incompatible for the European markets.



NOTE

The operator must ensure that the combination of the specific cryogenic test tube and the DYNATHaw instrument has been approved for use by the manufacturer.

2.5 Technical specifications of the instrument

Parameters of the instrument	
Principle of heating	Dry bath
Temperature range of control (heating, cooling)	5°C – 50°C
Temperature accuracy of control	max. +/-1 °C
Contactless sensing of cryogenic test tube's surface temperature	From -200°C
Number of positions per single cryogenic test tube	1
Dimensions of the position	Customized depending on shape of the test tube Max diameter 25mm Max length 92mm
Default temperature of the cryogenic test tube (typical)	-180° C (LN2) or -80° C (dry ice)
Thawing time (typically for dry ice and preparation volume of 1ml)	3-4 minutes
Integrated reader for ID of the preparation	1D and 2D codes of all common types
Control	Keyboard or PC connected via USB
Status indication	Colour LED (4 white, 8 RGB)
Number of memory positions for thawing profiles	4
Retaining of records from the thawing process	Internal memory, approximately thousands of records
Connection to PC (loading the thawing records, instrument remote control, service setup)	USB (mini), DYNATHaw software application, DynLab
Power supply through external power adapter:	100 – 240VAC / max 4,6 A max, 50 – 60Hz
Instrument power supply	24 V DC / max 4 A
Power input during normal operation	Max 60 W
Fuse	F 4A, 125V
Instrument dimensions	210 x 135 x 115 mm
Instrument weight	1.7kg
Maintenance	
Temperature calibration check	Annually

2.5.1 EU directives, technical standards



The product bears the CE symbol based on compliance with the requirements of the directives mentioned below:

* For more information, refer to the Declaration of Conformity.

Directive 2014/30/EU: Electromagnetic compatibility (EMC)

The instrument has been tested by an independent certified test laboratory with the conclusion that the instrument complies with the requirements of the following technical standards.

Measurement of radiated interference

The testing has been carried out according to ČSN EN 55011 Class B Industrial, scientific, and medical instruments – Characteristics of radio frequency interference – Limits and methods of measurement

Resistance

The instrument has been tested according to ČSN EN 61326-1 Electrical equipment for measurement, control and laboratory use. EMC requirements. Part 1: General requirements.

Directive 2014/35/EU low voltage directive (LVD).

The instrument is powered by a 24V adaptor and requirements related to electric safety according to 2014/35/EU do not apply.

ČSN EN 62304 Medical instrument software – Software life cycle processes.

The instrument software has been and is developed in compliance with requirements of ČSN EN 62304 standard.

Directive 2015/863/EU on restricting the use of some hazardous materials found in electrical and electronic products (RoHS).

The instrument complies with the directive requirements and contains no hazardous materials from the subjected directive.

Among the directives not identified for granting of the CE mark, but with significant impact on the instrument's life cycle, is the European directive on waste electrical and electronic equipment.

Rules being compliant with the European directive 2012/19/EU on waste electrical and electronic equipment have been determined for disposal of the instrument.

Recommendations for disposal



For recycling/disposal, please contact your supplier. Please be aware that it is the user's responsibility, for contaminated instruments, to ensure that the instrument is decontaminated prior to its disposal, and the user shall provide a declaration of decontamination to the supplier in charge of disposal of the product.

2.6 Description of the instrument

DYNATHaw performs standardized thawing of preparations stored in a frozen condition in cryogenic test tubes. The use of this instrument replaces manual thawing procedures in hand or in a water bath. In this manner, identical thawing conditions for the preparations can be achieved, and contamination is reduced.

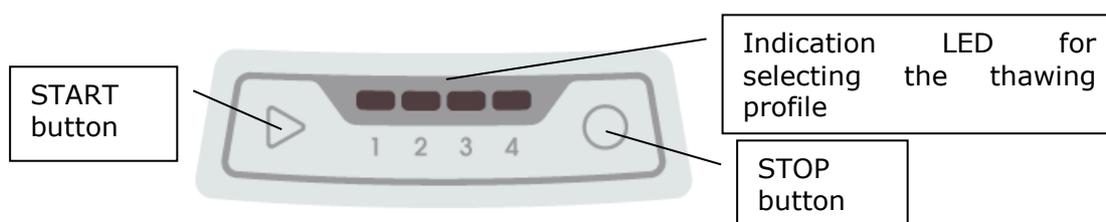
The thawing process in the instrument occurs on the basis of a dry bath. Upon thawing, the preparation is kept at low pressure through the instrument's active cooling system. Therefore, it is not necessary to remove the test tube immediately after thawing is completed.

The test tube surface temperature is continuously measured after the test tube is inserted in the instrument, and the values are stored in the instrument memory with some other data. Each record contains the data of one thawing cycle. The built-in barcode and matrix code reader facilitate the identification of the vials with the preparations. The records can be loaded using a USB connection to a personal computer and protocols created.

DYNATHaw can be operated in two different ways, either as standalone instrument or in a group of up to 6 instruments permanently connected to a PC. Therefore, the instrument can be used for thawing each test tube with the preparations (e.g. in clinical practice) or in the concurrent thawing of series of test tubes (e.g. in R&D and product quality control). Computer control of a set of the instruments expands the options for creating and retaining the protocols on the thawing process.



- 1 – hole for inserting the cryogenic test tube
- 2 – keyboard and 4 white LED indicators for selecting a thawing profile



- 3 – eight coloured LED indicators of the machine status
- 4 – reader of 1D and 2D codes for identification of the preparation



- 5 – 24V DC power supply connector
- 6 – mini USB connector
- 7 – cooling air inlet
- 8 – cooling air outlet

3 Installing the instrument

3.1 Included in the packaging

1. DYNATHaw
2. Power adaptor
3. Power cable
4. USB cable
5. User manual
6. Declaration of conformity
7. Protocol on output inspection
8. CD (instrument ID file, installation of DYNATHaw SW, manuals)

3.2 Unpacking procedure and inspection

1. Check the box visually before opening.
Any damage must be immediately recorded in the installation protocol.
2. Place the box in a vertical position and open the box.
3. Remove and set aside the included accessories.
4. Remove the instrument from the box and place it on a flat surface free of dust, vibrations, and away from sunlight.
5. Visually check the instrument for obvious mechanical damage. Immediately record any damage.
6. Compare the serial number on the rear panel of the instrument with the serial number on the delivery (transport) note.
7. Compare the accessories with the delivery (transport) note.
8. Retain all packaging materials for potential future use.

Contact DYNEX TECHNOLOGIES or their representative in the event that the supply is incomplete or damaged.

3.3 Power supply requirements

The external power adaptor of the instrument is powered by a mains supply that must comply with the technical parameters of the instrument.

Neither the adaptor nor the instrument needs to be configured to the correct voltage.

Connect the power cable to a system with a protective conductor only.

In case of power outage, the instrument's activity is interrupted.

3.4 Environmental requirements

The instrument is intended for placement indoors. The instrument should preferably be placed in an elevated position protected against dust, solvents, and acid vapours.

To guarantee correct results, the instrument should be protected against vibrations, strong magnetic field, direct sunlight, draught, high moisture, high temperature fluctuations.

	IMPORTANT: If the instrument is exposed to temperatures outside this range, let the instrument stand for some time to adapt to the surrounding temperature in order to operate in this temperature range. Neglecting this procedure may result in damage to the instrument.
Storage temperature:	1°C – 50°C
Operation altitude:	Up to 2,000 metres above sea level.
Maximum relative moisture:	80%, non-condensing
Contamination level	1
Disposal	Electronic waste

3.5 Procedure for installing the instrument



ATTENTION

Before you turn the instrument on for the very first time and proceed with the installation, let the instrument stand for at least 3 hours in the room to avoid risk of short-circuiting due to moisture condensation.

The following procedure defines the steps to be taken when installing the instrument.

1. Place the instrument on a flat surface.
2. Ensure that the distance between the rear side of the instrument and the wall is at least 20cm.
3. Ensure that the distance between the sides of the instrument and walls is at least 10cm.
4. Place the mains adaptor so that its cable comfortably reaches the instrument. Insert the cable into the power connector on the rear side of the instrument.
5. Insert the power cable into the adaptor and plug it in to the mains supply.



INFORMATION

The two-year guarantee applies only if the final report from the completed installation is delivered to the address of Dynex Technologies.

4 Instructions for use

4.1 Turning on

Make sure the output cable of the adaptor is connected to the instrument's power connector.

Connect the adaptor cable to the mains supply.

When the instrument has been correctly turned on, all indication LEDs will be lit and an acoustic signal will sound.

If the instrument is in standby mode, turn the instrument on by pressing the STOP key on the keyboard.

The acoustic signal indicates that the instrument has been turned on.

In both cases, one of the white LEDs of the selected profile position will remain on.

4.2 Instrument work cycle

The instrument work cycle consists of three phases:

1. Heating of the block and reading of the preparation ID by barcode and QR code reader.
2. Thawing of the preparation.
3. Keeping the preparation at low temperature before the test tube is removed from the instrument.

The work cycle is executed according to the thawing profile which includes parameters used to perform the thawing cycle.

No.	Name	Units/note
1	Profile name	Profile identification
2	Author/Note	Additional information
3	ID read	Setting used if preparation ID must be read using the code reader before inserting the test tube into the instrument.
4	Thawing temperature	Temperature of blocks during the thawing phase of the cycle (range from 0 to 50°C).
5	Turning on temperature	Maximum surface temperature of the test tube at which the thawing phase of the cycle starts automatically (range: -200 to 30°C).
6	Thawing time	Time period (1-600s) upon which the expiration of the thawing phase of the cycle terminates if the thawing termination mode based on time measurement is selected.
7	Target temperature	Test tube surface temperature (range: turned off, or 0 to 50°C) at which, when achieved, the thawing phase of the cycle terminates if the thawing termination mode based on target temperature is selected, or in case of manual turn-on.
8	Maintaining temperature	Block temperature at the maintaining temperature (range: turned off or 5-30°C). When "turned off" is selected, removal of the test tube will be required immediately after the instrument completes the thawing phase.

4.2.1 Selecting the thawing profile

There are four thawing profiles stored in the instrument memory. The selection of the profile to be started is indicated by the relevant white LED lit on the keyboard.

Press the START key while holding the STOP key to change the selection. First, press and hold the STOP key. Within 4 seconds, repeatedly press the START key until the indication LED of the required profile lights up. Then release both keys.

4.2.2 Starting and executing the work cycle

The START button starts the work cycle according to the selected profile. At the same time, a log file with records on the course of the cycle is created in the instrument memory.

First, the block starts heating up to the thawing temperature. While the block is heating up, the status LEDs of the instrument light in orange depending on the temperature increase. A flashing LED that lights up last indicates that the heat-up is in the preparation process. During the heating up phase, the block clamp is closed to avoid early insertion of the test tube into the instrument.

If reading the preparation ID is included in the selected profile, the code reader will light up. Successful reading of the code is indicated by an audio signal and the reader turning off. When the block temperature has achieved the required temperature and the preparation ID has not been read yet, all LEDs will flash in orange.

As soon as the thawing temperature has been achieved and the preparation ID is read, an acoustic signal sounds, the block clamp opens, and all LEDs are lit in orange. The instrument will wait in this state for the operator's intervention.

The operator may now insert a test tube into the instrument.

- If the instrument indicates that the test tube surface temperature is lower than the start up temperature in the selected profile, the acoustic signal will sound, and the block clamp will remain closed.

Depending on the setting in the thawing cycle ending mode in the profile, monitoring of the values that terminate the thawing part of the cycle phase is activated:

- **Time:** the timer which monitors the thawing time value according to the selected profile is started. The violet LED will light up as time passes. The last LED flashing indicates that the timer is on. Thawing finishes upon expiration of the thawing time.
 - **Target temperature:** the test tube surface temperature is monitored. The violet LED will light up as the temperature rises. The last LED flashing indicates that the monitoring of the test tube's surface temperature is on. The thawing finishes when the surface temperature of the test tube reaches the target temperature value.
- Thawing can be started manually if the test tube's surface temperature is not lower than the start up temperature. This option must be enabled in the selected profile together with target temperature setting. The violet LEDs will gradually light up as the test tube's surface heats up. The last LED flashing indicates that the monitoring of the test tube's surface temperature is on. The thawing finishes when the surface temperature of the test tube reaches the target temperature value.

In both cases, the end of the thawing process is indicated by an acoustic signal and the release of the block clamps.

Subsequent activity depends on the configured option of retaining in the selected profile.

- When retaining the preparation after the thawing is enabled, the block is cooled down to the retaining temperature value. Over the course of the cooling, status LEDs light up in blue based on the decreasing block temperature. When the last LED to light up is flashing, this indicates that the cooling is in the block temperature reduction process. As soon as the retaining temperature is achieved, all LEDs are lit in blue.

At any time during the retaining phase, pressing the Stop key will end the work cycle normally. Logging in the log file is ended and the test tube can be removed from the instrument. The instrument returns to default status.

- If no retaining is enabled, the acoustic signal will permanently sound after the thawing phase is complete. All LEDs will flash in green. The operator terminates the work cycle as soon as possible by pressing the Stop key, then removes the test tube from the instrument. Logging in the log file is ended and the instrument returns to default status.

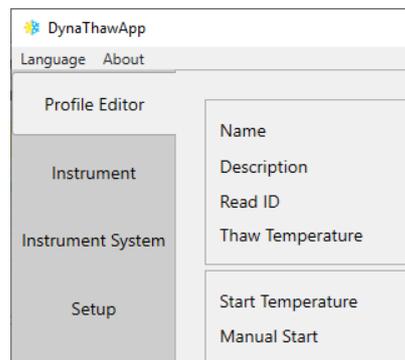
4.2.3 Extraordinary termination of the work cycle

The work cycle may be ended extraordinarily at any time before standard termination. After pressing the Stop key, all LEDs will flash in green for 4 seconds. For now, the work cycle still continues.

- If the Stop key is pressed again during that time, logging in the log files is ended, and the instrument returns to default status. If the cycle is terminated prior to inserting the test tube into the block, no log file of this work cycle will be saved in the memory.
- If the Stop button is not pressed again within 4 seconds, the instrument will continue performing the work cycle.

4.3 Connecting to PC and control of DynaThaw SW application

To connect the instrument to a computer, use a USB cable with mini USB type connector, and turn the instrument on. Launch DynaThawApp.



The top bar shows the menu.

- Language – to select language of the interface
- About – information about the application.

On the left side of the window there is a menu with four tabs. Click on the tabs to open the relevant functional windows:

- Profile editor – to create or edit the thawing profiles.
- Instrument – storing profiles in the instrument memory, log administration, instrument service control.
- Instrument System – for controlling a system with up to 6 instruments permanently connected to the PC.
- Set up – setting the application parameters.

4.3.1 Profile editor

The profile editor is used to create the thawing profiles and to save the profile files to the PC.

The thawing profile has the following parameters:

Name – identification of the profile; the text may contain up to 20 characters.

Description – any text with up to 40 characters.

Read ID – if checked, preparation ID reading from QR code is an essential condition.

Thawing temperature – block temperature value [°C] when thawing the preparation.

Start temperature – limit value of the surface temperature of the test tube needed to automatically start the thawing cycle. The thawing process starts if the surface temperature of the test tube inserted in the instrument is lower than the start-up temperature.

Manual start – if checked, thawing may be started manually by pressing the Start key if the test tube's surface temperature is not lower than the start-up temperature.

Thaw cycle finish mode – selection between *Time* mode (thawing phase of the cycle finishes upon expiration of the thawing time) or *Target temperature* mode (thawing phase of the cycle finishes when the test tube's temperature reaches the target temperature).

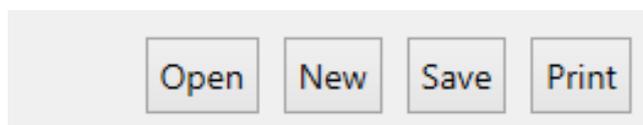
Thaw time – thawing time value [s].

Target temperature – temperature value measured on the test tube surface [°C]; thawing is finished when the temperature is reached.

Storage – if checked, the block temperature will change according to the following parameter after thawing finishes.

Storage temperature – block temperature value [°C] to which the block sets up after thawing finishes.

There are control buttons in the lower part of the window:

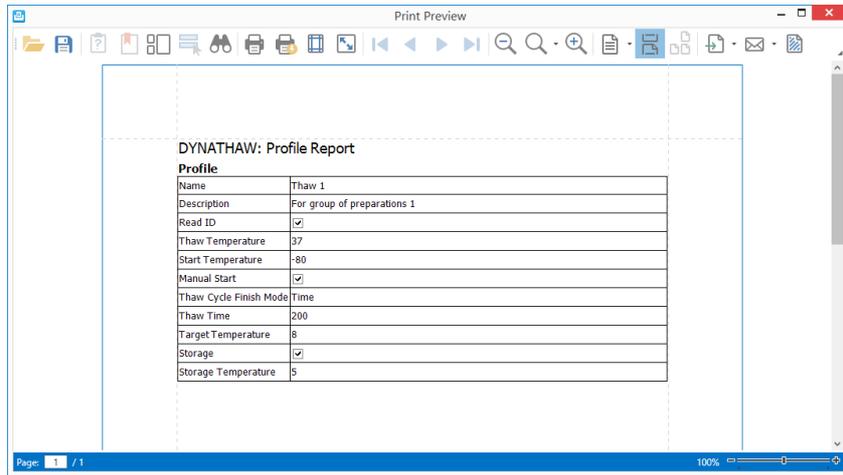


Open – opens a file of a previously created profile.

New – initializes fields to enter a new profile

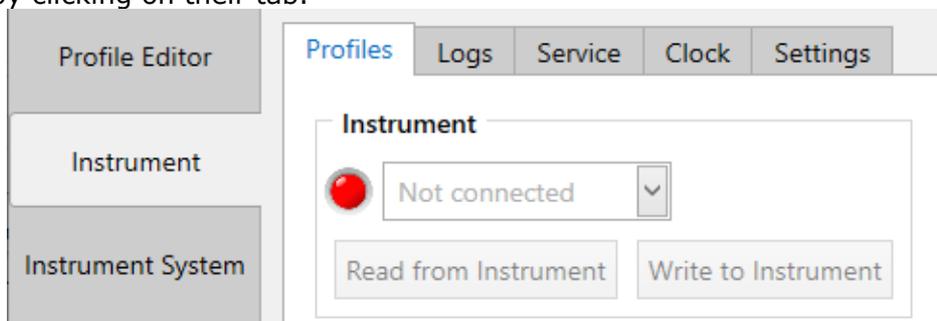
Save – saves the file of the created profile. The default name of the file being saved is identical to the profile name. The name may be changed when saving.

Print – opens a dialog box to print the profile parameters.



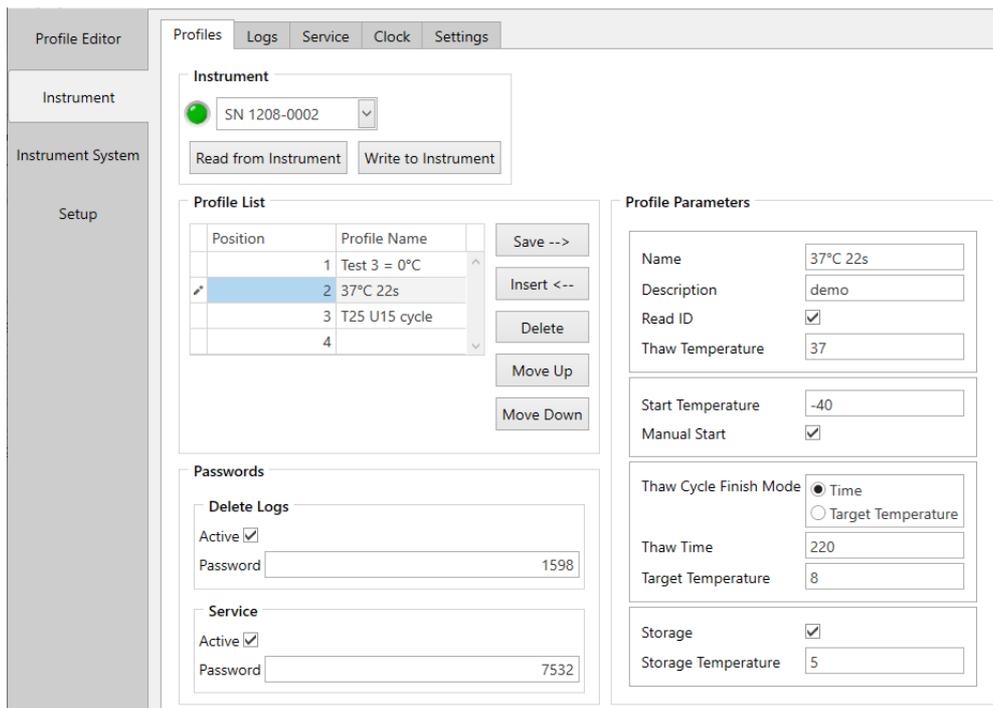
4.3.2 Instrument

The Instrument is used to transfer information between the instrument and PC. The menu dialog box contains some submenus (Profiles, Logs, Service, Clock, and Settings) that are selected by clicking on their tab.



4.3.2.1 Profiles

The Profiles menu is used mainly for saving the profiles in the instrument memory.



The Instrument frame includes:

- Instrument connection indicator – red colour indicates that no instrument is connected; green colour indicates that a instrument is connected.
- The box shows the serial number of the instrument connected to the PC.
- Read from Instrument button activates a profile transfer from the instrument memory to the profiles list table.
- Write to Instrument button activates the transfer of profiles listed in the profiles list table to the instrument memory. The button is enabled only when a licence file for the connected instrument is available (matching according to the instrument’s serial number).

The Profile list frame includes:

- A table showing the profile memory in the instrument. The Position column shows a number from 1 to 4 corresponding to the positions for profile selection on the instrument keyboard. The names of the inserted profiles are shown in the Profile name column. If no profile is inserted, the field remains empty.
- The Save button – saves the profile from a selected row (or multiple rows) to a file in the PC. Preferentially, the *.tpf files have their name coincident with the Profile name.
- The Insert button – opens a dialog box to open a profile file type (*.tpf), and the profile is inserted to the selected table row.
- Delete – deletes the profile from the selected table rows.
- Move up and Move down – changes the profile position in the selected table row.

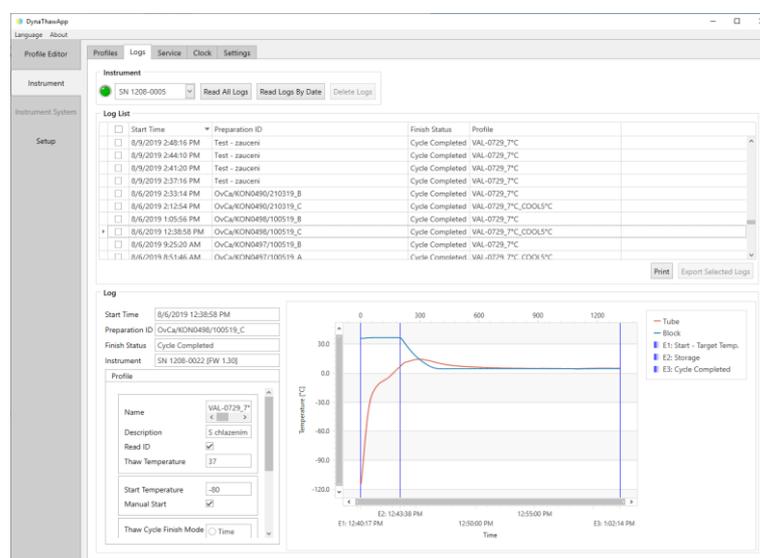
The Profile parameters frame shows the profile parameters of a selected table row in Profile List.

Passwords frame includes:

- Delete logs – the checkbox to enable protection against unauthorized deletion of logs from the instrument memory. If protection is enabled, the Password field is enabled as well. The password’s format is a four-digit number.
- Service – the checkbox to enable protection against unauthorized access to the instrument memory using the features of the Service menu. If protection is enabled, the Password field is enabled as well. The password’s format is a four-digit number.

4.3.2.2 Logs

This menu is used to display and manage records about thawing cycles initiated on the instrument.



Upon clicking the button to load the logs, the process of transfer from the instrument memory to the PC is initiated. A progress bar in the information window monitors the transfer.



- Load all logs – all logs included in the instrument memory are loaded.
- Load logs by date – a dialog box opens to select a specific date. Only logs created on the selected date are loaded.

Following the loading process, the List of logs table shows headers of each log with the basic identification data:

- Start time – the start time of the thawing cycle (pressing the START key).
- Preparation ID – text read by QR code reader, if reading the code is required for the thawing cycle by the selected profile.
- Finish status – this defines how the cycle finished (finished, interrupted, error, etc.).
- Profile – name of the profile used for the cycle.

Clicking on the column header will arrange the records alphabetically in the selected column.

Clicking on some of the rows in the list of logs will show log details in the Log frame.

The left part of the frame shows:

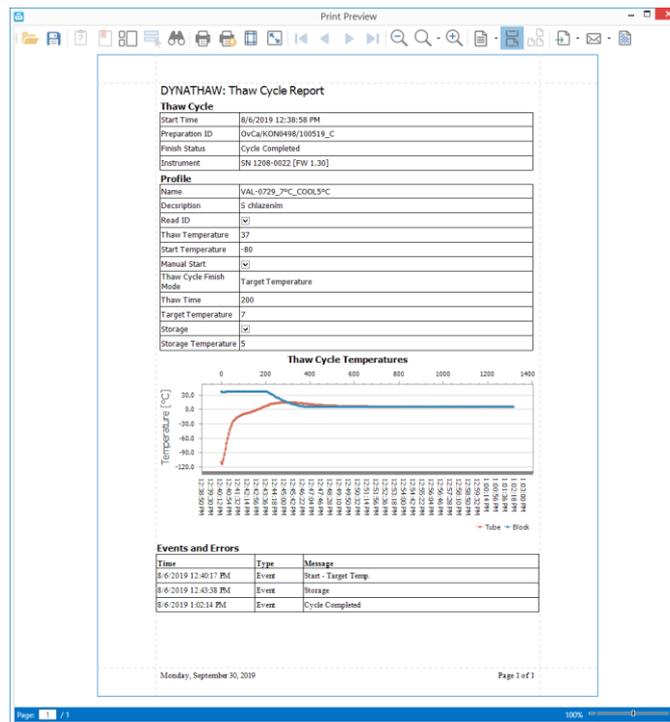
- Start time – start time of the thawing cycle
- Preparation ID – if read by the QR code reader
- Finish Status
- Instrument – serial number of the instrument and firmware version.
- Profile – parameters of the thawing profile used.

The right side shows a graph with time dependency of the instrument block temperature and the test tube surface temperature over the course of the thawing process as well as potential retention of the preparation. The lower timeline shows the value of real time (hour:minute:second) depending on the time setting in the instrument's control system. The upper timeline shows the time from the beginning of the thawing cycle (from inserting the test tube to the instrument) in seconds. When the mouse pointer is hovered over the graph, lines appear that assist in monitoring the time and temperature values.

Next to the graph is a field with explanatory notes to the colours used for the temperature curves in the graph, and the list of events from the course of the thawing cycle. The events are successively identified as E1, E2, ... These references can be used to look for them on the lower timeline of the graph.

Log print

Use the Print button to print the log from the selected row in the form of the protocol.



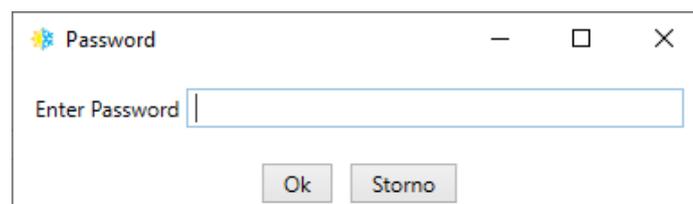
Retaining the logs

Click on the Export selected logs button to export the logs identified with the checkbox into PDF format into the folder defined in the Instrument / Setting menu.

File names are created by date and time of cycle start (e.g. 2019_06_20__10_29_22.pdf).

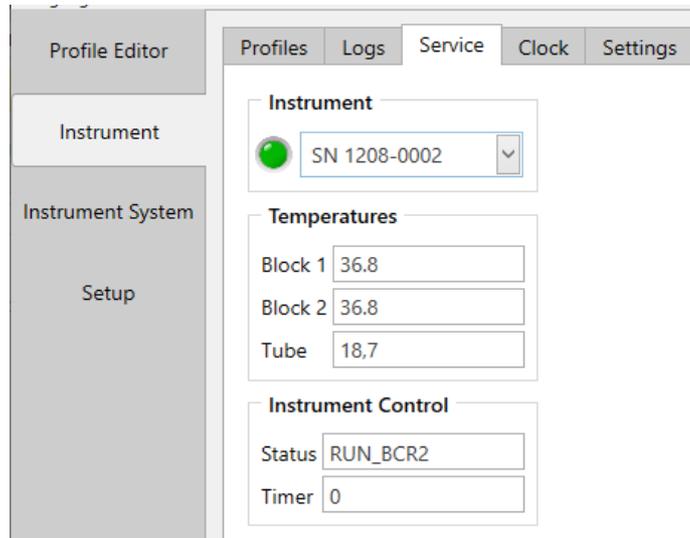
Deletion of logs

Click on the Delete logs button to delete the logs identified with the checkbox from the instrument memory. If protection against deletion of the logs is enabled (refer to Profiles, chapter 4.3.2.1) and no licence file of the instrument is available, a correct password must be entered.



4.3.2.3 Service

It is possible to monitor the operation values of the connected instrument before and during the course of starting up the thawing cycles.



The Instrument frame indicates connection and serial No. of the connected instrument. The Temperatures frame contains currently measured temperatures in °C.

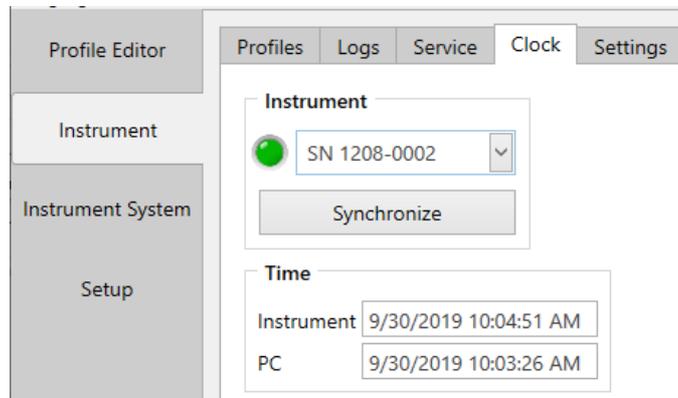
- Block 1, Block 2 – Thermometers of the first and second block
- Test tube – Infrared thermometer to measure the test tube surface temperature.

The Instrument control frame shows:

- Status – code of status that the instrument is currently in.
- Timer – current value of the timer in seconds to measure the thawing time.

4.3.2.4 Clock

The menu is used to configure the exact time in the instrument’s internal clock. The time data of the clock is used in creating the records of the logs.



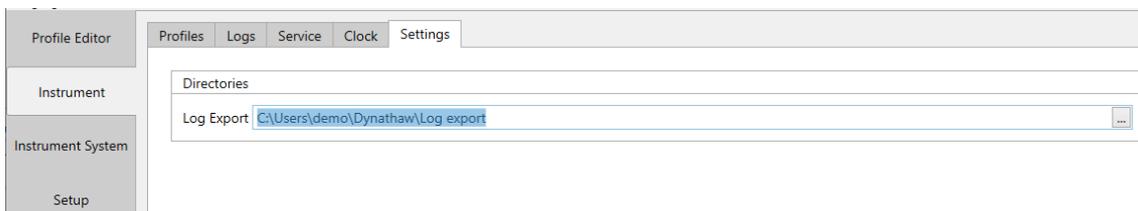
The Instrument frame indicates connection and serial No. of the connected instrument. The Time field shows the current time of the clock in the connected instrument.

Use the Synchronize button to synchronize the instrument and PC clock.

The Time frame includes two fields showing the current time.

- Instrument – time of the connected instrument
- PC – time of the PC

4.3.2.5 Settings



The Directories frame shows the Log export field used to enter the path to the folder for saving the PDF files of the retained protocols of the thawing cycles.

4.3.3 Instrument system

Not active at this moment.

4.3.4 Set Up

The menu contains items required to set up the application.

The screenshot shows the 'Setup' menu with the following details:

- Instrument Licences:** Directory: C:\Users\demo\Dynathaw\Licences; Licences: *****, SN 1208-0003
- Default Tab:** Profile Editor (unselected), Instrument (selected), Instrument System (unselected)
- Directories:** Profiles Directory: C:\Users\demo\Dynathaw\Profiles

The Instrument Licences frame includes the Directory field to define the path to the folder where the instrument licence files are saved. The Licence field shows the list of the serial numbers of the instruments for which licence files were found in the folder defined above.

The Default tab frame contains the selection of the folder that is displayed automatically when DynaThawapp launches.

The Directories frame includes the fields to enter the path to the folders preferentially used for saving the application files.

Profile Directory – the folder to save the thawing profile files to (*.tpf). This is used to save and open the files in the Profile editor and Instrument / Profiles menu.

4.4 Turning the instrument off

When the instrument is not in the work cycle phase, it can be turned off by pressing the STOP key for more than 4 seconds. All indicating LEDs will turn off, and the instrument switches into sleep mode with minimum power consumption.



WARNING

When all power cables are plugged in, the instrument electronic components remain under voltage even though the instrument is set to sleep mode – turned off.

To completely turn off the instrument and adaptor, you must unplug the power cable from the mains supply.



NOTE

The instrument can be turned off for safety reasons at any time.

5 Managing errors

In the event of an error status occurring during operation of the instrument, the activity is stopped, an acoustic signal sounds, and the root cause of the error is displayed using the status LED indicators of the instrument. You can mute the acoustic signal by pressing the STOP key. The power supply for heating/cooling the blocks, fans, and magnets to close the clamps is off. If the instrument is performing the work cycle immediately before the error, the work cycle is immediately terminated. The error record is saved in the log file of said cycle.

The error status of the machine can be terminated by pressing the STOP button or disconnecting the power supply.

5.1 Table of errors

Number	Instrument status indicator	Description	Solution (service intervention is required for a recurring error)
0x200		Thermometer communication error	Turn the instrument off and on.
0x201		Parity of block temperatures	Let the instrument cool down.
0x202		Block 1 temperature has exceeded limit value	Let the instrument cool down.
0x203		Block 2 temperature has exceeded limit value	Let the instrument cool down.
0x205		Block 1 temperature out of required range after set point reached	Let the instrument cool down.
0x206		Block 2 temperature out of required range after set point reached	Let the instrument cool down.
0x2061-B		Incorrect parameters of the started profile	Save a profile with correct parameters to the machine memory.
0x250-4		SD card error Various error types	Service – replacement of the SD card
0x260-1		SD card error Error writing and reading	Service – replacement of the SD card
0x270		USB error Unable to perform initiation	Turn the instrument off and on.
0x280		Time setting error	Use DynaThaw application to synchronize time between the instrument and PC. Service – replacement of backup battery in the instrument.

6 Maintenance

6.1 Cleaning

6.1.1 External surface and cover

Clean the external surface and cover using a soft cloth with water and detergent.



ATTENTION

Do not use organic solvents (e.g. acetone). The instrument's surface would be permanently damaged.

6.1.2 Disinfecting the instrument

Should the surface be contaminated by bio-hazard material, the user must conduct the proper decontamination procedure.



WARNING

Use of protective gloves, coat, and goggles is recommended when decontaminating the instrument.

The instrument must also be disinfected in the event that it is taken from the laboratory, or prior to service on the instrument.

The instrument must be disinfected prior to sending the instrument to the distributor for service intervention. This disinfection must be verified by a Certificate of Disinfection.

6.1.3 Disinfection procedure

In case of doubts, please consult the suitability of the composition of the disinfecting agent you use with the manufacturer or its representative regarding its impact on the machine components.



WARNING

Fire and explosion hazard!
Some disinfecting agents may be flammable and may result in explosion when used improperly. Proper safety measures for working at laboratories must be observed.



IMPORTANT

Leaking of the disinfecting agent inside the instrument may result in defective operation.

Surface disinfection.

1. Thoroughly spray the instrument surface and working area with a disinfecting agent (or use a disposable soft paper napkin soaked in the disinfecting agent).
2. Not earlier than 10 minutes after the first application, repeat the previous step.
3. Not earlier than 5 hours afterwards, wash the surface of the instrument and working area with a soft paper napkin soaked in a solution of water and detergent, or distilled water only, and remove the residues of the disinfecting agent.
4. Dry the surfaces with paper napkins.
5. Pack the instrument and accessories.
6. Disinfect your hands and wash with soap and water.
7. Fill in the Certificate of Disinfection (refer to Appendix No. 1) and place it on external side of the box so that it is well visible.



DECONTAMINATION PROTOCOL

The instrument must be prior to its sending for repair or maintenance to DYNEX TECHNOLOGIES, spol. s r. o. decontaminated, i.e. the health safety of the instrument for the transporting and repair purposes has to be documented in writing.

Sender

Address

Responsible Person

Contact

hereby declares that the subject of decontamination:

Instrument type

Serial number

Location

was prior to its sending thoroughly cleaned, decontaminated and there is no risk of contamination.

The sender also declares that he is aware of the responsibility for any damage resulting from contamination or other contamination of the above subject.

In on20.....

.....
Signature