

Risk Assessment Form

Procedure	Use of Microbiological Incubator
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Name(s) of person performing the work	Users (Lab manager & Lab Technician & Tenants)		
Name & position of assessor	Khwaja Islam & Laboratory Manager	Signature	
Date of assessment	04/08/2021	RA Number	BioE 0045

Outline of procedure / activity:

The INCU-Line microbiological incubator is designed to cultivate microorganisms at defined temperatures. It can be used e. g. for determining the number of microorganisms through plate count methods or detecting of pathogenic germs in clinical samples or product samples. It is intended for use in laboratories in these sectors: life sciences, clinical medicine, veterinary medicine, the pharmaceutical industry, the food industry, toxicology, and fundamental research into biology and preclinical medicine.

The INCU-Line incubator should not, in particular, be used to prepare foods intended for consumption or to sterilize or decontaminate medical products or medical equipment as defined by the Medical Device Directive 93/42/EWG (MDD).

The microbiological incubator is located in IL-2 (696.10.22).

Operator must be trained in operating microbiological incubator to guarantee safe daily use. Untrained Personnel are not be allowed to operate the microbiological incubator. Users should operate the microbiological incubator according to instructions in the manual. User must always ensure that power cable is in good condition, no wires exposed.

To guarantee your security and the longest efficiency of the unit, please comply with the following rules:

1. The unit cannot be installed:

- outside,
- in damp places or places which can be easily flooded,
- near flammable or volatile substances,
- near acids or in corrosive environments.

2. It is forbidden to:

- store inflammable or volatile substances inside the unit,
- touch live parts of the unit • operate the unit with wet hands,
- put water vessels on the unit, • climb or put any objects on the unit,
- overload the shelves (the maximum load is 250kg).

3. You should:

- place samples in such a way to provide proper air circulation in the chamber,
- open the door for the shortest period of time to reduce temperature fluctuations,
- secure samples from being blown out by the chamber fan e.g powdery samples,
- always check that the doors are closed • use only mains with earth to avoid electric shocks,
- unplug the power cable holding the protective cover and not the cable itself,
- disconnect the unit from the mains before undertaking any repairs or maintenance works,
- protect the power cable and the plug from any damage
- disconnect the power plug before moving the unit,
- disconnect the power plug if the device will not be used for a long period of time,
- disconnect the unit and protect it from reconnecting if it has any visual faults.

INCU-Line device is delivered with the following equipment:

2 stainless steel wire shelves with set of slides – 2 pcs. Each, keys to the lock (2 pcs.), manufacturer test certificate at 37°C.

Internal glass door:

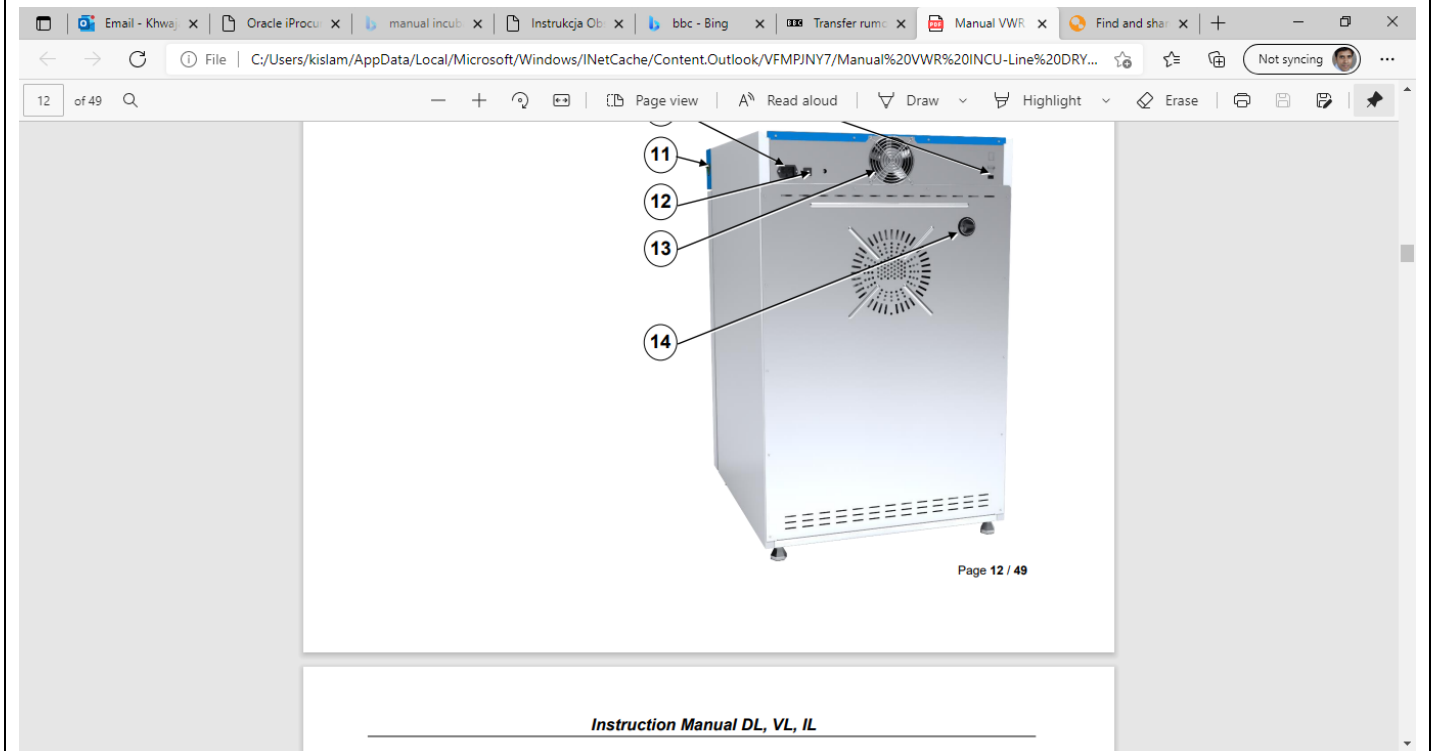
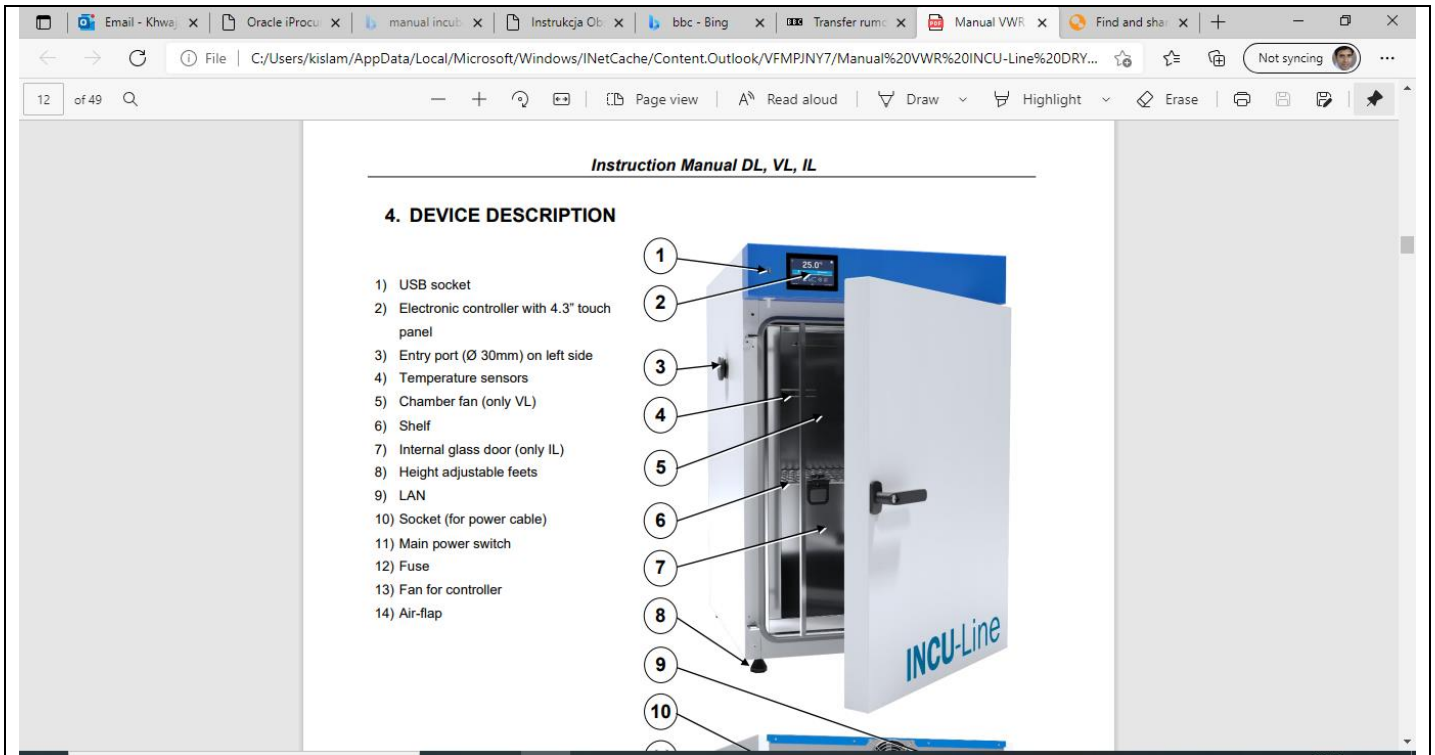
To open or close the internal glass door use the plastic handle installed on the glass. While operating the unit at high temperatures, do not touch the glass door or inner parts of the chamber. Always use safety gloves to protect yourself and minimise the risk of being burnt.

Closing the chamber:

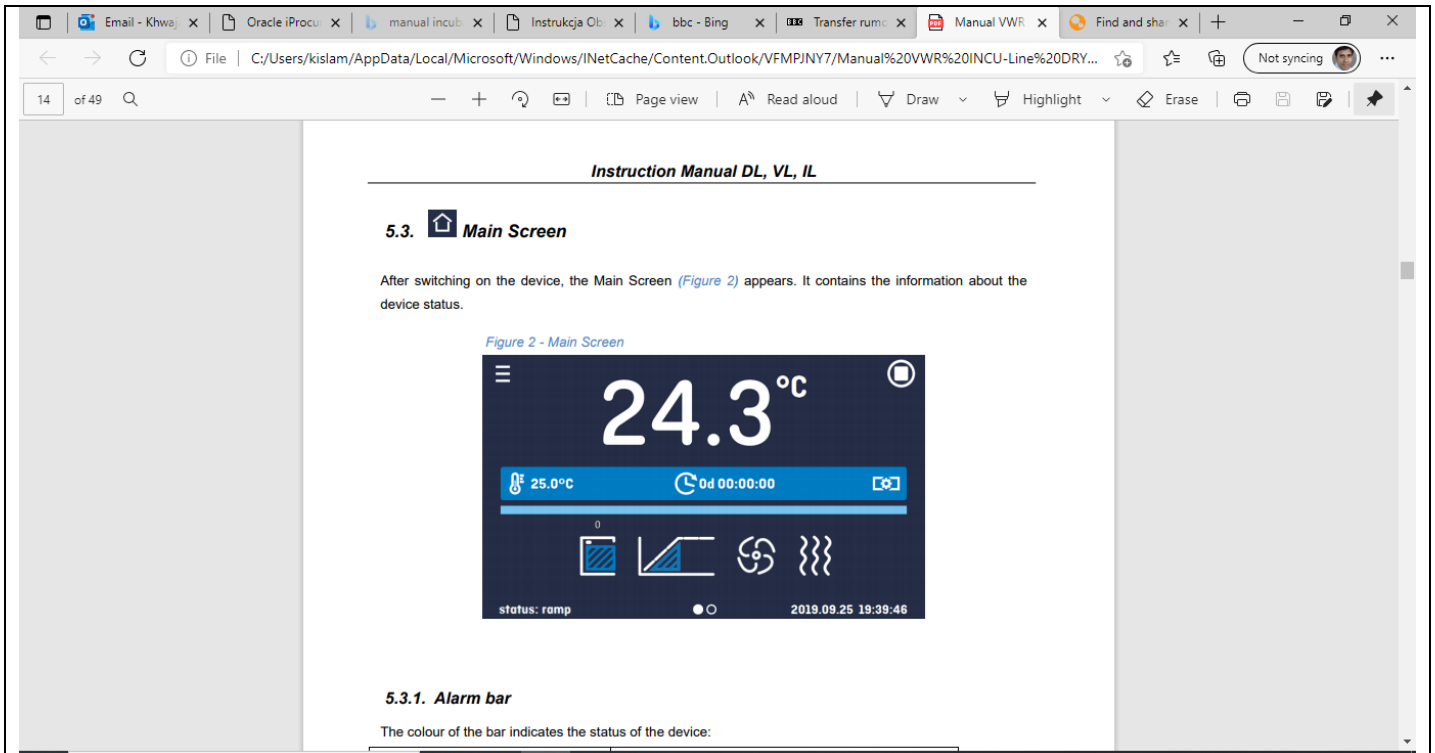
The door has been equipped with a door handle. To close the door, turn the handle to the vertical position, push the door gently and turn the handle to the horizontal position. Closing the door correctly reduces energy consumption and ensures proper temperature stability and uniformity.

Device description:

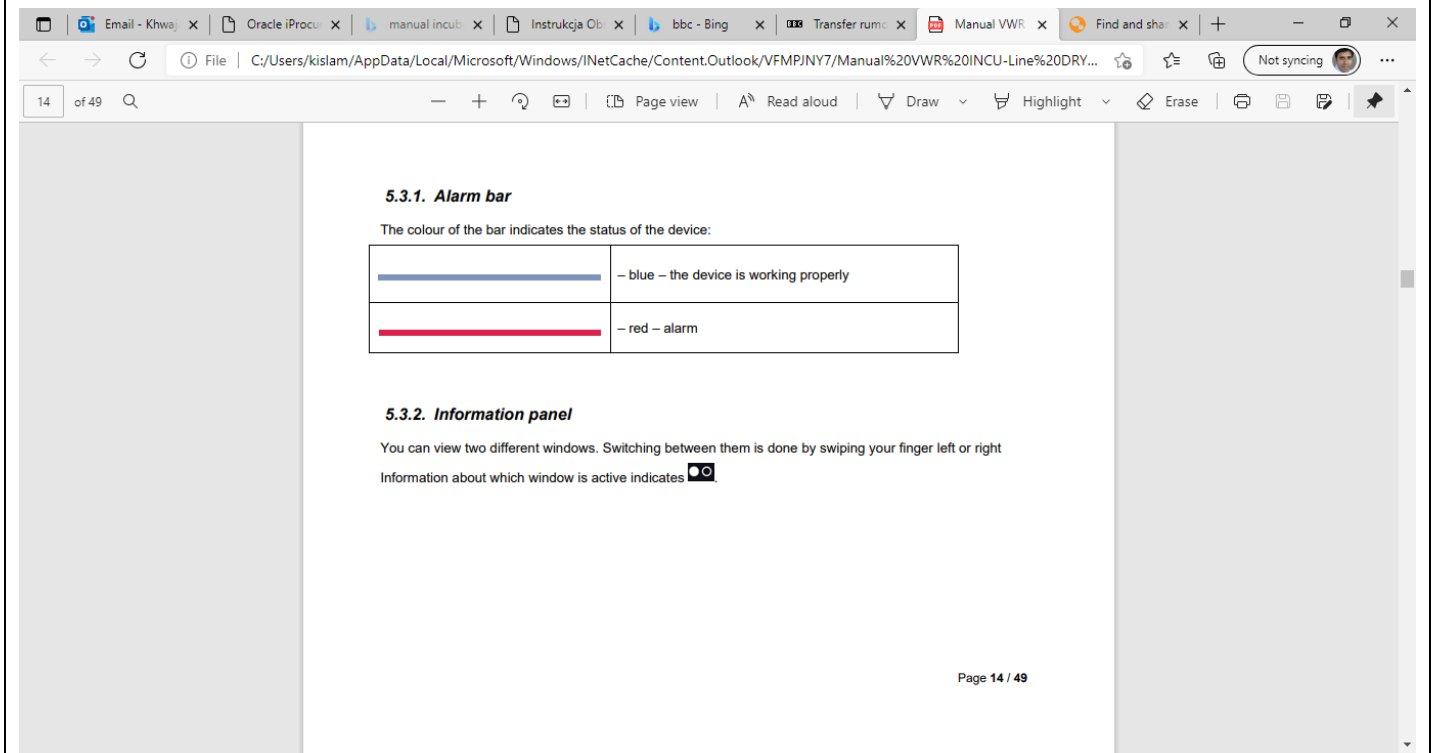
Main power switch is on the side of device (item 11).



Main screen and Alarm bar:



Alarm bar:

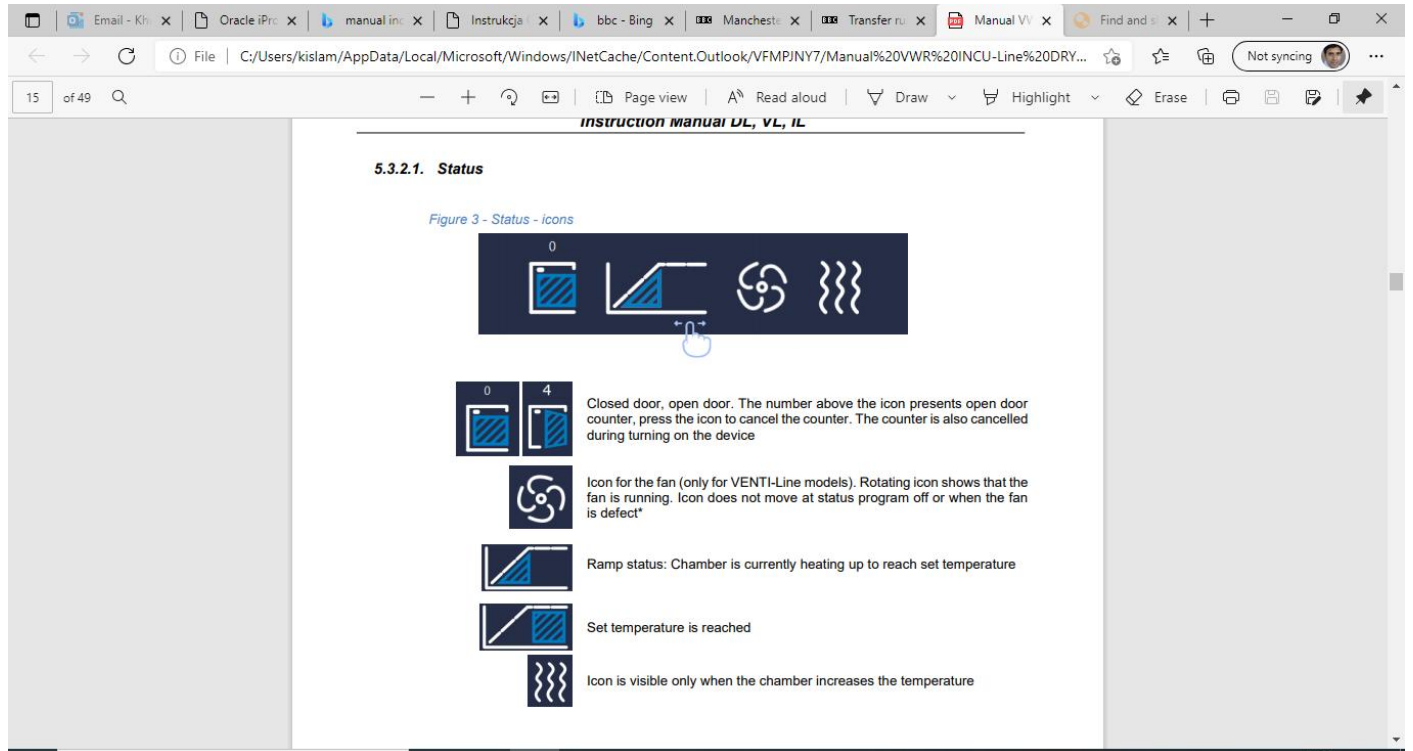


Information panel:

You can view two different windows. Switching between them is done by swiping your finger left or right

Information about which window is active indicates.

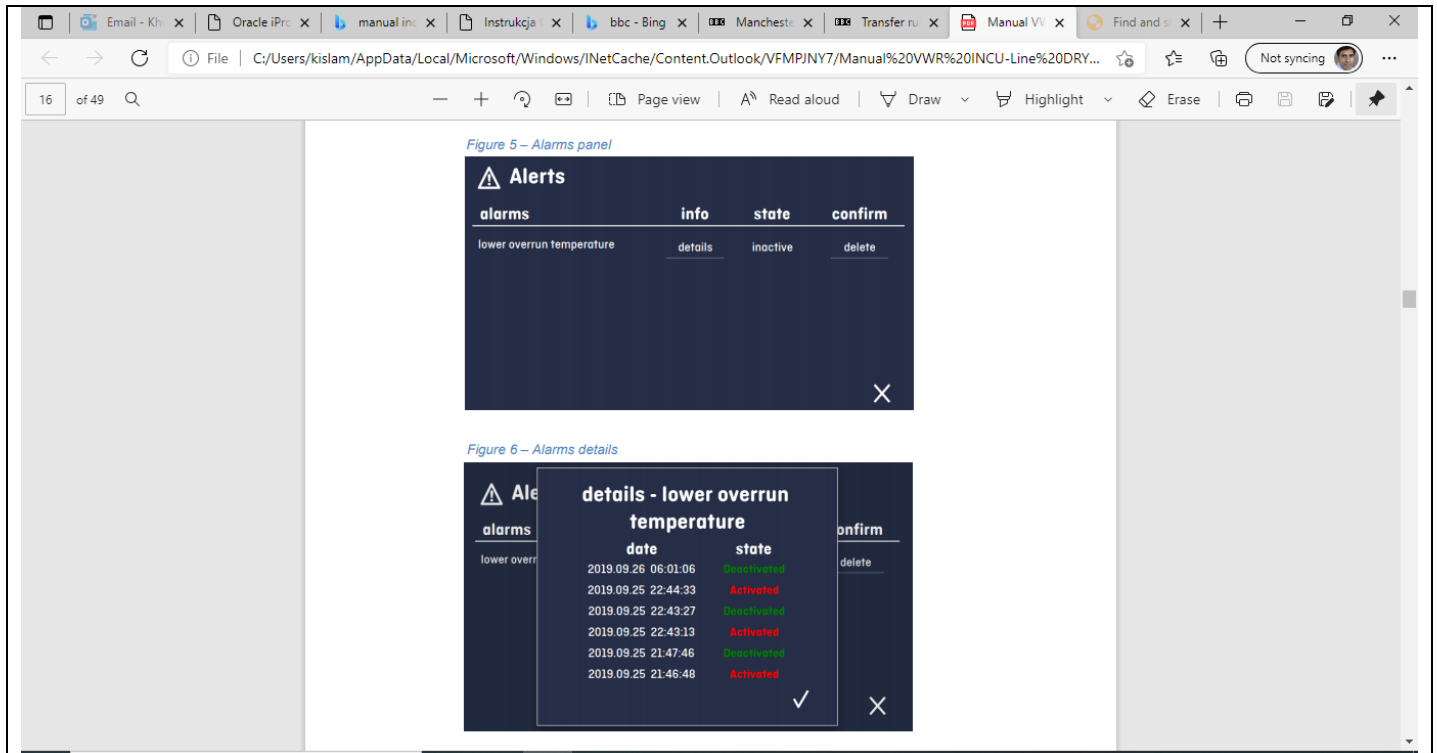
Status:



Alarm panel:

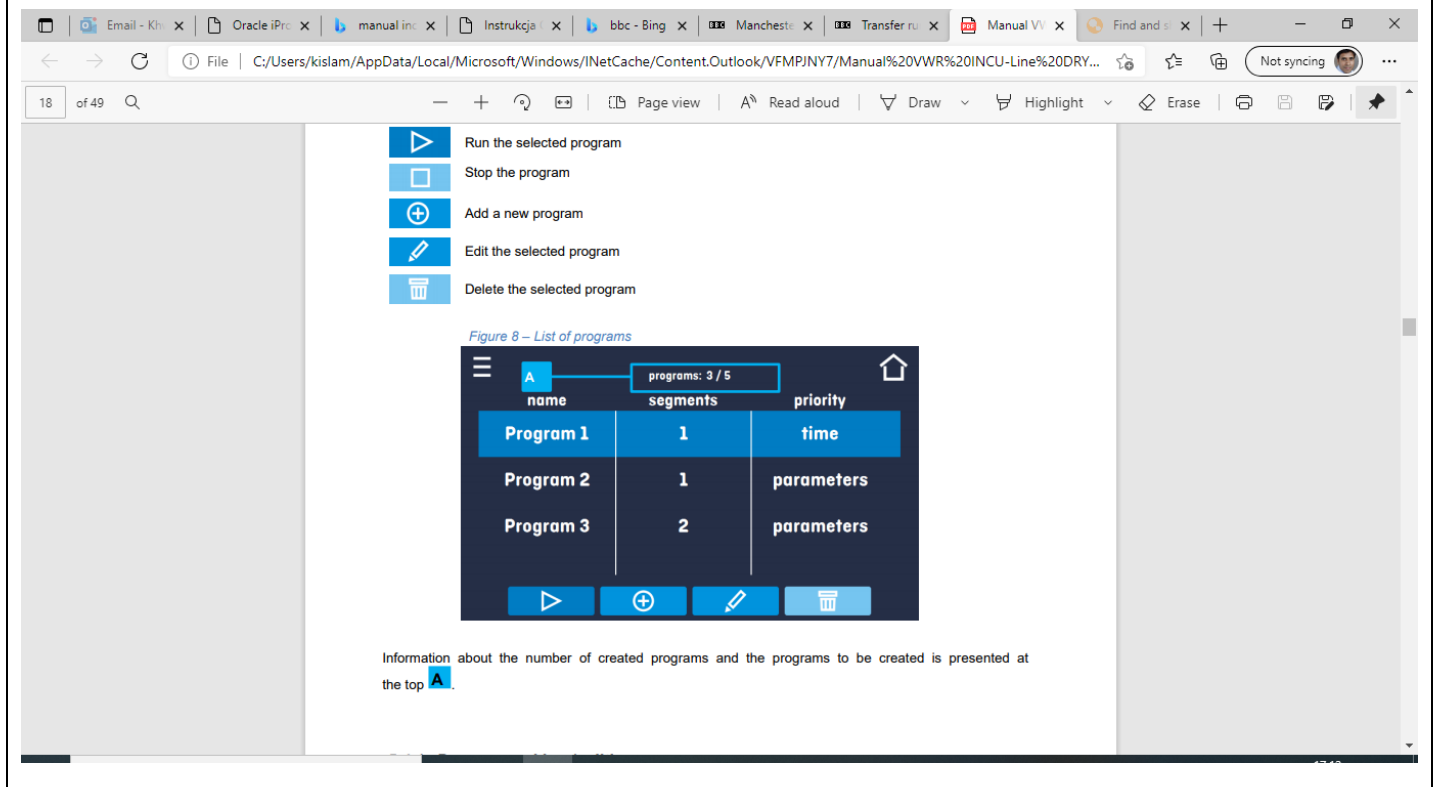
In this place appears the list of alarms. With active alarm, the control bar is red. The alarm event is displayed in the list, with the status alarm active. When an alarm event stops, the alarm remains in the list as inactive.

- “delete” button – confirms and removes the alarm from the list (only inactive alarms can be deleted),
- “confirm” button – confirms the class 2.0 alarm,
- “details” button – displays a preview of all instances of selected alarm (Figure 6).



Programs:

In this panel (Figure 8) you can run the selected program, add a new one, edit the program or delete it. Menu push button.



Starting the program:

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The first way



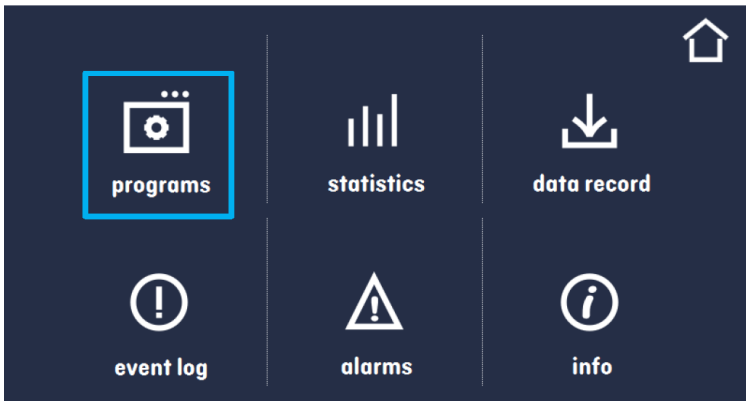
- Press the icon  „programs” in main menu (Figure 13).
- Then select the program you want to activate and press „Start” button  (Figure 14).

Figure 13 – Main menu



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The second way

- In the main panel (Figure 15) press the icon in the upper right corner. .
- By pressing the icon you will go to the program selection window (Figure 16).
- Select the program you want to activate, you have got two additional options:



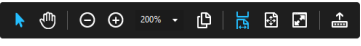
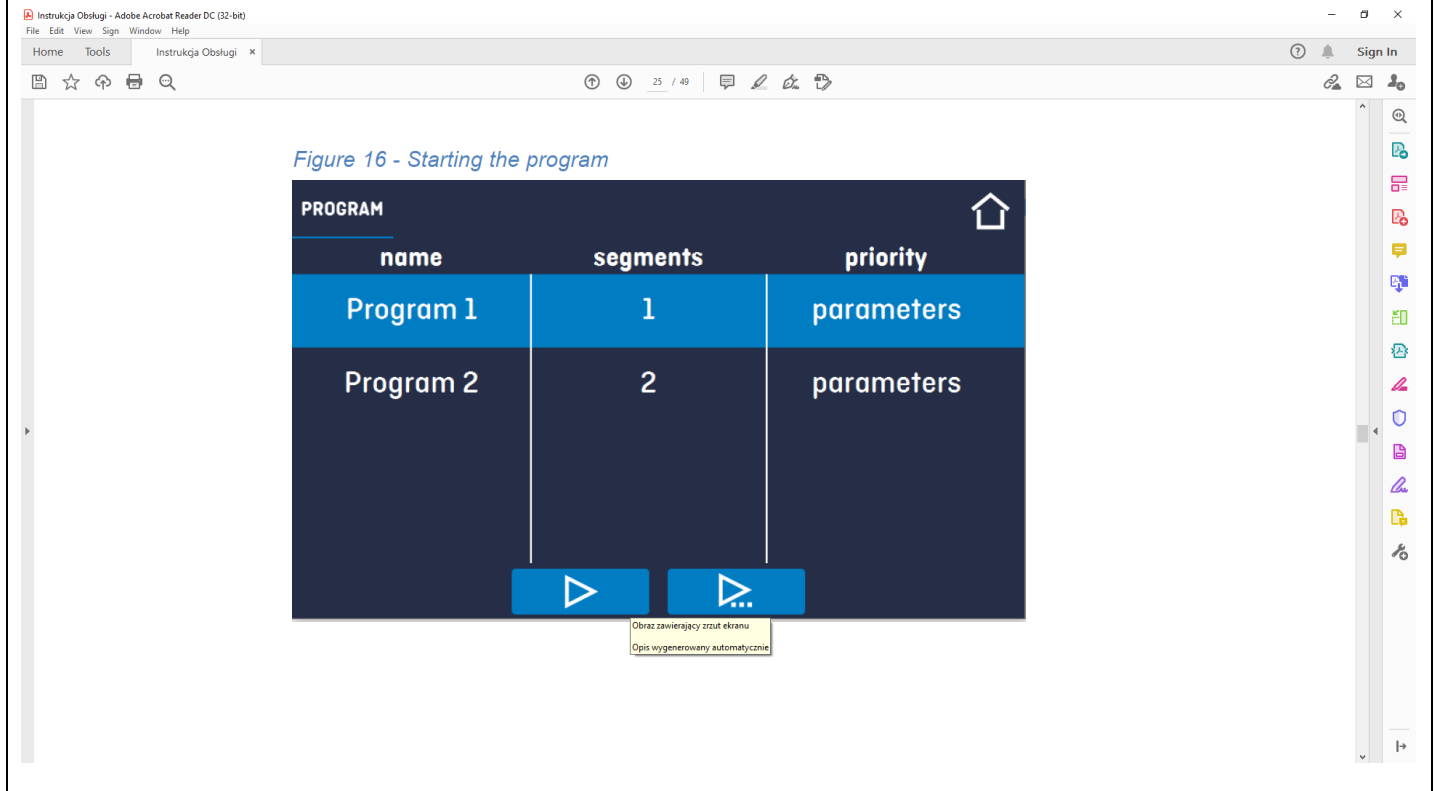
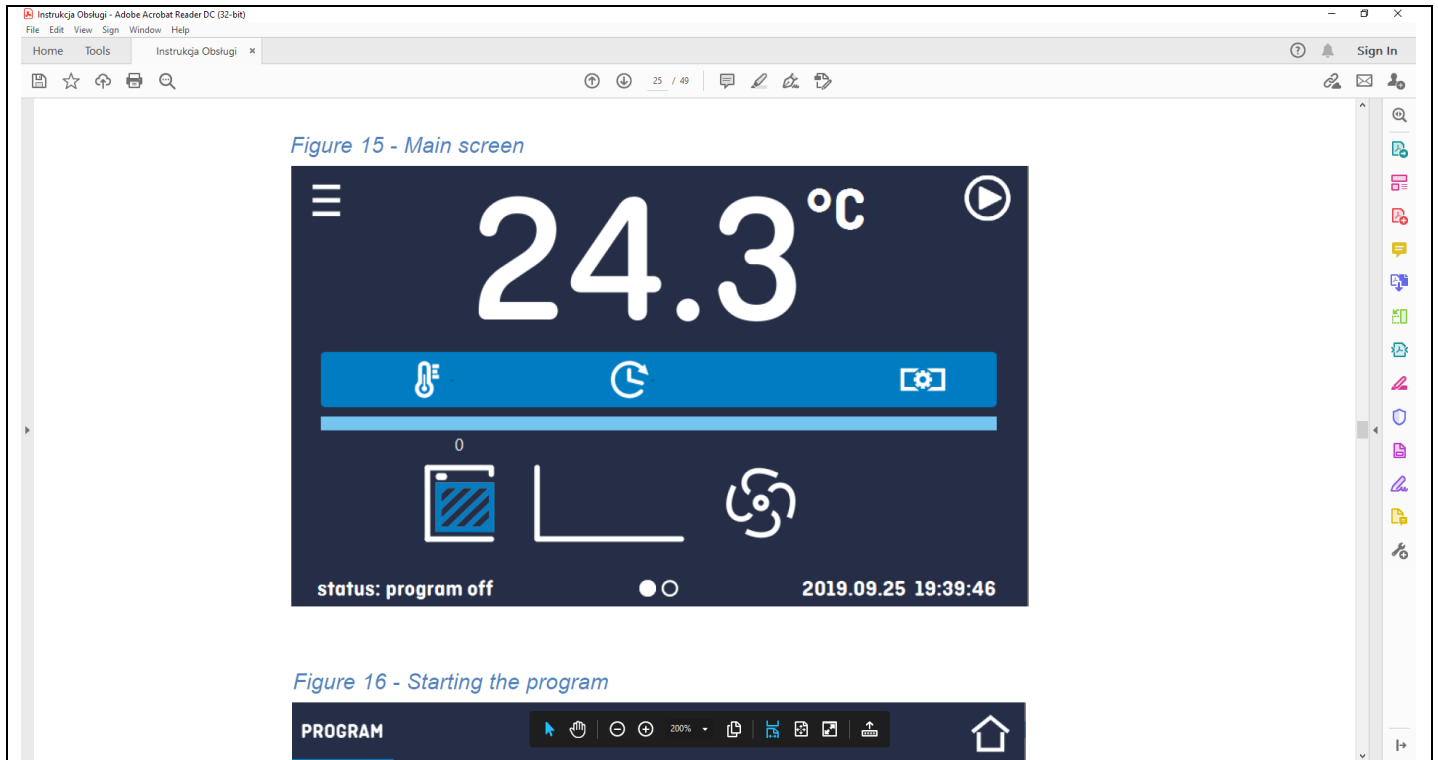
-  Immediate start of the program
-  Scheduled program start according to the set date and time

Figure 15 - Main screen





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It's possible to start a backdated scheduled program but only for programs with time priority and scheduled max. 7 days back. It is possible for time priority programs.
Program segments which last for a total period from the set date to the current date will be skipped.

5.6. Quick change of parameters

5.6.1. Quick change the set temperature

In order to quickly change the value of the set temperature of the program, press the icon  in main screen [\(Figure 2\)](#).
The value of the temperature should be selected by scrolling the list up or down [\(Figure 17\)](#). Confirm the change by pressing

Temperature cannot be higher than protection temperature (over temperature) -2°C.

[Figure 17 - Quick change of temperature](#)

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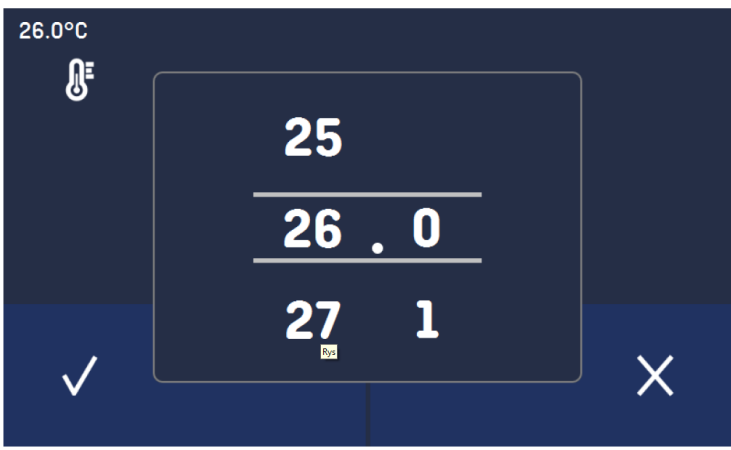
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[Figure 17 - Quick change of temperature](#)



26.0°C



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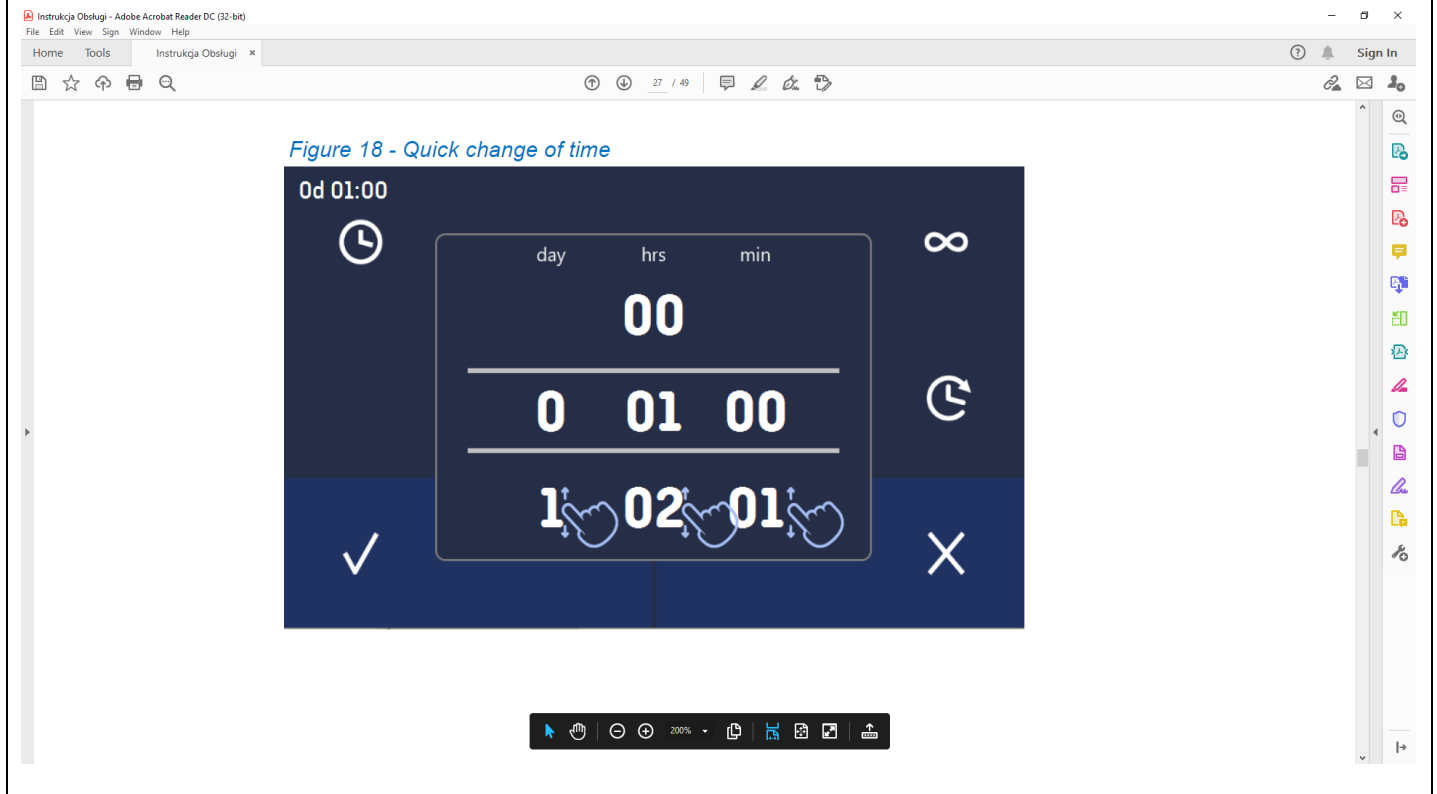
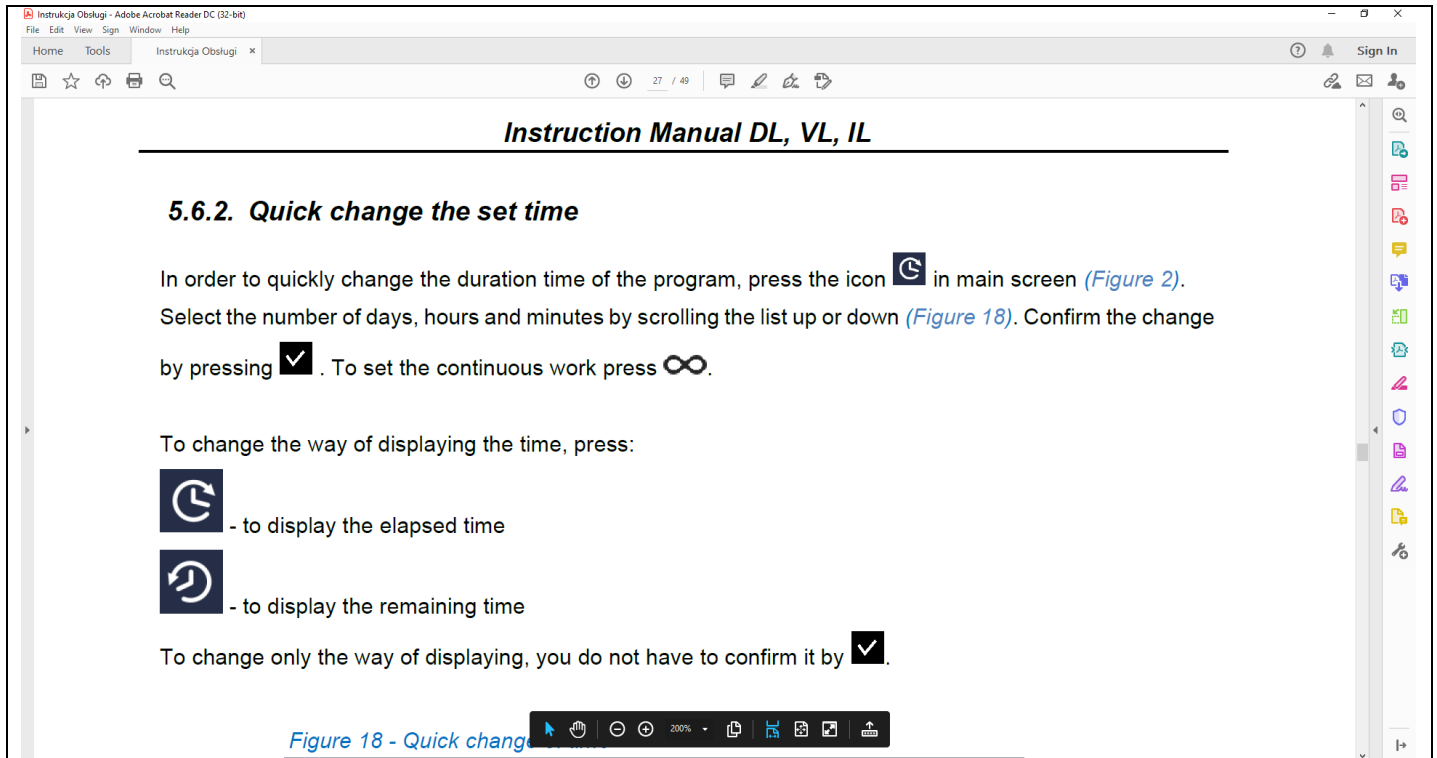
26 . 0

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✓

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200%



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5.13. Alarms

You can set parameters related to alarms.

- **lower alarm** – an alarm will be generated if the temperature drops below the value given in this field
- **upper alarm** – an alarm will be generated if the temperature rises above the value given in this field

The lower and upper alarm can only be generated after reaching the set temperature.

- **delay temp alarm:**
the alarm will be activated with a delay (1 min, 2 min, 5 min, 15 min) after exceeding the permitted temperature.
- **delay door alarm:**
the door alarm will be activated when the door is opened for the time selected by the user (5 s, 30 s, 1 min, 5 min, 10 min).

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lower alarm temp -1°C

upper alarm temp +2°C

delay exceed alarm 0s

delay door alarm 1min

✓
✕

✓

Confirms and saves changes

✕

Cancels the entered changes

In the field "lower alarm temp" you can set a value of -1°C to - 5°C and in the field "upper alarm temp" you can set a value of +1°C to +5°C.

Internal glass:

To open or close the internal glass door use the plastic handle installed on the glass. While operating the unit

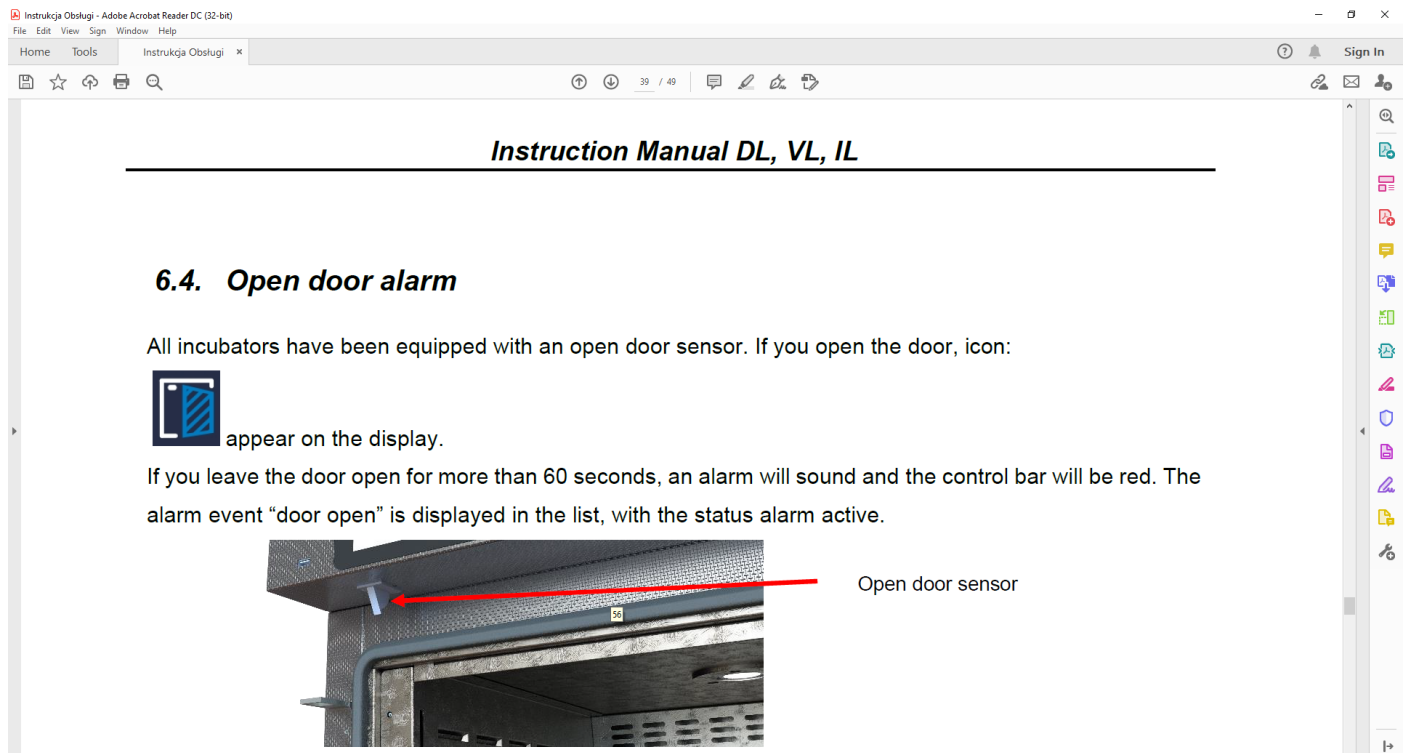
at high temperatures, do not touch the glass door or inner parts of the chamber. Always use safety gloves to protect yourself and minimise the risk of getting burnt.

Door lock:

All models have been equipped with a door lock located in the door handle. Two keys are attached on the backside of the device.

Access port:

A Ø30 mm access port can be used to insert an external temperature sensor, which has been secured with a silicon plug. The plug should cover the access port while the unit is operating. If multiple cables have been inserted through the access port and if it is not possible to use the plug, secure the access port with adhesive tape. If you leave the access port open, it may affect temperature stability and uniformity within the chamber.



Cleaning and maintenance of the device:

Before cleaning the device, it needs to be disconnected from the electrical supply!

Always use safety gloves while cleaning to avoid the risk of injury due to any sharp edges.

To clean products made of stainless steel we recommend using cleaning solution dedicated particularly to stainless steel material. It preserves the steel surface from permanent stains and at the same time retains aesthetic appearance of the product.

INOX products are manufactured with stainless steel. When used in standard laboratory conditions they do not rust. However it is possible that stains (which may look like rust) form on the steel surface (e.g. due to the kind of samples that are incubated in the chamber). In such case we recommend using cleaning solution (to clean the stains) which is dedicated to this particular application, e.g. Pelox.

Exterior cleaning:

1. The housing of the device should be cleaned at least once a week, depending on the working conditions.

2. The housing and door should be cleaned with caution using a soft cloth dampened with water.
3. Only mild cleaning products should be used to clean the device.
4. Electrical parts should not get in contact with water or detergent.
5. Clean the touch screen using a soft cloth for touch screens, or it is possible to use foam for cleaning touch screens.
6. **USB port** can be cleaned with a vacuum cleaner to prevent accumulation of dirt inside the socket.

Interior cleaning:

1. The chamber should be emptied of any samples before cleaning.
2. Open the door of the device and wait till the chamber has cooled down, take out the shelves and start 3. cleaning the device.
3. Only water or water with mild detergent should be used.
4. Having finished cleaning, you should allow the device to dry fully and fit all parts removed before cleaning.
5. During cleaning you should make sure not to damage the temperature sensor built in on the top of the chamber.
6. In drying oven could happened the internal bottom metal part becomes discoloured. It is caused be very high heaters temperature which are placed just under bottom metal part.

Troubleshooting:

1. Make sure that the operation complies with the instruction manual of the device.
2. Restart the device to make sure that the unit is not functioning properly. If it still does not work, disconnect the unit again from the mains and repeat the operation after one hour.

Potential hazards

Substance or item handled	Associated Hazard (s)	Existing Control Measures	Risk (L/M/H)	Further Action required	Risk (L/M/H)
Use of Incubators	Hot surface – danger of burning.	All operators must wear PPE (lab coat and heat resistance gloves and safety specs). The internal glass door, handle and the internal chamber will become very hot when used at >50°C.	M	No further action required if the existing control measures are adhere to.	M
Use of Incubator	Electrical hazard - Electrical shock – danger of death.	Only switch on the device if the device and power cable are undamaged. Only trained personal are allowed to use the machine. Incubator is earthed, protective earth connection for the machine is provided using 13A plug fitted to the machine (RCD protected). Make sure it has been PAT tested. The chamber must not become wet during operation or maintenance. Regular visual checks of power cords for fault, fraying or wear and regular electrical safety check. Any faults reported and repaired before use.	L	No further action required if the existing control measures are adhere to.	L

Persons potentially at risk:

Only the user or others near by

Action in event of an accident or emergency:

1. **Fire:** raise the fire alarm and evacuate the area.

Arrangements for monitoring effectiveness of control:

Daily inspection of equipment by lab technician.

Annual preventative maintenance and calibration carried by external contractor.

Instruction and training given to all operators which is reviewed annually.

Existing operators receive annual refresher training.

Annual pat testing by external contractor.

Arrangements for monitoring effectiveness of control:**Review of the Risk Assessment:**

Date of review		Name of reviewer	
Date of next review		Signature	

Have the control measures been effective in controlling the risk?

Yes	No
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Have there been any changes in the procedure or in the information available which affect the estimated level of risk from the listed substances

Yes	No
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What changes to the control measures are required?

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