Operational Qualification

Test Protocol for Qualification

ULTF 500 / ULTF 700

☐ First qualification

☐ Requalification

Note:
Before starting the OQ, the IQ tests should be completed

Aim of OQ:

Practical test if the unit is working according to the guidelines of the manufacturer and the specifications given by Vestfrost in the technical data. These are specified for standard units in the empty chamber at a defined ambient temperature.

Carried out by:	Date:
Checked by:	Date:

Generation date:	Date of alteration:
Author:	

Content

Carried out by:	Date:
Checked by:	Date:

Generation date:	Date of alteration:
Author:	

Carried out by:	Date:
Checked by:	Date:

Generation date:	Date of alteration:
Author:	

OQ 1. Documentation approval

OQ 1.1 Prior to performing the OQ

Checked / Approved	Name / Department / Company	Date	Signature

OQ 1.2 After performing the OQ

Checked / Approved	Name / Department / Company	Date	Signature

Carried out by:	Date:
Checked by:	Date:

Generation date:	Date of alteration:
Author:	

OQ 2. Personnel involved with completing the OQ tests

The following table serves for clear identification of signatures/initials of all persons involved with completing the OQ tests.

Name	Initials	Department / Company	Date	Signature

Carried out by:	Date:
Checked by:	Date:

Generation date:	Date of alteration:
Author:	

OQ 3. List of documents in appendix

Description	Location	Appendix no.

Comments:

Carried out by:	Date:
Checked by:	Date:

Generation date:	Date of alteration:
Author:	

OQ 4. Unit identification

Aim of test:

The following tests serve to check the identity of the unit.

OQ 4.1 Unit description

Ultra-low temperature freezer 352/528 Eco Premium with microprocessor temperature control for long-term storage of samples in the ultra-low temperature range.

OQ 4.2 Identification acc. to type plate

depending on chamber type (the first 3 lines from chapter IQ 4.3.)

		Yes	No
Model		☐	☐
Art. No.		☐	☐
Serial No.		☐	☐
Inventory No.			

Comments:

Carried out by:	Date:
Checked by:	Date:

Generation date:	Date of alteration:
Author:	

OQ 5. Starting situation

This chapter shall prove that the preparations have been completed which are necessary to execute the following tests in this OQ protocol.

	ok	Not ok	Corrected
Installation and connections carried out according to the IQ protocol. All supplies are connected and ready for operation.	☐	☐	☐

No problems occurred	☐

or

Following problems occurred:

	Yes	No
Problems solved	☐	☐

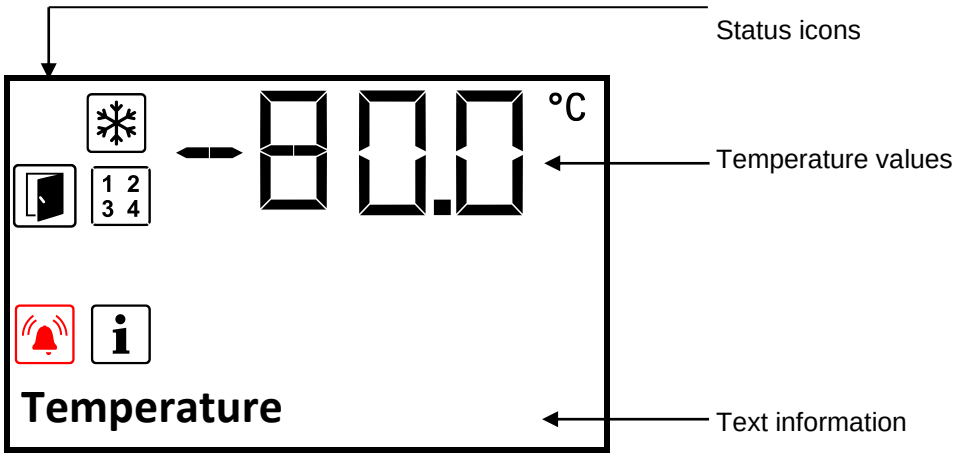
Comments:

Carried out by:	Date:
Checked by:	Date:

Generation date:	Date of alteration:
Author:	

OQ 6. Tests of basic functions

Overview of RD4 controller in normal display (example)



Note:
Handling instructions for the following tests are described in the instruction manual.

Comments:

Carried out by:	Date:
Checked by:	Date:

Generation date:	Date of alteration:
Author:	

OQ 6.1 Turning on the chamber, basic display and setting functions

Aim of test:

The following tests serve to check the unit's basic functions and the controller's basic display and setting functions.

Note:

If the function "Language selection at restart" has been activated (factory setting ON), the menu language, temperature unit, date and time are checked upon start up.

If the settings are not checked, you can perform the configuration in the according controller menus (OQ 6.2).

Starting situation:	Yes
Following transport, at least 8 hours have passed until start-up.	☐

Test and result:	ok	Not ok	Corrected
Turn on the chamber at the main power switch.	☐	☐	☐
If desired, use the arrow buttons to select the menu language. Confirm the setting with the OK button	☐	☐	☐
Selected menu language _____			
If desired, use the arrow buttons to select the temperature unit. Confirm the setting with the OK button	☐	☐	☐
Selected temperature unit _____			
Current date (format DD MM YYYY): If desired, use the arrow buttons to set the day. Confirm the setting with the OK button If desired, use the arrow buttons to set the month. Confirm the setting with the OK button If desired, use the arrow buttons to set the year. Confirm the setting with the OK button	☐	☐	☐

Carried out by:	Date:
Checked by:	Date:

Generation date:	Date of alteration:
Author:	

Test and result:	ok	Not ok	Corrected
Current time (format HH:MM): If desired, use the arrow buttons to set the hours. Confirm the setting with the OK button If desired, use the arrow buttons to set the minutes. Confirm the setting with the OK button	☐	☐	☐
➢ The unit shows the Normal display. The actual temperature value is displayed	☐	☐	☐

OQ 6.2 Setting the menu language, temperature unit, date and time

The required access level for this setting is “Admin”.

	Yes	No
These settings have been performed directly after turning on the chamber.	☐	☐

If “Yes”: Proceed with the next test OQ 6.4.

Starting situation:	Yes
The logged-in user has at least “Admin” authorization, or no password has been assigned for the “Admin” authorization level.	☐

OQ 6.3 Setting the menu language

	Yes	No
The menu is displayed in the desired language. Setting is not requested **or** These settings have been performed directly after turning on the chamber.	☐	☐

If “Yes”: Proceed with the next test OQ 6.3.1.

Test and result:	ok	Not ok	Corrected
Access the setting menu and select the desired menu language as described in chap. 13.1 of the instruction manual.	☐	☐	☐

Carried out by:	Date:
Checked by:	Date:

Generation date:	Date of alteration:
Author:	

Test and result:	ok	Not ok	Corrected
Go back to Normal Display. ➢ The menu is now displayed in the desired language	☐	☐	☐
Selected language setting _____			

OQ 6.3.1 Selecting the temperature unit

	Yes	No
Temperature is displayed in the desired unit. Setting is not requested	☐	☐

If “Yes”: Proceed with the next test OQ 6.3.2.

Test and result:	ok	Not ok	Corrected
Access the setting menu and select the desired temperature unit as described in chap. 13.2 of the instruction manual.	☐	☐	☐
Go back to Normal Display. ➢ In Normal display the temperature value is displayed in the desired unit.	☐	☐	☐
Selected temperature unit _____			

OQ 6.3.2 Setting the current date

	Yes	No
The current date is correctly displayed. Setting is not requested	☐	☐

If “Yes”: Proceed with the next test OQ 6.3.3.

Carried out by:	Date:
Checked by:	Date:

Generation date:	Date of alteration:
Author:	

Test and result:	ok	Not ok	Corrected
Access the setting menu and set the current day as described in chap. 13.3 of the instruction manual.	☐	☐	☐
Press the arrow-down button to change to setting the current time.	☐	☐	☐

OQ 6.3.3 Setting the current time

	Yes	No
The current time is correctly displayed. Setting is not requested	☐	☐

If “Yes”: Proceed with the next test OQ 6.4.

Test and result:	ok	Not ok	Corrected
Access the setting menu and set the current time as described in chap. 13.4 of the instruction manual.	☐	☐	☐
Go back to Normal Display.	☐	☐	☐

OQ 6.4 Network settings for the Ethernet interface

To display and configure the network settings see chap. 16 of the instruction manual.

	Yes	No
Network settings are already configured, or they are not needed. Setting is not requested.	☐	☐

If “Yes”: Proceed with the next test OQ 7.

Starting situation:	Yes
The logged-in user has at least “Admin” authorization, or no password has been assigned for the “Admin” authorization level.	☐

Carried out by:	Date:
Checked by:	Date:

Generation date:	Date of alteration:
Author:	

Test and result:		ok	Not ok	Corrected
Access the setting menu: **Settings** > **Ethernet** > **IP address assignment**		☐	☐	☐
Select as the type of IP address assignment the desired setting AUTO (automatic) and MANU (manual) as explained in chap. 16.2.1 of the instruction manual		☐	☐	☐
Selected configuration:				
Press the arrow-down button to change to the next parameter		☐	☐	☐
If manual IP address assignment was selected: Enter one after another the IP address, subnet mask and standard gateway as explained in chap. 16.2.3 to 16.2.5 of the instruction manual		☐	☐	☐
IP address		☐	☐	☐
Subnet mask				
Standard gateway				
If automatic IP address assignment was selected: Select as the type of assignment of the DNS server address the desired setting AUTO (automatic) and MANU (manual) as explained in chap. 16.2.2 of the operating manual		☐	☐	☐
Selected configuration:		☐	☐	☐
If manual IP address assignment or manual DNS server address assign was selected: Enter the DNS server address as explained in chap. 16.2.6 of the instruction manual		☐	☐	☐
DNS server address		☐	☐	☐

Carried out by:	Date:
Checked by:	Date:

Generation date:	Date of alteration:
Author:	

OQ 7. Check of the control function

OQ 7.1 Check of the control function and temperature performance check

Aim of test:

The following tests serve to check the control function as well as the temperature performance.

	Yes	No
Carrying out of test desired	☐	☐

Starting situation:	Yes
The freezer's temperature equals ambient temperature (25 °C)	☐
The safety controller is set to set point type "Offset" with set point 10 °C (factory setting). For setting see chap. 9 of the instruction manual.	☐

Entry of a temperature set-point and cooling-down

Test and result:	ok	Not ok	Corrected
Press the arrow-down button and select **Setpoints** > **Temperature**. Enter a set-point of -80 °C as described in chap. 8 of the instruction manual	☐	☐	☐
➢ The freezer reaches the new set-point within max. 7.5 hours.	☐	☐	☐

Comments:

Carried out by:	Date:
Checked by:	Date:

Generation date:	Date of alteration:
Author:	

OQ 7.2 Check of the pull-up time in case of power failure

Aim of test:

The following tests serve to check the pull-up time in case of power failure

	Yes	No
Carrying out of test desired	☐	☐

Starting situation:	Yes
The freezer's temperature is -80 °C	☐

Test and result:	ok	Not ok	Corrected
Turn off the chamber with the main power switch	☐	☐	☐
After 1 hour turn on again the chamber with the main power switch ➢ After a few seconds, the display shows the actual inner temperature of the chamber in °C.	☐	☐	☐
➢ The actual inner temperature is not warmer than -70 °C.	☐	☐	☐

OQ 8. Test of the safety controller (temperature safety device)

Aim of test:

Following test is to check controlling function of the safety controller in case of inadmissible temperature exceeding (see chap. 12 and 15 of the instruction manual).

	Yes	No
Carrying out of test desired	☐	☐

Starting situation:	Yes
Chamber is equilibrated to -80 °C	☐
The alarm buzzer is activated (see chap. 15.3 of the instruction manual).	☐

Carried out by:	Date:
Checked by:	Date:

Generation date:	Date of alteration:
Author:	

OQ 8.1 Safety controller configuration

Test and result:	ok	Not ok	Corrected
Press the arrow-down button and select **Setpoints** > **Safety controller** > **Mode**. Select the setting “Limit” as described in chap. 12.1 of the instruction manual	☐	☐	☐
Press the arrow-down button to proceed to setting the safety controller value	☐	☐	☐
Enter a safety controller setpoint of -70 °C as described in chap. 12.2 of the instruction manual	☐	☐	☐
Repeatedly press the **Back button** to go back to Normal Display	☐	☐	☐

OQ 8.2 State of alarm

Test and result:	ok	Not ok	Corrected
Open all unit doors (outer unit door and compartment doors).	☐	☐	☐
Opening the outer door will open the door contact switch. To test the alarm, the door contact switch must be placed in closed position (simulating a closed door). Proceed as follows: Open the outer door and lift the handle slightly as far as it will go, push the stop of door lock (inner L-shaped metal bracket) fully inwards and hold it, then release the handle. ➢ The door lock engages, and the door contact switch is closed. The "Door open" message on the controller disappears.	☐	☐	☐
➢ The inner chamber temperature begins to rise. When the temperature exceeds the safety controller set-point of -70 °C, the state of alarm is indicated in the display: In Normal display the red “collective alarm” icon flashes and the text message “Safety controller” is shown.	☐	☐	☐
➢ The buzzer sounds	☐	☐	☐
Press the **OK** button ➢ The buzzer is muted.	☐	☐	☐
➢ As the alarm condition persists, the visual alarm indication remains on the controller	☐	☐	☐

Carried out by:	Date:
Checked by:	Date:

Generation date:	Date of alteration:
Author:	

OQ 8.3 Resetting the alarm

Test and result:	ok	Not ok	Corrected
To be able to close the outer door after the alarm test, proceed as follows: Lift the handle slightly as far as it will go, pull the stop of door lock (inner L-shaped metal bracket) and hold it, then release the handle. ➢ The door lock engages, and the door contact switch is open. The "Door open" message on the controller appears.	☐	☐	☐
Close the doors.	☐	☐	☐
➢ When the chamber temperature falls below the safety controller temperature limit of -70 °C, the visual alarm indication on the controller disappears.	☐	☐	☐
After this test set the safety thermostat to a setting suitable for the customer process (recommended setting: set-point type “Offset” with value 15 °C).	☐	☐	☐
Selected setting: Offset ☐ ☐ Value: _____°C	☐	☐	☐

Comments:

Carried out by:	Date:
Checked by:	Date:

Generation date:	Date of alteration:
Author:	

OQ 9. Check of the alarm system

Aim of test:

The following tests serve to check selected alarm functions and the zero-voltage relay alarm contact

Starting situation:	Yes
The alarm buzzer is activated (see chap. 15.3 of the instruction manual).	☐

OQ 9.1 Tolerance range alarm

OQ 9.1.1 Temperature too low (under temperature alarm)

	Yes	No
Carrying out of test desired	☐	☐

Required resources

To carry out this test, precooled samples will be inserted to decrease the inner temperature beyond the alarm limit. Precooling can be done with liquid nitrogen or another suitable method.

	Yes	No
Suitable refrigeration method e.g., liquid nitrogen is available	☐	☐

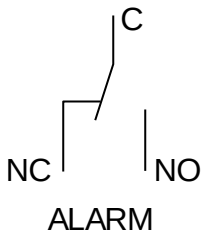
In case of “No” proceed with the next test OQ 9.1.2.

Test procedure and result

Starting situation:	Yes
The chamber is equilibrated to -60 °C.	☐
The temperature tolerance range alarm is set to +/- 5 K (factory setting), see instruction manual chap. 14.3.	☐

Carried out by:	Date:
Checked by:	Date:

Generation date:	Date of alteration:
Author:	

Test and result:	ok	Not ok	Corrected
Set the tolerance range alarm delay to 1 minute as described in chap. 14.2 of the instruction manual	☐	☐	☐
Insert sufficient quantities of precooled samples to decrease the inner temperature beyond the alarm limit.	☐	☐	☐
➢ After a few minutes the alarm message “Temp. range” appears on the controller.			
➢ The “collective alarm” icon flashes.	☐	☐	☐
➢ The buzzer sounds	☐	☐	☐
Press the **OK** button ➢ The buzzer is muted.	☐	☐	☐
➢ As the alarm condition persists, the visual alarm indication remains on the controller	☐	☐	☐
Check the zero-voltage relay output (9) on the rear of the unit with a continuity resistance tester ➢ With the alarm message on the display, the zero-voltage relay output is switched closing contact C with contact NC. 	☐	☐	☐
Open the doors and remove the cold material. Close the doors and let the chamber equilibrate.	☐	☐	☐
➢ As soon as the temperature is situated within the tolerance range limits, the alarm message “Temp. range” and the “collective alarm” icon are no longer displayed	☐	☐	☐
➢ The zero-voltage relay alarm output switches off (contact C closes with contact NO).	☐	☐	☐

Comments:

Carried out by:	Date:
Checked by:	Date:

Generation date:	Date of alteration:
Author:	

OQ 9.1.2 Temperature too high (over temperature alarm)

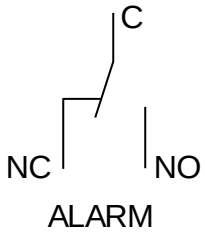
	Yes	No
Carrying out of test desired	☐	☐

Starting situation:	Yes
The chamber is equilibrated (e.g., to -60 °C or -80 °C).	☐
The temperature tolerance range alarm is set to +/- 5 K (factory setting), see instruction manual chap. 14.3.	☐

Test and result:	ok	Not ok	Corrected
Set the tolerance range alarm delay to 1 minutes as described in chap. 14.2 of the instruction manual	☐	☐	☐
Open the freezer's outer door and compartment doors.	☐	☐	☐
Opening the outer door will open the door contact switch. To test the alarm, the door contact switch must be placed in closed position (simulating a closed door). Proceed as follows: Open the outer door and lift the handle slightly as far as it will go, push the stop of door lock (inner L-shaped metal bracket) fully inwards and hold it, then release the handle. ➢ The door lock engages, and the door contact switch is closed. The "Door open" message on the controller disappears.	☐	☐	☐
➢ After a few minutes the alarm message "Temp. range" appears on the controller.	☐	☐	☐
➢ The "collective alarm" icon flashes.	☐	☐	☐
➢ The buzzer sounds	☐	☐	☐
Press the **OK** button ➢ The buzzer is muted.	☐	☐	☐
➢ As the alarm condition persists, the visual alarm indication remains on the controller	☐	☐	☐
Check the zero-voltage relay output (9) on the rear of the unit with a continuity resistance tester	☐	☐	☐

Carried out by:	Date:
Checked by:	Date:

Generation date:	Date of alteration:
Author:	

Test and result:	ok	Not ok	Corrected
➢ With the alarm message on the display, the zero-voltage relay output is switched closing contact C with contact NC. 	☐	☐	☐
To be able to close the outer door after the alarm test, proceed as follows: Lift the handle slightly as far as it will go, pull the stop of door lock (inner L-shaped metal bracket) and hold it, then release the handle.	☐	☐	☐
➢ The door lock engages, and the door contact switch is open. The "Door open" message on the controller appears.	☐	☐	☐
Close all the doors and let the chamber equilibrate.	☐	☐	☐
➢ As soon as the temperature is situated within the tolerance range limits, the alarm message “Temp. range” and the “collective alarm” icon are no longer displayed	☐	☐	☐
➢ The zero-voltage relay alarm output switches off (contact C closes with contact NO).	☐	☐	☐

Comments:

Carried out by:	Date:
Checked by:	Date:

Generation date:	Date of alteration:
Author:	

OQ 9.1.3 After the test

Test and result:	ok	Not ok	Corrected
Set the door alarm delay to a suitable value as described in chap. 14.1 of the instruction manual or continue with the test OQ 9.2. ☐ Proceed with OQ 9.2.: ☐ Selected setting: _____ min	☐	☐	☐
Set the tolerance range alarm delay to a suitable value as described in chap. 14.2 of the instruction manual Selected setting: _____ min	☐	☐	☐

Comments:

Carried out by:	Date:
Checked by:	Date:

Generation date:	Date of alteration:
Author:	

OQ 9.2 Alarm “door open”

	Yes	No
Carrying out of test desired	☐	☐

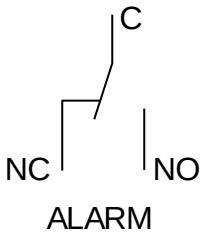
Starting situation:	Yes
The door alarm delay is set to 1 minute (factory setting), see instruction manual chap. 14.1.	☐

Test and result:	ok	Not ok	Corrected
Open the freezer’s outer door. ➢ 1 minute after the door is opened the alarm message “Door open” appears on the controller.	☐	☐	☐
➢ The “collective alarm” icon flashes.	☐	☐	☐
➢ The buzzer sounds	☐	☐	☐
Press the **OK** button ➢ The buzzer is muted.	☐	☐	☐
➢ As the alarm condition persists, the visual alarm indication remains on the controller	☐	☐	☐

Comments:

Carried out by:	Date:
Checked by:	Date:

Generation date:	Date of alteration:
Author:	

Test and result:	ok	Not ok	Corrected
Check the zero-voltage relay output (9) on the rear of the unit with a continuity resistance tester ➢ 1 minute after the door is opened, the zero-voltage relay output is switched closing contact C with contact NC. 	☐	☐	☐
Close the door	☐	☐	☐
➢ The alarm message “Door open” and the “collective alarm” icon are no longer displayed	☐	☐	☐
➢ The zero-voltage relay alarm output switches off (contact C closes with contact NO).	☐	☐	☐

OQ 9.2.1 After the test

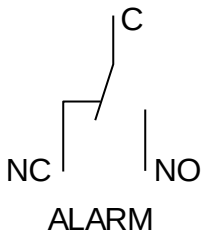
Test and result:	ok	Not ok	Corrected
If desired set the door alarm delay to a suitable value as described in chap. 14.1 of the instruction manual	☐	☐	☐
☐ Selected setting: _____ min			

Carried out by:	Date:
Checked by:	Date:

Generation date:	Date of alteration:
Author:	

OQ 9.3 Power failure alarm

	Yes	No
Carrying out of test desired	☐	☐

Test and result:	ok	Not ok	Corrected
Pull the power plug. ➢ The controller display is off	☐	☐	☐
Check the zero-voltage relay output (9) on the rear of the unit with a continuity resistance tester ➢ The zero-voltage relay output is switched closing contact C with contact NC. 	☐	☐	☐
Insert the power plug.	☐	☐	☐
➢ The zero-voltage relay alarm output switches off (contact C closes with contact NO).	☐	☐	☐

Comments:

Carried out by:	Date:
Checked by:	Date:

Generation date:	Date of alteration:
Author:	

OQ 10. IT qualification (interface test)

Aim of test:

Aim of this section is to check bi-directional data transfer of the temperature controller RD4 via its Ethernet interface. To connect the chamber to the Ethernet network or a computer, a patch cable or a crossover cable is needed.

	Yes	No
Carrying out of test desired	☐	☐

The interface test is not carried out because the interface is not used by the customer. OQ 10.1 to OQ 10.4 remains clear.	☐

Comments:

Carried out by:	Date:
Checked by:	Date:

Generation date:	Date of alteration:
Author:	

OQ 10.1 Connecting the chamber to the computer

The computer must be equipped with an Ethernet network board. Connection to the Ethernet is established via a RJ45 CAT5/CAT6 cable in analog manner to connecting a computer to the Ethernet. Please ask your system administrator. If there is no existent network, in case of questions please contact Vestfrost service.

	ok	Not ok	Corrected
Connection established.	☐	☐	☐

OQ 10.2 IP and MAC address of the chamber

The temperature chambers are identified in the network by Connection Tester by their MAC addresses.

The MAC address can be displayed via a controller menu.

An IP address is assigned to this MAC address in most cases by the DHCP server at the customer. If the IP addresses have not been assigned (address “0.0.0.0“) or shall be manually modified, you can use the program Lantronix DeviceInstaller, to assign the IP addresses (see OQ 10.2.2).

MAC address	Yes	No	Not used
The MAC address can be found in the respective controller menu. (see chap. 16.1.1 of the instruction manual)	☐	☐	☐

MAC address	

Comments:

Carried out by:	Date:
Checked by:	Date:

Generation date:	Date of alteration:
Author:	

OQ 10.2.1 Automatic assignment of the IP address with DHCP server

	Yes	No
Automatic assignment of an IP address with the DHCP server or manual assignment by the system administrator desired.	☐	☐

In case of „No“, continue with the next chapter OQ 10.2.2

IP addresses	Yes	No	Not used
Automatic assignment in an Ethernet network with DHCP server The DHCP server automatically assigns a valid IP address to the chamber. Procedure: 1. Connect chamber to the Ethernet network 2. Switch on chamber. 3. The IP address is automatically negotiated between the chamber and the DHCP server. No intervention on the part of the user is necessary here. Depending upon the load of the DHCP server, this procedure can take several minutes. 4. Following successful assignment of the address, when creating the chamber in Connection Tester you will find the MAC address and the IP address assigned to this chamber in a list box	☐	☐	☐

or

IP addresses	Yes	No	Not used
Manual assignment by the system administrator	☐	☐	☐

IP address	

Carried out by:	Date:
Checked by:	Date:

Generation date:	Date of alteration:
Author:	

OQ 10.2.2 Manual IP address assignment with the Lantronix DeviceInstaller

	Yes	No
A defined IP address shall be manually assigned with the Lantronix ChamberInstaller (XPort Installer)	☐	☐

In case of „No“, continue with the next chapter OQ 10.3

	OK	Not ok	Corrected
Download the Lantronix DeviceInstaller software https://www.lantronix.com/products/deviceinstaller/	☐	☐	☐
Download the Lantronix DeviceInstaller User Guide http://www.lantronix.com/wp-content/uploads/pdf/DeviceInstaller_UG.pdf	☐	☐	☐
Install the Lantronix DeviceInstaller.	☐	☐	☐
Start DeviceInstaller and hit button “Search”. ➢ The detected interfaces are displayed and can be assigned to a chamber by their MAC address.	☐	☐	☐
If the IP address is “0.0.0.0”, or if the existing address shall be manually modified, mark the chamber and click on “Assign-IP”.	☐	☐	☐
Select “Assign a specific IP address” and enter the IP settings	☐	☐	☐

IP address	

Test and result	OK	Not ok	Corrected
An IP address was successfully assigned.	☐	☐	☐

Carried out by:	Date:
Checked by:	Date:

Generation date:	Date of alteration:
Author:	

OQ 10.3 Checking the accessibility of the device on the network by ping-test

For the customer's IP address, the following example shows "192.168.0.100". Your IP address must be entered here. (see OQ 10.2.1 or OQ 10.2.2)

	OK	Not ok	Corrected
After you have assigned an IP address open the **command prompt** in windows	☐	☐	☐
➢ The following view appears: `C:\Users\username>`	☐	☐	☐
Now enter "ping" and the IP address of the target device. `C:\Users\username>ping 192.168.0.100` (example)	☐	☐	☐
Confirm with **Enter**	☐	☐	☐

If the network is reachable, the following response appears. (example)
`Ping is running for 192.168.0.100 with 32 bytes of data:`
`Ping statistics for 192.168.0.100:`
`Packages: Sent = 4, Received = 4, Lost = 0 (0% Loss)`
➢ The device is now accessible on the network.
	☐	☐	☐

If the test is negative, the device is not reachable on the network.
Example:
`Ping statistics for 192.168.0.100:`
`Packages: Sent = 4, Received = 0, Lost = 4 (100% Loss)`
	☐	☐	☐

No problems occurred	☐

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or

Following problems occurred:

	Yes	No
Problems solved	☐	☐

Comments:

Test and result	Yes	No	Corrected
The accessibility of the device on the network has been successfully verified.	☐	☐	☐

In case of „No“ check the cabling or the network.

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Author:	

OQ 10.4 Result of the IT qualification

If all tests are passed with either OK or Corrected, it is ensured that the interface of the chamber is working according to the guidelines of the manufacturer.

Summary assessment and comments:

Carried out by:	Date:
Checked by:	Date:

Generation date:	Date of alteration:
Author:	

OQ 11. Operation conditions

Aim of test:

This chapter defines the ambient conditions and the common working temperature values. These conditions should be the same when executing the OQ tests.

Note:
The specifications in the technical data are specified only for standard units in the unloaded chamber at a defined ambient temperature of +22 °C +/- 3 °C / 71.6 °F +/- 5.4 °F.

Common working conditions (storage temperature):

Operating temperature
°C

Ambient conditions:

Temperature	OQ conditions
°C	☐
°C	☐
°C	☐

Humidity	OQ conditions
% r.H.	☐
% r.H.	☐
% r.H.	☐

Comments:

Carried out by:	Date:
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Author:	

OQ 12. Calibration and adjustment

Aim of test:

A calibration is executed which serves to check if an adjustment of the temperature controller and the safety controller is necessary. If needed, Vestfrost Service will perform the adjustment and prove it by another calibration.

Starting situation:	Yes
The logged-in user has a “Service” authorization, or an activation code is available for the adjustment function.	☐

	Yes	No
Carrying out desired	☐	☐

Alternatives to execute a calibration:

	Yes	No
The very first calibration was ordered and carried out by the manufacturer. The calibration certificates are enclosed in appendix.	☐	☐
Other test protocols are used (enclosed by the operator)	☐	☐
Different reason _____	☐	☐

Notes:

Repeated calibrations are recommended in periods of 12 months.

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Author:	

OQ 12.1 Method overview

(1) Calibration

First a calibration (comparison chamber display / reference measuring device) is performed. It serves to check for the necessity of a new controller adjustment (OQ 12.4).

(2) Adjustment

If a new controller adjustment is necessary, then Vestfrost Service will perform the adjustment.

The single point adjustment is carried out in a single step. Select an adjustment value from the middle of the temperature range the chamber will be operated at. If there is a special working temperature (generally -80 °C), take this value.

(3) Verifying calibration

Finally, a new calibration (comparison chamber display / reference measuring device) will be performed in order to confirm the successful adjustment.

Comments:

Carried out by:	Date:
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OQ 12.2 Reference measurement device

- Use of an electronic measuring- and display device for temperature which is traceable to an acknowledged standards / calibration institution (DKD, PTB for Germany) with valid calibration certificate. **Traceability:** The calibration of the standard was performed by a testing laboratory accredited by the DKD (German calibration service, internationally recognized by the International Laboratory Accreditation Cooperation (ILAC) acc. to ISO/IEC 17025). The following measuring results, which are only valid at the time of measurement, were determined by comparing them to the reference standard.
- Measuring range at least -100 °C to +40 °C

Note: Also measuring equipment with a smaller measuring range can be used if it is sufficient to perform the tests described in this documentation

- The sensor cable should be laid over chamber's door gasket or through an access port with silicon plug without causing any leakage. The compartment doors and outer door must both be able to be closed and sealed.
- The sensor will be placed next to the chamber sensor.

Type / Manufacturer	Sensor	Display unit
Identification No.:		
Traceability:		
No. of calibration certificate – Date of last calibration		
Measuring range (according to the temperature range of the chamber)		
Measuring uncertainty of the measuring device:	Temperature set-point [°C]	Measuring uncertainty [± Kelvin]

		Yes	No
The calibration certificate of the reference measurement device is enclosed in appendix	Appendix No. ___	☐	☐

Carried out by:	Date:
Checked by:	Date:

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OQ 12.3 Installation

The temperature calibration is affected in one single procedure with set-point -80 °C in thermal stationary condition. The chamber is checked in empty condition with installed compartment shelves. The reference sensor is led into the inner chamber across the door gasket or through an access port with silicone plug and placed next to the chamber sensor. The unit doors remain closed during the calibration. The chamber has to equilibrate to the calibration value for at least 4 hours.

Test and result:	ok	Not ok	Corrected
Place the reference temperature sensor next to the controller sensor on the inner chamber's back wall, bottom right.	☐	☐	☐
Bring the sensor cable out over the door gaskets or through an access port with silicon plug in such a way that the compartment doors and outer door can both be closed and sealed.	☐	☐	☐
Close the compartment doors and the outer door. The doors remain closed during calibration.	☐	☐	☐
Set the temperature set-point to -90 °C.	☐	☐	☐
Following cooling down and reaching the temperature setpoint, the freezer must equilibrate to the calibration temperature for approx. 4 hours.	☐	☐	☐
Compare the value at the controller display with the value displayed on the reference-measuring instrument.	☐	☐	☐

Carried out by:	Date:
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OQ 12.4 Calibration: Test for the necessity of an adjustment of the temperature control

First the necessity of a new controller adjustment is checked. An adjustment of the temperature controller together with the safety controller is only necessary in case there is a deviation between the temperature shown on the reference measuring device and the reading of the actual temperature displayed on the controller, which is larger than +/- 2.5 K (confidence criteria). In case the reference instrument has a measuring uncertainty larger than +/- 2.5 K (see its calibration certificate), this is the confidence criteria.

Test for the necessity of an adjustment of the temperature controller and safety controller	
Temperature set-point	°C
Actual temperature value of the controller	°C
Actual temperature value of the safety controller	°C
Display reading of the reference instrument	°C
Divergence between the actual temperature value of the controller and the reading of the reference instrument	°C
Divergence between the actual safety controller value and the reading of the reference instrument	
Measuring uncertainty of the reference instrument	°C

	Yes	No
Adjustment of the temperature controller and safety controller necessary	☐	☐

In case of “Yes”, please contact Vestfrost service or perform the adjustment as described in the service manual.

In case of “No” the adjustment of the temperature controller is not necessary and **Fejl! Henvisningskilde ikke fundet.** can be skipped

OQ 12.5 Adjustment of the temperature controller and the safety controller

See service manual: Adjustment of the temperature controller, adjustment of the safety controller

Test and Result		ok	Not ok	Corrected
Adjustment performed		☐	☐	☐
Adjustment value:	°C			

Carried out by:	Date:
Checked by:	Date:

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OQ 12.6 Verifying calibration: Result of the adjustment of the temperature control

After the adjustment of the controller the temperature display reading of the reference instrument is compared to the display reading of the controller again (new calibration). The temperature set-point value should be the same as previously taken for testing the necessity of a temperature adjustment of the controller (first calibration). The values are checked in equilibrated state.

Test for a successful adjustment	
Temperature set-point	°C
Actual temperature value of the controller	°C
Actual temperature value of the safety controller	°C
Display reading of the reference instrument	°C
Divergence actual temperature – Reading of the reference instrument	°C
Divergence actual temperature of the safety controller – Reading of the reference instrument	°C
Measuring uncertainty of the reference instrument	°C

	Yes	No
Successful adjustment – Confidence criteria met	☐	☐

Carried out by:	Date:
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OQ 13. Result of the OQ-Test protocol

If all tests of the present protocol are passed with either OK or Corrected, it is ensured that the chamber is working according to the guidelines of the manufacturer. Deviations have to be substantiated.

The successfully passed tests permit the conclusion that the whole chamber works duly and reliable according to the mentioned tests.

It is recommended to direct an authorized specialist for maintenance services and to repeat the tests at adequate periods of time.

Signature was created electronically

Vestfrost

OQ 13.1 Summary assessment and comments

Carried out by:	Date:
Checked by:	Date:

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Author:	

OQ 13.2 Summary of OQ test results

	Designation of test / title	Test passed		Date / Name (abbrev.)
		Yes	No	
OQ 1.	Documentation approval	☐	☐	
OQ 1.1	Prior to performing the OQ	☐	☐	
OQ 1.2	After performing the OQ	☐	☐	
OQ 2.	Personnel involved with completing the OQ tests	☐	☐	
OQ 3.	List of documents in appendix	☐	☐	
OQ 4.	Unit identification	☐	☐	
OQ 4.1	Unit description	☐	☐	
OQ 4.2	Identification acc. to type plate	☐	☐	
OQ 5.	Starting situation	☐	☐	
OQ 6.	Tests of basic functions	☐	☐	
OQ 6.1	Turning on the chamber, basic display and setting functions	☐	☐	
OQ 6.2	Setting the menu language, temperature unit, date and time	☐	☐	
OQ 6.3	Network settings for the Ethernet interface	☐	☐	
OQ 7	Check of the control function	☐	☐	
OQ 7.1	Check of the control function and temperature performance check	☐	☐	

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Author:	

	Designation of test / title	Test passed		Date / Name (abbrev.)
		Yes	No	
OQ 7.2	Check of the pull-up time in case of power failure	☐	☐	
OQ 8.	Test of the safety controller (temperature safety device)	☐	☐	
OQ 8.1	Safety controller configuration	☐	☐	
OQ 8.2	State of alarm	☐	☐	
OQ 8.3	Resetting the alarm	☐	☐	
OQ 9	Check of the alarm system	☐	☐	
OQ 9.1	Tolerance range alarm alarm	☐	☐	
OQ 9.2	Alarm “door open”	☐	☐	
OQ 9.3	Power failure alarm	☐	☐	
OQ 10	IT qualification (interface test)	☐	☐	
OQ 10.1	Connecting the chamber to the computer	☐	☐	
OQ 10.2	IP and MAC address of the chamber	☐	☐	
OQ 10.3	Checking the accessibility of the device on the network by ping-test	☐	☐	
OQ 10.4	Result of the IT qualification	☐	☐	
OQ 11	Operation conditions	☐	☐	
OQ 12	Calibration and adjustment	☐	☐	

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Author:	

	Designation of test / title	Test passed		Date / Name (abbrev.)
		Yes	No	
OQ 12.1	Method overview	☐	☐	
OQ 12.2	Reference measurement device	☐	☐	
OQ 12.3	Installation	☐	☐	
OQ 12.4	Calibration: Test for the necessity of an adjustment of the temperature control	☐	☐	
OQ 12.5	Adjustment of the temperature controller and the safety controller	☐	☐	
OQ 12.6	Verifying calibration: Result of the adjustment of the temperature control	☐	☐	
OQ 13	Result of the OQ-Test protocol	☐	☐	
OQ 13.1	Summary assessment and comments	☐	☐	
OQ 13.2	Summary of OQ test results	☐	☐	

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Checked by:	Date:

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Author:	