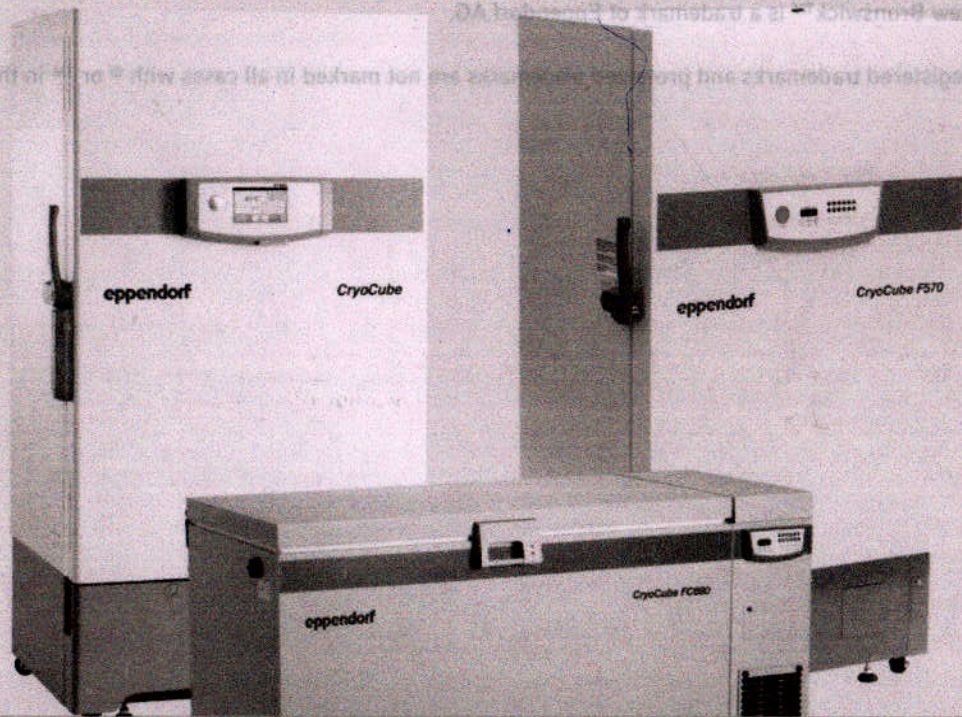


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Freezer

SOP - Installation Qualification - English

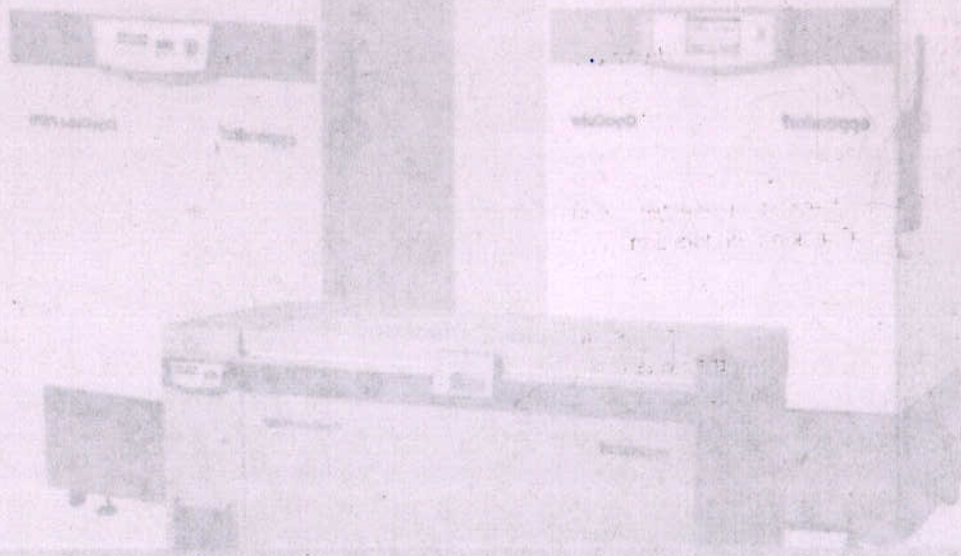
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Freezer

Table of contents

1	Introduction	4
1.1	Using this manual	4
1.2	Information on liability	4
1.3	User profile	4
1.4	Note on this document	4
1.5	Abbreviations	5
1.6	IQ version overview	5
1.7	Device data	6
1.8	Responsible persons	6
2	IQ – Freezers	7
2.1	Identifying the device	7
2.2	Checking the delivery condition and delivery package	8
2.2.1	Checking the packing	8
2.2.2	Checking the delivery package	8
2.2.3	Checking the delivery condition	8
2.3	Installing the device	9
2.3.1	Checking the electrical connections	9
2.3.2	Checking the location	9
2.3.3	Checking the installed device	9
2.3.4	Checking the network and the external ports	10
2.4	Checking the device and instructing the user	11
2.4.1	Configuring the system	11
2.4.2	Initial setup	11
2.4.3	Instructing users	11

1.4 Note on this document

include other documents, such as explanations, printouts, recordings and results, with the IQ. List these documents under "Appendices".

- Successful participation in service trainings with certification by Eppendorf AG for the product that is to be maintained, repaired or tested.
- Qualification as a specialist with knowledge of the applicable local and international standards.
- Qualification to evaluate the work assigned to him.
- Recognition of potential hazards and how to prevent or correct them.

1 Introduction

1.1 Using this manual

- ▶ Make sure that the service manual and the operating manual are available in the latest versions. To do so, compare the version numbers. The latest versions of the manuals can be downloaded from www.eppendorf-support.com.
- ▶ Read the service manual before commencing work on the device.
- ▶ Read the chapters "Installation" and "Operation" of the operating manual.
- ▶ Observe the safety instructions in the operating manual.

1.2 Information on liability

The Eppendorf sales and service organization responsible for the installation, service, repair or testing is liable for ensuring that all work is performed in a professional manner.

- ▶ The existing construction of the device must not be altered as a result of any installation, repair, service or check. The safety of the original condition must be maintained.
- ▶ Only accessories and original spare parts recommended by Eppendorf as well as test and measuring equipment recommended by Eppendorf may be used for installation, service, repair and inspection.

1.3 User profile

The specialist entrusted with maintenance, repair or testing must meet the following prerequisites:

- Successful participation in service trainings with certification by Eppendorf AG for the product that is to be maintained, repaired or tested.
- Qualification as a specialist with knowledge of the applicable local and international standards.
- Qualification to evaluate the work assigned to him.
- Recognition of potential hazards and how to prevent or correct them.

1.4 Note on this document

- ▶ Include other documents, such as explanations, printouts, recordings and results, with the IQ. List these documents under "Appendices".

1.5 Abbreviations

- OM – Operating manual
- HWM - Hardware manual
- IQ – Installation qualification
- n/a – not available
- SF – Service function
- SM – Service manual
- SWM - Software manual

1.6 IQ version overview

Version	Issue date	Chapter	Change
00	2017-05	-	• Created new
01	2017-09	All	• Field n/a added
02	2018-01	All	• Version overview added • Corrections after feedback from the market • Fields for set values for the interior temperature, warning limits, alarm limits added
03	2018-08	2	• Devices F740, F740i, F740iw deleted • Devices F740h, F740hi added
04	2019-07	2	• Device F101h added
05	2021-01	2	• Device F570n added
06	2021-07	2	• Devices F440n, F440h added

1.8 Responsible persons

Responsible technician

Name, first name: *Mohammed Omar*

Company: *Greenberg Engineering Pvt. Ltd.*

Certificate (issued on ... / valid until ...): *24-02-2020 / 24-02-2025*

Signature: *[Signature]*

Copies of the technician's certificates can be enclosed as appendices. List these documents at the end, under "Appendices".

User / Responsible for quality

Name, first name: *Dr. Amrikumar Joglekar*

Company: *Consultant Pathologist*

Signature: *[Signature]*

Reg. No. *37297*

M.P.U.H. Emp. No. *728*

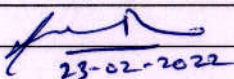
Date: *20/02/2022*

1.7 Device data

Company/owner	Mulji Patel Urological Hospital
Location of the device (building, floor, room, lab, etc.)	Pathology Department, Dr. Virendra Desai Road - 387001 Nadiad, Gujarat.
Storage site of the operating manual	Pathology Department
Operating manual version (index number on the inside of the front cover)	
Service manual version (index number on the inside of the front cover)	NA
Inventory number of the device	
Manufacturer	Eppendorf AG
Type designation	-86 Deep Freezer.
Serial number	F571K0600814
Software version and firmware version	NA.
Voltage in V	230V
Frequency in Hz	50-60Hz
Date of installation (day/month/year)	23-02-2022

1.8 Responsible persons


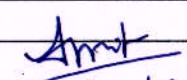
Responsible technician

Name, first name: Mohammed Umar
 Company: Eppendorf India Pvt. Ltd.
 Certificate (issued on ... / valid until ...): 14-02-2020
 Signature: 
 23-02-2022



Copies of the technician's certificates can be enclosed as appendices. List these documents at the end, under "Appendices".

User / Responsible for quality

Name, first name: 
 Company: Dr. Amitkumar Jojera
 Consultant Pathologist
 M.P.U.H. Emp. No.:- 728
 Signature: 
 23/02/2022
 Reg. No. 37297

2 IQ – Freezers

2.1 Identifying the device

This inspection can be performed on different devices. Please mark on which device you have performed the inspection.

Tab. 2-1: Device

Innova U101	<input type="checkbox"/>	CryoCube F101h	<input type="checkbox"/>
Innova U360	<input type="checkbox"/>		
Innova U535	<input type="checkbox"/>	CryoCube F440n	<input type="checkbox"/>
Innova U725	<input type="checkbox"/>	CryoCube F440h	<input type="checkbox"/>
Innova C585	<input type="checkbox"/>		
Innova C760	<input type="checkbox"/>	CryoCube F570	<input type="checkbox"/>
		CryoCube F570h	<input type="checkbox"/>
HEF U410	<input type="checkbox"/>	CryoCube F570hw	<input type="checkbox"/>
HEF U570	<input type="checkbox"/>	CryoCube F570n	<input checked="" type="checkbox"/>
HEF C660	<input type="checkbox"/>		
		CryoCube FC660	<input type="checkbox"/>
Premium U 410	<input type="checkbox"/>	CryoCube FC660h	<input type="checkbox"/>
Premium U570	<input type="checkbox"/>		
Premium U570 -45 °C	<input type="checkbox"/>	CryoCube F740h	<input type="checkbox"/>
Premium U700	<input type="checkbox"/>	CryoCube F740hi	<input type="checkbox"/>
Premium C340	<input type="checkbox"/>	CryoCube F740hiw	<input type="checkbox"/>
Premium C660	<input type="checkbox"/>		
U725-G water-cooled	<input type="checkbox"/>		
U725-G air-cooled	<input type="checkbox"/>		

Tab. 2-2: Door lock

Padlock	<input checked="" type="checkbox"/>
Cylinder lock	<input type="checkbox"/>
Electrical door lock	<input type="checkbox"/>

2.2 Checking the delivery condition and delivery package

2.2.1 Checking the packing

No.	SM/OM section	Inspection	n/a	Yes	No
IQ01	—	Is the packing undamaged on the outside?		✓	
IQ02	—	Does the information on the label match the order?		✓	
IQ03	OM	Has the color of the tilt indicator changed? Has the color of the impact indicator changed?			✓



- ▶ If the color of an indicator has changed, do **not** perform the IQ.
- ▶ Inform Eppendorf AG, the authorized service, and the shipping company.

2.2.2 Checking the delivery package

Details on the delivery package can be found on the delivery note and in the operating manual.

No.	SM/OM section	Inspection	n/a	Yes	No
IQ04	OM	Does the delivery match the order, the delivery note, and the information in the operating manual?		✓	
IQ05	OM	Is the delivery complete?		✓	
IQ06		Does the supplied mains/power cord match the country-specific earth/grounded socket form?		✓	

2.2.3 Checking the delivery condition



Keep the packing and the transport securing device for later use. The device may only be shipped in its original packing.

No.	SM/OM section	Inspection	n/a	Yes	No
IQ07	—	Does the device show any signs of damage on the outside?			✓
IQ08	—	Are the accessories undamaged on the outside?		✓	

2.3 Installing the device

2.3.1 Checking the electrical connections

No.	SM/OM section	Inspection	n/a	Yes	No
IQ09	OM	Do the existing mains/power supply voltage and the existing mains/power frequency correspond to the information on the name plate?		<input checked="" type="checkbox"/>	
IQ10	OM	Is the device connected to an external voltage stabilizer (optional)? Stabilization rateW			<input checked="" type="checkbox"/>

2.3.2 Checking the location

No.	SM/OM section	Inspection	n/a	Yes	No
IQ11	OM	Do the ambient conditions at the user's site correspond to the information in the operating manual, e.g., temperature?		<input checked="" type="checkbox"/>	
IQ12	OM	Is the location stable, horizontal and non-resonant?		<input checked="" type="checkbox"/>	
IQ13	OM	Is there a clearance of 15 cm around the device?		<input checked="" type="checkbox"/>	
IQ14	OM	Can the outer door or lid be opened wide enough to allow samples to be removed easily?		<input checked="" type="checkbox"/>	

2.3.3 Checking the installed device

No.	SM/OM section	Inspection	n/a	Yes	No
IQ15	OM	Are the leveling feet or heavy-duty castors locked with the brake to prevent the device from rolling?		<input checked="" type="checkbox"/>	
IQ16	OM	Have the rack and inner shelves been installed inside the device?		<input checked="" type="checkbox"/>	
IQ17	OM	Has the protective foil been removed from the inner shelves?		<input checked="" type="checkbox"/>	
IQ18	OM	Is the vent tube blocked by the rack or inner shelves?		<input checked="" type="checkbox"/>	

For specifications for devices with water supply, please refer to the operating manual.

2.3.4 Checking the network and the external ports



The following ports are optional.

- ▶ Install the device according to the user's specifications.
- ▶ Check the existing ports.

No.	SM/OM section	Inspection	n/a	Yes	No
IQ19		Is the device connected to a network or connected to the Internet?	✓		
IQ20		Is a temperature sensor for the interior connected to the device?	✓		
IQ21		Is a chart recorder connected to the device?	✓		
IQ22		Is the device connected to an external building management system?	✓		
IQ23		Is the device connected to the independent temperature monitoring system TCA3?	✓		
IQ24		Is the device connected to a CO ₂ back-up system?	✓		
IQ25		Is the device connected to an LN ₂ back-up system?	✓		
IQ26		Have other devices been connected? Device name:	✓		
IQ27		Have other devices been connected? Device name:	✓		
IQ28		Have other devices been connected? Device name:	✓		

No.	SM/OM section	Inspection	n/a	Yes	No
IQ15	OM	Are the leveling feet or heavy-duty castors locked with the brakes to prevent the device from rolling?		✓	
IQ16	OM	Have the rack and inner shelves been installed inside the device?		✓	
IQ17	OM	Has the protective foil been removed from the inner shelves?		✓	
IQ18	OM	Is the vent tube blocked by the rack or inner shelves?		✓	

For specifications for devices with water supply, please refer to the operating manual.

2.4 Checking the device and instructing the user

► Switch on the device.

2.4.1 Configuring the system

No.	SM/OM section	Inspection	n/a	Set value	Yes	No
IQ29	OM	Only for devices with touch screen Has the system been configured, e.g., address, date?	✓			
IQ30	OM	Has the set temperature for the interior been entered in the software (set point)?		-70°C	✓	
IQ31	OM	Have the alarm limits been entered in the software? High alarm limit (high alarm) Low alarm limit (Low alarm)		-60°C -80°C	✓	
IQ32	OM	Have the warning limits been entered in the software? High warning limit (high warning) Low warning limit (low warning)	✓			

2.4.2 Initial setup

No.	SM/OM section	Inspection	n/a	Yes	No
IQ33		The device was switched on and is working properly.		✓	

2.4.3 Instructing users

No.	SM/OM section	Inspection	n/a	Yes	No
IQ34	OM	The user has been instructed in the operation of the device.		✓	

Comments

Done Operational Qualification Satisfactorily.

Appendices (e.g. calibration certificates, technician certificates,):

1:	Tracability of Digital Thermometer.	OM	1029
2:			
3:			
4:			
5:			

Nadiad, 23-02-2022

Place, date

[Signature]
23-02-2022

Technician: Signature

The user confirms that he has received training on the device and its functions.

Nadiad, 23-02-2022

Place, date

[Signature]

Company: Signature and function

Dr. Amitkumar Jojera
Consultant Pathologist
M.P.U.H. Emp. No.:- 728
Reg. No. 37297

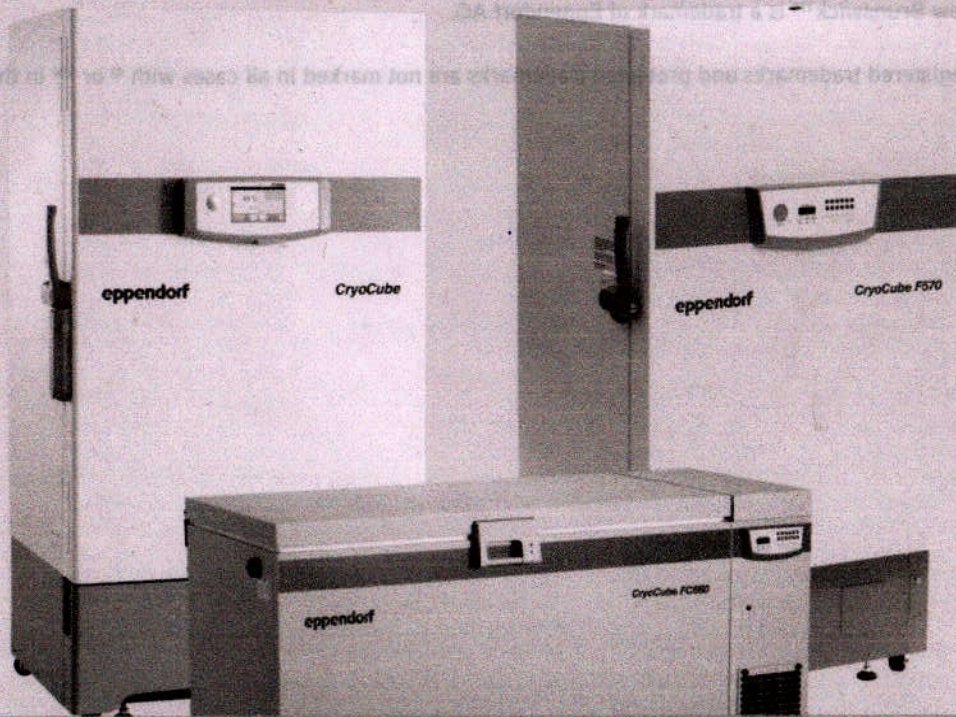
No	Yes	NA	
	<input checked="" type="checkbox"/>		

No	Yes	NA	
	<input checked="" type="checkbox"/>		

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Freezer

SOP - Operational Qualification - English

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Table of contents

1	Introduction	4
1.1	Using this manual	4
1.2	Information on liability	4
1.3	User profile	4
1.4	Notes on this document	4
1.5	Abbreviations	5
1.6	OQ version overview	5
1.7	Device data	6
1.8	Responsible persons	6
2	OQ – Freezers	7
2.1	Identifying the device	7
2.2	Test equipment	8
2.3	Visual inspection	8
2.4	Functional checks	8
2.4.1	Checking the display	8
2.4.2	Devices with LED: checking the control panel	8
2.4.3	Checking the alarm	9
2.4.4	Checking the vent valve	9
2.4.5	Checking the battery circuit	9
2.4.6	Integration into the network (optional)	9
2.4.7	Check interface for external communication (RS 485) (optional)	9
2.4.8	Checking the CO ₂ /LN ₂ safety system (optional)	10
2.4.9	Checking the chart recorder (optional)	10
2.4.10	Performing a test run	10
3	List of inspections – Freezers	11
3.1	Recurring operational qualification (OQ) inspections	11

Notes on this document

- ▶ Do not use a new list for each test.
- ▶ If a list is already available at the customer's premises, enter the test you have performed into this list.
- ▶ At the end of this OQ, you will find a list for documenting all inspections which were completed on a device. Enter the test you performed, and the date of the next test, into this list.
- ▶ Include other documents, such as explanations, printouts, recordings and results, with the OQ list; these documents under "Appendices".

1 Introduction

1.1 Using this manual

- ▶ Make sure that the service manual and the operating manual are available in the latest versions. To do so, compare the version numbers. The latest versions of the manuals can be downloaded from www.eppendorf-support.com.
- ▶ Read the service manual before commencing work on the device.
- ▶ Read the chapters "Installation" and "Operation" of the operating manual.
- ▶ Observe the safety instructions in the operating manual.

1.2 Information on liability

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- ▶ The existing construction of the device must not be altered as a result of any installation, repair, service or check. The safety of the original condition must be maintained.
- ▶ Only accessories and original spare parts recommended by Eppendorf as well as test and measuring equipment recommended by Eppendorf may be used for installation, service, repair and inspection.

1.3 User profile

The specialist entrusted with maintenance, repair or testing must meet the following prerequisites:

- Successful participation in service trainings with certification by Eppendorf AG for the product that is to be maintained, repaired or tested.
- Qualification as a specialist with knowledge of the applicable local and international standards.
- Qualification to evaluate the work assigned to him.
- Recognition of potential hazards and how to prevent or correct them.

1.4 Notes on this document

- ▶ Include other documents, such as explanations, printouts, recordings and results, with the OQ. List these documents under "Appendices".
- ▶ At the end of this OQ, you will find a list for documenting all inspections which were completed on a device. Enter the test you performed, and the date of the next test, into this list.
- ▶ If a list is already available at the customer's premises, enter the test you have performed into this list. Do not use a new list for each test.

1.5 Abbreviations

- OM – Operating manual
- HWM - Hardware manual
- IQ – Installation qualification
- n/a – not available
- SF – Service function
- SM – Service manual
- SWM - Software manual

1.6 OQ version overview

Version	Issue date	Chapter	Change
00	2017-03	-	• Created
01	2017-09	alle	• Field n/a added
02	2018-08	2	• Version overview added • Devices F740, F740i, F740iw deleted • Devices F740h, F740hi added
03	2019-07	2	• Device F101h added
04	2021-01	2	• Device F570n added
05	2021-07	2	• Devices F440x, F440h added

1.8 Responsible persons

Responsible technician

Name, first name: *Mohammed Umar*

Company: *Opentech India Pvt. Ltd.*

Certificate issued on ... / valid until ...: *14-02-2020*

Signature: *[Signature]*

Copies of the technician's certificates can be enclosed as appendices. List these documents at the end, under "Appendices".

User / Responsible for quality

Name, first name: *Dr. Amikumar Jeyaraj*

Company: *Consultant Pathologist*

Reg. No. *37297*

M.P.U.H. Emp. No.: *728*

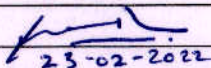
20/02/2022

1.7 Device data

Company/owner	Mulji Patel Oncological Hospital
Location of the device (building, floor, room, lab, etc.)	Pathology Department, Dr. Vinendra Desai Road, 387001 Nadiad - Gujarat
Storage site of the operating manual	Pathology Department.
Operating manual version (index number on the inside of the front cover)	
Service manual version (index number on the inside of the front cover)	NA
Inventory number of the device	
Manufacturer	Eppendorf AG
Type designation	-86 Deep Freezer
Serial number	F571K0600814
Software version and firmware version	NA
Voltage in V	230V
Frequency in Hz	50-60 Hz
Date of installation (day/month/year)	23-02-2022

1.8 Responsible persons

Responsible technician

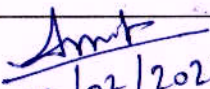
Name, first name:	Mohammed Umar
Company:	Eppendorf India Pvt Ltd.
Certificate (issued on ... / valid until ...):	14-02-2020
Signature:	 23-02-2022



Copies of the technician's certificates can be enclosed as appendices. List these documents at the end, under "Appendices".

User / Responsible for quality

Name, first name:	Dr. Amitkumar Jojera
Company:	Consultant Pathologist M.P.U.H. Emp. No.:- 728
Signature:	Reg. No. 37297


23/02/2022

2 OQ – Freezers

2.1 Identifying the device

This inspection can be performed on different devices. Please mark on which device you have performed the inspection.

Tab. 2-1: Device

Innova U101	<input type="checkbox"/>	CryoCube F101h	<input type="checkbox"/>
Innova U360	<input type="checkbox"/>		
Innova U535	<input type="checkbox"/>	CryoCube F440n	<input type="checkbox"/>
Innova U725	<input type="checkbox"/>	CryoCube F440h	<input type="checkbox"/>
Innova C585	<input type="checkbox"/>		
Innova C760	<input type="checkbox"/>	CryoCube F570	<input type="checkbox"/>
		CryoCube F570h	<input type="checkbox"/>
HEF U410	<input type="checkbox"/>	CryoCube F570hw	<input type="checkbox"/>
HEF U570	<input type="checkbox"/>	CryoCube F570n	<input checked="" type="checkbox"/>
HEF C660	<input type="checkbox"/>		
		CryoCube FC660	<input type="checkbox"/>
Premium U 410	<input type="checkbox"/>	CryoCube FC660h	<input type="checkbox"/>
Premium U570	<input type="checkbox"/>		
Premium U570 -45 °C	<input type="checkbox"/>	CryoCube F740h	<input type="checkbox"/>
Premium U700	<input type="checkbox"/>	CryoCube F740hi	<input type="checkbox"/>
Premium C340	<input type="checkbox"/>	CryoCube F740hiw	<input type="checkbox"/>
Premium C660	<input type="checkbox"/>		
U725-G water-cooled	<input type="checkbox"/>		
U725-G air-cooled	<input type="checkbox"/>		

Tab. 2-2: Door lock

Padlock	<input checked="" type="checkbox"/>
Cylinder lock	<input type="checkbox"/>
Electrical door lock	<input type="checkbox"/>

2.2 Test equipment



- You can find information on the test equipment specification in the Service Manual.
- Copies of the calibration certificates for this test equipment can be added as appendices to this OQ. List these documents at the end of this OQ, under "Appendices".

Test equipment	Type/serial number	Calibrated on	Calibration certificate number
Thermometer with ± 0.5 °C accuracy	200923448	17-01-2022	NCQC-T/170122/26
Multimeter	NA	NA	NA
	NA		

2.3 Visual inspection

No.	SM/OM section	Inspection	n/a	Yes	No
OQ01		Are the device and accessories undamaged?		<input checked="" type="checkbox"/>	

2.4 Functional checks

2.4.1 Checking the display

No.	SM/OM section	Inspection	n/a	Yes	No
OQ02	SM	Devices with LED <ul style="list-style-type: none"> All segments of the display light up (8888). All LEDs light up. Devices with a touchscreen <ul style="list-style-type: none"> The display works without any errors. 		<input checked="" type="checkbox"/>	

2.4.2 Devices with LED: checking the control panel

No.	SM/OM section	Inspection	n/a	Yes	No
OQ03	SM	All softkeys work without any errors. The value in the display changes (except for softkey 7).		<input checked="" type="checkbox"/>	

2.4.3 Checking the alarm

No.	SM/OM section	Inspection	n/a	Yes	No
OQ04	SM	In the event of a mains/power outage, an alarm is triggered (power fail alarm).		✓	
OQ05	SM	Remote alarm is triggered in the event of a mains/power outage. Remote alarm is triggered if the alarm limits for the internal temperature are exceeded (high alarm, low temperature alarm).		✓	
OQ06	SM	An alarm is triggered if the internal temperature falls below the low alarm limit (low temperature alarm).		✓	
OQ07	SM	An alarm is triggered if the internal temperature exceeds the high alarm limit (high alarm).		✓	
OQ08	SM	If the outer door is open for too long, an alarm is triggered (optional).		✓	

2.4.4 Checking the vent valve

No.	SM/OM section	Inspection	n/a	Yes	No
OQ09	SM	The vent valve works without any errors.		✓	

2.4.5 Checking the battery circuit

No.	SM/OM section	Inspection	n/a	Yes	No
OQ10	SM	The battery circuit works without any errors.		✓	

2.4.6 Integration into the network (optional)

No.	SM/OM section	Inspection	n/a	Yes	No
OQ11	SM	The device is connected to the network.	✓		

2.4.7 Check interface for external communication (RS 485) (optional)

No.	SM/OM section	Inspection	n/a	Yes	No
OQ12	SM	The interface for external communication (RS 485) works without any errors.	✓		

Dr. Amikumar Jørgen
 Consultant Psychologist
 M.K.U.H. Emp. No. 728
 Reg. No. 37297

2.4.8 Checking the CO₂/LN₂ safety system (optional)

No.	SM/OM section	Inspection	n/a	Yes	No
0Q13	SM	The CO ₂ /LN ₂ safety system works without any errors.	✓		

2.4.9 Checking the chart recorder (optional)

No.	SM/OM section	Inspection	n/a	Yes	No
0Q14	SM	The chart recorder works without any errors.	✓		

2.4.10 Performing a test run

No.	SM/OM section	Inspection	n/a	Yes	No
0Q15	SM	The test run was carried out successfully. The device reaches the setpoint for the internal temperature.		✓	

Comments

Done Installation Qualification Satisfactorily.

Appendices (e.g. calibration certificates, technician certificates,):

- 1: *Traceability of Digital Thermometer.*
- 2:
- 3:
- 4:
- 5:

Nadiad, 23-02-2022
Place, date

[Signature]
23-02-2022
Technician: Signature

Nadiad, 23-02-2022
Place, date

[Signature]
Company: Signature and function

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