

OPERATING MANUAL

K-Series Cryogenic Storage Systems – CryoCE 10K, CryoCE 24K, CryoCE 38K

This is a class IIa Medical Device according to 93/42/EEC Annex VIIII.

Review and understand all safety procedures before attempting to install, operate or perform maintenance on the cryo-storage system. Do not attempt to use or maintain this unit until you have read and understand these instructions.

The vessels are not intended for applications in direct contact with patients.

Do not permit untrained persons to use or maintain this unit. If you do not fully understand these instructions contact your supplier for further information.

Manufacturer:

Taylor Wharton Germany GmbH

Mildstedter Landstraße 1

25866 Mildstedt

Tel.: 0049 - 4841 - 985 - 0 Fax: 0049 - 4841 - 985 - 130 Email: info@taylorwharton.com

For the MDD products exists EC declaration of conformity 44 236 090637. Audited via the notified body:

TÜV NORD CERT GmbH, Langemarkstr. 20, D-45141 Essen

C € 0044









OPERATING MANUAL				
	Symbols page			
2.	Safety Precautions page			
3.	General Information page			
4.	Specificationpage			
5.	Transport and Installationpage			
6.	Set Uppage			
7.	Operationpage 1			
8.	Spare Partspage 1			
9.	Maintenance page 1			
10.	Cleaning, taking Unit Out of Servicepage 1			



1. Symbols



Hazard Fire and Explosions hazard



Hazard
This symbol is used to show possible risk of injury or mortal danger for users



Information
This symbol marks additional information or application details



Instruction Wear face shield



Instruction Wear protection gloves (Cryogenic level)



Note Inert gas, Nitrogen, UN Number 1977

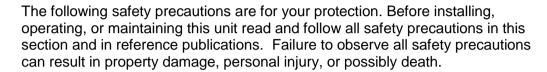


Asphyxiation hazard Special warning special risk of suffocation due to oxygen depletion



2. Safety precautions

WARNING



Safety Precautions for Liquid Nitrogen

Nitrogen is an inert, colourless, odourless, and tasteless gas makes up 79% of the air breathe. Liquid nitrogen is obtained by cooling air until it becomes a liquid and then removing the oxygen. Air is roughly 21% oxygen. Under normal atmospheric pressure Liquid Nitrogen has a temperature of -196°C.

Extreme Cold - Cover Eyes and Exposed Skin

Accidental contact of liquid nitrogen or cold issuing gas with the skin or eyes may cause a freezing injury similar to frostbite. Handle the liquid so there is no splashing or spilling. Protect your eyes and cover the skin where there exists the possibility of contact with the liquid, cold pipes, cold equipment or cold gas. Safety goggles or a face shield should be worn at all times when operating this equipment. Insulated gloves that can be easily removed and long sleeves are recommended for arm protection. Trousers without cuffs should be worn outside boots or over the shoes to shed liquid in the case of spillage.



Keep Equipment Area Well Ventilated

Although nitrogen is non-toxic and non-flammable, it can cause asphyxiation in a confined area without adequate ventilation. Any atmosphere not containing enough oxygen for breathing can cause dizziness, unconsciousness or death. Nitrogen, a colourless, odourless and tasteless gas, cannot be detected by the human senses and will be inhaled normally as if it was air. Without adequate ventilation, the expanding nitrogen will displace the normal oxygen in the air resulting in a non-life-supporting atmosphere.



Liquid Nitrogen System

The liquid nitrogen supply pressure at the inlet to the refrigerator should be in the range of 10 psig (0.7bar/69 kPa) to 20 psig (1,4bar/138 kPa) for optimum performance. Higher operating pressures will increase transfer losses and create excessive turbulence of the liquid in the refrigerator which can generate false signals to the liquid level controller causing the refrigerator to under-fill. In "liquid phase" storage applications, excessive turbulence can cause splashing which could result in personal injury and/or damage to the refrigerator. When installing piping or fill hose assemblies, make certain suitable safety relief valves are installed in each section of plumbing between shut-off valves. Trapped liquefied gas will expand extremely as it warms and may burst hoses or piping causing damage or personal injury. Relief valves are installed in the refrigerator plumbing to protect the line between the customer supplied shut-off valve and the refrigerator solenoid valve.







CAUTION: When installing field fabricated piping, make certain a suitable safety valve is installed in each section of piping between shutoff valves.



For more detailed information concerning safety precautions and safe practices to be observed when handling cryogenic liquids consult CGA pamphlet P-12 "Handling Cryogenic Liquids" available from the Compressed Gas Association, 1235 Jefferson Davis Highway, Arlington, VA 22202.



Warning: Inlet pressure should not exceed 1,5 bar 22 psig /152 kPa). Higher pressures could result in damage to equipment.



Dispose of Waste Liquid Nitrogen Safely

Dispose of waste liquid nitrogen out-doors where the cold temperature cannot damage floors or driveways and where it will evaporate rapidly. An outdoor pit filled with clean sand or gravel will evaporate liquid nitrogen safely and quickly.

Electrical

Electrical Shock Can Kill – the liquid level controllers used with these refrigerators operate from 24VAC. However, the external transformer has a 230VAC primary. Do not attempt any service on these units without disconnecting the electrical power cord.

<u>Please pay attention to the instruction manuals of our controller supplier</u> Mowden Controls Ltd.

Note: Units are supplied with Taylor-Wharton approved controllers. If other liquid level controllers are used, please contact Taylor-Wharton before putting the refrigerator into service.



Freight Damage Precautions

Any freight damage claims are your responsibility. Cryostorage systems are delivered to your carrier from Taylor-Wharton's dock in new condition. When you receive our product you may expect it to be in that same condition. For your own protection, take time to visually inspect each shipment in the presence of the carrier's agent before you accept delivery. If any damage is observed, make an appropriate notation on the freight bill. Then ask the driver to sign the notation before you receive the equipment. You should decline to accept containers that show damage, which might affect serviceability.

Spare Parts Please use only Taylor Wharton approved spare parts for maintenance work.



3. GENERAL INFORMATION

The Taylor Wharton Cryostorage 10K, 24K and 38K systems are vacuum insulated (double wall) stainless steel freezers and are designed for applications where extremely low temperature storage of biological products is required. They are also appropriate for industrial or other applications where liquid nitrogen temperatures and high capacity are needed. The Freezers are open to atmosphere and therefore **not** covered by the European Pressure Equipment Directive 97/23 EC.

The 10K, 24K and 38K refrigerators covered by this publication are designed for, but not limited to, the laboratory environment. The 10K and 24K feature a square, modular cabinet that facilitates grouping several units together in a Cryostorage area. The 38K features a cylindrical stainless steel storage chamber. Storage area can be accessed via an insulated one piece Lid. The lid is hinged and opening is support with two gas cylinder springs. The gas cylinder springs keep the Lid open while working with samples.

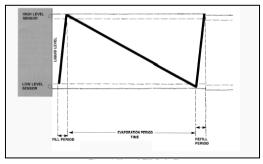
All of the models will accommodate inventory control systems and/or provide unobstructed storage area for larger product. All models are supplied with casters to enable limited mobility for cleaning purposes.

The addition of a liquid level controller, for liquid nitrogen supply, like the Taylor Wharton Liquid Cylinder product line, and inventory control racks for systematic retrieval of stored product completes the total Cryostorage system.

Operation

The cryogenic temperatures required for long term storage of biological samples is achieved by constant evaporation of liquid nitrogen. Necessary evaporation heat is absorbed from the environment resulting lower temperature within the storage area.

As a result the liquid level in the cryogenic freezers drops constantly. Regularly topping off of liquid nitrogen is required in order to maintain cryogenic storage temperatures for the samples. Refill can be done either by hand or more convenient and safely with automatic level controllers, e.g. Taylor Wharton



CryoCon products. The graphs show resulting level characteristics.



In order to avoid LIN losses and ice built up around the cabinet top area inlet pressure shall not exceed 1,5 bar. LIN needs to be saturated at 0.7 bar – 1.4 bar. Higher pressures could result in damage of equipment and / or sufficient depletion of oxygen, resulting in an unsafe environment. See safety precautions above.



Taylor-Wharton cryogenic vessels are based on the principle of complete thermal insulation. They consist of an inner vessel and an outer body separated by a stable vacuum, which precludes any transfer of heat from the ambient environment to the inner vessel. Any loss of vacuum pressure between the two parts will result in a massive increase of LIN consumption and without any increase of feed this can cause damage to the stored samples. Beside this risk, the high consumption of LIN results in substantial amounts of nitrogen gas, resulting in sufficient depletion of oxygen, see safety precautions above.



4. Specifications

	<u>10K</u>	24K	<u>38K</u>
LIN capacity (I)	165	365	590
Width x depth (mm)	587 x 775	864 x 965	1067 x 1397
Overall depth (mm) Lid open	864	1232	1397
Overall height (mm)	1118	1118	1245
Overall height (mm) Lid open	1753	1930	2286
Internal diameter (mm)	533	787	991
Useable height (mm)	737	737	737
Weight, empty (kg)	111	184	256
Weight, full without ICS* (kg)	243	474	732
Evaporation rate** (litre / day)	5,0	7,0	8,0
Static holding time** (days)	33	52	74

^{*} ICS – Inventory Control System

Our policy of continuing product improvement may cause changes in the specifications without prior notice.

^{**} Evaporation rate and static holding time are nominal. Actual rate may be affected by the nature of the contents, atmospheric conditions, container history and manufacturing tolerances



5. Transport and Installation

Unpacking and Inspection

Inspect received containers for external damage. All claims for damage (apparent or concealed) or partial loss of shipment must be made in writing within five (5) days from receipt of goods. If damage or loss is apparent, please notify the shipping agent immediately.



Open the shipping containers; a packing list is included with the system to simplify checking that all components, cables, accessories, and manuals.

Installation

Please use the packing list to check off each item as the system is unpacked. Inspect for damage. Be sure to inventory all components supplied before discarding any shipping materials. If there is damage to the system during transit, be sure to file proper claims promptly with the carrier and insurance company. Please advise Taylor-Wharton of such filings. In case of parts or accessory shortages, advise Taylor-Wharton immediately. Taylor-Wharton cannot be responsible for any missing parts unless notified within 30 days of shipment.

Repackaging for Shipment

If it is necessary to return any part of the system for repair or replacement, a Material Return Authorization (MRA) number must be obtained from an authorized factory representative before returning the instrument to our service department. Contact your distributor for return authorization.



When returning an instrument for service, the following information must be provided before obtaining an MRA:

- A. System model and serial number and controller serial number
- B. User's name, company, address, and phone number
- C. Malfunction symptoms
- D. Description of system
- E. Material Return Authorization (MRA) number

F. Decontamination Certificate – Mandatory for return shipments.

If possible, the original packing material should be retained for reshipment. If not available, consult Taylor-Wharton for shipping and packing instructions. It is the responsibility of the shipper to assure that the goods are adequately packaged for return to the factory.



Liquid Nitrogen Supply Connection

The package included with the refrigerator includes a filter and an elbow. The liquid fill hose (not included) from a low pressure source of liquid nitrogen must be connected to the inlet through both the filter and the elbow. The liquid nitrogen source must have a shut-off valve, and may be any portable liquid cylinder or a bulk supply. The liquid nitrogen supply pressure at the inlet to the refrigerator should be in the range of 10 psig (0.7 bar/69 kPa) to 20 psig (1.4 bar/38 kPa) for optimum performance. Higher operating pressures will increase transfer losses and create excessive turbulence of the liquid in the refrigerator which can generate false signals to the liquid level controller causing the refrigerator to under fill. In "liquid phase" storage applications, excessive turbulence can cause splashing which could result in person injury and/or damage to the refrigerator.

6. Set Up

The units can be used in two different modes:

Manual

LIN supply should be connected via suitable transfer hose and standard pipe connection with a 3/8" NPT female thread or filled by hand through the open lid. For the filling by hand the transfer hose should be equipped with a phase separator. Manual fill requires strict routines for liquid level check and LIN top up according to the required level.

With respect to the valuable stored contents it is recommended to install automatic level control devices, e.g. Taylor Wharton CryoCon models.



Automatic

The CryoCon level control systems are designed to provide simple, reliable level control in your LN2 freezer. LIN supply system has to be connected via transfer hose; the connection is made to the freezer by 3/8" NPT female thread.

The CryoCon systems maintain the LIN level between the low and high sensor. Extra low and extra high sensors are used for alarms and safety features. For further details please check the relevant controller manual.

Maximum LIN level must be set at a minimum 2,5 cm below the booted Lid. The Lid should not be permanent immersed in LIN. Overfilling must be avoided and may damage the freezer, control system or the floor and excess amounts of gaseous nitrogen could displace the breathable air resulting in an unsafe environment.



Initial Fill or Restart after Unit was Out of Service

Before starting filling the unit with liquid nitrogen the Inventory Controls System should be placed inside the vessel. The refrigerator can now be filled according to the required level. When an automatic level controller is installed the liquid nitrogen source needs to be connected to the inlet connection of the vessel and the controller must be started to fill the unit.

Cooling down a warm container (at room temperature) will cause excessive amount of cold nitrogen gas. It is important to allow for adequate ventilation. The Temperature of the material will change more than 200°K. All measures must be taken to avoid any **Asphyxiation hazard for** people involved with installation, set-up or testing the unit.



We recommend storing samples only after the unit has been cooled down and after a test run of min. 48 hours.

If the filling process does not stop when the HIGH level is reached, the manual valve of the supply line of the LN2 source must be closed immediately. In case of an overflow situation an excessive amount of cold nitrogen gas will be created though evaporation and cause an **Asphyxiation hazard.**

The reason for the overflow could be a blocked solenoid valve. This can be caused by ice build up or by contamination with dirt inside the solenoid valve. After closing the LN2 supply, the ice will thaw by itself after a period of time so no disassembly of the valve is needed. If the valve is blocked by dirt, it might be removed by the flow of gas by switching the valve on and off for a few times. If the valve stays continuously open the solenoid valve needs to be cleaned or replaced by the technical service.

In general the supply hoses should not be disconnected if cold. After disconnecting the hose from the supply tank (like the XL-vessel) the open hose connection must be positioned with the opening downward in order to avoid that moisture entering the hose.



7. Operation

When operating a Taylor Wharton Cryostorage System following should be avoided:

- Leaving lid open for too long
- Inserting several warm inventory racks in a short time
- High humidity in the storage room

These conditions may lead to excessive ice build-up and accumulation of ice inside the vessel. A large amount of ice around the lid may cause difficulties opening the lid. Excessive ice can make it necessary to use force to open or close the lid which may damage the gasket, lid or cabinet top.

During the fill process (through the fill pipe of the unit) cold nitrogen gas will leave the vessel through the vent port at the rear side of the unit. The area will be cooled down which will lead to some snow build up. The snow will melt shortly after the filling has stopped.



o. Spare raits						
-	I0K	24K	38K			
Description	Part-Nr.	Part-Nr.	Part-Nr.			
Rear Panel	R10K-9C35	R23K-9C35				
Front Panel	R10K-9C33	R23K-9C33				
Side Panel	R10K-9C34	R23K-9C34				
Cabinet Top	R10K-9C10	R17K-9C10	R033K-9C10			
Gasket for Cabinet Top	7701-0088	7701-0087	7701-0088			
	2,0 m req	2,5 m req.	3,2 m req.			
Lid Assembly	R10K-9C86	R23K-9C85	R27K-9C00			
Lid Gasket, 7701-0089	2,0 m req.	2,7 m req.	3,3 m req.			
Bezel for Controller board	R06K-9C21	R06K-9C21				
Access Plate for Fill Connection	R06K-9C32	R06K-9C32				
Castor	7300-9020	7300-9C20	7301-2031			
			7301-2032			
Fill Tube	R10K-9C66	R23K-9C66	R40K-9C36			
Sensor Tube	R23K-9C96	R23K-9C96	R23K-9C96			
Gas Spring	8958-0130	8958-0130	8958-0135			
Hinge Upper Part	R17K-9C52	R17K-9C52				
Hinge Lower Part	R17K-9C53	R17K-9C53				
Lid Lock with 2 Keys	8254-2021	8254-2021	R27K-9C35			
Options for automatic Level Controller:						
Installation Kit	R17K-8C40	R17K-8C40	R20K-8C40			
Solenoid Valve 24 AC	SCB26320	SCB26320	SCB26320			
Lid Switch electro-magn.	5140-1195	5140-1195	5140-1195			

9. Maintanaince

Normally the refrigerators and controllers are maintenance free.

In general ice build-up is normal on all refrigerators. In order to avoid ice accumulation inside the storage compartment ice, snow and water should be removed from the lid / cabinet top area. The amount of ice and the frequency of removal depends on the operating and ambient conditions the vessel. When removing the ice, avoid ice falling into the vessel because it will restrict refilling the regulatory system.

Although all measures have been taken to avoid ice accumulation the vessel will have to be de-iced. For this action the vessel must be taken out of service and warmed up. During this time the samples must be stored in another vessel.



Retrofitting of an Automatic Level Controller

When a vessel which has been in service and has not been filled (manually), the integrated fill pipe could be clogged with ice (at the approximately fill level). The ice is built up by some moisture which enters from the ambient air into the open pipe and then freezes once it comes in contact with the cryogenic temperature in the vessel. This must be checked before the controller is installed. In case of a clogged fill tube the vessel must be emptied, the platform must be removed and then the fill tube can be removed and warmed up. It may be easier to take the whole unit out of service and warm it up completely until all ice and water is removed.

10. Cleaning, taking out of service

For cleaning and disinfection of the vessel suitable and approved solutions must be used. The selection of the right product is in the responsibility of the user due to the high number of applications and kinds of stored product. Taylor-Wharton does not have the expertise to give a judgment about the effectivity of such solutions.



Spray the surfaces of the vessel with the selected solution. After 5 minutes the solution must be rinsed with 70% solution of alcohol and water. After 15 minutes all liquid must be removed from the container and the container must be wiped dry.

Discarded products have to be professional disposed of. The vessel must be mechanically broken down into its individual parts. All necessary materials from stainless steel, aluminium and aluminium foil can be reused as recyclable materials. All plastics, epoxy tube, glass paper and the molecular sieve must be disposed of as industrial waste or incinerated. Electronic components (controller / control unit) must be supplied to the hazardous waste. Your local authority will give all disposal information.

Important:

If a vessel has to be returned to your supplier or to the manufacturer it must be cleaned and disinfected. A written statement must be confirmed by the sender (see attachment Reclamation Return Receipt 082011) If such document is missing the vessel will not be accepted and will be returned to the sender (freight unpaid).



Revision: October 2013