For the attention of the medical device vigilance coordinator

Bussy Saint Georges, 22nd January 2020

Reference: SQHE_CO_19_0004_EN

Reference ANSM: R2000902

Objet: Safety Information

Dear customer,

CryopAL is voluntarily initiating the following safety information:

Products concerned

ARPEGE 55 and ARPEGE 75 cryogenic containers equipped with the CRYOMEMO regulation accessory

ARPEGE 55	ARPEGE 75
ARPEGE55N-L-101	ARPEGE75N-L-101
ARPEGE55N-L-102	ARPEGE75N-L-102
ARPEGE55N-L-103	ARPEGE75N-L-103

Description of the problem

The CRYOMEMO regulation accessory has the following functions: regulation of level of liquid in the container, overflow protection, alarm and levels display.

During inspections, a few cases were found where the regulation system of nitrogen liquid was not functional. The origin of the defect is the failure of the measuring chain, occurring in particular when the CRYOMEMO accessory is switched on.

This failure has the following effects:

- Level display blocked at a fixed value of 100%.
- Triggering of a high level crossing alarm

 Stop of level regulation of the container, the system considering the container always full, independently of the real level.

The high temperature and overflow alarms remain functionals, even in case of failure of liquid level regulation system.

Risk related to the problem

Risk of samples loss due to the total evaporation of liquid nitrogen and to the reheating of the container.

Actions implemented by CryopAL and its distributors

A corrective solution is under development to be deployed as soon as possible. If users request a temporary alternative solution, the distributors should contact CryopAL

Actions to be implemented by the customer

As part of preventive measures, we ask you to perform a daily visual check of the level measured by the CRYOMEMO, read on the display. Each user will be able to adjust their frequency of inspection *.

If the displayed level is at the fixed value of 100%, users are asked to check the liquid nitrogen level closely using the slide provided and to fill the container manually. A possible alternative to frequent level monitoring is to move the samples to another functional container.

In the event of CRYOMEMO failure, please contact your distributor to find an alternative solution.

If any failure is recorded, we advise you to pay particular attention to the CRYOMEMO alarms, especially high level trigger alarm.

*The frequency of the level monitoring must be established according with the daily evaporation rate of the container and its rate of use.,It is also recommended to record these checks in a register in the format of your choice (electronic file, paper register, ect...)

Reminder: refer to the good practices given in the user manual ref. NH78451 for manual filling of the container.

Transmission of this safety information

Please distribute this letter to all your user customers and/or any person of your establishment who needs to be informed.

We also request that you return the enclosed acknowledgment of receipt, confirming that you have received and read this safety information **before 15 march 2020**

We confirm that this information has been transmitted to the French competent authority (ANSM).

The after-sales team of CryopAL or your distributor are at your disposal to provide you with any further information or clarification you may require.

For any question concerning this operation, you can contact within CryopAL:

After-sale team	Phone: + 33 (0)1 64 76 15 39 or + 33 (0) 1 64 76 15 21 Email: fsncryomemo@airliquide.com
	From 9h00 to 12h00 and from 13h30 to 17h00
Vincent MICHELET	SQHE & RA manager Vigilance manager Email: vincent.michelet@airliquide.com
Olivier LARTIGUE	General manager Email: olivier.lartigue@airliquide.com

We would like to thank you for your co-operation in advance and regret any inconvenience caused by this safety information.

Vigilance manager

Vincent Michelet

Acknowledgment of receipt

Safety information: SQHE_CO_19_0004 of 22-01-2020.

Reference ANSM: R2000902
Customer Information
Company name:
Customer code:
Address:
Contact name:
Title or role:
Phone / Email:
In case of equipment failure, please contact your distributor or the CryopAL team as soon as possible by phone or email.
I confirm that I have received, read and understood the safety information from CryopAL.
Full name:
Role/Title:
Service:
Date and signature:
Please send this completed document to CryopAL by email fsncryomemo@airliquide.com or by fax: +33 (0)1 64 76 16 99 before 15 march 2020