



A member of the **VRV** Group

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SUBJECT: SECURITY NOTICE, RECALL ON ALUMINIUM VESSELS

Field Safety Notice, selon Meddev 2.12 rev 8
Field Safety for Corrective Action

Date: 18/06/2018

Details of affected devices

B 2009M

1 dewar, Number: AC1151

B 2015M

1 dewar, Number: AH7997

B 2020M

3 dewars, Number: AD4226, AD4191; AD5851

B 2036M

6 dewars, Number: AE3626; AD1983, AD3344; AD3343, AD3369; AD6786

B 2048M

28 dewars, Number: AD5301, AD5302 ; AD5527; AD5538; AD5548; AD5524; AD5529; AD5533; AD5534; AD5537; AD5549;
AD5552; AD5553; AD5554; AD6112; AD6123; AD6102 ; AD6105; AD6106; AD6110; AD6113; AD6118; AD6120; AD6122;
AD6124; AD6126; AD6127; AD6131

BR 2048M

6 dewars, Number: AD6711; AD6712; AD6714; AD6715, AD6717; AD6716

BS 2002M

13 dewars, Number: AD6033; AD6024; AD6040; AD6034; AD6035; AD6037; AD6038; AD2492; AD2493; AD2501, AD2504, AD6024
and AD6040

BS 2004M

6 dewars, Number: AD6064, AD6066, AD6071; AD6080; AD6054; AD4249



Problem description:

Cryogenic tanks are vacuum-insulated double-wall tanks that retain liquid nitrogen at -196 °C with a daily evaporation rate of 3-4%. It has been reported (and confirmed at the factory) that there have been vacuum losses with some aluminum tanks. In the case of vacuum loss, the nitrogen will evaporate in a just few hours.

A batch of glue used for the assembly of the fiberglass neck in the aluminium tanks, is the source of the problem, and it is for this reason that the tanks affected includes different models that were manufactured in different batches at the same period.

As soon as the first cases were reported, we decided to carry out systematic cooling tests. A limited number of cryogenic tanks, from batches that had been manufactured and shipped before the first cases appeared, were properly tested and data recorded. As a precaution, we then proceeded to recall and replace of all the tanks that were known to be manufactured using this bad batch of glue.

For your information: at the same time, another manufacturer CHART/MVE had the same problem and this prompted a large recall campaign (CHART notice of April 23, 2018, transmitted by ANSM June 1, 2018).

Action to be taken by users:

All samples stored in the tanks listed above must be immediately transferred to another tank and the tank being recalled must be recorded so that it cannot be used.

To effectively destroy this unit and ensure that it can no longer be used, we would ask you to drill a hole in the outer wall of the tank close to tank serial number and send us a picture of this (showing the serial number of the tank and hole that has made in it).

We remind that cryogenic tanks containing biological samples must be daily monitored and must be equipped with continuous monitoring and alarm reporting systems (to demonstrate liquid Nitrogen level and/or temperature). This is to warn end users (in real time) of any potential risk to the samples stored in that tank.

Transmission of this incident report:

As part of this recall procedure, we ask that you confirm receipt of this letter and confirm that the end user has been duly informed and that the samples have been removed from the affected tank are now safe and secure. If you have sent a cryogenic tank from the list above to a Third Party, it is your responsibility to inform the Third Party of this official recall notice as soon as possible.

Action to be taken by Cryo Diffusion:

In consideration of the problems caused to our customers and as part of this official product recall notice:
We hereby confirm that on receipt of proof that the affected tank has been decommissioned as described above, we will then send out a free of charge replacement. Thank you for your support and understanding...

Contact of referees:

Philippe DOINEL
Directeur général

Matthias BIGOT
Responsable produit

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This notice has been sent to the appropriate regulatory agency (ANSM, France).

LERY, le 18/06/2018