Teleflex Medical Sdn. Bhd.
(128555-V)
Lot No PT 2577,
Jalan Perusahaan 4,
Kamunting Industrial Estate,
34600 Kamunting, Perak,
Malaysia.
Phone: 605-8295 111
Fax: 605-8912 699
www.teleflex.com

Field Safety Notice

To all users of the Arrow® AutoCAT®2 Intra-Aortic Balloon Pump & Arrow® AC3 Optimus® Intra-Aortic Balloon Pump

Re: EIF-000522-01 – Intra-Aortic Balloon Pump (IABP), Short Battery Run Times - Advisory Notice

Dear customer,

This letter is to inform you of a potential malfunction and hence hazard to patients when using the

Model Information	Product Name	Product Code
Arrow® AutoCAT®2 Intra-Aortic Balloon Pump	AutoCAT 2 Spanish	IAP-0400E
	AutoCAT 2 French	IAP-0400F
	AutoCAT 2	IAP-0400
	AutoCAT 2 Japanese	IAP-0400J
	AutoCAT 2 Refurbished	IAP-0400X
	AEROAUTOCAT2	IAP-0435
	AutoCAT 2 WAVE	IAP-0500
	AutoCAT 2 WAVE German	IAP-0500D
	AutoCAT 2 WAVE Spanish	IAP-0500E
	AutoCAT 2 WAVE Refurbished Spanish	IAP-0500EX
	AutoCAT 2 WAVE French	IAP-0500F
	AutoCAT 2 WAVE Italian	IAP-0500I
	AutoCAT 2 WAVE Japanese	IAP-0500J
	AutoCAT 2 WAVE Dutch	IAP-0500NL
	AutoCAT 2 WAVE Swedish	IAP-0500SV
	AutoCAT 2 WAVE Refurbished	IAP-0500X
	AEROAUTOCAT 2 WAVE	IAP-0535
	AEROAUTOCAT 2 WAVE Spanish	IAP-0535E
	AEROAUTOCAT 2 WAVE Italian	IAP-0535I
	AEROAUTOCAT 2 WAVE Japanese	IAP-0535J
	AEROAUTOCAT 2 WAVE Refurbished	IAP-0535X

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Arrow® AC3 Optimus® Intra-Aortic Balloon Pump	AC3 IABP NA/EMEA	IAP-0600
	AC3 IABP NA/AJLA	IAP-0601
	AC3 Optimus IABP NA/EMEA	IAP-0700
	AC3 Optimus IABP NA/EMEA Refurbished	IAP-0700X
	AC3 Optimus IABP NA/EMEA	IAP-0701

When does this malfunction occur and what are the potential risks ?

When operating the IABP device using battery power, the expected duration of pumping, after a full charge, is 90 minutes. However, Teleflex has received complaints reporting that some users of the affected IABP devices have experienced short battery run-times, including loss of power during use.

What steps can the user take to avoid the potential risk of this issue?

- If the IABP device battery fails while in use, immediately connect to an AC power source to continue therapy
- If a source of AC power is not readily available, transfer the patient to an alternative IABP. Teleflex recommends that you have a back-up IABP device fully charged and readily available.
- If pumping cannot be restored within 15 – 30 minutes, manually inflate and deflate the IAB several times per hour to reduce the risk of thrombus formation and consider removing the balloon. Refer to the IAB user manual for additional instructions, cautions and warnings for proper battery operation and maintenance.

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How will the issue finally be resolved?

- Ensure the IABP is plugged into an AC outlet whenever possible during patient use to prevent the battery from depleting.
- Ensure the IABP is plugged into an AC outlet when the system is not in use as the batteries should be kept at a full charge even when not being used on a patient.
- Prior to transporting patients, ensure the battery is fully charged.
- Ensure a backup IABP device is fully charged and readily available.
- As described in the Arrow® AutoCAT®2 Intra-Aortic Balloon Pump / Arrow® AC3 Optimus® Intra-Aortic Balloon Pump Operator Manuals, it is recommended to replace the batteries when:

o Battery run time is less than 90 minutes
o There is visual damage to the battery
o There has been 3 years of service with the battery

- As described in the Operator Manuals, Teleflex recommends that a battery load test is performed at least every 12 months by qualified service personnel. If an issue with the battery load is identified, immediately quarantine the device and contact Teleflex Customer Service using the contact details provided below to report the issue and receive support for servicing the affected IABP device.

Note: If a battery load test has not been performed in the past 12 months, Teleflex advises against transporting patients with affected IABP devices until the battery load test is performed.

We appreciate your understanding and cooperation with this Field Safety Notice and ask you to immediately instruct your personnel accordingly. Please ensure that this safety notice is placed in the System's instructions for use. Your personnel should maintain awareness over an appropriate defined period.

If you have sold this medical device and it is no longer in your possession, we kindly ask that you forward this safety notice to the new owner of this medical device. Please inform us about the new owner of the medical device.

The **Medical Device Authority** will be informed of this notice.

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Sincerely Yours

Lim Yi Hui

Date: 28 April 2023

Contact person of this notification

Ms Lim Yi Hui

Department: Regulatory Affair

Telephone: 05-829 5111

Fax: 05-829 5111

E-mail: yihui.lim@teleflex.com