Issue date
3 August 2023

Distributed to:
Chief Executives
Directors of Clinical Governance
Director, Regulation and Compliance Unit

Action required by:
Chief Executives
Directors of Clinical Governance

We recommend you also inform:
Directors, Managers and Staff of:
- Intensive Care Units
- Dialysis Units

Clinicians who may use PrisMax

Expert Reference Group Content reviewed by:
Representatives from:
ACI ICNSW
ICU Clinical Nurse Consultant Advisory Group
HealthShare NSW
SPRU

Clinical Excellence Commission
Tel: 02 9269 5500
Email: cec-recalls@health.nsw.gov.au
Internet:
https://www.health.nsw.gov.au/sabs/
Intranet:
http://internal.health.nsw.gov.au/quality/sabs/

Review date
December 2023

PrisMax Continuous Renal Replacement Therapy Device: B2222 Alarm

Situation

PrisMax is a Continuous Renal Replacement Therapy device used in critical care environments. Since Software Version 3.2 was introduced in February 2022 there have been multiple “system failure” alarms (known as B2222 alarm). The alarm can occur at any stage of the therapy and, depending on the machine, may allow resumption of treatment or be unrecoverable and end treatment. If treatment ends, blood in the circuit may be unable to be returned to the patient, resulting in unacceptable blood loss. Baxter are working with affected sites and have provided education and slides to assist staff to navigate the alarm.

Background

During operation, the PrisMax conducts continuous testing to monitor the operation of the system to ensure the safety of the patient. These tests are referred to as the Built In Ongoing Tests (BIOT).

In program version 3.2, for some BIOT the PrisMax enters a safe state (pumps stopped and return clamp closed), then automatically attempts to restart and allow the treatment to continue. This is known as the Therapy Recovery process. The Therapy Recovery process occurs so the device can do a system reset before restarting therapy. This process takes approximately 60 seconds. When the restart is complete, the operator is given the option to continue the treatment provided certain conditions are met or end treatment.

Assessment

Baxter ANZ has advised that the B2222 alarm is a therapy recovery process and not an error (or system failure). The screen will come up as a ‘System Failure alarm’. The implementation of the Therapy Recovery process in software version 3.2 is less than ideal with limited information available to the operator while the process is being executed, and an audible alarm sounding during the restart which can be silenced.

The Recovery Process should take 60 seconds, with 3 phases- a black screen, constant alarms and flashing power LED indicators. Next followed by a standard PrisMax start up procedure and final part of the Recovery process will end with the machine providing you with options to continue treatment or cease treatment without the option to pump the blood back into the patient.

The new program version 3.3 has been approved and Baxter is expected to install this software at each hospital and provide training on the updates.

Clinical Recommendations

1. In Therapy Recovery mode be prepared to manually return blood to the patient once the device has shut down
2. To reduce the risk of screen freezing ensure screens on devices are thoroughly cleaned, there is no chemical residue, and there is a docking procedure for the alarm.

Education

Baxter ANZ will provide education to staff in ICU as interim solution (until program version 3.3 is deployed). This will include a slide deck and video which details the therapy recovery process and return of blood to the patient.

Required actions for the Local Health Districts/Network

1. Distribute this Safety Notice to all relevant clinicians and clinical departments where PrisMax is used.
2. Include this Safety Notice in relevant handovers and safety huddles.
3. Escalate any concerns related to patient safety to CEC-Recalls@health.nsw.gov.au
4. Report any incidents associated with these devices into iims+ and TGA.