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Request Type: FMI  
Request Number: 1-9998449573

Customer Details

Customer Name:717063 - HUNTER NEW ENGLAND LOCAL HEALTH DISTRICT

Equipment Location:JOHN HUNTER HOSPITAL, LOOKOUT ROAD, NEW LAMBTON HEIGHTS, NSW, Australia, 2305

Contact Name:Durga Sompalle

Contact Phone:+61249213147

Email Address:durga.sompalle@health.nsw.gov.au

Equipment Number:34210

Room Department:Neonatal Intensive Care Unit (NICU)

Purchase Order Number:--

Equipment Details

System ID:ANZM+740\_6650-0068-902\_HDGN50373

Serial Number:HDGN50373

Product Description:OMNIBED ENG EBASE S-HUMID w /Australian Plug

Service Agreement Type:--

Service Agreement Number:--

Next Scheduled PM:--

Activity Description

Field Engineer:ATHAR ZAIDI

Activity Number:1-4LC TH2K

Activity Closed Date:30/05/2023

Activity Type:Field Support

**Reported Problem:** "TGA Ref # RC-2021-RN-02150-1. GEHC Ref 32079 GE Healthcare continues to monitor the issue where the bedside panels of Giraffe Incubator, Giraffe OmniBed, Giraffe Incubator Carestation, and Giraffe OmniBed Carestation can be upright and look closed but not be latched. The portholes also can look closed when not latched. If a bedside panel or porthole that is not latched falls open, it will no longer protect the patient from falling. GE Healthcare is launching an updated latch design for bedside panels and portholes for the Giraffe Incubator, Giraffe OmniBed, Giraffe Incubator Carestation, Giraffe OmniBed Carestation. Design of the latches for both the bedside panels and portholes were updated to address the before mentioned situations."

**Identified Problem:** FMI 32079 Giraffe Incubator and OmniBed Side Wall and Porthole Latch Replacement

**Solution:** Completed FMI 32079. Replaced the side wall and porthole latches and provided customer documentation per FMI Instructions. Removed, defaced, and disposed of removed parts, old design parts and posters.

**Test Procedure:** 1.Confirmed Bedside Panel latches are working properly and check out was done successfully.2.Confirmed Porthole latches are working properly and check out was done successfully.3.Confirmed Wall Warning and Latch labels are present on bedside panels.4.Confirmed User IFU is placed with the Operation/User manual.5.Confirmed Service Addendum and customer FMI instruction are in Service manual.6.Confirmed poster is hung in a visible area.7.Confirmed with customer that all hospital staff who open panels/portholes or otherwise interact with the device have been trained on the proper closing and latching of Incubators and OmniBeds.8.Confirmed facility was checked for old design latch spare parts on bedside panels or as spares. If found on site, the old spare parts are defaced and disposed.9.Confirmed removed parts from the medical device and old posters defaced and disposed.Test Conclusion: Equip passed all required tests and has been returned to the customer fully functional.

**Test Passed:** --

Date	Description	Start Time - End Time	Hours
05/29/2023	Onsite Repair	14:00 - 15:00	1

Date	Part Number	Quantity	Description
30/05/2023	5697332-01	1	R-FMI 32079 Kit, Giraffe OmniBed, Wall Latch, w/5 Port Hole Latches_EN

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