

Corrective Action Report

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| Customer | Bluepoint Medical |
| Product name | IRMA AX+ |
| Serial number | 900714 |
| PRI number | 2918 |
| CAPA number | 3202 |

Failure description from customer

Mechanical damage.

Hello service team, based on photos Artur gave an estimation regarding this case: "This type of damage you see in the pictures is caused by rough handling or misuse, we have no experience of the unit crack/break during normal use, e.g. connecting and disconnecting the IRMA with the adapter. Also the damage/crack you can see on the red plastic cover indicates that the device is dropped to the floor. We would treat this as a case that is not covered by our warranty. " The customer does not expect this answer, because they say the leaflet states an Shockproof design: IRMA CO2/AX+ Withstands repeated 1.8 m drops. No chance they dropped it from higher. Can you analyse the IRMA, even if it costs service fee, and give us an written statement wich states that this is not a general product problem. I appreciate your help in this.

Cause or reason of failure

The damage is caused by extremely rough handling.
IRMA is tested to withstand repeated 1.8 m drops. As part of the investigation for this case the R&D dept. has performed testing on undamaged units in order to try to generate similar damages. It was not possible to damage the units by trying to mount an Airway Adapter turned the wrong way into place by force, and it was not possible to provoke damages by squeezing the probe with hand power (without Airway Adapter mounted). It was possible to crack the unit and generate similar damages by placing it under the foot and applying heavy force, but not even in this case was the damage as large as for SN 900714. The conclusion of the test was that the unit 900714 has been exposed to considerably rough handling outside intended use.

There has been a total number of 4 (four) returned IRMA units manufactured after Q2 2010 (including SN 900714) with similar types of mechanical damage, which corresponds to a return rate below 0.1% accumulated over the last 3 years. This also includes veterinary use in rough environments.

Action taken to prevent recurrence

N/A. No actions taken.

Comments

N/A

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| Name | Peter Karlsson | Title | Quality Manager |
| Signature |  | Date | 2014-01-14 |