


Medical Devices Safety Notice

The National Health Regulatory Authority would like to alert all governmental and private healthcare facilities, local agents and distributors that the below medical device:

| Device Details | |
|-------------------------------|---|
| Device Name | Mini Med 640 G Insulin Pump |
| Device Model | MMT- 1711 |
| Manufacturer | Medtronic |
| Country of Origin | USA |
| Reference | https://www.fda.gov/medical-devices/medical-device-recalls/medtronic-recalls-minimed-insulin-pumps-incorrect-insulin-dosing |
| Device picture | <div style="text-align: center;">  <p>The images show a normal pump retainer ring vs a damaged or missing pump retainer ring.</p> <p>NORMAL pump retainer ring DAMAGED pump retainer ring MISSING pump retainer ring</p> </div> <p><small>Image: Location of the retainer ring on the MiniMed™ 600 series insulin pump</small></p> |
| Reason of Recall | <p>NHRA initiates this FSN due to damaged clear retainer ring within MiniMed™ 600 series insulin pump causing a loose reservoir that can no longer be locked into the pump. The reservoir can become loose due to a broken or missing retainer ring that prevents a proper lock.</p> <p>the reservoir is not properly locked into the pump, the improper locking could lead to over or under delivery of insulin, which could then result in hypoglycemia or hyperglycemia. Severe hypoglycemia can be life-threatening or may result in death.</p> |
| Action should be taken | <p>Please stop using the above mentioned medical device and contact the authorized representative Universal Medicals at dhanya@ume-bh.com to take the necessary action for recall.</p> |

Your cooperation is highly appreciated in improving health services in the Kingdom of Bahrain.

For more information please contact Medical_Devices@nhra.bh