

Safety Communication

Temperature of Dialysis Fluid May Be outside Programmed Values

Device/ Product Description:	Dialog+ Hemodialysis Machines
Brand Name:	B Braun
Lot numbers/Serials:	Software versions 9.xx (excluding versions 9.18, 9.1A, 9.1B)
Manufacturer:	B Braun Medical Inc
Problem:	<p>It has been identified that if the temperature sensor at the Dialyser inlet (TDSE) experiences a malfunction, the Dialog+ machine may try to incorrectly heat or cool the dialysis fluid anywhere between 33 and 41°C.</p> <p>The machine will continue to operate but will not alarm to indicate that the temperature of the dialysis fluid is $\pm 1^\circ\text{C}$ outside its prescribed value.</p> <p>Implementing the service kit SW9.1B will resolve this issue.</p> <p>If the temperature of the dialysis fluid falls below 33°C or exceeds 41°C at the temperature sensor in the machine, treatment will stop and the machine will alarm.</p>
Recommendation/ Actions:	<ul style="list-style-type: none"> • Contact the manufacturer to obtain service kit SW 9.1B or to schedule machines for a service upgrade. • Ensure this upgrade is scheduled at the next planned service, prioritising patients who use this machine at home. • Whilst waiting for the scheduled upgrade: <ul style="list-style-type: none"> ○ Be aware of the potential for incorrect dialysis fluid temperatures whilst patients are undergoing treatment. The machine will alarm and stop treatment if the temperature goes outside the range 33 to 41 °C. ○ Consider adding a check for dialysis fluid temperature if a patient complains about unexpectedly feeling warmer or cooler than usual during treatment. <p>You can find more information and recommendations from (HERE).</p>



You **should** be aware of the mentioned risks in the notice and **contact** the Authorized Representative of your product for corrective action.

Healthcare Professionals should **report any adverse events** suspected to be associated with affected devices above (or other Medical Devices) to:

[National Center for Medical Devices Reporting.](#)

Medical Devices Sector

Saudi Food and Drug Authority

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Or

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Sincerely,
NCMDR Team