

Please forward this to all users and biomedical staff concerned

Subject: Offline mode

Products affected: Jostra HL30

Dear Jostra HL30 users,

It has come to our knowledge that in rare cases the offline mode will not be possible to activate as intended.

Our HL30 safety concept includes the possibility of running the pumps in offline mode which adds additional safety during the unlikely event of communication problems.

If the pump control module (PCM) report "No COM" on the screen during perfusion, try to set the pumps offline and run them in offline mode.

During offline mode the pumps are operating without alarms and interventions. Please read the user manual for more information.

If PCM-screen however reports an error other than "No COM", the pumps need to be restarted by a power switch (off/on) in order to reset the pump alarms before the pumps can be put into offline mode.

If it is not possible to set the pumps in offline mode with the normal procedure, please perform following backup procedure.

- Switch off all pumps and the monitor switch.
- When the control unit panel (monitor) turns black, the pumps can be switched on and set into offline mode.
- Leave the monitor switch in its off position and run the pumps.

In worst case it can take several minutes from the monitor switch off until the control unit panel turns black. Hand cranking the pump may be necessary. A normal shutdown time is approximately 30 seconds.

Please note:

- It is not possible to restart the pump during hand cranking.
- It is not possible to set the pump in offline mode if the lid is open or if the flow adjustment knob is not zero.

Please read the user manual regarding emergency procedures to consider and practice.

Picture from HL30 User's manual

Switch panel

A. Mains power switch - Switch off when not using the HL 30.

B. Mains power operation light - Lit during mains power supply operation.

C. Monitoring system switch - The Indicator is lit when the switch is on.

D. Pump (and electric venous clamp) switches - An Indicator is lit when the corresponding switch is on.

E. Battery operation light - Lit during battery operation.

F. Battery charging light - Lit when the batteries are being charged. Not lit when the batteries are fully charged.

WARNING! Once the monitoring system has been switched off using either the Monitoring switch or the mains power supply switch, it will take approximately 1.5 minutes to restart monitoring. However, pumps can still be run in off-line mode.

Note: Unplugging the system from the mains power supply will not shutdown the system. The system will be operated using the internal battery.

We strongly recommend to discuss the contents of this letter within your team of perfusionists and to assure the availability of hand cranks during perfusion at all times.

We apologize for any inconveniences this has caused you. If you have questions or require additional information regarding the content of this letter, please contact your local MAQUET representative.

Sincerely,



Vice President, Quality Management



Product Manager, Perfusion systems

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MAQUET

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Att. MCC-Q

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Confirmation of completion

Safety Alert Letter 2006-11-21

Product Name: Jostra HL30

Subject: Offline mode

We herewith confirm that all customers concerned have received this Safety Alert Letter.

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Country

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Name of Med Country Manager

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Date

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Signature