

Supplement

Fabius MRI

WARNING

To properly use this medical device,
read and comply with the instructions
for use and this supplement.

**Anesthesia Workstation
Software 3.n**

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Supplement to the instructions for use

This supplement applies to Fabius MRI with part number **9039036** and SW 3.n.

The supplement updates the information of the instructions for use in the following chapter:

- Keep this supplement with the instructions for use of the medical device.

Appendix – Daily and Pre-use Checkout Form

Please note that this Daily Pre-use check list takes into consideration all possible configurations of the Fabius MRI. The clinician need only use those areas that apply to their specific Fabius MRI configuration.

All checks must be carried out daily before equipment is used. The person who carries out the checks must be fully conversant with the Supplement. Checks marked with a **P** must be carried out before each patient use. These pages should be removed and copied to establish a daily record of machines checks.

Mark each function when checks have been satisfactorily completed.

**Fabius MRI
Serial Number**

Pre-conditions

- Inspection intervals for machine and accessories are current
- P** Machine fully assembled and connected
- Monitors (O₂, P, V, CO₂, anesthetic agent) (when present) switched on and functioning, self test carried out satisfactorily
- System diagnostics for Fabius MRI carried out

- P** Sampling line for gas monitoring (when present) connected to Luer Lock on the Y-piece, correct anesthetic agent selected

Checking Reserve Power

- P** Verify that battery is fully charged. (If the battery does not show full a charge, the battery operation time is not guaranteed to be 45 minutes.)

Checking the Medical Gas Connections

- Visually inspect all gas supplies from the medical gas pipeline system and cylinders to make sure that they connect properly and fit securely
- Verify that all medical gas pipeline supplies are within acceptable pressure ranges.
- Open reserve gas cylinders (when present).
- O₂ pressure more than 1000 psi (70 kPa x 100)
- N₂O pressure greater than 600 psi (43 kPa x 100) if present
- AIR pressure greater than 1000 psi (70 kPa x 100) if present
- Close reserve gas cylinders.

O₂ Flush Function

- Press O₂ flush: A strong flow of gas should be emitted from the patient connection.
- Release O₂ flush button: flow of gas from patient connection stops.

Checking the Flow Control/Metering System

- Activate ManSpont mode.
- Fully open the O₂ metering valve. O₂ flow of at least 10 L/min present.
- Close air metering valve. Fully open the N₂O metering valve. N₂O flow of at least 10 L/min present.
- Verify that the float ball of the total fresh gas flowmeter moves up.
- Turn off the O₂ supply. Remove the O₂ connector and close the O₂ cylinder valve. The O₂ Low Supply Pressure Alarm LED is blinking. N₂O does not flow.
- Verify that the float ball of the total fresh gas flowmeter shows 0 L/min.
- Restore the O₂ supply: N₂O flow is present.
- Set O₂ metering valve to 1.5 L/min. N₂O flow = 3 L/min to 5 L/min
- Close the O₂ metering valve: No N₂O flow.
- Open the AIR flow control valve. Air flow of at least 10 L/min present.
- Close all metering valves.

Sensor Calibration

- Remove O₂ sensor housing from inspiratory valve dome
- Calibrate O₂ sensor
- Calibrate flow sensor
- Replace O₂ sensor

Checking the Gas Type

- Set the O₂ metering valve to approx. 3 L/min.
- Verify an O₂ concentration indication of approx. 100 vol. %.
- Close O₂ metering valve.

Vapor 2000

- P** Fastening; Latched down firmly and set vertically
- P** Handwheel; In zero position and engaged
- P** Filling level between min. and max.
- P** Interlock; Locking function OK (when present)
- P** Key-indexed filling system; Sealing key or pin inserted and closed tight. (when present). Filler opening locked shut.
- P** Quik Fil or Funnel filling system; Locking screw tight (when present)

Checking the Condition of CO₂ Absorbent

- P** Color change is no more than half the canister of CO₂ absorbent.

Testing the PAW sensor

Switch to standby mode and press the function key for the leak test.

- Close all fresh gas valves.
- Fit the Y-piece to the fixture on the bag holder.
- Seal the sample line connection, if necessary.
- Remove the hose of the connection socket for the breathing pressure sensor on the rear.
- Check the pressure display on the leak test start screen: "0" to ± 2 is OK. If the deviation is greater, contact DrägerService.

- Reconnect the hose of the connection socket for the breathing pressure sensor on the rear.

Leak Testing the Fresh Gas Circuit

Test once without the vaporizer and once with each Dräger Vapor with the handwheel set to zero.

- Go to Standby and press the Leak Test soft key.
Follow the instructions on the screen.

If the system leaks (i.e. pressure drops):

- Check that all plug-in, push-fit and screw connectors fit tightly.
- Replace any missing or damaged seals. If necessary, call DrägerService or your local authorized service organization.

Inspiratory and Expiratory Valves (Compact Breathing Systems)

- Press the ManSpont key and confirm.
- Set APL-valve to MAN position and adjust to 30 cmH₂O (hPa).
- Press O₂ flush.
- P Breathing bag for manual ventilation fills
- P Inspiratory and expiratory valve discs move freely when the breathing bag is squeezed and released.

Pressure-Limiting (APL) Valve (Compact Breathing System)

- P Set APL valve to MAN and 30 cmH₂O (hPa).
Set fresh gas flow to 20 L/min.
- P Press the ManSpont key and confirm.
- P When the pressure waveform on the Breathing Pressure Trace window stabilizes (e.g., a flat line), flip the APL-valve to SPONT to release pressure.
- P Peak pressure display on monitor reads 24 to 36 cmH₂O (hPa).

Checking Ventilator Operation

- P Connect a breathing bag to the Y-piece to act as test lung.
- P Press the Pressure Control key and confirm.
- P Check that ventilation measurements are displayed.
- P Check that the ventilator piston is cycling.
- P Monitor the operation of the inspiratory and expiratory valve discs.
- P Check that the breathing bag (test lung) on the Y-piece is ventilating.
- P Press the Standby key and confirm.

Monitors

The alarm function can be tested by setting alarm limits to levels that are certain to trigger an alarm.

Check the alarm limit settings. The monitor alarm limits are automatically set to a default configuration when the ON/OFF switch is turned on. Check these settings and adjust them if necessary. Alarm limits can be adjusted at the beginning of or during a procedure. Also, make sure that any external monitors (if any) are connected properly.

Test the alarm functions for all monitors. Simulate alarm conditions and check for appropriate alarm signals.

- Test the O₂ monitor and alarm module.
- Test the volume monitor and alarm module.
- Test the pressure monitor and alarm module.
- Press the Standby key and confirm.

Additional Monitors (when present)

- Check the CO₂ monitor and alarm module.
- Check the anesthetic agent monitor and alarm module.

Anesthetic Gas Scavenging System

- P Check the hose connections.
- P Adjust the flow regulator to place the float between the "Minimum" and "Maximum" marks.
- P Change to Man/Spont mode.
Press and hold the O₂ flush button and verify that airway pressure is <10 cmH₂O (hPa) with Y-piece occluded.
Wait until flow curve is refreshed.
- P Close all flow control valves on the machine, with Y-piece occluded, and verify that airway pressure is ≥0.5 cmH₂O (hPa).

Manual Ventilation Bag for Emergency Ventilation

- Check that the bag is functioning correctly by pumping manually.
 - When the bag is squeezed, air must audibly and tangibly flow out of the mask cone; when the bag is released, it must rapidly recover its original shape.
 - Block off the mask connector (cone) with the ball of your thumb: you should only be able to squeeze the bag a little.
- P **Before Connecting to Patient**
Verify that
- all vaporizers are off (the handwheels are set to zero),
 - the APL Valve is set as desired,
 - all flowmeters indicate 0,
 - the patient suction is level adequate, and
 - the breathing system is ready to use (the bag is in place and all hoses are connected properly)

If any check can not be carried out satisfactorily, the machine must not be used.

Daily Checkout Signature

Name	
Date	

Pre-use Checkout Signature

Name	
Date	

Pre-use Checkout Signature

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Dräger reserves the right to make modifications
to the device without prior notice.

