SERVICE MANUAL

MEDICAL DEVICE FOR AIRWAY CLEARANCE

KALOS

CE 1936

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1. Specifications

This chapter details the specifications for KALOS device.

1.1 Environmental

	Operating	Storage
Temperature	5°C to 38°C	-25°C to 5°C 5°C to 35°C (non condensing to 90%) 35°C to 70°C (to 50hPa)
Relative Humidity	15 to 90% (non condensing)	
Atmospheric Pressure	700 to 1060hPa	NA

1.2 Physical

Dimensions and weight: 27 x 30 x 18 cm – 2,9kg.

1.3 Electrical

AC Voltage Source	100 to 240V AC, 50/60 Hz
DC Voltage Source	12V DC, 3.2Ah NiMh
Type of Protection Against Electric Shock	Class II
Degree of Protection Against Ingress of Water	Exposure Protection, IP21
Degree of Protection Against Electric Shock	Type BF Applied Part
Mode of Operation	Continuous

1.4 SD Card

Use only SD Cards from Medical Products Research.

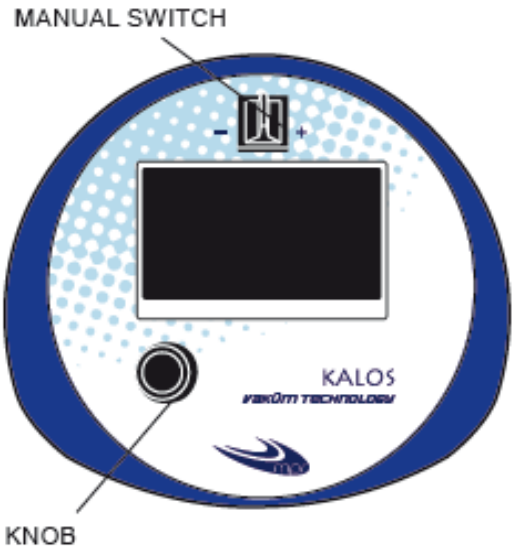
1.5 Accuracy

Parameter	Range	Accuracy
Pressure	-70 to 70 cmH_2O	± 5 cmH_2O
Inhale time	0.5 to 5 s	± 0.1s
Exhale time	0.5 to 5 s	± 0.1s
Pause time	0 to 10 s	± 0.1s
Vibration frequency	1 to 20 Hz	±10% of set value
Vibration amplitude	1 to 10 cmH_2O	± 3cmH_2O

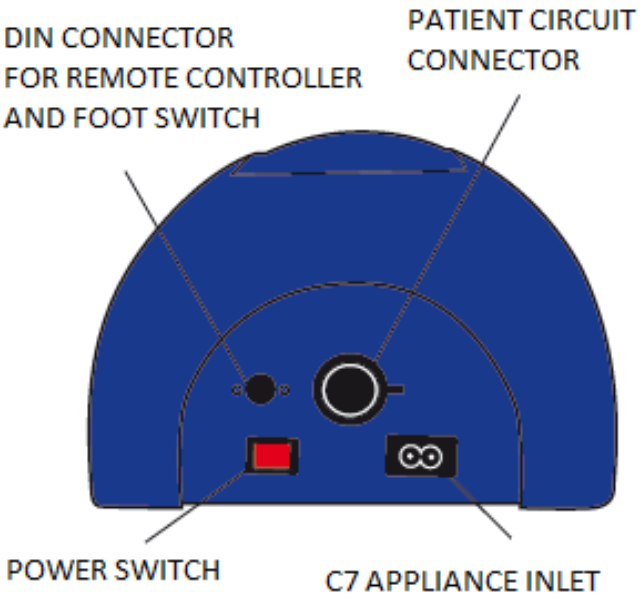
2. System overview

This chapter details the specifics of KALOS device.

2.1 Front Panel Features



2.2 Back Panel Features



Monitor Screen Content

Symbol	Description
	Full access symbol: displays if clinical mode is enabled.
	Alarm signal
	Cancel choice
	Save choice
	low battery, broken battery or missing battery
	Battery 20% charged
	Battery 40% charged
	Battery 60% charged
	Battery 80% charged
	Battery 100% charged
	Charging indicator
	Mains supply without battery charging (battery charged or cooling down)

3. Troubleshooting

This chapter identifies the error messages that may appears on screen and identifies necessary troubleshooting procedures. It should be used by service technicians to help diagnose problems with KALOS device, along with determining what parts, if any, need to be replaced.

3.1 Error messages

Message	Description
FAULT ALARM: type 001 param 002	Errore turbina - overvoltage
FAULT ALARM: type 001 param 004	Errore turbina - undervoltage
FAULT ALARM: type 001 param 032	Errore turbina – speed regulation
FAULT ALARM: type 001 param 128	Errore turbina – SW error
FAULT ALARM: type 002 param ---	Errore motore in/ex
TECH ALARM: type 001 param ---	Errore scrittura EEPROM
TECH ALARM: type 002 param---	Errore lettura EEPROM
TECH ALARM: type 003 param ---	Timeout su bus (EEPROM o sensori)
TECH ALARM: type 004 param ---	Errore interno MCU
TECH ALARM: type 005 param---	Timeout specifico EEPROM

3.2 Troubleshooting

Q: Why my device doesn't turn on?

A: If you are using AC power: Check the outlet and verify that the device is properly plugged in; Make sure there is power available at the outlet and that the AC power cord is connected correctly to the power supply and the power supply cord is securely connected to the device's power inlet.

If you are using a battery power source: Make sure your DC power is charged checking the battery icon on the display; check if broken battery is displayed. It may need recharged or replaced.

Q: Why the airflow doesn't turn on?

A: Make sure the device is powered correctly; make sure you pressed the "start therapy" button on the display.

Q: Why is the airflow much warmer than usual?

A: The air filters may be dirty. Clean or replace the air filters; The temperature of the air may vary somewhat based on your room temperature. Make sure the device is properly ventilated, placed on a stiff surface, away from bedding or curtains that could block the airflow. Make sure the device is away from direct sunlight and heating equipment.

Q: Why doesn't my manual switch work?

A: The manual switch only works when therapy is active in Manual Mode and when the optional Foot Pedal is not attached.

3.3 Troubleshooting table

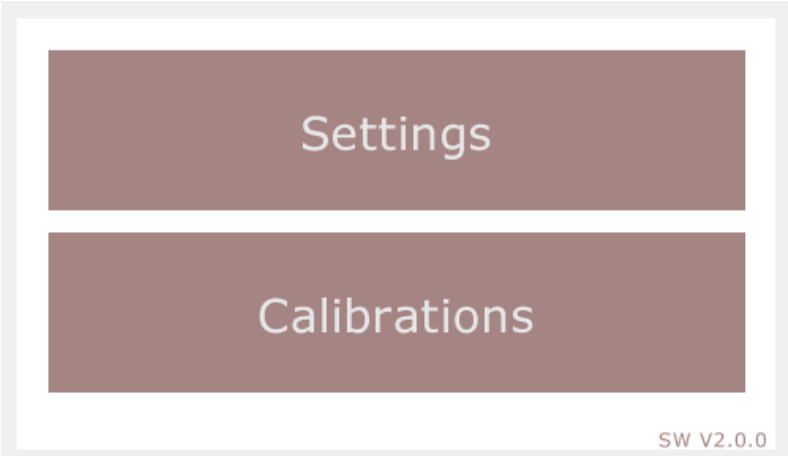
DEVICE ACTION	POSSIBLE CAUSES	CORRECTIVE ACTION
Unit does not power ON	- No power available - Failed power cord - Failed AC inlet cable - Failed DC power inlet cable - Failed main board - Failed power board - Failed power supply	- Verify AC power and charged battery - Replace power cord - Replace AC inlet cable - Replace DC power inlet cable - Replace main board - Replace power board - Replace power supply
Unit power ON but blower does not start	- Blower not connected to main board - Blower faulty - Main board faulty	- Check connection from blower to main board - Replace blower - Replace main board
Unit power ON but immediately an error occurs	- Motor not connected - Motor not working - Anterior Optical sensor not working	- Check the connection from motor to main board - Replace motor - Replace anterior optical sensor
Toggle switch locked up	- Faulty toggle switch - Faulty main board	- Replace toggle switch - Replace main board
Pressure variation during operation	- Failed blower - Failed device's central core	- Replace blower - Check or Replace device's central core

	- Internal leak - Failed oring or seal	- Replace oring or seal
Device not achieving max pressure	- Failed blower - Failed device's central core - Internal leak - Failed oring or seal	- Replace blower - Check internal leak or Replace device's central core - Replace oring or seal
Device not achieving max flow	- Failed blower - Failed device's central core - Internal leak - Failed oring or seal - Failed air filter	- Replace blower - Check internal leak or Replace device's central core - Replace oring or seal - Replace air filter
Timing therapy incorrect	- Failed main board - Failed motor	- Replace main board - Replace motor
Noisy therapy	- Obstruction in the tube	- Clear obstruction
Battery not charging	- Failed power board - Failed battery - Failed battery cable	- Replace power board - Replace battery - Replace cable
Failure to recognized SD card	- Failed main board - Corrupted SD card	- Replace main board - Replace SD card
Free Aspire circuit not recognized	- Failed optical sensor	- Replace posterior optical sensor

4. Settings

Technical menu access: move the manual switch to "+" symbol (to the right) and in the meanwhile press the control knob and switch on the device pressing the power switch on the back of the device.

The following screen shows:

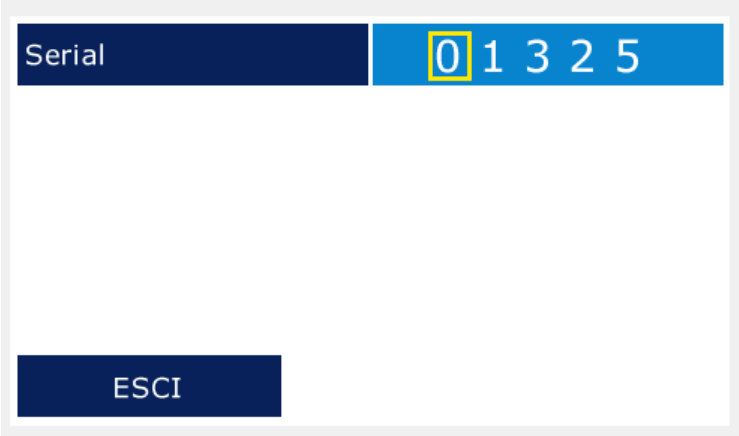


Selecting "Settings" it is possible to set date and hour, as shown in the figure below:

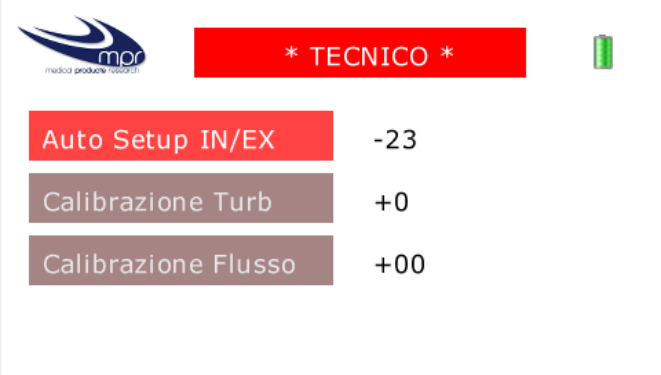
Press the knob to can change the parameter value: the parameter is modifiable when the background is white:

Rotate clockwise or anticlockwise the knob, in order to increase or decrease, respectively, the parameter value.

From this screen press the knob for 5 seconds in order to set the serial number of the device

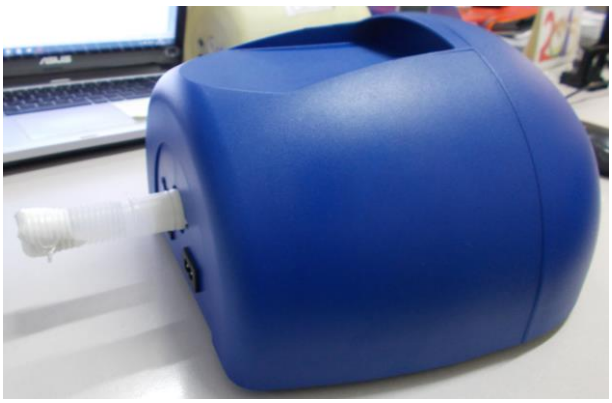


By selecting "Calibrations" it is possible to access to the three automatic calibrations that the machine needs for its correct functioning. Stepper motor , blower and



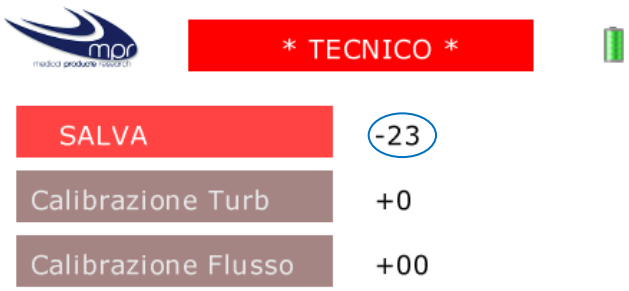
1. Auto setup IN/EX

   The procedure needs to be done with the patient circuit connection completely closed (use the suitable cap), as illustrated in figure below



Select Auto Setup IN/EX and press the control knob.

The calibration is automatic and will be completed when the writing “In corso…” changes into “Salva”.
Press the control knob to save the calibration.



In order to be sure the calibration finishes with success, take in mind the final value (in the blu circle) and repeat the calibration at least another time. The new value must be similar to the first one (accuracy ±1). If the two values are different, make sure of the device is assemble correctly and that the three silicone tubes are connected to the sensors.

2. Calibrazione Turb
   The procedure needs to be done with the patient circuit connection completely closed (use the suitable cap), like the first one
   Select Calibrazione Turb and press the control knob

Press the control knob to start the calibration.

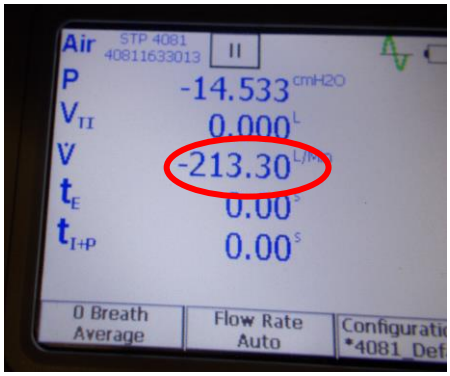
The calibration is automatic and will be completed when the writing “In corso…” changes into “Salva”.
Press the control knob to save the calibration.

The value that appears is always zero.
During the calibration, the value next to “Calibrazione Flusso” will first decrease and then increase.
Be sure that the value next to “Calibrazione turb” surpass 70 in positive and -70 in negative

3. Calibrazione Flusso
   The procedure needs to be done connecting the flow analyzer TSI to the device. After the flow analyzer, connect at least half meter of tube without closing it. The correct set up is in the following image

Select Calibrazione Flusso and press the control knob

A green editable value will appear on the screen



The procedure is the following:
Wait for the black value is stable (in the black circle), read the instant flow value on the TSI screen ($\dot{V}$ in l/min in the red circle), rotate the control knob as long as the green value (in the green circle) is equal to the value read by TSI (round off the value). Reached the equivalence, press the knob to confirm it.
The calibration automatically will change value. Repeat the procedure till the end.

If the black value next to “Calibrazione Flusso” is very different from the green value (like 1400), the flow sensor needs to be reset. In order to make the reset, press “Calibrazione Flusso” without the TSI. Press the knob at each level without changing the value.

5. Final test

In order to ensure the correct functioning of the KALOS device:

- Verify that it can be turned on;
- Verify the zero of the device: plug the airflow exit placed on the rear of the device and set a manual program of the cough assist mode (e.g. pressure: 40 cmH2O, inhale time: 3 s, exhale time: 3s, pause time: 2 s). Start the therapy and verify that during the pause time the pressure level read by the machine is zero. Repeat the procedure at least five times;
- Using a flow analyzer, check the airflow provided by the device: set the maximum inhaling and exhaling pressure (equal to +/- 70 cmH2O) and verify that the airflow is between 190 and 250 l/min.
- Verify the free aspire mode (flow and connector identification) following the values in the table below (accuracy ±2l/min)

Free Aspire level	Flow [l/min]
1	19.6
2	27.2
3	38.2
4	48.2
5	58.2

- Verify the peak test at the three levels

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