

Instructions for use

Valid from software ver 1.6.0



Updates and new features

Information in this addendum supersedes any overlap in the Instructions For Use (“IFU”) released prior to 2021-10.31. All O2matic PRO devices with software version 1.6.0 or later have received following new updates and features:

- **Battery Mode:** When changing to battery mode, the top and bottom part of the home screen turns red, and a warning appears on the screen, notifying that the battery mode is initiated. This warning disappears after 10 seconds.

If the battery capacity is at a critical level the warning reappears with a “shut down eminent” warning.

- **Automatic mode:** The active treatment mode has been updated to be more adaptive to patients. O2matic PRO 100 will react faster on a change in high flows compared to low flows.

Flow response can only be changed in the settings file (see section 2.4 in the IFU). All default profiles have the same flow response, except the “Walking” profile. (See table A5).

- **Pulse range:** (see section 3 – alarm updates):
 - User can set minimum heart rate between 40 and 80 BPM
 - Minimum pulse critical alarm limit is 40 BPM.
 - Maximum pulse critical alarm is 200 BPM
 - If a pulse alarm limit is set to higher than 150 BPM, it is considered a risky profile.
- **Menu:**
 - It is possible to secure access to the admin menu with a pin code. To enable the feature, go to admin – settings – security and enable admin pin.
 - Pause screen can be changed to not show physiological parameters.
 - Pause screen timer can be set between 1 minute and 2 hours.
 - Font colors in menu changed to be more visible

New feature – Patient wizard

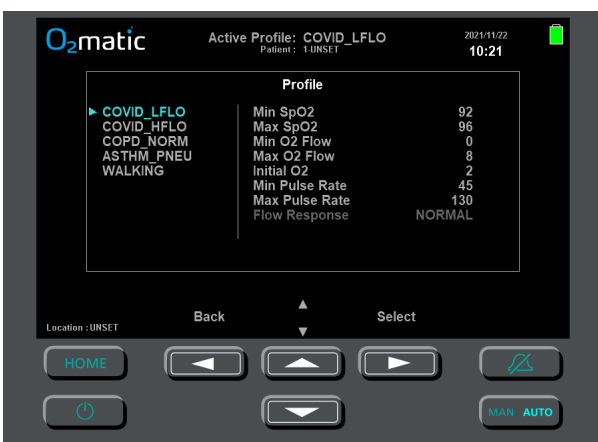
This section replaces section 3.1 in the IFU.

When pressing 'Patient' on the home screen, the following menu will appear:



Follow the instructions on the screen to setup a patient setup. The patient configuration parameters consist of:

- Patient ID
- Patient Name
- Location (descriptive)
- Oximeter alarm delay (can be set to 'No delay', 1 minute, 2 minutes and 5 minutes.)
- Profile selection



Alarm updates

Critical profiles (described in chapter 4.3 of the IFU) have been updated to also include broader pulse ranges. The O2matic now supports a pulse rate up to 200, however if a setting higher than 150 is chosen the profile is considered risky and the user is notified with a warning.

The following possible alarm definitions and events replaces the ones described in section 5.3 of the IFU.

Type	Visual indications	Audible	Audio Alarm Signal Priority	Audible indications	Delay
Warning	Yellow font (constant)	Yes	None	None	None
Alarm	Blinking orange font	Yes	Medium	3 beeps every 10 sec	2 minutes
Critical alarm	Blinking red font	Yes	High	10 beeps repeated every 5 sec	None

Figure 3: Alarm level indicators

Area	Visual indication	Alarm type	Alarm description	Solution
SpO ₂	SpO ₂	Warning	SpO ₂ higher than defined	Verify patient condition
	SpO ₂	Warning	SpO ₂ 1-3 % below defined	Verify patient condition
	SpO ₂	Alarm	SpO ₂ more than -3% below defined	Verify patient condition
	SpO ₂	Critical Alarm	SpO ₂ lower than 80%	Verify patient condition
Pulse	Pulse	Alarm	Pulse higher than defined	Verify patient condition
	Pulse	Alarm	Pulse Lower than defined	
	Pulse	Critical Alarm	Pulse higher than 200 BPM	
	Pulse		Pulse lower than 40 BPM	
Signal	No signal	Alarm	No signal from oximeter for <u>fewer</u> than 300 secs (adjustable)	Readjust the sensor on the patient's finger
	No signal	Critical Alarm	No signal from oximeter for <u>more</u> than 300 secs (adjustable)	
	No signal		Oximeter power failure	Restart device, if alarm persist O ₂ matic needs service
	Not connected		Not connected to oximeter	Connect the oximeter to O ₂ matic. If the problem persists, send O ₂ matic for service
Oxygen	Flow Error	Critical Alarm	Incorrect O ₂ flow into device	Check oxygen source. If problem isn't from source O ₂ matic needs repair
	O ₂	Alarm	Oxygen control error	Check oxygen source. If problem isn't from source O ₂ matic needs repair
Power /Battery	Check status	Critical alarm	"Battery failed" under device status	Restart device, if alarm persist O ₂ matic needs service
	Battery symbol alarm constant	Alarm	Low battery	If device has been without external power, recharge the battery. Else have the battery changed

	Check status Battery symbol alarm blinking	Critical alarm	Critically low battery	If device has been without external power, recharge the battery. Else have the battery changed. It is not recommended to use device in this alarm state
	Power symbol alarm blinking	Alarm	No power	Connect power adapter to power source and to O ₂ matic

Device	Check status	Alarm	Memory fail	Restart device, if alarm persist O ₂ matic needs service
	Sensor error	Critical alarm	Oximeter sensor	O ₂ matic needs service
	Check status	Alarm	Acoustic alarm	Restart device, if alarm persist O ₂ matic needs service
	Check status	Alarm	Back up circuit	
	Check status	Alarm	Memory full	Do full export of patient data, if alarm persist reset device to factory default, if alarm persist O ₂ matic needs service
	Check status	Alarm	Valve	Restart device, if alarm persist O ₂ matic needs service
	Check status	Alarm	Flowmeter	

Figure 4: Possible alarm events

Appendix A – Detailed Specifications

Table A1 - Input validation:

Validation Type	Validation Rate
Heart rate alarm upper limit input range	85 – 150 BPM
SpO ₂ alarm limit input range	80 – 100 %
Oxygen flow - O ₂ matic mode	0 – 15 l/min
Oxygen flow - Manual mode	0 – 15+ l/min*
Oximeter Signal Alarm delay	0 – 300 secs

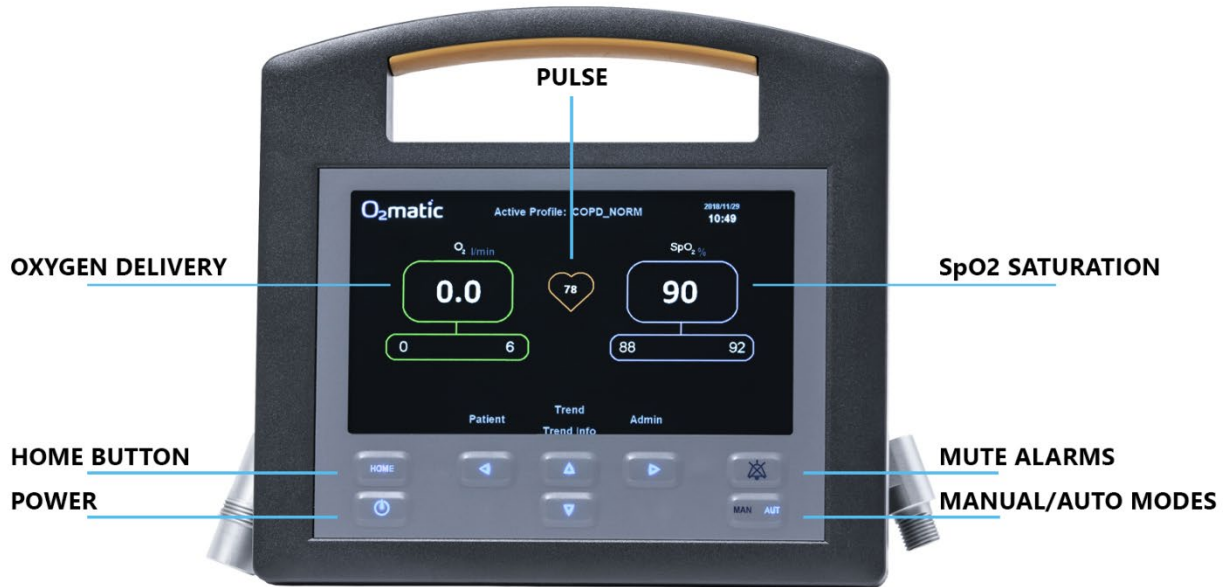
* In manual mode flow it is possible to open up the valve at maximum. When doing this the O₂matic device shows 15+ l/min and shows a warning of “inaccurate flow”. The actual output is based on current oxygen source. At 4 bars pressure input the O₂matic delivers 30 l/min.

Table A3 - Default settings table

Default Type	Default Value
Pause screen timer	30 mins
Pause screen layout	Vitals
Mute button timer	120 secs
Oximeter Signal Alarm delay	60 secs
Mode	O ₂ matic

Table A5 – Factory set profiles

Name	Min SpO ₂	Max SpO ₂	Min O ₂ Flow	Max O ₂ Flow	Initial O ₂ Flow	Max Pulse rate	Flow response
COVID_LFLOW	92	96	0	8	2	130	NORMAL
COVID_HFLOW	92	96	0	15	5	130	NORMAL
COPD_NORM	88	92	0	6	2	130	NORMAL
ASTHM_PNEUM	94	98	0	10	3	130	NORMAL
WALKING	90	94	0	15	2	150	FAST



This user manual booklet is current as of January 2022. For information of device updates and news please visit

www.o2matic.com

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