

MIR SMART ONE OXI data sheet

code 911120xx



Technical specification

Width	49 mm
Length	109 mm
Thickness	21 mm
Weight	60.7 g (batteries included)

Turbine



Single Patient Reusable Turbine with Mouthpiece (code 910013)

Mouthpiece	Ø 30 mm (1.18 inches)
Power supply	2 batteries AAA 1.5 V
Consumption	max 12 mA average 8 µA (Stand by)
Lifetime	5 years
IP protection level	IP22
Connectivity	Bluetooth® 5.0 ready
Type of electrical protection	Internally powered
Safety level for shock hazard	Type BF Apparatus
Conditions of use	Apparatus for continuous use
Storage conditions	Temperature: MIN -25 °C, MAX + 70 °C Humidity: MIN 10% RH; MAX 93% RH
Operating Conditions	Temperature: MIN + 5 °C, MAX + 40 °C Humidity: MIN 15% RH, MAX 93% RH
Shipping conditions	Temperature: MIN -25 °C, MAX + 70 °C Humidity: MIN 10% RH; MAX 93% RH

Spirometry

Flow sensor	bi-directional digital turbine
Flow range	16L/s (960 L/m)
Volume range	10 L
Volume accuracy	±2.5% or 0,05 L

Peak Flow accuracy	±10% or 0,33 L/s
Dynamic resistance	<0.5 cm H ₂ O/L/s (@ 12 L/s)
Temperature sensor	none
Available test	Peak Flow
Measured parameters	FEV1, PEF
Memory capacity	the application on the remote device (smartphone/tablet) stores data

Oximetry

Measuring method	double wavelength
%SpO ₂ range	70%-100%
%SpO ₂ accuracy	±1.9%
Average number of beats for the calculation % SpO ₂	12 beats
Pulse Rate range	30-200 BPM
Pulse Rate accuracy	±2 BPM
Average interval for BPM calculation	12 seconds
Quality signal indicator	0-8 lines
Available tests	spot
Measured parameters	%SpO ₂ MIN, %SpO ₂ MEAN, %SpO ₂ MAX, BPM _{MIN} , BPM _{MEAN} , BPM _{MAX} , T _{TOTAL}
Wavelength sensors	Red 660 nm Infrared 880nm

Maximum optical output power	1.2 mW
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Certification & registration

CE 0476	MDR 2017/745
FDA 510 (k)	pending
Health Canada	107185 (class II)
EMDN liv.4	Z121501
CND Code	Z12150102
GMDN Code	46906 45607

Applicable standards	ATS/ERS:2005, 2019 Update ISO 26782:2009 ISO 23747:2015 EN ISO 14971:2019 ISO 10993-1:2018 2011/65/UE Directive EN ISO 15223-1:2021 IEC 60601-1:2005 + A1:2012 A2:2020 IEC 60601-1-2:2014 + A1:2020 IEC 60601-1-6:2010 + A1:2013 + A2:2020 IEC 60601-1-11:2015 + A1:2020 ISO 80601-2-61: 2017
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