



|                             |   |
|-----------------------------|---|
| <b>Applicable standards</b> | ATS/ERS Guidelines: 2005<br>ISO 26782: 2009<br>ISO 23747: 2015<br>EN ISO 14971: 2012<br>ISO 10993-1: 2018<br>2011/65/UE Directive<br>EN ISO 15223:2016<br>IEC 60601-1:2005 + A1: 2012<br>EN 60601-1-2: 2015<br>IEC 60601-1-6:2010+Amd2013<br>IEC 60601-1-11: 2015<br>ISO 80601-2-61: 2017 |
|-----------------------------|---|

### Technical specification

|                  |                             |
|------------------|-----------------------------|
| <b>Width</b>     | 49 mm                       |
| <b>Length</b>    | 109 mm                      |
| <b>Thickness</b> | 21 mm                       |
| <b>Weight</b>    | 60.7 g (batteries included) |

### Turbine



Single Patient Reusable Turbine with Mouthpiece (code 910013)

|                                      |  |
|--------------------------------------|--|
| <b>Mouthpiece</b>                    | Ø 30 mm (1.18 inches)  |
| <b>Power supply</b>                  | 2 batteries AAA 1.5 V  |
| <b>Consumption</b>                   | max 12 mA<br>average 8 µA (Stand by)   |
| <b>Autonomy</b>                      | 5-10 years (Stand by)  |
| <b>IP protection level</b>           | IP22   |
| <b>Connectivity</b>                  | Bluetooth® 4.0   |
| <b>Type of electrical protection</b> | Internally powered   |
| <b>Safety level for shock hazard</b> | Type BF Apparatus  |
| <b>Conditions of use</b>             | Apparatus for continuous use   |
| <b>Storage conditions</b>            | Temperature: MIN -25 °C,<br>MAX + 70 °C<br>Humidity: MIN 10% RH;<br>MAX 93% RH |
| <b>Operating Conditions</b>          | Temperature: MIN + 5 °C,<br>MAX + 40 °C<br>Humidity: MIN 10% RH,<br>MAX 93% RH |
| <b>Shipping conditions</b>           | Temperature: MIN -25 °C,<br>MAX + 70 °C<br>Humidity: MIN 10% RH;<br>MAX 93% RH |

### Spirometry

|                            |   |
|----------------------------|---|
| <b>Flow sensor</b>         | bi-directional digital turbine          |
| <b>Flow range</b>          | 16L/s (960 L/m)                         |
| <b>Volume range</b>        | 10 L                                    |
| <b>Volume accuracy</b>     | ±2.5% or 0,05 L                         |
| <b>Peak Flow accuracy</b>  | ±10% or 0,33 L/s                        |
| <b>Dynamic resistance</b>  | <0.5 cm H <sub>2</sub> O/L/s (@ 12 L/s) |
| <b>Temperature sensor</b>  | none                                    |
| <b>Available test</b>      | Peak Flow                               |
| <b>Measured parameters</b> | FEV1, PEF                               |

**Memory capacity** the application on the smart phone memorizes data

### Oximetry

|  |                              |
|--|------------------------------|
| <b>Measuring method</b>  | double wavelength            |
| <b>Range %SpO<sub>2</sub></b>  | 70%-100%                     |
| <b>Accuracy %SpO<sub>2</sub></b>                                     | ±1.9%                        |
| <b>Average number of beats for the calculation % SpO<sub>2</sub></b> | 12 beats                     |
| <b>BPM range</b>   | 30-200 BPM                   |
| <b>BPM accuracy</b>  | ±3%                          |
| <b>Average interval for BPM calculation</b>                          | 12 seconds                   |
| <b>Quality signal indicator</b>                                      | 0-8 lines                    |
| <b>Available tests</b>   | spot                         |
| <b>Measured parameters</b>   | %SpO <sub>2</sub> , BMP      |
| <b>Wavelength sensors</b>  | red 660 nm<br>Infrared 880nm |
| <b>Maximum optical output power</b>                                  | 1.2 mW                       |

### Certification & registration

|                      |           |
|----------------------|-----------|
| <b>CE 0476</b>       | MED 9826  |
| <b>FDA 510 (k)</b>   | pending   |
| <b>Health Canada</b> | pending   |
| <b>CND Code</b>      | Z12150102 |
| <b>GMDN Code</b>     | 46906     |