



# RP Check Operating Manual



MD Diagnostics Ltd  
15 Hollingworth Court  
Turkey Mill  
Ashford Road  
Maidstone  
Kent ME14 5PP  
UK

Tel: + 44 (0) 1622 682686  
Fax: + 44 (0) 1622 681693

Email: [sales@mdd.org.uk](mailto:sales@mdd.org.uk)  
[www.mdd.org.uk](http://www.mdd.org.uk)

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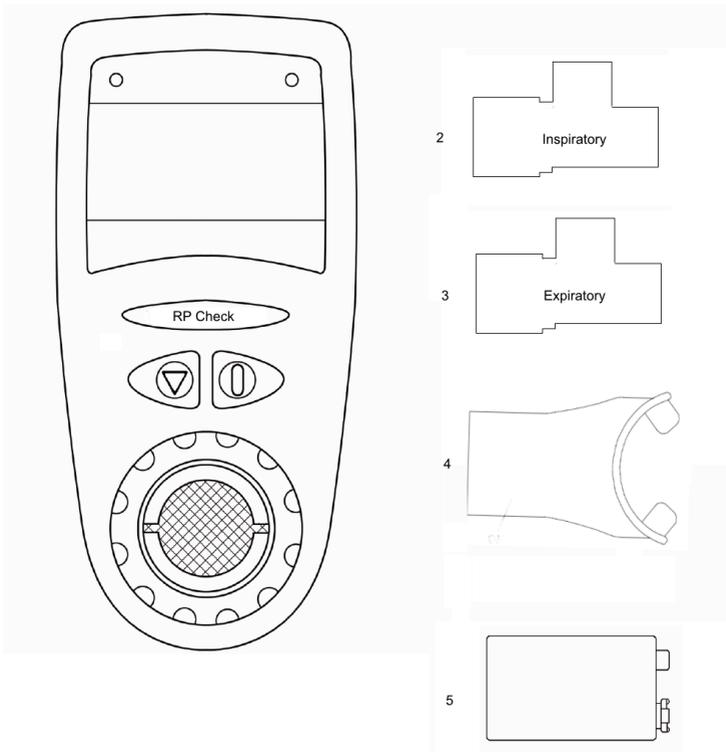
Caution: Federal Law restricts this device to sale by or on the order of a physician (or licenced practitioner)

**1639**

## Package Contents

The RP Check is supplied in a hard-shell carry case containing:

1. RP Check
2. 2 x Pink Inspiratory Test valves with integral bacterial/viral filter (Single patient use only)
3. 2 x Blue Expiratory Test valves with integral bacterial/viral filter (Single patient use only)
4. 4 x Flanged mouthpiece (Single patient use only)
5. PP3 Battery
6. 3 sizes of nasal probe (single patient use)
7. Operating Manual
8. Nasal probe adaptor
9. USB cable
10. USB stick containing RP Check PC software



## Overview

The RP Check is a handheld, portable, battery-operated device used for rapid assessment of respiratory muscle strength. The unit can measure mouth pressures - maximum inspiratory (MIP); maximum expiratory (MEP) pressures and sniff nasal inspiratory pressure (SNIP). The unit measures the pressures generated in cmH<sub>2</sub>O, and these are displayed on the backlit display.

After either the inspiratory or expiratory mouth pressure manoeuvre, the unit will display the maximum average pressure over one second in cmH<sub>2</sub>O. To repeat the test, press the select key  and keep it depressed until the blow icon appears. Additional indices and the pressure/time curve can be viewed by pressing the select key  momentarily.

After a sniff nasal pressure, the unit will display the peak pressure obtained in cmH<sub>2</sub>O for the manoeuvre to repeat the test press the select key and keep it depressed until the sniff icon appears. The pressure/time curve can be viewed by pressing the select key  momentarily.

A Maximum of 10 tests are recorded for reviewing on the display along with the corresponding pressure time curves. For mouth pressure measurements (MIP and MEP) the variation from the best test obtained is also shown and guidance that the ATS/ERS (American Thoracic Society) reproducibility criteria has been met.

Once the patient has been tested the results may be uploaded to the PC software using the USB cable provided, alternatively the unit can be connected to the PC to allow tests to be performed and the results instantly displayed on the PC screen – please see section on PC connectivity.

The unit does not require any form of calibration and is restricted to use in a physician's office or medical healthcare facility.

The device should be used under the guidance of a healthcare professional.

## Intended Use

The RP Check is intended to measure both inspiratory (MIP) and expiratory (MEP) mouth pressures and Sniff nasal pressures (SNIP) generated by a patient after being trained in the technique by a qualified healthcare professional. The RP Check is suitable for both adult and

paediatric patients from 6 years and older, there is no upper age limit providing the patient can comply and perform the test as instructed. Interpretation of the values obtained should only be performed by an appropriate healthcare professional.

## Contraindications

Mouth or nasal pressure testing should be avoided in patients with:

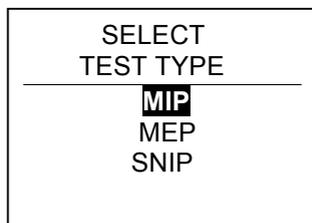
- Aneurisms
- Uncontrolled hypertension
- Urinary incontinence

*T. Trooster et al, Eur Respir Mon, 2005, 31, 57–71*

## Operation

Insert the 9V PP3 battery [6LR61] (supplied) by removing the battery cover and clipping the battery in place, replace the battery cover. The unit will switch ON when the battery is connected. The initial displayed screen is the MD Diagnostics logo along with the version of RP Check.

The display will then change to the below screen requiring the user to select the test type: MIP, MEP or SNIP.



To select the desired test, press the ENTER key holding it down on the highlighted test type and the display will change to show the appropriate manoeuvre. To scroll to a different test type, press the ENTER key to move the cursor to the next option, once the test has been selected and highlighted keep the ENTER key depressed to select that option. A maximum of 10 of each test type can be performed.

If a patient has previously been tested, then the results are stored on the device along with the corresponding mouth or nasal pressure graphs. The options available will then be displayed:

UPLOAD LAST TEST TO COMPUTER?
<b>YES</b>
NO
CONTINUE TESTING

The three options available are:

**YES** – to Upload the current test records to the PC software, to perform this please see section on PC Report.

**NO** – selecting this will change the screen to the test type option.

**NOTE:** If NO is selected, the previous patients' tests will be over written, the device only keeps the last test results in the memory.

**CONTINUE TESTING** – the display will change the display back to the test screen with the last graph displayed, pressing the ENTER key will change back to the test icon and allow tests to be performed.

**NOTE:** The continue testing option allows the previous test type to continue, there is not an option to change the test type – for example if the patient was performing MIP tests and needed a rest and the device turned OFF due to timing out or was turned OFF, the results and graphs are saved on the device and MIP testing will be resumed if the Continue Testing option is chosen.

**NOTE:** Once a test type has been selected the unit will continue giving an audible beep to advise the operator that no flow is currently detected through the unit. Once the patient begins the manoeuvre the audible beep will be longer, to signify the start of the test.

A total of 10 tests can be performed and stored on the RP Check, as tests are performed the storage bar in the top left of the display will slowly become shaded to signify that tests are being stored.

For mouth pressures MIP and MEP tests, if the reproducibility criteria have been met – (3 tests performed and the highest 2 tests are within 20% of each other), a flag will be displayed in the top bar of the display between the test storage icon and the battery icon.

Switch OFF the unit by pressing the power button  and keeping it depressed for 3 seconds, the display will show the symbol  and switch off.

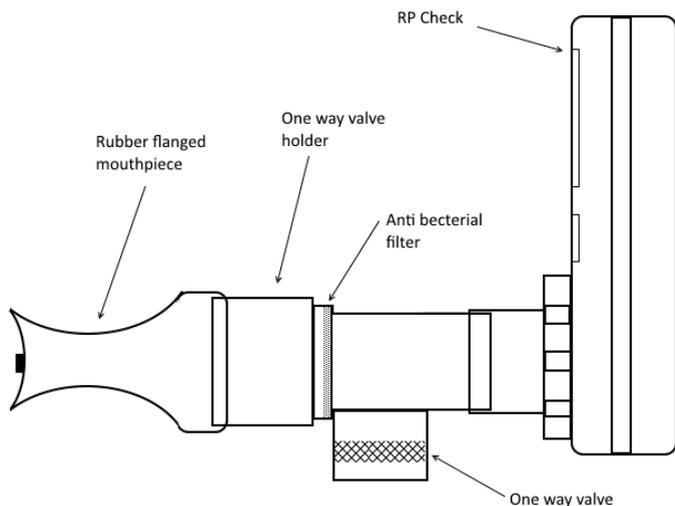
**NOTE:** If the RP Check has been left without being used for 5 minutes then then it will turn itself OFF to save the battery power.

## MIP Test

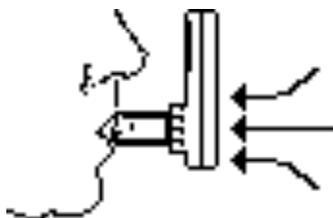
Insert the pink inspiratory disposable T piece valve. Connect the flanged mouthpiece to the valve.



The valves are colour coded and are single patient use and should be disposed of after each patient in accordance with your local infection control policies. The inspiratory T piece valve have a proven bacterial and viral efficacy >99% and offer protection to both patient and device. The flanged mouthpiece is also a single patient use accessory. Failure to dispose of the inspiratory T piece valve and flanged mouthpiece after each patient may lead to cross infection between patients.



Switch the unit ON and select the MIP test, wait for an exhale icon to appear.



Request the subject to insert the mouthpiece into their mouth, ensuring the flange is positioned over the gums and inside the lips, whilst the 'bite blocks' are between the teeth. The subject should exhale as much air as possible to empty their lungs, to residual volume (RV) and then inhale with

as much effort and for as long as possible (minimum 1.5 seconds). If no inhalation has occurred the alarm will constantly make an audible beep indicating it is waiting for a test to be performed, when inhalation starts a longer audible beep will be heard.

The display will show maximum average inspiratory pressure sustained over a one second period of the test - MIP. If the manoeuvre was less than 1.5 seconds, the unit will beep and a stopwatch with an exclamation mark will be displayed indicating that the expiration needs to be longer. When 2 seconds exhalation has occurred, an audible noise will be made indicating the acceptable time period has been met. After each manoeuvre has been performed pressing the select key  momentarily will allow the operator to view the Pressure time trace and the additional indices PMax, PAv, MRPD, and MRR.

Pressing the select key and keeping it held down will change the display back to the MIP blow icon.

It is recommended to perform three good tests and use the best result as the maximum achievable MIP, MEP or SNIP. The ATS recommends for reproducibility that the three tests performed should be within 20% of the highest MIP pressure obtained. As tests are performed the highest value acceptable test (over 1.5 seconds) will be displayed along with a cup to indicate the best test, if subsequent tests are within 20% they will be shown with a smiley face and if not within the 20% reproducibility a sad face will be displayed, indicating further testing should be performed.

**NOTE:** Once three acceptable tests have been performed a flag will be shown at the top of the display to indicate the reproducibility criteria has been met.

- ⚠ The maximum reading the RP Check can measure is equivalent to 300 cmH<sub>2</sub>O. Any reading above that will be displayed as --- (overflow).

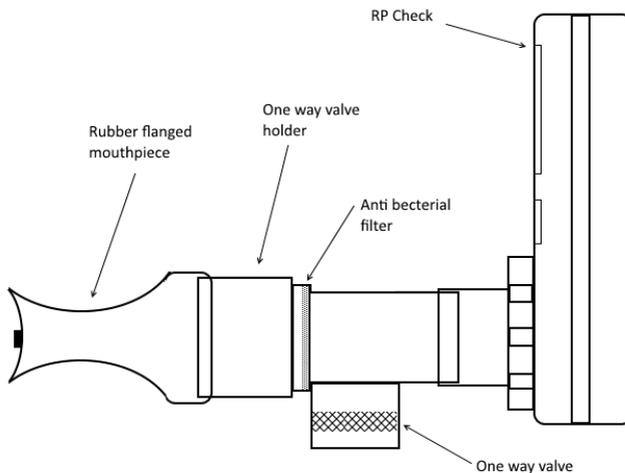
**NOTE:** If the patient does not inhale for the minimum period of 1.5 seconds the display will show the stopwatch icon  pressing the select key  will display the test icon so testing can be repeated

## MEP Test

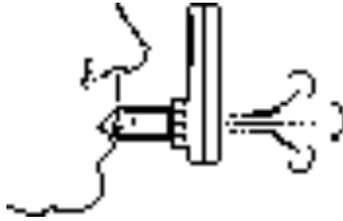
Insert the blue expiratory disposable T piece valve. Connect the flanged mouthpiece to the valve.



The valves are colour coded and are single patient use and should be disposed of after each patient in accordance with your local infection control policies. The expiratory T piece valves have a proven bacterial and viral efficacy >99% and offer protection to both patient and device. The flanged mouthpiece is also a single patient use accessory. Failure to dispose of the expiratory T piece valve and flanged mouthpiece after each patient may lead to cross infection between patients.



Switch the unit ON the unit and select the MEP test, wait for the exhale icon to appear.



Request the subject to insert the mouthpiece into their mouth, ensuring the flange is positioned over the gums and inside the lips, whilst the 'bite blocks' are between the teeth. The subject should inhale as much air as possible until the lungs are fully (Total Lung Capacity – TLC) and then exhale with as much effort and for as long as possible (minimum 1.5 seconds). If no exhalation has occurred the alarm will constantly make an audible beep indicating it is waiting for a test to be performed, when exhalation starts a longer audible beep will be heard.

The display will show maximum average expiratory pressure sustained over a one second period of the test - MEP. If the manoeuvre was less than 1.5 seconds, the unit will beep and a stopwatch with an exclamation mark will be displayed indicating that the expiration needs to be longer. When 2 seconds exhalation has occurred, an audible noise will be made indicating the acceptable time period has been met. After each manoeuvre has been performed pressing the select key  will allow the operator to view the Pressure time trace and the additional indices PMax, PAv, MRPD, and MRR.

Pressing the select key and keeping it held down will change the display back to the MEP blow icon.

It is recommended to perform three good tests and the best result as the maximum achievable MIP, MEP or SNIP. The ATS recommends for reproducibility that the three tests performed should be within 20% of the highest MIP pressure obtained. As tests are performed the highest value acceptable test (over 1.5 seconds) will be displayed along with a cup to indicate the best test, if subsequent tests are within 20%, they will be shown with a smiley face and if not within the 20% reproducibility a sad face will be displayed, indicating further testing should be performed.

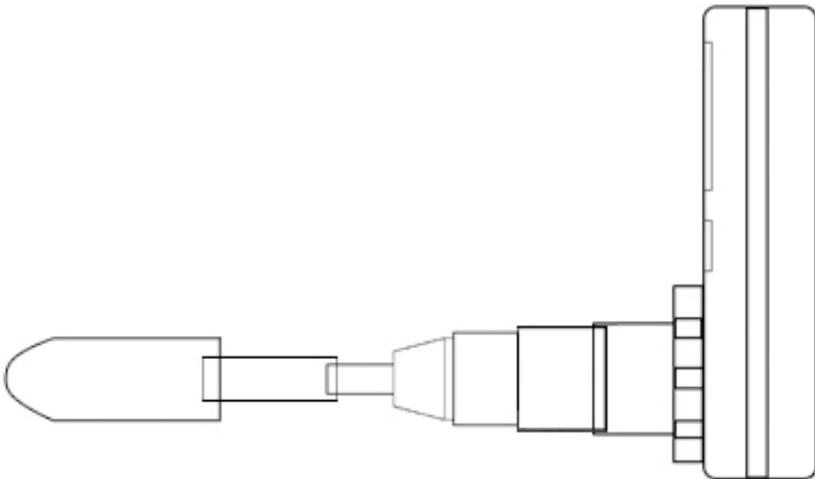
**NOTE:** Once three acceptable tests have been performed a flag will be shown at the top of the display to indicate the reproducibility criteria has been met.

**NOTE:** If the patient does not exhale for the minimum period of 1.5 seconds the display will show the stopwatch icon  pressing the select key  will display the test icon so testing can be repeated.

- ⚠ The maximum reading the RP Check can measure is equivalent to 300 cmH<sub>2</sub>O. Any reading above that will be displayed as --- (overflow).

## SNIP Test

Insert the nasal probe adaptor to the front of the RP check, select the appropriate sized nasal probe for the patient to be tested and connect to the nasal probe adaptor ensuring it is twisted into place.



Switch the unit ON and select the SNIP test, wait for the SNIP icon to appear.



Ask the patient to insert the nasal probe into their nostril so it fits snugly and will not fall out during testing. The patient should take a maximum sniff through the occluded nostril. The manoeuvre is a hard-short sharp sniff and the measurement taken is the maximum peak pressure as a result of the sniff manoeuvre.

It is recommended to take a maximum of between 5 and 10 SNIP tests and take the highest test achieved.

**NOTE:** The contralateral nostril should not be occluded during the sniff manoeuvre.



The nasal probes are single patient use and should be disposed of after testing in accordance with local disposal policy. Failure to use a new nasal probe for individual testing may result in patient cross contamination and infection.

## **Indices**

### **P<sub>peak</sub> – Maximum Peak Pressure**

P<sub>peak</sub> is the maximum pressure achieved during the test.

### **MEP - Maximal Expiratory Pressure**

MEP is the highest average expiratory pressure achieved over one second.

### **MIP – Maximal Inspiratory Pressure**

MIP is the highest average inspiratory pressure achieved over one second.

### **MRPD – Maximum Rate of Pressure Development**

MRPD is the highest rate of change of pressure on the upward stroke (before the one second average is achieved) of either a MIP or MEP test.

### **MRR – Maximum Relaxation Rate**

MRR is the maximum rate of change of pressure on the downward stroke (after the one second average) of either a MIP or MEP test, divided by the one second sustainable pressure value (the MIP or MEP value respectively)

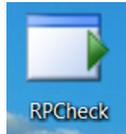
### **SNIP - Sniff nasal inspiratory pressure**

SNIP is the peak pressure obtained from a maximum sniff nasal manoeuvre

# PC Software installation and report

## Installation

Attach the memory device supplied, to your PC USB port. When prompted, open the folder and execute the setup.exe file. This will guide you through the installation process. This will load the required software and drivers to communicate with the device. It will also add an icon on your desktop.



## Modes of operation when connected to the PC

The RP Check can be used in two modes:

1. USB connection to the PC to upload the last patients tests that have been stored on the unit
2. “Live tests” performed on the RP Check and the results will be displayed on the PC software as well as on the unit.

For both of the above modes of operation, turn the RP Check ON and connect the USB cable to the side of the unit and to a free USB port on the PC.

**Note:** When the RP Check is connected to the PC via the USB cable it will gain power from the USB port and will not use the battery. To turn the unit OFF disconnect the USB and press the ON/OFF button of the keypad until the unit turns OFF.

Uploading a patient’s tests to the RP Check software from the unit:

- a) Connect the USB cable to a free port of the PC and to the USB port of the PC
- b) Turn the RP Check unit ON using the keypad
- c) Double click on the RP Check desktop icon
- d) Click on the Connect button of the RP Check software and the patient demographics fields will be displayed

- e) Enter the patient’s details and also the physician/healthcare professionals name and the Hospital or organisations name – these will appear on the PDF report that is created for the patient.

The screenshot shows a software interface with a blue header bar containing navigation buttons: 'Connect', 'COMS connected', 'C:\Users\Oisin\Documents', 'Select Save Directory', 'Export PDF', and 'Show Patient Details'. Below the header, there are two main sections for data entry. The first section, 'Enter the organisation details', includes fields for 'Physician/Health care professional' (Dr Quake) and 'Organisation' (TM Hospital). The second section, 'Enter the patient details', includes fields for 'ID' (ABC 123), 'First Name' (Oisin), 'Last Name' (McMangan), 'Gender' (Male), 'Date of Birth' (08/07/1969), 'Height (cm)' (176), 'Weight (Kg)' (65), and 'Smoking Info' (Non-Smoker). A 'Confirm Details' button is located below the patient details. At the bottom of the form, there are two buttons: 'Upload existing tests' and 'Start new tests'.

**Note:** ALL fields must be completed.

- f) Once complete click on the button “Confirm Patient details”  
 g) The software will then offer the options to Upload Existing tests (from the RP Check unit) or “Start New Test” using the PC software.  
 h) Select Upload Existing Tests and the individual tests will be uploaded for viewing.

“Live tests” performed on the RP Check and displayed on the PC whilst connected to the PC.

Follow the same procedure as if Uploading from the RP Check but select Start new Test.

**Note:** It is important that you tell the PC software which test you are performing MIP, MEP or SNIP, using the drop-down menu on the PC software.

## PC software Functionality

The screenshot shows a software interface with a blue header bar containing navigation buttons: 'Connect', 'COMS connected', 'C:\Users\Oisin\Documents', 'Select Save Directory', 'Export PDF', and 'Show Patient Details'. Below the header, there is a section for test selection. It includes a 'Select Test Type' dropdown menu with 'MEP' selected, a 'Wilson (7-70 yrs)' dropdown menu, and three buttons: 'Start Test', 'Show all Tests', and 'Delete current test'.

**Select Save Directory** - this will allow you to select the directory as the default directory where you wish to save the PDF reports created by the RP Check Software

**Export PDF** – this will create and export the PDF report document to the selected folder – the format for saving PDF's is the patients ID followed by the date and time the PDF was created.

**Show Patient details** – this will show the patient details that have been completed for the patient, along with the healthcare professionals name and the organizations name. These details can be changed at any time prior to exporting the tests to a PDF format.

**Select Test type** – this is required when the RP Check is connected to the PC for performing "live" tests, the PC software needs to be told which test is being performed, select MIP, MEP or SNIP from the drop down. The corresponding predicted value should also be chosen from the drop down choice.

The + symbol will show a list of numbers in circles and these will correspond to the individual tests. The circles encasing the numbers are colour coded as follows:

Gold/yellow is the Best test

Green shows the test is within 20% of the best test – as per the ATS/ERS Guidelines

Blue shows the test is technically acceptable and lasted for the required 1.5 seconds but falls outside of the 20% reproducibility criteria. Selecting the individual circle will display the corresponding test.

Once a test has been selected and reviewed and it is deemed unacceptable by the healthcare professional then selecting the **Delete current Test**, will delete the test from the list.

**NOTE:** the numbering will stay the same but the numbered circle will now appear grey.

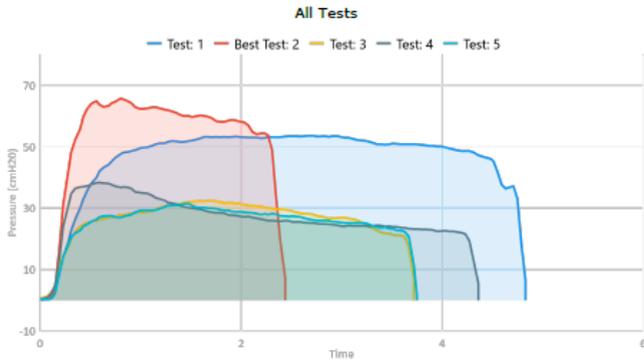
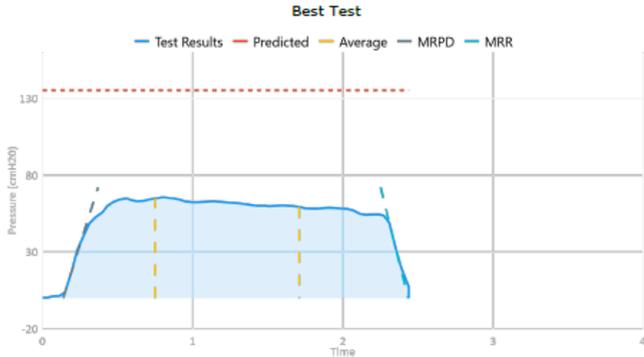
Selecting Show ALL Tests will display all the tests performed overlaid on top of each other.

Selecting Export to PDF will export the PDF to the chosen directory and will show the patients details, a table of results, the Best pressure trace graph and All pressure trace graphs

A

Patient ID: 1234556 First Name: O Last Name: M  
 Gender: Male Date of Birth: 08/07/1969 Age: 49  
 Height: 176Cm Weight: 66Kg Smoking Info: Non-Smoker  
 Date of Test: 18/07/2018 15:30:33

Indices	Value	Min Predicted	Predicted	Max Predicted	% Predicted
MIP	62	0	135	0	45.7
MRPD	390	N/A	N/A	N/A	N/A
MRR	6	N/A	N/A	N/A	N/A
Quality Check					



Physician/Health care professional: B

Signature: \_\_\_\_\_

## Calibration

The unit contains a pre-calibrated temperature compensated pressure sensor which requires no calibration during its lifetime.

## Battery Life

The 9V PP3 battery should provide at least 20 hours of continuous use. When the battery is low, the battery low icon will show only one segment.



The device can still be used, but it is advisable to replace the battery.

Please dispose of the battery for recycling according to your local procedures.



Please remove the battery when the RP Check is not in use.



The battery should be changed when the low battery icon appears on the display.

## Power Saving

During the normal operation the unit will automatically switch OFF five minutes after the last operation.

## Cleaning

The RP Check unit requires no routine maintenance and is protected from contamination by the Bacterial Filter. The inspiratory and expiratory valves with integral filter have a bacterial/viral efficacy of >99% and are single patient use. The flanged mouthpiece and nasal probes are also designed as a single patient accessory. After patient testing, the valves and flanged mouthpiece should be disposed of in accordance with local policy.

External surfaces of the device may be wiped with a disinfection wipe, acceptable wipes include but are not limited to Clinell Universal wipes, and SaniCloth AF3 wipes. Wiping the screen should be avoided.

## Servicing

-  Please only use accessories supplied by MD Diagnostics to ensure the device performs as intended.
-  Please return the device to MD Diagnostics or its authorised distributor for recycling at the end of its useful life.

If your unit requires servicing, then please contact your authorised distributor or MD Diagnostics Ltd directly.  
On request, MD Diagnostics Ltd will provide circuit diagrams, component part lists, descriptions, calibration instructions to assist to service personnel in parts repair.

service@mdd.org.uk  
Tel: + 44 (0) 1622 682686

## Spares

Catalogue Number	Description
MEP50	50 Single patient use Expiratory Valve with bacterial filter and flanged mouthpiece
MIP50	50 Single patient use Inspiratory Valve with bacterial filter and flanged mouthpiece
PP3B	Alkaline PP3 Battery
NPR01	Small nasal probes (pack of 10)
NPR02	Medium nasal probes (pack of 10)
NPR03	Large nasal probes (pack of 10)
ANPA01	Nasal probe adaptor

## Specifications

<b>Operating Pressure</b>	± 300 cmH <sub>2</sub> O
<b>Burst Pressure</b>	± 2000 cmH <sub>2</sub> O
<b>Accuracy</b>	±3%
<b>Resolution</b>	1 cmH <sub>2</sub> O
<b>Operating Temperature</b>	0-40 °C
<b>Operating Pressure</b>	Atmospheric 10%
<b>Operating Humidity</b>	30% to 90% RH
<b>Operating Altitude</b>	Sea level to 6000 ft (~2000m)
<b>Storage Temperature</b>	-20 to + 70 <sup>o</sup> C
<b>Storage Humidity</b>	10% to 90% RH
<b>Display</b>	128 X 64 Pixels Graphic LCD
<b>Power Supply</b>	Single 9v PP3 battery
<b>Weight (approximate)</b>	160g including battery
<b>Dimensions</b>	135mm x 65mm x 30mm
<b>RP Check Software</b>	Suitable for Windows 7 32 & 64 bit; Windows 8.1 64 bit; Windows 10 64-bit operating systems

 Not suitable for use in an oxygen rich environment

 Not intended for continuous use

IP Rating: IPx0

 Do not modify this equipment without authorisation from MD Diagnostics Ltd.

## Symbols



In accordance with Directive 93/42/EEC

1639



Type B Device

## Environment

This instrument complies with directive EEC89/336 electromagnetic compatibility but may be affected by cellular phones and by electromagnetic interference exceeding levels specified in EN 50082-1:1992



To avoid the potential effects on the environment and human health as a result of the presence of hazardous substances in electrical and electronic equipment, end users of electrical and electronic equipment should understand the meaning of the crossed-out wheeled bin symbol. Do not dispose of WEEE as unsorted municipal waste and have to collect such WEEE separately.

## **Special Instructions / Notes regarding the RP check and Electromagnetic compatibility (EMC) testing to EN60601-1-2:2007**

### **WARNING**

Use of portable telephones or other radio frequency (RF) emitting equipment near the system may cause unexpected or adverse operation

The RP check has been tested to EN60601-1-2:2015 4th Edition, regarding its ability to operate in an environment containing other electrical/electronic equipment (including other medical devices).

The purpose of this testing is to ensure that the RP check is not likely to adversely affect the normal operation of other such equipment and that other such equipment is not likely to adversely affect the normal operation of the RP check.

Despite the testing of the RP check that has been undertaken, normal operation of the RP check can be affected by other electrical/electronic equipment and portable and mobile RF communications equipment.

As the RP check is medical equipment, special precautions are needed regarding EMC (electromagnetic compatibility).

It is important that the RP check is configured and installed/put into service, in accordance with the instructions/guidance provided herein and is used only in the configuration as supplied.

Changes or modifications to the RP check may result in increased emissions or decreased immunity of the RP check in relation to EMC performance.

The RP check should be used only with the cables specified by MD Diagnostics. The cable should not be extended by the user. If the cable is extended by the user, this may result in an increased level of emissions or decreased level of immunity, in relation to the RP check EMC.

The RP check should not be used adjacent to or stacked with other equipment. If adjacent or stacked use with other equipment is necessary, the RP check and the other equipment should be observed/monitored, to verify normal operation in the configuration in which it will be used.

For the purposes of EN60601-1-2 the RP check has an essential performance (the device should not unintentionally perform a respiratory measurement during the emc tests as this could affect the results of any intentional measurement data and the device should function normally after the emc tests).

### Guidance and Manufacturer's Declaration – Electromagnetic Immunity

The RP Check is intended for use in the electromagnetic environment specified below. The customer or the user should assure that it is used in such an environment.

<b>Immunity Test</b>	<b>IEC 60601 Test level</b>	<b>Compliance level</b>	<b>Electromagnetic environment guidance</b>
Radiated Immunity IEC 61000-4-3	10V/m	10V/m	Avoid use in environments likely to exceed 10V/m
Electrostatic Discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	No restrictions in the intended environment
Electrical fast transient/ burst IEC 61000-4-4	N/A	N/A	None
Surge IEC 61000-4-5	N/A	N/A	None
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	N/A	N/A	None
Power Frequency (50/60 Hz) magnetic field IEC 61000-4-8	N/A	N/A	None

NOTE: UT is the a.c. mains voltage prior to application of the test level.

### **Guidance and Manufacturer's Declaration - Electromagnetic Emissions**

The RP Check is intended for use in the electromagnetic environment specified below. The customer or the user should assure that it is used in such an environment.

<b>Emissions Test</b>	<b>Compliance level</b>	<b>Electromagnetic environment guidance</b>
RF Emissions CISPR 11	Group 1	The RP Check uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class B	The RP Check can be used in domestic, light and heavy industrial environments.
Harmonic emissions IEC 61000-3-2	[Not Applicable]	
Voltage fluctuations / flicker emissions IEC 61000-3-3	[Not Applicable]	
	[See 5.2.2.1 c) and Figure 1]	The RP Check is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplied buildings used for domestic purposes.
	[See 5.2.2.1 c) and Figure 1]	The RP Check is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplied buildings used for domestic purposes.
RF Emissions CISPR 14-1	Complies	The RP Check is not suitable for interconnection with other equipment.
RF Emissions CISPR 15	Complies	The RP Check is not suitable for interconnection with other equipment.

### Guidance and Manufacturer's Declaration - Electromagnetic Immunity

The RP Check is intended for use in the electromagnetic environment specified below. The customer or the user should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test level	Compliance level	Electromagnetic environment guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 KHz to 80 MHz	[V1] V	<p>Portable and mobile RF communications equipment should be used no closer to any part of the RP Check, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p><b>Recommended separation distance</b></p> $d = \left[ \frac{3.5}{V_1} \right] \sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	[E1] V/m	<p><math>d = \left[ \frac{3.5}{E_1} \right] \sqrt{P}</math>      80 MHz to 800 MHz</p> <p><math>d = \left[ \frac{7}{E_1} \right] \sqrt{P}</math>      800 MHz to 2.5 GHz .....E1</p> <p>Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, a, should be less than the compliance level in each frequency range. b</p> <p>Interference may occur in the vicinity of equipment marketed with the following symbol:</p> <div style="text-align: center;">  </div>

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by

absorption and reflection from structures, objects and people.

a Field strengths from fixed transmitters, such as base stations for radio (cellular / cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RD transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the RP Check is used exceeds the applicable RD compliance level above, the RP Check should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the RP Check.

b Over the frequency range 150 KHz to 80 MHz, field strength should be less than [V1] V/m