DESCRIPTION
This product was especially developed by calling upon the new advanced wireless data communication processing technologies (Bluetooth) towards PDA or PC, with the close cooperation with the respiratory experts in physiology and in strict conformity with the ATS and ERS standards currently in strength.

Thanks to options, it is extensible with the three following principal functions:

SPIROMETER:
The "Pocket-Spiro BT100" is a pneumotachometer device of high precision, portable, reliable, robust, handy, compact and easy to use at patient bedside to realize easily and quickly:
- Classical slow spirometry with possible determination of "Expiratory flow limitation" and "dynamic hyperinflation". (Hyperinflation test is efficient for testing broncho-dilatation therapy and discard the need to measure multiple FEV1 manoeuvres)
- Classical forced spirometry, flow-volume curves and associated times-volume curves. The software is also able to manage reversibility tests by pre / post broncho-dilation with choice of the data base and time of action. Compare best pre and best post and presentation of the results compared with the normal values and broncho-provocation challenge tests, necessary to the recognition of specific respiratory disorders.

RESPIRATORY MECHANICS:
Device can be equipped with mouth pressure transducer and optional modules for measurement of lung mechanics and muscle strengths: PImax; PEmax; P.1; Rint, static and dynamic compliance ... and other important measurements necessary to differentiate difficult respiratory disorders.

MONITORING:
Further on, our device can also be equipped for Sleep studies with:
- Pulse oximeter SpO2 monitoring
- Respiratory inductive plethysmography RIP (V thorax, V abdomen, V tot) for differentiation between obstructive and central apnoea
- Nose and nose-mouth pressure monitoring during sleep.

The collected Cardio Respiratory parameters and the curves are recorded with the date and the hour of the test and can be called and restored via suitable database software for further analysis, calculation, interpretation, report edition with associated protocols via internet, printer, archives, intranet etc..
**M.E.C. Pocket Spirometer BT100 - “Wireless Handheld Spirometer”**

**Flow sensor:**

V.O.M. (Variable Orifice Membrane) “Pneumotachometer” with electronic linearization offers a number of great benefits, including:

- Higher linearity and better sensitivity to very low flow
- Insensitivity to humidity, no ‘dry air’ challenge as no heating is required
- Extremely low flow resistance and dead space
- No moving parts and no inertia corrections to overcome
- Easy cleaning and sterilisation

Easy-care in every respect.

**TIPS:**

- Portable Unit with “Bluetooth” technology (wireless) and RFID Radio communication towards any PDA or PC computer.
- Also possibility for Serial Com and for USB com with any PDA or PC computer
- Compatible Windows & WinCE
- Very complete with Pre/post, SVC, FEV1, Flow volume curves, MIP / MEP, Airway resistance (Rint), hyperinflation, expiratory flow-limitation, etc...
- Data synchronisation PC <-> PDA
- Export of data to many medical databases (hospital & practices)
- Answer to ATS/ERS diagnostic device recommendations
M.E.C. Pocket Spirometer BT100 - “Wireless Handheld Spirometer”

Most important TIPS and features

1. Quality
Measuring apparatus and spirometry program with identical precision to those used in the laboratories of respiratory functional exploration and in full conformity to the ATS / ERS standards.

2. Price
Very good and accessible Price/Quality ratio

3. Accessible anywhere and to all
Format for easy transport, attractive design also conceived for the children in order to improve their participation in the respiratory tests. Increased Safety and freedom from the patient. Wireless communication towards PDA or PC.

4. Guidance software
Thanks to guidance software during the measurement, the operator can appreciate test quality by reproducibility factors, analyse measurements curves and values in order to check their perfect execution. These feature improve interactive relation between the patient and the operator and improve quality of results.

5. Normal Values
Comparison between measurements and selected normal values, for adult, children, with ethnic corrections.

6. Patient data Identification
Spirometry program use data record filing and automatically indexes the tests by Nr of identification, dates and hour, each patient has his own card and user can work with 4 open patients’ cards in the same time. This feature facilitates tracking, the diagnosis and the therapeutic follow-up in routine use.

7. Data storage
Storage in memory of an unlimited number of patients.

8. Analysis of tendencies
Supervision of the pulmonary health of the patient, thanks to data storage tools for tracking, statistics and fast tendency evaluation by colour graphics the data can be treated objectively. These features facilitate the Self-management of the respiratory affections and allows control of the evolution of the treatment (Asthma for instance)

9. Communication with patient data records
Thanks to MEC PDI software, no need anymore to manually introduce the patient data into the spirometry program, these are generated by the medical file of the doctor’s patient data base in the test data and the results of measurements automatically safeguarded in the patient data records after the test. This feature facilitates the management of the data and decreases the risks of errors related to the bad readings or manual encoding of the data.

Easy export of the results by synchronisation capability on powerful data base.

10. Easy “Report Designer”
As far as report documentation is concerned, you will be supported by the new MEC PFT Report Designer program, which provides you several handy report tools on the basis on which you can clearly structure and tailor each reporting to your individual needs and integrate your headings and hospital or practice logos. MEC PFT report can be evaluated on screen before printed on paper and/or forwarded by email, archived.

11. Easy calibration
The flow transducer identification data is downloaded towards the PC or the PDA using a Radio bidirectional communication RFI technology. Software selects appropriate linearity table and Calibration factors? Every new calibration is stored in logger file with values, date and hour.

12. Hygienic
Breathing tube independent of the spirometer, can be disassembled easily for cleaning and disinfection and no risk of cross contamination
Specifications Safety and Quality requirements

The "Pocket-Spiro BT100" devices are individually gauged to answer the recommendations of ATS 94 (Diagnostic devices) for variable atmospheric pressure, temperature and relative humidity parameters.

The methods of calibration and checking are based on the use of a motorized syringe of high precision [1] which makes it possible to deliver the curves spread out definite by the ATS [2] with a reproducibility better than 1%.

At the end of the manufacture each apparatus is checked for two curves (PW15 and PW24) selected for their extreme values. A complete control (based on 50 curves) is carried out for an apparatus on 100.

The measuring accuracy is defined by three parameters:
- "Accuracy" is the variation with the value standard.
- "Intradevice Variability" is the variability of measurement on an apparatus.
- "Interdevice Variability" is the variability of measurement between all the apparatuses.

Bibliographies:
[1] PULMONARY WA VEFORM GENERATOR SYSTEM PWG - MH CUSTOM DESIGN &MFG. L. C. - 70FERN DRIVE - MIDVALE, UTAH 84047 - USA
[2] ATS has defined 50 calibration curves for verifying Spirometry measurement. Curves PW1 to PW24 for FEV1 & FVC values – Curves FT1 to FT26 for PEF values
[4] Normes de qualité, indications et standardisation des épreuves fonctionnelles respiratoires (Consensus de la société belge de Pneumologie ) 27 Nov 2001

<table>
<thead>
<tr>
<th>Flow measurement</th>
<th>Variable orifice membrane</th>
</tr>
</thead>
<tbody>
<tr>
<td>Range</td>
<td>±0.02 – ±20l/s</td>
</tr>
<tr>
<td>Accuracy</td>
<td>0.05 – 15l/s ±2%</td>
</tr>
<tr>
<td>Resistance</td>
<td>&lt; 0.01 kPa/(l/s) at 10 l/s</td>
</tr>
<tr>
<td>Resolution</td>
<td>&lt;5ml</td>
</tr>
<tr>
<td>Back pressure</td>
<td>&lt;0.93kPa at 14l/s</td>
</tr>
<tr>
<td>Volume determination</td>
<td>digital integration</td>
</tr>
<tr>
<td>Range</td>
<td>0 - ± 20 l/s</td>
</tr>
<tr>
<td>Accuracy</td>
<td>5 ml</td>
</tr>
<tr>
<td>Mouth pressure</td>
<td>Solid state pressure transducer</td>
</tr>
<tr>
<td>Range</td>
<td>± 20 kPa</td>
</tr>
<tr>
<td>Accuracy</td>
<td>Accuracy: 0.2%, full scale (Resolution: 16 bit)</td>
</tr>
<tr>
<td>Temperature</td>
<td>+10°C to +40°C.</td>
</tr>
<tr>
<td>Barometric pressure</td>
<td>850 to 1200 mbar</td>
</tr>
<tr>
<td>Humidity</td>
<td>25 – 85% (non condensing)</td>
</tr>
<tr>
<td>Batteries</td>
<td>Reloadable batteries (NIMH)</td>
</tr>
<tr>
<td>Software</td>
<td>Compatible with PDA, iPAQ, PC IBM Windows 2000 , XP</td>
</tr>
</tbody>
</table>

Certification/Safety standards:
- 93/42/EEC: Medical Device Directive
- EN60601-1: General Requirements for Safety
- EN60601-1-1: Safety Requirements for Medical Electrical Systems
- EN60601-1-2: Electromagnetic compatibility

CE approval:
- DGM-163: Final inspection and test of cardiopulmonary function test equipment in class I (93/42/EEC Annex VI Section 3.2 - Product quality assurance)

Manufacturer:
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