**Technical Specification:**

<table>
<thead>
<tr>
<th>Feature</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Product Name:</strong></td>
<td>Hand Held Spirometer</td>
</tr>
<tr>
<td><strong>Variant Name:</strong></td>
<td>In2itive e-Diary</td>
</tr>
<tr>
<td><strong>Model No:</strong></td>
<td>2120</td>
</tr>
<tr>
<td><strong>Environmental Data:</strong></td>
<td>Temperature (built in sensors)</td>
</tr>
<tr>
<td><strong>Test Types:</strong></td>
<td>Expiratory and inspiratory tests</td>
</tr>
<tr>
<td><strong>Customisable Parameters</strong>:</td>
<td>PEF, FEV1, FVC, PIF, IC, FEF25-75, FEV6</td>
</tr>
<tr>
<td><strong>Flow Technology:</strong></td>
<td>Fleisch Pnuemotachograph (No. 3 size)</td>
</tr>
<tr>
<td><strong>Resolution:</strong></td>
<td>10 ml volume; 0.01 L/s flow</td>
</tr>
<tr>
<td><strong>Data Storage:</strong></td>
<td>Stores more than one year’s data for a single subject</td>
</tr>
<tr>
<td><strong>Accuracy Volumes</strong>:</td>
<td>Better than ± 3% for Max 10L/ Min 0L</td>
</tr>
<tr>
<td><strong>Flows</strong>:</td>
<td>Better than ± 10% for Max 16L/s/ Min 0.02L/s</td>
</tr>
<tr>
<td><strong>Linearity</strong>:</td>
<td>± 5% in range 0.1L/s to 16L/s</td>
</tr>
<tr>
<td><strong>PowerSAFE™</strong></td>
<td>Input 100 – 240V AC 50-60Hz, output 5V DC</td>
</tr>
<tr>
<td><strong>Battery Pack</strong></td>
<td>Lithium Polymer 3.7v 2000mAH</td>
</tr>
<tr>
<td><strong>Dimensions</strong>:</td>
<td>Device: 160mm x 100mm x 45mm with flowhead attached</td>
</tr>
<tr>
<td><strong>Nett Weight</strong>:</td>
<td>Device: 230g</td>
</tr>
<tr>
<td><strong>Storage Humidity</strong>:</td>
<td>10% to 95%</td>
</tr>
<tr>
<td><strong>Storage Temperature</strong>:</td>
<td>0°C to 50°C</td>
</tr>
<tr>
<td><strong>Recommended Operating Temperature Range</strong>:</td>
<td>17 – 37°C</td>
</tr>
<tr>
<td><strong>Connectivity</strong>:</td>
<td>USB 2</td>
</tr>
<tr>
<td><strong>Max Test Duration</strong>:</td>
<td>20s FVC</td>
</tr>
<tr>
<td><strong>Safety Standards</strong>:</td>
<td>IEC 60601-1:2005</td>
</tr>
<tr>
<td><strong>Medical Safety Standard</strong>:</td>
<td>Medical Devices Directive 2007/47/EC</td>
</tr>
<tr>
<td><strong>Designed &amp; Manufactured Under:</strong></td>
<td>ISO 13485:2003; DIN 20460:2005</td>
</tr>
</tbody>
</table>

**Ordering Info:**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>79500</td>
<td>2120 Hand Held In2itive e-Diary &amp; Charging Cradle</td>
</tr>
<tr>
<td>79501</td>
<td>2120 Hand Held In2itive e-Diary</td>
</tr>
<tr>
<td>79196</td>
<td>2120 Hand Held In2itive PTO: cradle</td>
</tr>
<tr>
<td>79197</td>
<td>2120 Hand Held In2itive GPRS/COM: cradle</td>
</tr>
<tr>
<td>36020</td>
<td>2400 Precision Spirometer 3L</td>
</tr>
<tr>
<td>20242</td>
<td>2024 SafeTway® mouthpieces (200)</td>
</tr>
<tr>
<td>20980</td>
<td>2024 SafeTway® mini mouthpieces (50)</td>
</tr>
<tr>
<td>40128</td>
<td>Plastic mouthpieces</td>
</tr>
<tr>
<td>79191</td>
<td>Flowhead complete</td>
</tr>
<tr>
<td>79195</td>
<td>Carry bag</td>
</tr>
<tr>
<td>79198</td>
<td>Device cap</td>
</tr>
</tbody>
</table>

**References:**

4. Kamps AJL, Roosa RL, Brand PLP: Peak flow diaries in childhood asthma are unreliable; Thorax 2001; 56: 180-182
8. ISO 26782:2009: Anaesthetic and respiratory equipoipment; Spimeters intended for the measurement of time强制 expire volumes in humans
9. ISO 23747:2007: Anaesthetic and respiratory equipment; Peak flow expire flow meters for the assessment of pulmonary function in spontaneously breathing humans
The pioneering In2itive e-Diary combines an integrated spirometer, featuring a removable flow head, with an easy to use touch screen. This versatile ePRO system is the first of its kind and can be customised for use in any protocol-driven clinical trial in a wide range of therapeutic areas.

Designed to improve on the success of the already well-proven PEF/FEVi Diary, with its documented 92% subject compliance, the In2itive e-diary excels in the following key areas:

**Communication:**
- Secure data transfer from the study centre or transmitted directly from the subject’s home for immediate population of centralised study database
- Real time data access via the VIEWER™ web portal allowing site, CRO and sponsor to review the data and monitor compliance
- Ability to transmit data over phone networks allowing real time data capture and population of study database
- Secure mirrored backups, local on device and remote at data management centre, for absolute protection of source data

**Spirometry:**
- Diagnostic spirometry accuracy
- Ability to capture full flow-volume data and a range of parameters in respiratory studies
- Test QA feedback to the subject on PEF and FEV1 to maximise data quality in respiratory studies
- Complies with the ATS/ERS 2005 standards

**Electronic Diary:**
- Records symptoms, medication use, patient reported outcomes & quality of life questions for any therapeutic area
- Removable spirometry flowhead so that the e-Diary can be used in non-respiratory studies
- Simple to use large touch screen interface
- Meets international data protection requirements
- Compliant with the FDA’s guidance on patient reported outcomes
- FDA 21CFR Part 11 compliant
- Automated date/time stamped records

**Additional Features:**
- Completely tailored to meet the targets and endpoints of your study protocol
- Stores more than 1 year’s data for a single subject
- The ability to ship identical devices to all sites irrespective of language
- The user can continue where they left off if a diary session is interrupted
- Automatic adjustment for daylight savings changes
- Integrated within a single centralised database including site spirometry, FeNO and other study data
- Validation against international standards for spirometry and peak flow

**Patient compliance:**
- On-screen quality feedback for diagnostic spirometry
- Available in all languages with a clear and bold font
- Fully customisable subject alerts
- Time windows for record entry so that the subject can only record results within a specified period
- Responses to diary questions are mandatory before proceeding

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Technical Specification:

Product Name: Hand Held Spirometer
Variant Name: In2itive e-Diary
Model No: 2120

Environmental Data:
- Temperature (built in sensors)
- Test Types: Expiratory and inspiratory tests, single breath and multi-breath tests, flow-volume loops

Customisable Parameters (depending on model):
- PEF, FEV1, FVC, PIF, IC; FEF25-75; FEV6 and many more

Flow Technology:
- Fleisch Pneumotachograph (No. 3 size)

Resolution:
- 10 ml volume; 0.01 L/s flow

Data Storage:
- Stores more than one year’s data for a single subject

Accuracy Volumes:
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- 0°C to 50°C

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- 17 - 37°C

Connectivity:
- USB 2

Max Test Duration:
- 20s FVC

Performance Standards:

Safety Standards:
- IEC 60601-1:2005

Medical Safety Standard:
- Medical Devices Directive 2007/47/EC

Designed & Manufactured Under:
- ISO 13485:2003, FDA 21CFR820, CMDR

Ordering Info:
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- 79600 2120 Hand Held In2itive e-Diary
- 79196 2120 Hand Held In2itive FTTN cradle
- 79197 2120 Hand Held In2itive GPRS/GSM cradle
- 36020 2040 Precision Syringe 3L
- 20243 2024 SafeTway® mouthpieces (200)
- 22980 2024 SafeTway® mini mouthpieces (50)
- 46128 Plastic mouthpieces
- 79191 Flowhead complete
- 79195 Carry bag
- 79198 Device cap

References:
1. FDA Guidance for Industry - Patient-Reported Outcome Measures; Use in Medical Product Development to Support Labeling Claims, December 2009
4. Kamps AJ, Ronica RL, Brand PLP: Peak flow diaries in childhood asthma are unreliable, Thorax 2001; 56: 180-182
8. ISO 25678:2003: Anaesthetic and respiratory equipment: Spirometers intended for the measurement of forced expiratory volumes in Normals
10. ISO 22986:2009: Anaesthetic and respiratory equipment: Spirometers intended for the measurement of time forced expired volumes in Normals

Vitalograph® In2itive e-Diary
Revolutionising ePRO