ZOE® - Technical Specifications

Class II Medical Device

Operation:
• Intermittent Use

Power:
• 5 volts DC ZOE® medical grade power adapter
• 4 AA Alkaline Batteries

Enclosure:
• Flame-resistant AVS plastic

Dimensions:
• 8” x 5” x 2”
• 20cm x 12.5cm x 2 cm

Weight:
• 1 lb excluding accessories, options, cables

Measurement Current:
• 2.0 mA, 100kHz

Electrodes:
• ZOE® disposable hydrogel leads only

Operating & Storage Temperature:
• 15ºC – 40ºC (40ºF – 113ºF)

Relative Humidity for Operation & Storage:
• 20% - 80% non-condensing

IP20

This equipment has been tested and found to comply with the EMC limits for the Medical Device Directive 93/42EEC

(EN 55011 Class II & EN 60601-1-2). These limits are designed to provide reasonable protection against harmful interference in a typical medical installation. The equipment generates uses and can radiate radio frequency energy and, if not installed and use in accordance with these instruction, may cause harmful interference to other devices in the vicinity.

ZOE® is a registered trademark of the NMT Corporation
Specifications subject to change without notice.

All Med Medical Supply
800-434-2909
www.amms.net

• Detect congestive heart failure as early as two weeks prior to weight gain
• Lightweight, easy to use and affordable for Home Care
• Power: AC or AA Batteries
• FDA (510k) Cleared
About ZOE®

The ZOE® Fluid Status Monitor was designed for objectively monitoring fluid levels.

The ZOE® measures thoracic base impedance which is simply a measurement of the resistance of a small frequency electric current as it travels from the top to the bottom of the thorax.

The more resistance the current meets, the drier or less fluid that exists and conversely, the less resistance that the current meets, the wetter or more fluid that exists in the chest.

Zo measurement is a quick and easy method for determining whether individuals are experiencing fluid congestion or dehydration. Research indicates that Zo is an early predictor of congestion in heart failure, showing decreases as early as two weeks prior to weight gain.


What is Zo?

Zo refers to “Z naught”, or base resistance in ohms. The symbol for electrical resistance or ohms is “Ω”. Zo has been measured for years in cardiopletysmograph technology. Normal Zo in human subjects has been determined to range from 19-30 ohms. Less than 19 ohms indicates that the subject may be over-hydrated and Zo greater than 30 indicates that the subject is becoming dehydrated.

The ZOE® provides objective data for the early intervention of heart failure, dyspnea, hypertension, and other critical events related to hemodynamic status.

<table>
<thead>
<tr>
<th>Early Signs &amp; Symptoms Exacerbation</th>
<th>Late Signs &amp; Symptoms Exacerbation</th>
<th>Acute Exacerbation</th>
</tr>
</thead>
<tbody>
<tr>
<td>*Appetite</td>
<td>*Peripheral edema</td>
<td>Pitting edema</td>
</tr>
<tr>
<td>*Fatigue</td>
<td>*SOB with exertion</td>
<td>*SOB at rest</td>
</tr>
<tr>
<td>*Bloating feeling</td>
<td>*Weight gain</td>
<td>*Develops S3</td>
</tr>
<tr>
<td>*Fullness in ears</td>
<td>*Abdominal girth</td>
<td>*Develops crackles</td>
</tr>
<tr>
<td>*Zo</td>
<td>*Pillow use</td>
<td>*SaO2</td>
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<tr>
<td></td>
<td>*Develops a cough</td>
<td>*JvD</td>
</tr>
<tr>
<td></td>
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<td>Zo less than 15 ohms</td>
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</tbody>
</table>

*This is when home care nursing intervention must occur to prevent CHF and hospitalization.


### Indications for Use

The ZOE® monitor is FDA cleared for monitoring of:

- Patients living with fluid management problems
- Patients taking diuretic medication
- Patients living with heart failure
- Patients living with End-Stage Renal Disease
- Patients recovering from a coronary artery disease related event
- Patients suffering from recurrent dehydration

### Contraindications

- Patients with allergies to electrode hydrogel
- Patients with skin sensitivities to electrode hydrogel
- Patients with skin breakdown in areas on the chest where ZOE® electrode placement is required

This device is intended for use by qualified health care practitioners, under the direction of a physician, for the noninvasive monitoring and management of patients with fluid management problems in a variety of medically accepted clinical applications.