HYGIENE INSTRUCTIONS FOR In Check and In Check DIAL
ISSUE 04 – November 1, 2019 c/o Clement Clarke

Introduction

The device is suitable for multiple patients use when used and maintained in the following way.

We recommend that if the last user was diagnosed or suspected of having a serious communicable disease that the meter should be disposed of.

Instructions

Clement Clarke (device manufacturer) does not recommend autoclaving In Check meters as the process destroys the accuracy and distorts the meter. Everyone should thoroughly wash their hands before use. Disposable gloves may also add to the safeguard against cross contamination.

Cleaning and Disinfection Instructions

It is recommended that hospitals and clinics provide one of the following for each new patient using the In Check meter

a) Disposable One-Way Valved Inspiratory cardboard mouthpiece (pt. #3122069), or
b) Disposable Bacterial/Viral Filter (low resistance, PFT All0FLOW™ type pt. #5551100) or
c) Disposable plain cardboard mouthpiece – no valve – (pt. # 3122200), or
d) Sterilizable Plastic Mouthpiece (pt. #3122005 – each)

DISCARD or REPROCESS mouthpieces as appropriate after use per patient.

a) Disposable One-Way Valved cardboard mouthpiece

Disposable Mouthpieces with inspiratory valves, only allow the patient to inhale through the meter and will prevent exhalation through the meter. Discarded after individual use, they prevent the patient from exhaling potentially contaminated air through any In Check device. Clean device weekly or more often if preferred. Wipe outside surface of device with alcohol prep/disinfectant wipe, between patients.

b) Disposable Bacterial/Viral Filter

Low resistance filter provides a barrier against 99.99% of micro organisms. Discard after individual use. Reprocess device weekly or more often if preferred. Wipe outside surface of device with alcohol prep between patients.
c) **Disposable plain cardboard mouthpiece – no valve**

Open system that allows exhalation back through the device. With no barrier there is potential risk of cross-contamination. Discard mouthpiece after each use. Reprocess meter after each use.

d) **Sterilizable Plastic Mouthpiece**

Open system that allows exhalation back through the device. With no barrier there is potential risk of cross-contamination. Discard or Reprocess mouthpiece after each use. Reprocess meter after each use.

**Reprocessing - Sterilizable Plastic Mouthpiece**

- Refer to cold sterilization and autoclaving protocols established by solution manufacturer’s and autoclave manufacturer’s. Use semi-critical protocol for solution and saturated steam protocol (max. 134°C - 137°C) for autoclave. The In Check device should not be autoclaved.

**Reprocessing Cleaning Methodology – In Check and In Check DIAL meters**

1) Inspect the unit for signs of damage or wear, if any is evident replace the meter.

2) For Cleaning: Do not use any mechanical aids such as brushes or cloths. Rinse thoroughly shaking gently to remove excess water and allow to dry naturally. A clean blow dryer may also aid the process of drying.

3) As the In-Check Device is designed for inspiratory flow assessment/measurement, the risk of cross infection is greatly reduced when compared to an expiratory peak flow meter because clean air is being drawn in. However, the meter can become compromised if a patient accidentally blows or coughs into the device.

4) In an effort to reduce the risk of cross contamination to its lowest possible level we recommend the use of inspiratory one-way valve mouthpieces or Spirometry-type anti-bacterial/anti-viral filters.

5) For **personal** use the In-Check Device can be cleaned by immersing the device in warm (but not hot) mild detergent solution for 2-3 minutes (maximum 5 minutes). Move the meter vigorously (Agitate) in the solution to ensure thorough cleaning. Rinse in warm water and shake/tap gently in a towel to remove any excess water. It is important to rinse thoroughly to prevent mineral deposits (spots) appearing on the inside of the body and the spindle.

6) When gently shaking/tapping out excess water from the In-Check Device, hold only at the end furthest away from the device selector (use caution to not fling the loose magnet inside the device as this can damage the mechanism).

7) Allow to dry thoroughly before using again.

8) For more intensive, **institutional**, cleaning/disinfection (Reprocessing) between patients the In-Check Device can also be cleaned and disinfected using “Steris Revital-Ox Resert” or
“Rely+On/PeraSafe” protocols. It is important to follow the manufacturer’s instructions and recommended contact times for these products.

9) The In-Check Device can be sterilized using the “Steris, V-PRO® Low Temperature Sterilization System” using the cycles listed below or other similar protocols.

<table>
<thead>
<tr>
<th>STERILIZER / Cycle</th>
<th>Lumen / Standard cycle</th>
<th>Non Lumen cycle</th>
<th>Flexible cycle</th>
<th>Non Lumen Fast cycle</th>
<th>Fast cycle</th>
</tr>
</thead>
<tbody>
<tr>
<td>V-PRO 1</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>V-PRO 1 Plus</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>V-PRO maX</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>V-PRO maX 2</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>V-PRO 60</td>
<td>✓</td>
<td>✓</td>
<td>(permits only a flexible device)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>V-PRO s2*</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
</tbody>
</table>

Cleaning Frequency

10) The following recommendations for disinfection frequencies are presented as a guide only. In practice, the person responsible for the clinical wellbeing of the patient should consider the specific circumstances of the next patient and the risk of infection posed by cross-contamination.

11) If used with a one-way valved mouthpiece or anti-bacterial filter the In-Check device should be cleaned weekly

12) If used with an open mouthpiece the device should be cleaned between patients.

Note 1: Revital-Ox™ Resert® is a product of Steris. Rely+On™/Perasafe™ is a product of Lanxess. Please refer to the manufacturer’s instructions for information concerning use, dilution, rinsing, disposal, etc.

<table>
<thead>
<tr>
<th>Mouthpiece Type</th>
<th>IF using disposable inspiratory cardboard one-way valved mouthpieces (#3122069)</th>
<th>IF using disposable bacterial/viral filters (#5551100)</th>
<th>IF using disposable un-valved cardboard mouthpieces</th>
<th>IF using sterilizable plastic mouthpieces</th>
</tr>
</thead>
<tbody>
<tr>
<td>Frequency</td>
<td>weekly</td>
<td>weekly</td>
<td>Between patients</td>
<td>Between patients</td>
</tr>
</tbody>
</table>