**PRODUCT INDICATION**

<table>
<thead>
<tr>
<th>Product type</th>
<th>Lateral Flow Reader</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Indication</strong></td>
<td>The ORALyzer® is designed to perform reflective optical measurements that can be used to detect and/or quantify target analytics on lateral flow test strips.</td>
</tr>
</tbody>
</table>

**PRODUCT PROPERTIES**

<table>
<thead>
<tr>
<th>Origin</th>
<th>Germany</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Storage temperature</strong></td>
<td>5°C – 40°C</td>
</tr>
</tbody>
</table>
| **Product specifications** | - Size (L x W x H): 236 x 215 x 104 mm  
- Weight approximately: 2.5 kg  
- User interface: Interactive 17.8 cm touchscreen  
- GUI with several languages  
- Internal 2D barcode reader  
- Connections: 4 + 1 x USB, Ethernet  
- Connectivity:  
  - External barcode reader  
  - Label printer support  
  - Data management software  
  - Power supply: 100–240 VAC, 50/60 Hz  
  - Operating conditions: 15–35°C, humidity 10–70% |
| **Component Parts**   | - Frontend with 7´ display and processor unit  
- Backend with detector unit, drive, and connectors |
| **Sterilization / disinfection** | - To clean the device, use a damp cloth. If the dirt is persistent, rub the surface of the device with a cloth that has been moistened with 70% (v/v) alcohol. Do not use aggressive cleaning agents such as acetone. If the inside of the device is contaminated, contact the service department for advice.  
- For more persistent stains and for disinfecting the instrument, clean the instrument surface with a cloth dipped in 1% (w/v) bleach containing 1% active chlorine and then wipe with a damp cloth. This procedure can be repeated 2-3 times. It is also possible to use the 70% (v/v) alcohol to remove any residual traces of bleach.  
- Spillage of potentially infectious material should be wiped off the device immediately using absorbent paper tissue and then the contaminated areas should be wiped with 1% (v/v) bleach (1% active chlorine) or 70% (v/v) alcohol. Materials used to clean spills, including contaminated cloths and gloves, should be disposed of as biohazardous waste. |
| **Shelf life**        | 5 years |
| **Regulatory status** | EU: CE-IVD (Class 1) |
| **Entry on the market** | July 2017 in EU |
### MANUFACTURING

**Product**

The ORALyzer® is manufactured according to Quality Management ISO 9001 and ISO 13485 standards at an FDA-registered manufacturing facility at QIAGEN Lake Constance in Germany.

**Packaging**

- Each package contains:
  - 1 aLF Reader
  - Quick Start Guide
  - USB stick containing a PDF of user manual
  - Power supply including international connection cables
  - DYMOLabelWriter 450 plus power supply and USB cable (to connect printer to reader)
  - 1 roll of DYMOLabelWriter 450, 100 × 54 mm
  - Cartridge Number 4 for use with PerioSafe® PRO DRS (Mouth Rinse Test)
  - Cartridge Number 5 for use with:
    - ImplantSafe® DR (Site-Specific Test)
    - PerioSafe®/ImplantSafe® POOL (Pool-Specific Test)

### AVAILABLE PRODUCT LINE

<table>
<thead>
<tr>
<th>Product</th>
<th>Type/Size/Amount</th>
<th>Art.-No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>The ORALyzer®</td>
<td>1 item per unit</td>
<td>970-00001</td>
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</tbody>
</table>

### HOTLINE

<table>
<thead>
<tr>
<th>UK</th>
<th>GERMANY</th>
<th>ITALY</th>
</tr>
</thead>
<tbody>
<tr>
<td>(+44) 01 293 651230</td>
<td>(+49) 761 450 13 50</td>
<td>(+39) 800 810 500</td>
</tr>
</tbody>
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