

### 1.1.9. General description of the key functional elements

Illustration Humazon® ProMedic:



**Note:**

The product does not comprise any software. It is a firmware that is used.

**Note:**

Details of composition are outlined below (section "Materials of construction").

Further details including description of parts / components, functionality, etc. already have been described in section 1.1.2. (General Description) of this document)

#### Digital display: Ozone dose / vacuum

is indicated by the LEDs of the 7-segment display according to the key pressed.

#### Ozone and dose calculation

The last ozone concentration set is displayed in  $\mu\text{g}/\text{ml}$  by pressing the dose key.

The ozone concentration of 0-1-2-3- and so on up to  $80\mu\text{g}/\text{ml}$  can be set by means of the adjustment knob.

When the Humazon® Promedic is switched off, the last ozone concentration set is saved. If ozone is extracted via the sampling valve, the display switches over to the total dose in  $\mu\text{g O}^3$ . This dose calculation and display only take place during ozone release, i.e. when the sampling valve is pressed and activated, and the dose key pressed.

The displayed dose calculation is saved when the sampling valve is active, independently of whether the dose key was pressed for ozone release. This temporary storage is only deleted when the sampling valve is deactivated. In practice, the advantage of that is that gassing can be carried out in stages during autohaemotherapy and so the total dose is detected.

A maximum of  $9999\mu\text{g}$  ozone is displayed, and the calculation then restarts at  $0000\mu\text{g}$ . After a sampling of ozone, Humazon® Promedic is automatically purged with oxygen.

**Time**

With the time key, a gassing time of 1-15 min can be preselected on the step switch. Ozone is only released when the ozone sampling valve is pressed, and ends at the preselected time. A locking adapter together with sterile filters is used for continuous gassing. The gas flow can be checked with the 5-seconds setting.

**Vacuum**

The vacuum key activates the 4 x 7-segment LED display and the LED "vacuum". The internal vacuum pump is switched on at the same time, and the measured vacuum is displayed in mbar. The set vacuum is maintained constant.

This display indicates the vacuum obtained in the Sangiset®.

The maximum suction can be adjusted by pressing on the timer and simultaneously turning from 0mbar up to -500mbar. This setting is saved for the next vacuum function.

**Fault detection**

The 4 x 7 segment LED display also indicates error codes.

**Sampling valve**

You can unscrew this new type of sampling valve for cleaning or replacement of the gaskets, if necessary.

Screw the sampling valve out of its holder by rotating it counterclockwise approx. 10 times. Then pull the movable plunger out of the holder. Clean and sterilize it just like any other surgical instrument.

Before reassembling, make sure that the cleaned parts (sampling slider and plunger) are grease-free and dry. Refit the sampling valve in reverse order and carry out an instrument test.

**1.1.10. Materials of construction**

The subsequent table provides an overview of materials incorporated in the product.

Part description	Material
Humazon® case	ABS plastic
Ozone sampling valve	Stainless steel
Display	Red plexiglass
Front plate	Printed lexan film
Adjusting knobs	Plastic
Suction connection	PVC
Device label	Ultra-resistant foil label
IFU Humazon®	Paper
Cardboard box	Printed card box

All materials used inside that come into contact with ozone gas are completely ozone-resistant.

Humazon® devices are not in contact with biological tissues, cells and body fluids. For the recommended disposable items, biocompatibility is externally proven.

Note:

*With regard to further details about patient contact as well as chemical / biological / physiological characterization of materials / components also please refer to relevant biological assessment and section 6.2. (Biocompatibility) of this STED-document.*

**1.1.11. Suppliers**

“Supplier approval / Supplier assessment” is part of the approved Quality Management System. The relevant processes are described in a separate procedure (Standard Instructions SI-05.08 (Lieferantenbeurteilung)).

For all relevant suppliers valid certificates as well as contracts are on file at Humares® GmbH. Certificates and contracts can be reviewed during annual audit by Notified Body.

## 1.2. Product Specification

The STED should contain a list of the features, dimensions and performance attributes of the medical device, its variants and accessories (if such are within the scope of the STED), that would typically appear in the product specification made available to the end user, e.g. in brochures, catalogues and the like.

### 1.2.1. Dimensions

#### 1.2.1.1. Humazon® ProMedic

4550 mm x 380mm x 150mm

#### 1.2.1.2. Humazona® / Humadent® / Humadent Unit®

300 mm x 280mm x 120mm

### 1.2.2. Further characteristics of the Humazon® Ozone-/Oxygen Therapy Devices

- Product shelf-life: 8 years
- Voltage: 90-250 V AC, 50/60 Hz
- Power consumption: 130 VA
- Overvoltage category: II
- Ozone concentration: 0 - 80 µg/ml (+/-5 % +/-1 digit)
- Gas flow: ProMedic: 600 ml/min (+/-5 %)  
Humazona® / Humadent® / Humadent Unit®: 300 ml/min (+/-5 %)
- Gas supply: Medical oxygen with 4.5 bar
- Oxygen pressure: 2.5 to 5bar
- Ambient temperature: +15°C....35°C
- Storage temperature: + 5°C....60°C
- Relative humidity: 0....75 %, non-condensing
- Protection class: II, may only be used with protective ground connection
- Device fuses: fuses, 2\* T5AL