DDM

SPENGLER SAS

INSTRUCTIONS FOR USE

Pressure inflator

MADE IN FRANCE

1 – Device identification

Marquage	Indice de classement	Organisme notifié	~~PHTALATES~~ ~~LATEX~~
CE 0459	Im	G-MED	

This device is used for inflating balloon and control of laringeal tubes and endotracheal tubes.
Simple design and sturdy this pressure gauge is calibrated in cm H^2O.

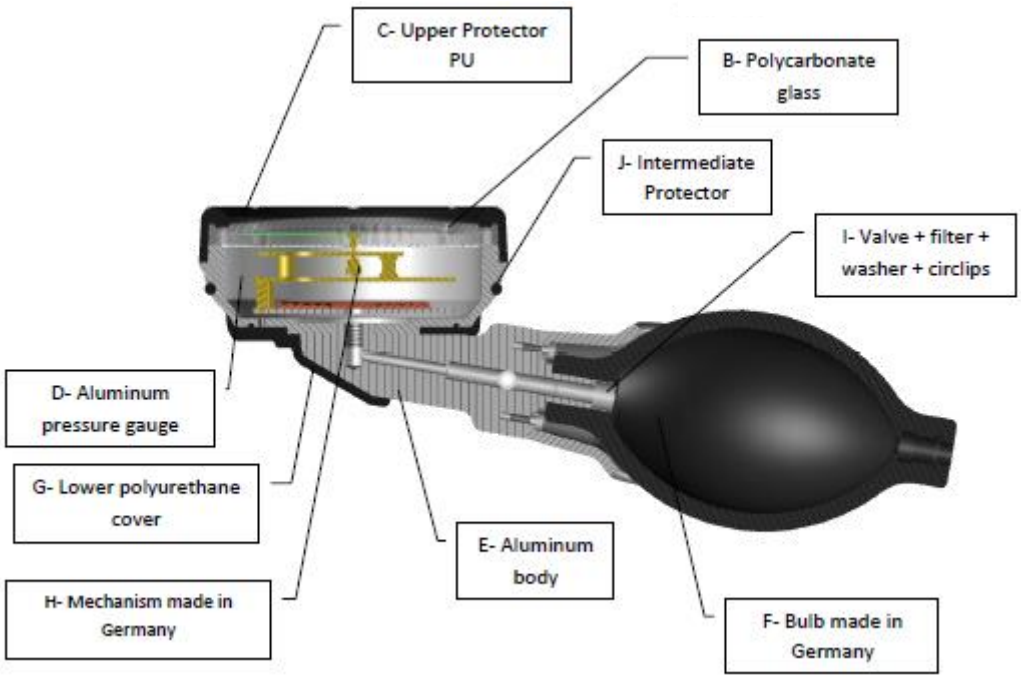
- 22 to 32 cm H2O for tracheal tube
- 60 to 70 cm H2O for tube and mask laryngeal

2 - References

Reference	Designation	Dimensions in mm	
		Lenght	Width
IP01	Pressure inflator	180	70

3 – Technicals characteristics

Identifier	Reference	Designation	Characteristic
A		Pressure inflator	High frequency welded PU fabric
B	A10362	Glass	Polycarbonate
C	A10363	Upper protector	Polyurethane
D	A10364	Pressure gauge	Aluminium
E	A10365	Body	Aluminium
F	A10226	Bulb	Phtalates - free PVC
G	A10366	Lower cover	Polyurethane
H	A10374	Mechanism 0-600 mmHg	Brass
I	A10368	Valve + filter + washer + circlips	Silicone - polyamide - steel - steel
J	A10372	Intermediate protector	EPDM
	TIP01	Connecting tube	Phtalates - free PVC



4 – Operating instructions

- Connect the cuff pressure gauge with the connecting tubing to the inflation line.
- Afterwards inflate by pumping a few times so that the cuffs are pressurized to 60 to 90 mbar/H2O. This ensures that the cuff is in close contact with the tracheal wall.
- Now press the decompression knob to adjust to the desired pressure between 22 and 32 mbar/H2O, green range on the dial.
- Lock the decompression knob.
- Due to the permanent connection to the tracheal tube the cuff pressure gauge works as a monitor and possible pressure increase can be read and released with the red release valve to the desired pressure.

5 - Maintenance :

Visual inspection / Watertight	Calibration test
Before use each day	Every 12 months

Control test required : before use
-Close connecting piece with the finger
-Inflate with ballon to 120 cmh2o
Value must be constant for 2 sec, if pressure drops off, device needs repair by the manufacturer Check calibration every 12 months

6 - Cleaning :

If necessary the device can be cleaned with a soft and fluff-free cloth dampened in a mild soap-sud.
The device must not be dipped into any liquid.
For desinfection wipe the device a commercially available desinfectant for surfaces on the base of alcohol.
The device cannot be sterilized or cleaned mechanically. The connecting tube is for single patient use only. Do not reuse.

7 - Storage

Type of packaging	Storage area	Temperature	Humidity	Atmospheric pressure
Original packaging	Ventilated area	-10° à 40 ° c	30 to 40 %	500 to 1060 hpA

8 - Warranty

This warranty provides assurance for the customer who purchases a D & D product from SPENGLER that should the product fail to function to D & D published specifications during the term of this warranty, will either replace or repair.

The guarantee period is 2 (two) years from the date of purchase. The product must be used in accordance with its labeling and may not be altered or subjected to misuse, abuse, accident or improper handling.

Symboles utilisés :

	Medical device	Packaging label
	Catalogue number	Packaging label
	Batch code	Packaging label
	Date of Manufacture	Packaging label
	Do not use if package is damaged	Packaging label
	Limit of temperature	Packaging label
	Humidity limitation	Packaging label
	Authorised Representative in the European Community (Swiss here)	Packaging label
	Medical device with european conformity assessment	Product
	Manufacturer : Spengler SAS 30 rue Jean de Guiramand 13290 Aix-en-Provence-Fr	Packaging label
	Consult instructions for Use	Product label