



 **Shvabe**
ZURICH

**CATALOGUE
OF SHVABE-ZURICH GMBH
MEDICAL EQUIPMENT**

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«Our main purpose is to help healthcare providers diagnose, monitor and treat diseases of even the smallest patients so that everyone can live life to the fullest»

John T.C. McGough
Managing Director

Dear Partners and Friends!

We are glad to present to you our medical product-range of neonatal devices, which fully meets the requirements and needs, not only of mothers and babies, but also of professionals and specialists in the neonatal field.

Shvabe-Zurich GmbH, is a Swiss company which manufactures and promotes high-quality neonatal equipment since 2007.

Our product range is constantly being updated with new models according to the newest market trends which includes incubators, phototherapy lamps, infant warmers and etc. We focus on the needs of our customers and constantly seeking the best solutions and ways to improve our products. Innovative development skills and know-how, together with careful production practices, and processes of optimizations allow us to offer our customers the safest products with both high quality and reasonable prices, meeting the personal requirements and individual needs of our clients. We work on the principle in production – a good device should be adapted to the client and not the client to the device.

We value the highest production standards, uncompromising quality of materials and component parts, and attractive design. Shvabe-Zurich GmbH medical products are certified under medical devices directive 93/42/EEC (CE designation), meet the requirements of Medical Devices Act and all relevant safety and electromagnetic compatibility requirements. This means that our business is subject the strictest quality regulations and we take care about efficiency through all stages from initial production to customer service.

True Swiss quality of our products is combined with a flexible policy of our company and the willingness to open new markets. Since the foundation our company it has gained a reputation of a trusted partner in many European, Asian and African markets and created a network of representatives and dealers in over 40 countries in the world. Our policy in international trade - to build a long-term partnership based on trust. For our clients we are ready to offer a full product consulting, installation technical training and service support.

Our main principles:

- Constant improving and modernization of the products according to the customer's needs and market developments
- Ensuring global product quality
- Creating an effective work environment
- Orientation to have a long-term business relations to our partners
- Openness and efficient support of our clients all over the world

Modern technology from the very beginning, innovative development, flexibility and openness to the changes in a global marketplace and creating safe technologies: Shvabe-Zurich GmbH– Competence and care everywhere.

TOMORROW'S TECHNOLOGY TODAY

We invite you to be part of our global team!

John T.C. McGough
Managing Director
Shvabe-Zurich GmbH



Competence
and care
everywhere!



IDN-03 INFANT INTENSIVE CARE INCUBATOR

Advanced technologies



The infant intensive care incubator IDN-03 is intended for nursing and carrying out of intensive therapy for neonates, including premature babies having critically low weight (from 500 g) in departments of neonates resuscitation, intensive therapy wards, neonates pathology sections, maternity hospitals.

Micro processing control of incubator allows to adjust temperature, oxygen concentration, air humidity, neonate's temperature and to output vital parameters on the monitor and PC.



Advantages of IDN-03

- infant module lifting and tilting mechanism (Trendelenburg function)
- system of infant module's automatic horizontal alignment
- self diagnostics system controlling functioning of all incubator units
- color liquid crystal display and membrane keyboard
- audio-visual alarm system under deviations from preset modes of temperature, external power supply damages, sensors and ventilator failures
- double walls of infant module
- 6 windows of access to baby, hinged panels from two sides
- 12 ports and a slot for X-ray cassette
- 4 mains sockets for additional equipment connection
- automatic self cleaning of humidifier
- options: camera (video-monitoring) scales
- built-in memory (record up to 7 days)

IDN-03

INFANT INTENSIVE CARE
INCUBATOR

Technical specifications

Adjustment of temperature inside infant module	from 30 to 39 °C
Adjustment of temperature over neonate's skin	from 34 to 39 °C
Control step	0,1
Measurement channel error	0,8
Control of relative air humidity	from 20 to 95 %
Oxygen concentration control	from 21 to 75 %
Measurement of mass	from 0,02 to 10 kg
Vertical displacement (lift) of infant module	240 mm
Infant module tilt angle	10 degrees
Continuous operation time	more than 72 hours
Level of sound in infant module	50 dBA
Concentration of CO ₂ in module, no more than	0,4%
Class of safety	IIb
Overall dimensions:	
Height	1650 mm
Width	750 mm
Length	1100 mm

IDN-02 INFANT INTENSIVE CARE INCUBATOR

Time-proved reliability



The infant intensive care incubator IDN-02 is intended for nursing and effective treatment of premature and weak infants in maternity homes, emergency care and therapeutic pediatric wards.

The infant compartment provides reliable protection from the environment and creates optimum conditions for infants: steady temperature, even distribution of heat, air humidification, regulated oxygen supply.

The built-in scales allow to monitor the infant's weight.



Advantages of IDN-02:

- built-in scales
- infant module lifting and tilting mechanism (Trendelenburg function)
- air humidifier
- audio-visual alarm system under deviations from preset modes of temperature, external power supply damages, sensors and ventilator failures
- double walls of infant module
- transportation trolley for free movement
- 5 windows of access to the neonate
- slot for X-ray cassette

IDN-02

INFANT INTENSIVE CARE
INCUBATOR

Technical specifications

Adjustment of temperature inside infant module	from 25 to 38,5 °C
Adjustment of temperature over neonate's skin	from 35 to 36,9 °C
Control step	0,1
Measurement channel error	0,3
Relative humidity adjustment	from 60 to 85 %
Oxygen concentration adjustment	from 21 to 95 %
Vertical displacement (lift) of infant module	200 mm
Infant module tilt angle	10 degrees
Continuous operation time	more than 72 hours
Level of sound in infant module	60 dBA
Concentration of CO ₂ in module not more than	0,4%
Class of safety	IIb
Overall dimensions:	
Height	1720 mm
Width	620 mm
Length	1650 mm

SNO INFANT WARMER

At the first minutes...

Infant warmer SNO is intended for adaptation of the newborns by carrying out of activities for recovery of vital functions in resuscitation departments, perinatal hospitals, ICU.

The resuscitator provides automatically controlled heating of infants by infrared radiation and urgent oxygen therapy.



Advantages of SNO:

- SNO infant warmer provides automatic adjustable heating of the infant by infrared radiation and emergency oxygen therapy.
- Possibility to install additional equipment for:
 - radiography
 - blood transfusion
 - dosed introduction of medical solutions
 - cardiac massage
 - infant bed height adjustment
- Audio-visual alarm system

SNO

INFANT
WARMER

Technical specifications

Temperature adjustment range by skin sensor	from 35 to 37,9°C
Displayed temperature range	from 30 to 39,9°C
Adjustment range of oxygen under the neonatal cover	40 – 95%
Maximum mattress inclination angle	10 degrees
Heating module rotation angle, degrees	65 ±5 degrees
Maximum infrared radiation density: – in all the range, – in near range (760 – 1400 nm)	60 kW/cm 10 kW/cm
Continuous operation time	72 hours
Overall dimensions: – height – width – length	1950 mm 710 mm 1100 mm

OFN-02 NEONATAL PHOTOTHERAPY LAMP

Useful light



Neonatal phototherapy lamp OFN-02 is intended for efficient treatment of jaundice of the newborn without using additional medicines in the perinatal centers, maternity and child hospitals.

In the lamp are used high-brightness LEDs of narrow spectrum, which allow to increase lamp life time without losing the power over 40 000 hours. Lamp operation principles is based on the irradiation of infant skin by light radiation in spectral range 450-500 nm (blue radiation), that can help decrease of bilirubin concentration in blood.



Advantages of OFN-02:

- absence of side adverse effects inherent to lamp light sources
- infant irradiation time is reduced by half
- long life time of the lamp (40 000 hours)
- two operating modes
- noiseless operation
- power consumption decrease
- large area of useful irradiation
- models: with pole
without pole

OFN-02

NEONATAL
PHOTOTHERAPY LAMP

Technical specifications

Light radiation spectral range	450 – 500 nm
Radiation power spectral density at distance 460 mm from the protective glass:	
Maximum, at least	40 mcW/cm ² nm
Mean	20 mcW/cm ² nm
Continuous operation time	over 72 hours
Operation mode entering time	less than 10s
Irradiation useful area	660 cm ²
Overall dimensions:	
– illuminator with pole	329×442×60 mm
– without pole	308×308×68 mm
– pole	698×575×(1173-1523)mm
Weight:	
– illuminator without pole	1,2kg
– illuminator with pole	10,5 kg
Power consumption:	30 VA
Safety class	Ila

OFN-03 NEONATAL PHOTOTHERAPY LAMP

Useful light

Neonatal phototherapy lamp OFN-03 is used for treatment of hyperbilirubinemia (jaundice) for infants by means of reducing the concentration of indirect bilirubin in blood by irradiation of infant's skin with light flux of 430-530 nm.

The extra bright blue light diodes allow to reduce the period of treatment and nursing of the neonates in neonates' pathology departments, decrease the percentage of diseases and complications caused by jaundice and increase lamp life time without losing the power over 50 000 hours.



Advantages of OFN-03:

- integrated: CLOCK and TIMER (time countdown)
- two operating modes
- extra bright light diodes of narrow spectrum
- noiselessness and low energy consumption
- built-in protection from overheating
- sound and visual alarm systems
- displaying of irradiator operation hours
- long life time (50 000 hours)
- models: with pole
without pole

OFN-03

NEONATAL
PHOTOTHERAPY LAMP

Technical specifications

<p>Total radiation intensity for bilirubin in the center of efficient irradiation area at a distance of 450 mm from the protective glass for the following radiation level:</p> <ul style="list-style-type: none"> – maximum – mean 	<p>5500±900 mcW/cm² 3000±600 mcW/cm²</p>
<p>Mean value of spectral intensity density in the center of efficient irradiation area at a distance of 450 mm from the warmer protective glass for the following radiation level:</p> <ul style="list-style-type: none"> – maximum – mean 	<p>not less than 40 mcW/(cm²·nm) not less than 20 mcW/(cm²·nm)</p>
<p>Efficient irradiation area</p>	<p>300x220 mm</p>
<p>Power consumption</p>	<p>50 V·A</p>
<p>Class of safety</p>	<p>Ila</p>
<p>For irradiator with pole:</p> <ul style="list-style-type: none"> – minimum height from the illuminator protective glass to the floor – height adjustment range of the illuminator location (from the ultimate low position to the ultimate upper) – illuminator rotation angles on the pole stud around horizontal axis 	<p>950 mm not less than 350 mm 90°</p>

ODN-01 INFANT WARMING MATTRESS

Mother's warmth is always with you

The infant warming mattress ODN-01 is intended to compensate heat loss of the newborn with hypothermia or during resuscitation activities in hospitals.

The heater allows to maintain high accuracy the preset optimum temperature on the surface of mattress or patient skin depending on the selected mode.



Advantages of ODN-01:

- can be used separately or additionally to other neonatal equipment
- support contact between mother and a child
- two temperature adjustment modes
- built-in alarm system
- easy cleaning and disinfection

ODN-01

INFANT
WARMING MATTRESS

Technical specifications:

Set temperature range	from 35 to 39 °C
Maximum mattress surface temperature deviation in different parts	± 1°C
Alarm triggering – at temperature deviation	0,4
Continuous operation time	over 72 hours
Power consumption	50 VA
Mattress overall dimensions: a) version 3170.10000000: – height – width – length b) version 3170.1000000001: – height – width – length	20 mm 410 mm 555 mm 20 mm 600 mm 760 mm
Control unit overall dimensions, mm: – height – width – length	220 mm 150 mm 200 mm
Heater's weight	4 kg

RADIANT HEAT-BONO NEONATAL INFRARED HEATER

Heat, bringing health

The neonatal infrared heater «Radiant heat - BONO» is intended to use as a basic or additional heat source and also for treatment of hyperbilirubinemia during nurse and therapy of neonates in maternity homes, departments of neonates pathology, obstetric institutions.



Advantages:

- 3 operation modes: preliminary heating, manual and automatic modes
- 2 methods of phototherapy time setting: CLOCK, TIMER (time countdown)
- Adjustment of heating power and phototherapy radiation intensity
- Sound and visual alarm systems
- Active protection from overheating and combustion during improper operation
- Vertical movement of the heater (height adjustment)

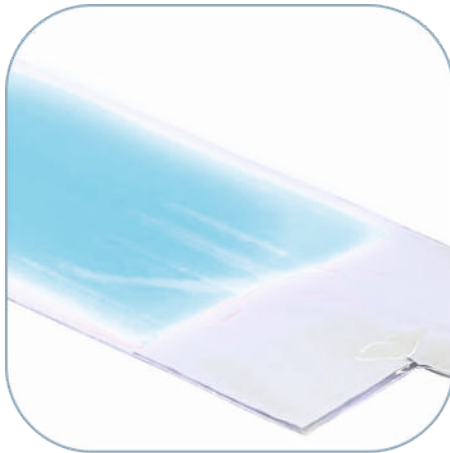
RADIANT HEAT-BONO

 NEONATAL
INFRARED HEATER

Temperature adjustment range	from 30°C to 38°C
Maximum level of operating field irradiance: – in all infrared spectrum – in near field of infrared spectrum (from 760 to 1400 nm)	60 mW/cm ² 10 mW/cm ²
Spectral range of light radiation	430-530 nm
Level of noise of the working field area at a distance of 800 mm from the warmer module at standard operation	not more than 60 dBA
Level of total radiation intensity for bilirubin at a distance of 800 mm from the warmer protective glass in the efficient irradiation area center: – maximum – mean	3800±700 mcW/cm ² 1900±400 mcW/cm ²
Mean value of radiation intensity spectral density at a distance of 800 mm from the warmer module protective glass for the following radiation level: – maximum – mean	36 mcW/(cm ² ·nm) 18 mcW/(cm ² ·nm)
Relative distribution of total radiation intensity for bilirubin on the efficient irradiation area	not less than 40 %
Class of safety	IIa
Overall dimensions in upper/low position of the warmer module	1830/1580 x 700 x 900 mm
Weight	15 kg

BILIFLEX FIBROOPTICAL SYSTEM FOR NEONATES PHOTOTHERAPY

Useful light



Biliflex is intended for efficient and quick decrease of bilirubin level in neonates with jaundice owing by the use of high intensive, constant and uniform therapeutic light of narrow medical spectrum 450-480 nm hitting directly to the neonate's skin.

The potentially harmful ultraviolet and infrared irradiation is absent, thus decreasing risk of skin and eyes injury (including medical staff) and also hazard of hyperthermia and dehydration.



Advantages

- Compact and light
- Flexible fiber mattress with removable single use hoods
- Radiation efficiency 30 mW/cm/nm even through diaper
- Removable light guide for ease of storing, cleaning and disinfecting
- Bracket of fixation onto incubator pole, tool shelf
- Possibility for domestic use
- No blinding for neonate and medical staff
- Radiation area 300x200 mm covers 90% of the neonate's body
- Radiation source resource is 5 years without replacement

BILIFLEX

FIBROOPTICAL SYSTEM
FOR NEONATES PHOTOTHERAPY

Technical specifications

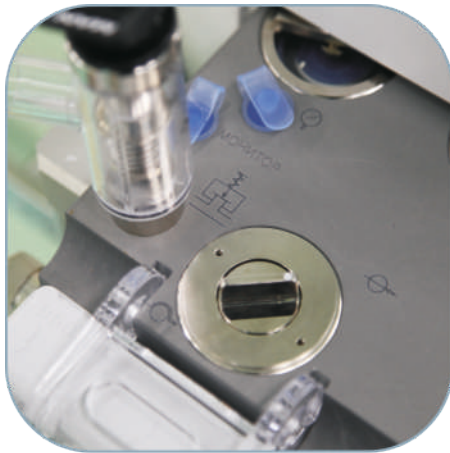
Total radiation intensity for bilirubin in the center of cloth efficient irradiation area with connector for the following radiation level: – maximum – mean	2700±675 mcW/cm ² 1800±450 mcW/cm ²
Peak value of radiation spectral density in the center of cloth efficient irradiation area with connector for the following radiation level: – maximum – mean	30 mcW/(cm ² ·nm) 20 mcW/(cm ² ·nm)
Local distribution of total radiation intensity for bilirubin over cloth efficient irradiation area with connector	40%
Noise level, produced by the product at a distance of 1 m from the control unit	60 dBA
Duration of one phototherapy cycle in the mode TIMER (time countdown of phototherapy carrying out) – minimum duration – maximum duration	5 min 72 h
Step of time change in the mode TIMER	5 min
Duration of one phototherapy cycle in the mode CLOCK	72 h
Mean life time	5 years
Class of safety	Ila
Voltage	98 - 242 V
Frequency	50±0,5 Hz
Power consumption	100 V·A
Control unit dimensions (width x length x height)	200x180x200 mm

MAIA-01 MULTIFUNCTIONAL DEVICE OF INHALATION ANESTHESIA

Safety dream

Multifunctional device of inhalation anesthesia MAIA-01 is intended for carrying out of inhalation anesthesia (IA) for adults and children using any breath circuit in case of surgical interventions of any complexity providing artificial lung ventilation in surgery departments of medical institutions of any capacity.

Convenient system of monitoring allows to control IA, artificial pulmonary ventilation and important parameters of the patient.



Advantages of MAIA-01:

- Possibility to use new, safe and effective anesthetics
- Wide variety of ventilation modes
- Full monitoring integrated in complex
- Operation in autonomous power supply mode (built-in accumulator)
- Automated and understandable by intuition control
- For adults and children older than 1 year

MAIA-01 MULTIFUNCTIONAL DEVICE
OF INHALATION ANESTHESIA

Technical specifications:

Anesthetics	<ul style="list-style-type: none"> – Nitrous oxide (N₂O) – Isoflurane (Iso) – Sevoflurane (Sev) – Xenon (Xe)
Ventilation modes	<p>Controlled:</p> <ul style="list-style-type: none"> – volume-controlled ventilation (VCV) with inspiration pause (plateau) – pressure-controlled ventilation (PCV) – periodic lungs inflation (VCV+Sigh) (“sigh”) – positive end expiratory pressure (electronic PEEP) <p>Mandatory assisted:</p> <ul style="list-style-type: none"> – pressure support ventilation (PSV) – apneic ventilation (VCV+Apn) – synchronized intermittent preiodic ventilation (pSIMV+PSV and vSIMV+PSV) <p>Spontaneous breath (Spont)</p> <p>Manual ventilation (Manual)</p>
Parameters on the integrated monitor screen	<ul style="list-style-type: none"> – Pressure (P) – PEEP – Tidal volume, ventilation frequency – Fin O₂ – Fin Xe
Parameters on the patient monitor screen (additional kitting)	<ul style="list-style-type: none"> – Arterial blood oxygenation (SpO₂) – Pulse rate (PR) – Heart rate (HR) – Levels of ST-segments displacement along all leads – Respiratory rate (RR) – Concentration of N₂O at inspiration (Fin N₂O) and expiration (Fet N₂O) – Concentration of liquid anesthetics vapors at inspiration (Fin Iso/Sev) and expiration (Fet Iso/Sev) – Content of CO₂ at inspiration (Fin CO₂) and at the end of expiration(Fet CO₂) – Arterial pressure, non-invasive (NIBP) - DIA/SYS/Mean – Temperature of patient's body (T) – two channels

TEVLAR BREATHING MIXTURE HUMIDIFIER

Life-giving air



Humidifier TEVLAR is intended for heating and increase of the water content of breathing mixture coming to the patient from the artificial lung ventilation device (ventilator), inhalational anesthesia device or the oxygen inhaler.



Advantages of TEVLAR:

- Automatic control of temperature parameters selected by a doctor and respiratory gas humidity at the feeding hose outlet (for patient) in the wide range of minute ventilation;
- Autonomous channels of temperature and respiratory gas humidity content control;
- Indication of the preset and measured temperature at the feeding hose outlet on the numeric display;
- Availability of the spiral airway of foamed metal in the evaporation chamber (reservoir) reduces the water heat degree (not more than 65 °C), increases the reliability and serviceability.
- Availability of alarms on respiratory gas overheat and disfunction.
- Simple service and safety of use, can be use cefficiently with any ventilators, inhalational anesthesia devices and oxygen inhalers.

Technical specifications:

Overall dimensions (width x length x height)	145x175x195 mm
Weight	2,7 kg
Attaching holes of the reservoir	22 mm
Maximum volume of poured reservoir water (per set)	250 ml
Breathing mixture temperature measurement at the supply hose outlet	from 25°C to 45°C
Relative humidity	75% or 100%
Range of breathing mixture flows	from 2 to 50 l/min
Duration of temperature reach 33eC and relative humidity 85% at the feeding hose outlet (at the ambient temperature not less than 20eC and breathing mixture flow within 30 l/min)	not more than 20 min
Ambient temperatures range	from 15°C to 35°C

APDN-01 NASAL CPAP
INFANT VENTILATOR

Breathing the life



Noninvasive Nasal CPAP Infant Ventilator for neonates (APDN-01) is intended for respiratory therapy on newborns in CPAP (continuous positive airway pressure) mode.

Nasal cannulas provide newborn infant with continuous positive airway pressure (up to 12cm H₂O, respiratory gas flow rate is up to 15l/min) that prevents the drop of respiratory saccules, as well as stimulates respiration of newborn infants. The APDN-01 reduces the risk of development of chronic pulmonary diseases.



Advantages of APDN-01

- oxygen and Air mixture monitoring (pressure, flow, O₂ concentration)
- pole with fixture elements for the humidifier
- compact size
- variable flow generator

Technical specifications:

Pressure at the blender inlet	Oxygen: 0,35 ±0,15 MPa (3,5 ±1,5 atm) Air: 0,35 ±0,15 MPa (3,5 ±1,5 atm)
Gas pressure at outlet	0 – 15 cm H ₂ O
Oxygen concentration in gas	21 – 100%
Gas flow rate	0 – 15l/min
Blender weight, not more	2,7 kg
Pole weight, not more	6 kg
Overall dimensions	320x190x230 mm.
Pole height	635x365x1350 mm.



*When the
smallest thing
matters*



QUALITY MANAGEMENT SYSTEM



CE Certificate
Issued to

Shvabe-Zurich GmbH,
Registered office:
Talacker 42, CH-8001 Zurich, Switzerland
Operative site:
Schaffhauserstrasse 560, 8052 Zürich, Switzerland

Bureau Veritas Italia S.p.A. certifies that the Full Quality Assurance System of the above organization has been audited and found to be in accordance with the requirements of

DIRECTIVE 93/42/EEC as amended
(in accordance with Annex II - excluding paragraph 4)

In relation to the following products

Subcategory:	See Annex
Generic group:	See Annex
Model:	See Annex
Class:	See Annex

(may refer to the Annex of the certificate that lists all the products / models of devices subject to certification)

Reference BV practice: ZIG. N. 60546335

Certification cycle start date: **20 September 2018**
Subject to the continued satisfactory operation of the organization's Management System, this certificate expires on: **19 September 2021**
Original certification date: **20 September 2018**

Certificate N. **IT285277** Rev. N. 1 of: **20 September 2018**


ANDREA FILIPPI - Local Technical Manager

This certificate is issued by Bureau Veritas Italia S.p.A. Via Moscova, 347 - 20126 Milan, as a notified body for the Directive 93/42/EEC, with identification number 1370



Annex CE Certificate
IT285277

Subcategory:	Respiratory devices, devices for oxygen therapy, anesthesia for inhalation	
Generic group:	Model:	Class:
Infant nasal respiratory breath support device	APDN-01 - «UOMZ»	Ila
Breathing mixtures humidifier	TEVLAR - «UOMZ»	Ila
Multifunctional inhalation anesthesia device for adults and children	MAIA-01	Ilb
Subcategory:	Devices for stimulation or inhibition	
Generic group:	Model:	Class:
Neonatal irradiator for phototherapy	OFN-02 - «UOMZ», OFN-03	Ila
Subcategory:	Devices for hypothermia / hyperthermia	
Generic group:	Model:	Class:
Neonatal table with automatic heating temperature control	SNO - UOMZ	Ila
Neonatal infrared heater	«Radiant heat-BONO»	Ila
Infant neonatal heater	ODN-01-«UOMZ»	Ila
Intensive care infant incubator	IDN-02-UOMZ, IDN-03 - «UOMZ»	Ilb

Reference BV practice: ZIG. N. 60546335

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