GaleMed

Neonatal Care Solution

Small Steps For Big Journey

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Babi.Plus®

Over the past decades, the increase in preterm births has become a challenging problem globally. Unlike healthy newborns, premature babies may have more health problems, including brain, heart, eyes, and respiratory issues. Owing to their premature lungs, most premature babies have breathing difficulties to survive.

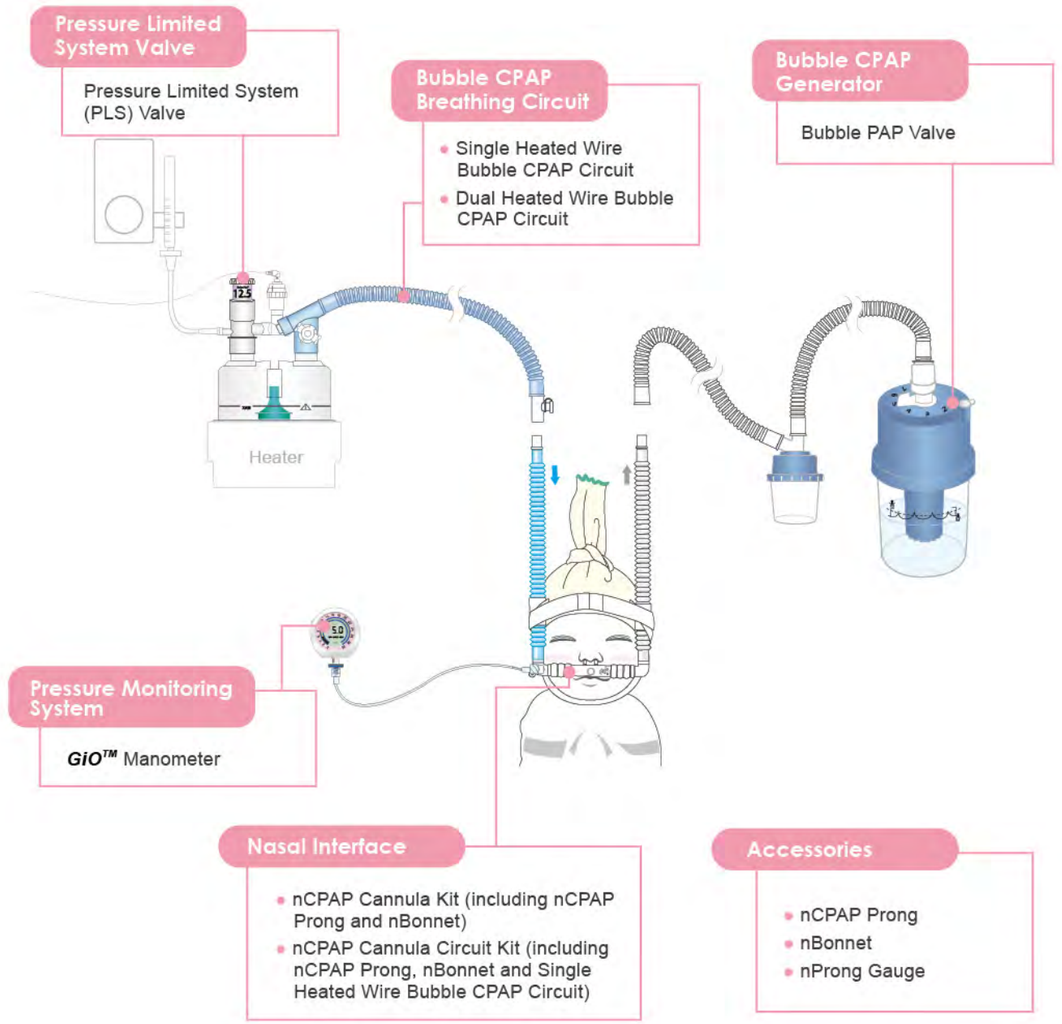
The invention of Babi.Plus was supported by a team of experienced physicians, engineers, and respiratory therapists, who work effectively to provide a comprehensive range of medical care solutions for neonates. We trust these innovative solutions could offer healthcare professionals a superior option for delivering medical care and achieving better outcomes.

We care for the most fragile lungs.

nBubble CPAP System

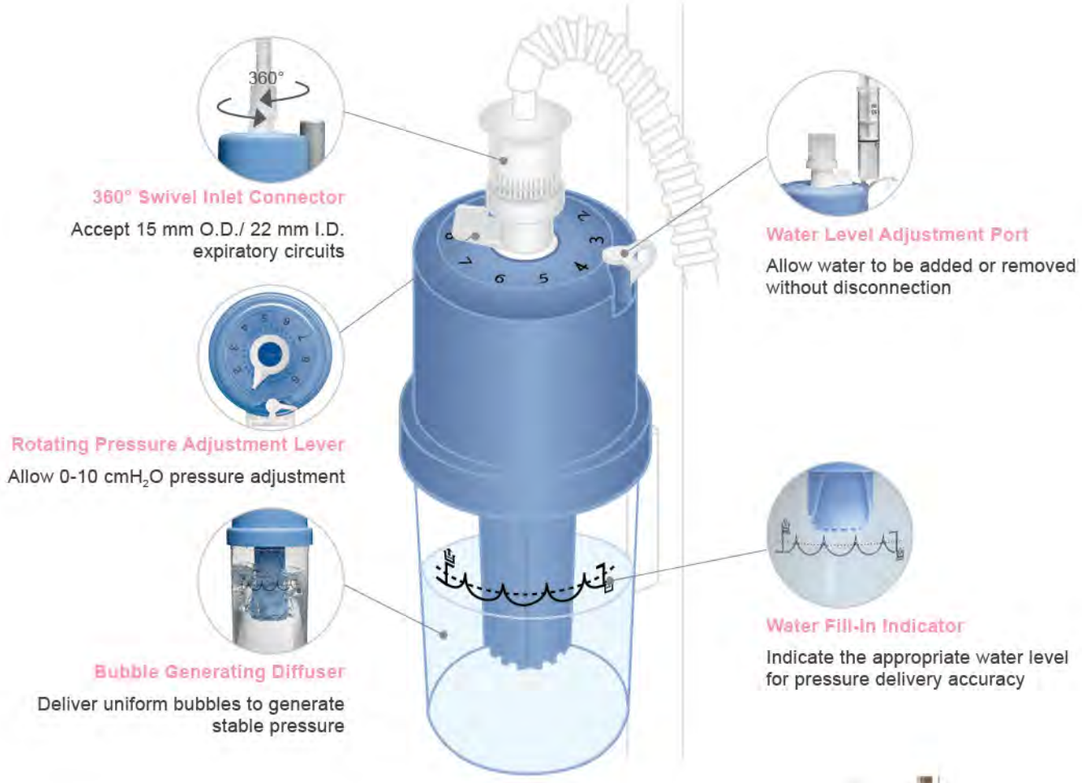
Bubble continuous positive airway pressure (CPAP) is a safe and effective respiratory support to neonates with respiratory distress syndrome (RDS) as an alternative to ventilator CPAP. The early use of Bubble CPAP reduces intubation days on mechanical ventilation, postnatal steroids use and increases postnatal weight gain with no increased complications.[1]

Babi.Plus® Bubble CPAP System provides comprehensive designs specially for premature infants, completing with Bubble CPAP generator, pressure limited safety valve, full ranges of nasal CPAP interfaces, Bubble CPAP heated wire circuit, and pressure monitoring system.



Reference[1] Narendran V, Donovan EF, Hoath SB, Akinbi HT, Steichen JJ, Jobe AH. Early bubble CPAP and outcomes in ELBW preterm infants. J Perinatol 2003;23:195-9

Bubble PAP Valve



360° Swivel Inlet Connector

Accept 15 mm O.D./ 22 mm I.D. expiratory circuits

Rotating Pressure Adjustment Lever

Allow 0-10 cmH_2O pressure adjustment

Bubble Generating Diffuser

Deliver uniform bubbles to generate stable pressure

Water Level Adjustment Port

Allow water to be added or removed without disconnection

Water Fill-In Indicator

Indicate the appropriate water level for pressure delivery accuracy

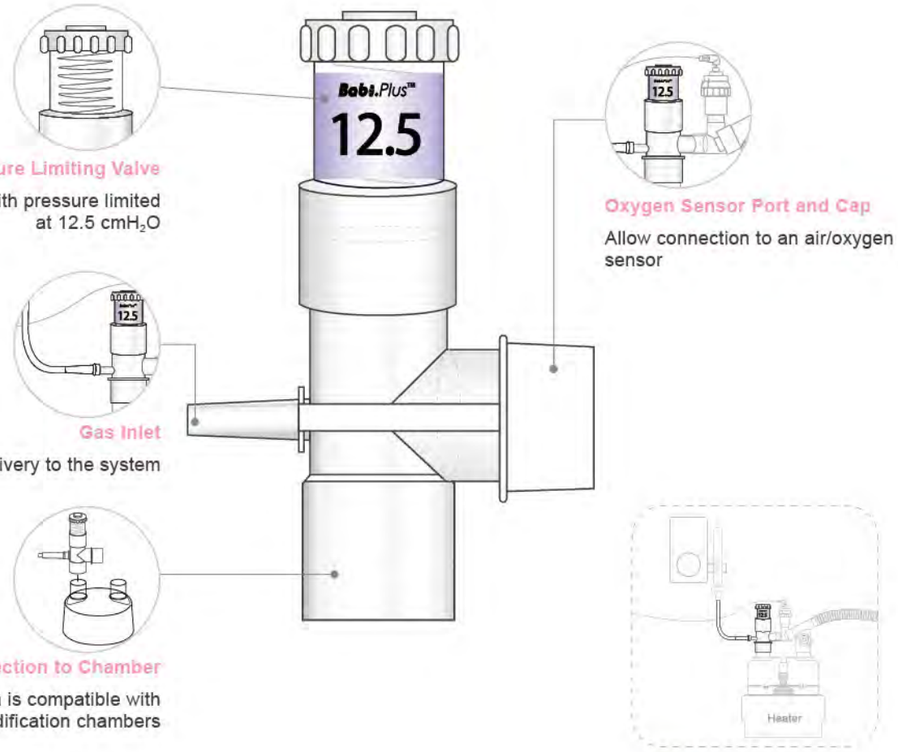
Babi.Plus® Bubble PAP Valve provides a continuous positive airway pressure to pre-terms, terms and infants weighing less than 10 kg for spontaneously breathing.

Bubble PAP Valve is adjustable from 0 to 10 cmH_2O for gas flow 1-12 liters per minute with accuracy of ± 1 cmH_2O.

Note: Bubble PAP Valve set does not come with a Pole Clamp. For Pole Clamp information, please find page 38.

REF	Description	QTY
AN0018	Bubble PAP Valve	12 pcs/box

Pressure Limiting System Valve



Fixed Pressure Limiting Valve

Fixed system with pressure limited at 12.5 cmH_2O

Gas Inlet

Allow gas delivery to the system

22F Connection to Chamber

22F connection is compatible with most of humidification chambers

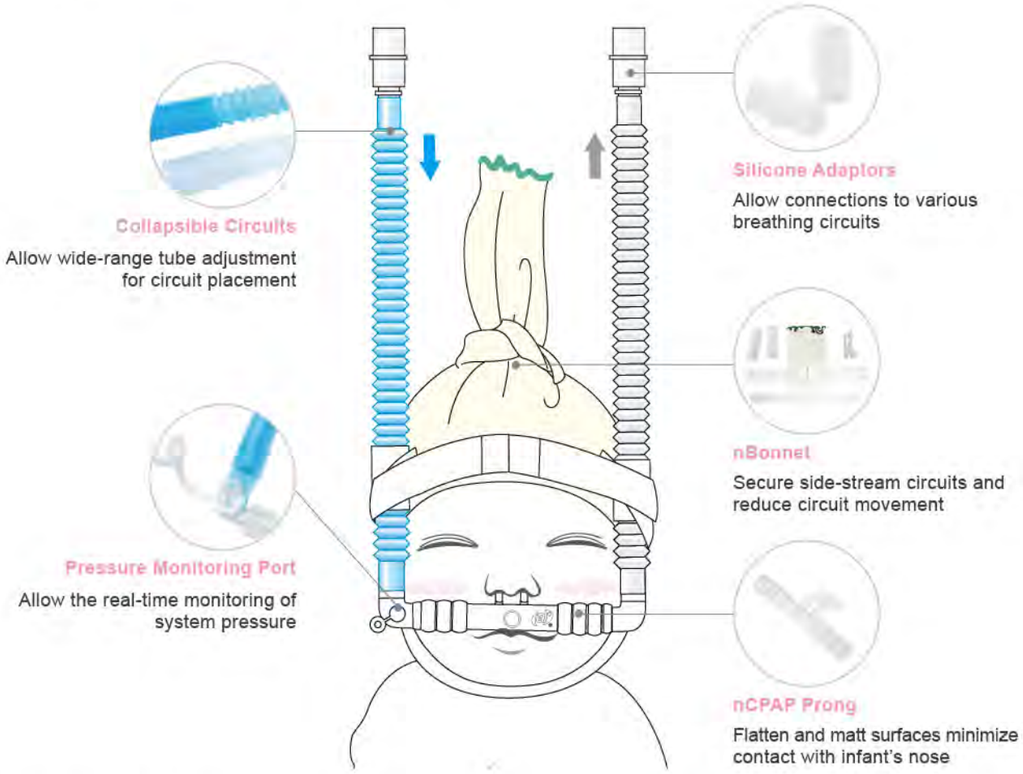
Oxygen Sensor Port and Cap

Allow connection to an air/oxygen sensor

Babi.Plus® Pressure Limiting System (PLS) Valve is a safe guard to the pressure level in the circuit or bubble CPAP system. The fixed pressure limiting valve releases pressure when it is exceeding the preset level for patient's safety. PLS Valve is intended for use on pre-terms, terms and infants less than 10 Kg during continuous gas flow therapy up to 12 liters per minute. Each valve comes with a pressure-relief valve, a gas supply line and a capped oxygen sensor port.

REF	Description	QTY
AN0099	PLS Valve, 12.5 cmH_2O, 22F	12 pcs/box
AN0019	PLS Valve, 10 cmH_2O, 22F	12 pcs/box
AN0066	Adj PLS Valve, 2-10cmH_2O, 22F	12 pcs/box

nBubble CPAP Cannula Kit

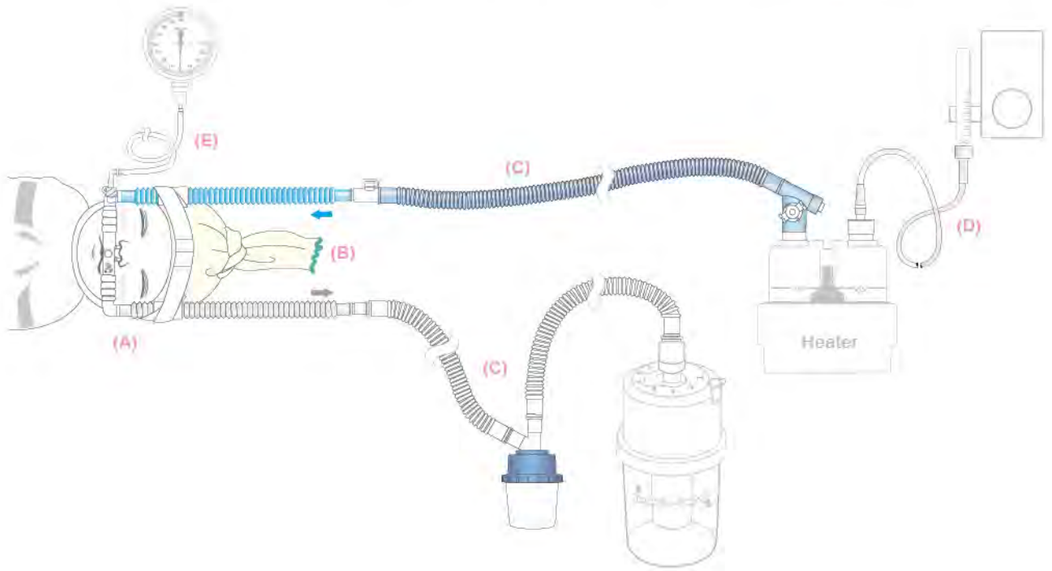


Babi.Plus® nBubble CPAP Cannula Kit can provide an effective way of gas delivery, and is uniquely designed to provide stability and safety during treatment. Each kit includes a silicone prong, a nBonnet, two 20 cm collapsible color-coded circuits (blue for inhale and transparent for exhale) and two silicone adaptors.

Contents

REF	Description	Prong Size	nBonnet Size	QTY
AN0020	nCPAP Cannula Kit, #0 w/ nBonnet Kit, #1	0	1	20 pcs/carton
AN0021	nCPAP Cannula Kit, #1 w/ nBonnet Kit, #1	1	1	20 pcs/carton
AN0022	nCPAP Cannula Kit, #2 w/ nBonnet Kit, #2	2	2	20 pcs/carton
AN0023	nCPAP Cannula Kit, #3 w/ nBonnet Kit, #2	3	2	20 pcs/carton
AN0024	nCPAP Cannula Kit, #4 w/ nBonnet Kit, #3	4	3	20 pcs/carton
AN0025	nCPAP Cannula Kit, #5 w/ nBonnet Kit, #3	5	3	20 pcs/carton
AN0026	nCPAP Cannula Kit, #6 w/ nBonnet Kit, #4	6	4	20 pcs/carton
AN0027	nCPAP Cannula Kit, #7 w/ nBonnet Kit, #4	7	4	20 pcs/carton

nBubble CPAP Cannula Circuit Kit



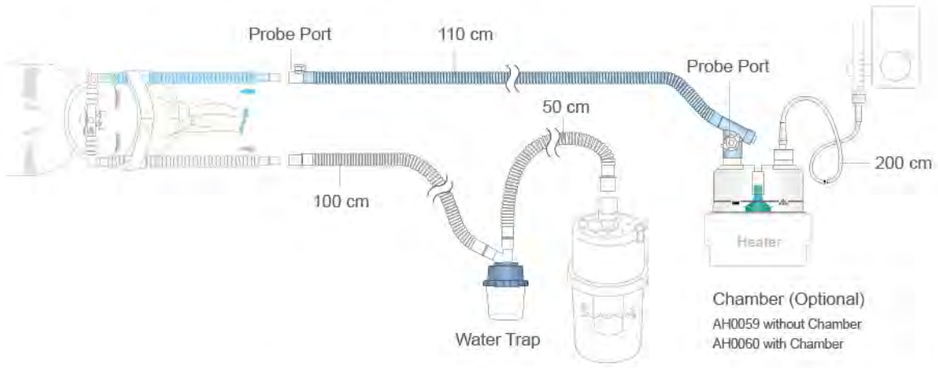
Babi.Plus® nBubble CPAP Cannula Circuit Kit offers a complete interfaces for ***Babi.Plus***® and other various bubble CPAP systems.

(A) Each kit includes a silicone prong ,
Two collapsible color-coded circuits ,
Two silicone adaptors ,
(B) A nBonnet,
(C) Single heated wire circuit ,
(D) An oxygen tubing ,
(E) A pressure monitoring line .

Contents

REF	Description	Prong Size	nBonnet Size	QTY
AN0030	nCPAP Cannula Circuit Kit, #0 w/Single Heated Wire Circuit	0	1	5 pcs/carton
AN0031	nCPAP Cannula Circuit Kit, #1 w/Single Heated Wire Circuit	1	1	5 pcs/carton
AN0032	nCPAP Cannula Circuit Kit, #2 w/Single Heated Wire Circuit	2	2	5 pcs/carton
AN0033	nCPAP Cannula Circuit Kit, #3 w/Single Heated Wire Circuit	3	2	5 pcs/carton
AN0034	nCPAP Cannula Circuit Kit, #4 w/Single Heated Wire Circuit	4	3	5 pcs/carton
AN0035	nCPAP Cannula Circuit Kit, #5 w/Single Heated Wire Circuit	5	3	5 pcs/carton
AN0036	nCPAP Cannula Circuit Kit, #6 w/Single Heated Wire Circuit	6	4	5 pcs/carton
AN0037	nCPAP Cannula Circuit Kit, #7 w/Single Heated Wire Circuit	7	4	5 pcs/carton

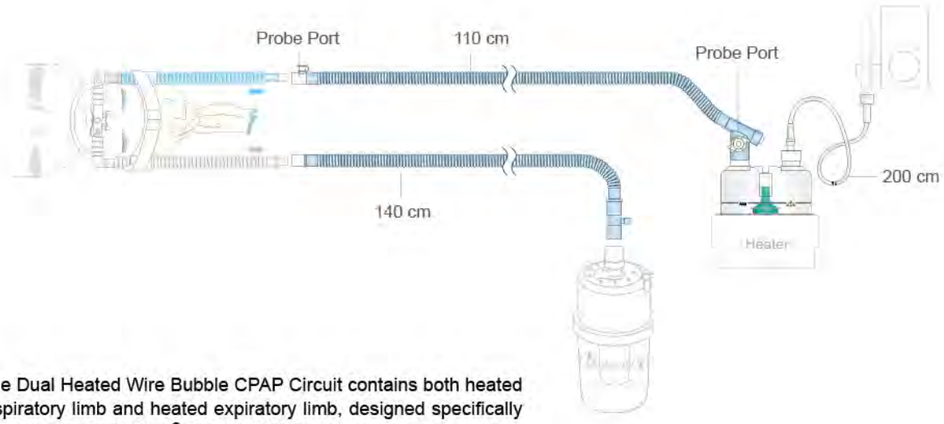
Single Heated Wire Bubble CPAP Circuit



The Single Heated Wire Bubble CPAP Circuit contains heated inspiratory limb designed specifically for use with ***Babi.Plus***® Bubble CPAP system.

REF	Description	QTY
AH0059	HW1 Circuit for Bubble CPAP	10 pcs/carton
AH0060	HW1 Circuit for Bubble CPAP w/chamber	10 pcs/carton

Dual Heated Wire Bubble CPAP Circuit



The Dual Heated Wire Bubble CPAP Circuit contains both heated inspiratory limb and heated expiratory limb, designed specifically for use with ***Babi.Plus***® Bubble CPAP system.

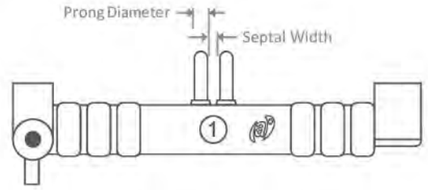
REF	Description	QTY
AH0061	HW2 Circuit for Bubble CPAP w/chamber	10 pcs/carton

nBubble CPAP Prong

Ergonomic Arc Prongs
Allow full insertion into nostrils and minimize air leakage

Bump Connection
Reduce displacement incident with stronger fixation

Flattened and Matt Surface
Free from skin irritation



Babi.Plus® nBubble CPAP Prong is made of super soft silicone material to minimize skin irritation. Each nBubble CPAP Prong Kit includes a prong, two elbow connectors, one port elbow connector with a cap and two silicone adaptors.

REF	Description	Size	Septal Width (mm)	Prong Diameter (mm)	QTY
AN0010	nCPAP Prong, #0 w/ Pressure Port Elbow	#0	2.1	2.8	5 pcs/box
AN0011	nCPAP Prong, #1 w/ Pressure Port Elbow	#1	2.4	3.2	5 pcs/box
AN0012	nCPAP Prong, #2 w/ Pressure Port Elbow	#2	2.6	3.8	5 pcs/box
AN0013	nCPAP Prong, #3 w/ Pressure Port Elbow	#3	3.8	4.4	5 pcs/box
AN0014	nCPAP Prong, #4 w/ Pressure Port Elbow	#4	4.2	5.0	5 pcs/box
AN0015	nCPAP Prong, #5 w/ Pressure Port Elbow	#5	5.0	5.0	5 pcs/box
AN0016	nCPAP Prong, #6 w/ Pressure Port Elbow	#6	5.6	5.5	5 pcs/box
AN0017	nCPAP Prong, #7 w/ Pressure Port Elbow	#7	6.8	6.0	5 pcs/box

nBubble CPAP Prong Gauge

Babi.Plus® nProng Gauge is a prong size measuring devices made of soft silicone material to minimize skin irritation. This ergonomic gauge assists clinicians with the selection of the appropriate size of nBubble CPAP Prong, and is also used as a gadget to gently dilate the nares.

AN0001 nProng Gauge

Package: 5 pcs/box

nBonnet

Babi.Plus® nBonnet is designed to secure the side-stream CPAP delivery system. With elastic strap fixtures and open top design, nBonnet is able to reduce up & down movement and to accommodate more head shapes. Each nBonnet kit includes a bonnet, two adhesive hook style fasteners, one chin strap and one ribbon.

REF	Description	Color	Size	Head Circumference (cm)	Package
AN0005	nBonnet Kit, #1, XS, Green	●	#1	22~25	25 pcs/box
AN0006	nBonnet Kit, #2, S, Yellow	●	#2	25~28	25 pcs/box
AN0007	nBonnet Kit, #3, M, Red	●	#3	28~31	25 pcs/box
AN0008	nBonnet Kit, #4, L, Blue	●	#4	31~34.5	25 pcs/box
AN0009	nBonnet Kit, #5, XL, Black	●	#5	34.5~38	25 pcs/box

Resuscitation

Dispo-Bag™ Manual Resuscitator

Monitoring Port

Allow attachment to pressure or CO_2 monitoring system

40 cmH_2O Safety Valve

Release excessive pressure at fixed level

30 mm O.D. Exhale Port

Connect to diverter cap or PEEP valve

High transparency bag

Slip-free texture and arrow-shape bag

The ***Dispo-Bag™*** is a disposable, single patient use system for manual ventilation equipped with transparent medical grade PC, PVC materials for ergonomic, lightweight and visual feedback during resuscitation.

The premium medical grade PVC bag provides an economic design, offering fast rebound and less operational force to reduce operator fatigue.

REF	Description	Mask Size	Pop-Off (cmH_2O)	Bag capacity (ml)	Reservoir Bag (ml)	Oxygen Tube (length:2m)	QTY
AR0079	DispoBag, Infant w/Pop-Off, Mask	#0	40	280	500	●	12 pcs/carton
AR0080	DispoBag, Infant w/Pop-Off, Reservoir	N/A	40	280	500	●	12 pcs/carton

Rescu-6™ Manual Resuscitator

Built-in airway pressure gauge

For monitoring airway and lung pressure

40 cmH_2O Safety Valve

Release excessive pressure at fixed level

CO_2 measuring port

For patient air circulation ratio measurement

Resuscitator bag

Non-PVC material and fast rebound

Rescu-6™ is a disposable manual resuscitator with economic model, a feature built-in pressure manometer and an unique pop off valve with a cap for monitoring airway pressure and avoiding pulmonary injuries due to excessive pressure.

An unique Non-PVC bag gives highly responsive with minimal mechanical resistance to provide optimum stroke volume with perfect recoil.

REF	Description	Mask Size	Pop-Off (cmH_2O)	Bag capacity (ml)	Reservoir Bag (ml)	Oxygen Tube (length:2m)	QTY
AR0027	R6 Resuscitator, Infant w/ Mask, #1	#1	40	280	500	●	12 pcs/carton
AR0028	R6 Resuscitator, Infant w/ Mask	N/A	40	280	500	●	12 pcs/carton

Rescu-7™ Manual Resuscitator

Diverter
Can attach bacterial filter or PEEP

40 cmH$_2$O Safety Valve
Release excessive pressure at fixed level

Soft silicone resuscitator bag
Can rebound swiftly

All-in-one intake valve
Reduce assembly time

Rescu-7™ is a manual resuscitator which accompanies with an unique air bagwhich has high responsiveness and minimal mechanical resistance. It offers portability and cost-effective with perfect recoil.

REF	Description	Mask Size	Pop-Off (cmH_2O)	Bag capacity (ml)	Reservoir Bag (ml)	Oxygen Tube (length:2m)	QTY
AR0070	R7 Resuscitator, Infant w/ Mask	#0	40	280	600	●	12 box/carton

MR-100™ Manual Resuscitator

Diverter
Can attach bacterial filter or PEEP valve

40 cmH$_2$O Safety Valve
Release excessive pressure at fixed level

Product ID
On major components for traceability

Soft silicone resuscitator bag
Slip-free surface texture and fast self-inflating rate

MR-100™ Manual Resuscitator is sub-series of ***MR-100 Plus™*** (280 ml infant, 550 ml child, 1600 ml adult), supplied with an independent reservoir valve. Accessories consisted with silicone parts and PSF connectors, which guaranteeing longer life spans even after numerous sterilization cycles to meet economic needs.

REF	Description	Mask Size	Pop-Off (cmH_2O)	Bag capacity (ml)	Reservoir Bag (ml)	Oxygen Tube (length:2m)	QTY
AR0002	MR-100 Resuscitator set, Infant	#0	40	280	600 (PVC)	●	12 boxes/carton
AR0039	MR-100 Resuscitator, Infant	#1	40	280	600 (PVC)	N/A	12 boxes/carton
AR0113	MR-100 Resuscitator set, Infant	#1	40	280	500 (Silicone)	N/A	12 boxes/carton
AR0112	MR-100 Resuscitator, linfant	N/A	40	280	N/A	N/A	12 boxes/carton

MR-100 Plus™ Manual Resuscitator

40 cmH_2O Safety Valve

Releases excessive pressure at fixed level

High transparency silicone bag

Rapid recoil for optimum ventilation

All-in-one intake valve

Reduce assembly time

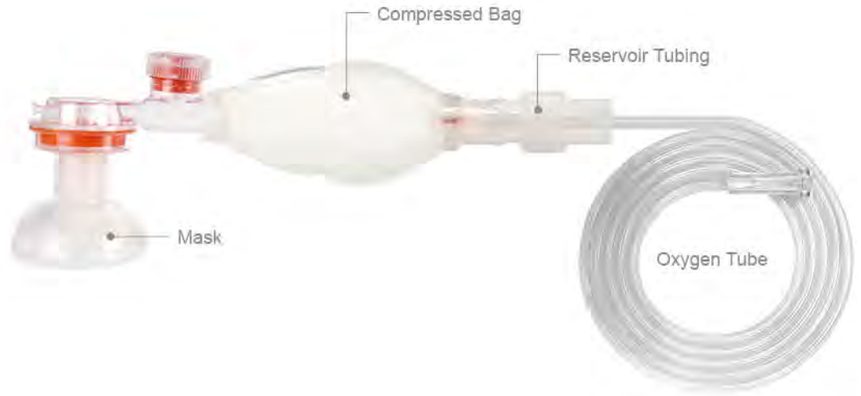
High transparency silicone reservoir bag

Longer life span for sterilization

MR-100 Plus™ are our most delicate reusable manual resuscitators (280 ml infant, 550 ml child, 1500 ml adult) that consist of semi-transparent silicone parts and PSF connectors, which provide visual check of the patients' conditions and longer life spans after numerous sterilization cycles.

REF	Description	Mask Size	Pop-Off (cmH_2O)	Bag capacity (ml)	Reservoir Bag (ml)	Oxygen Tube (length:2m)	QTY
AR0046	MR-100 Plus Resuscitator Kit, Infant	#0, 1	40	280	500 (Silicone)	●	10 boxes/carton
AR0058	MR-100 Plus Resuscitator, Infant	#0	40	280	500 (Silicone)	●	12 boxes/carton
AR0062	MR-100 Plus Resuscitator, Infant	N/A	40	280	600 (PVC)	N/A	12 boxes/carton

nBag



Pressure Monitoring Port

Allow prompt pressure measurement

25 cmH_2O 40 cmH_2O

Pressure Safety Valve

Allow limiting level adjustment of 25 cmH_2O and 40 cmH_2O

20 ml 50 ml

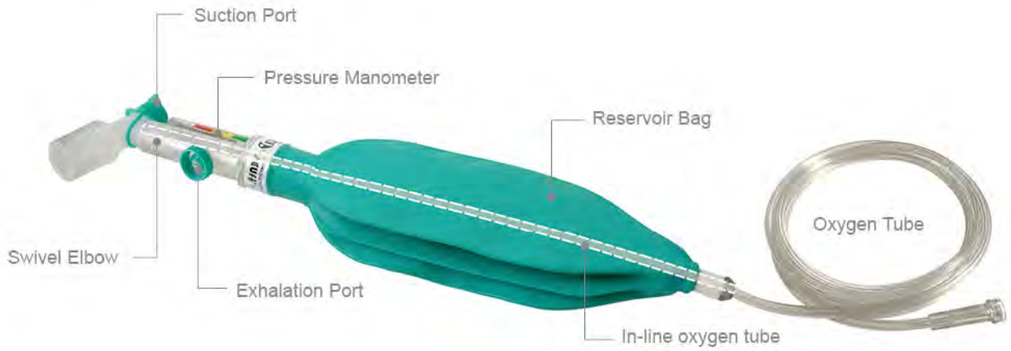
Resuscitation Volume

Precise volume prevents baby from volutrauma.

Babi.Plus® nBag minimizes patient's risk during operation through two pressure limiting levels, 25 cmH_2O and 40 cmH_2O. With the unique design, it's able to deliver two different smaller stroke volume, 20 ml or 50 ml. This safe pulmonary-assisted device, which is specially designed for premature and newborn infant up to 5 kg, is made of biocompatible, latex and phthalate-free silicone material.

REF	Description	QTY
AN0003	nBag Resuscitator	12 pcs/carton

Hyperinflation System



Swivel elbow

Permit 360° positioning of the resuscitator in relation to the patient.

Exhalation Port

Circular smooth adjustable exhalation port valve controls pressure level

Suction Port

Permit convenient suction without disengagement

Hyperinflation Bag

Soft breathing bag with response of the lung compliance

Pressure Manometer

Allow real-time pressure measurement

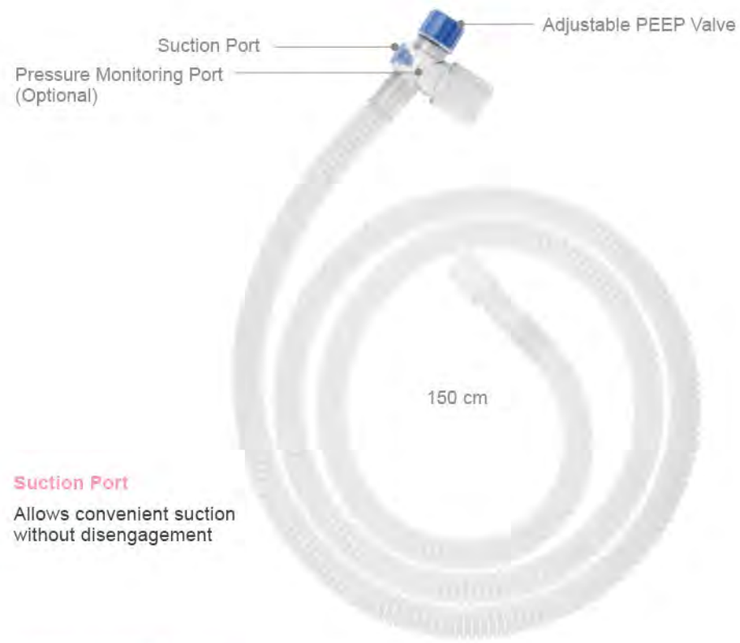
In-Line Gas Supply

Oxygen delivery close to the patient, which reduces possible CO_2 retention

Hyperinflation System includes a built-in pressure manometer which ranges 0-60 cmH_2O with accuracy of 5 cmH_2O. It continuously monitors the pressure that enters patient's lung, maximizing the survival rate.

REF	Description	QTY
AR0023	Venti.Plus Hyperinflation Kit, 0.25 L	20 pcs/carton
AR0024	Venti.Plus Hyperinflation Kit, 0.5 L	20 pcs/carton
AR0025	Venti.Plus Hyperinflation Kit, 0.5 L Mask	10 pcs/carton
AR0026	Venti.Plus Hyperinflation Kit, 1.0 L	20 pcs/carton

nAPV Circuit



Suction Port

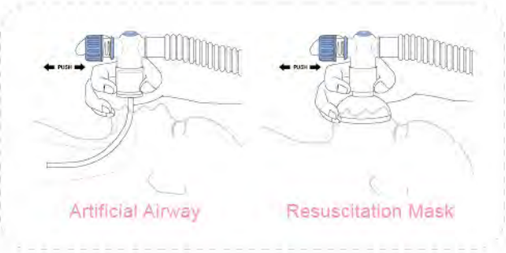
Allows convenient suction without disengagement

Adjustable PEEP Valve

PEEP level adjustment 2-25 cmH_2O

Pressure Monitoring Port (Optional)

Connect to pressure monitoring system for proximal airway pressure



Babi.Plus® nAPV Circuit is a T-piece resuscitator for neonates weighing under 10 kg, which provides emergency pulmonary ventilation by means of mask or artificial airway through a gas power source. Operated under flow rate of 5-15 LPM, nAPV Circuit is available to deliver pressure up to 22 ± 2 cmH_2O at 15 LPM and PEEP level adjustment 2-25 cmH_2O.

REF	Description	QTY
AN0028	nAPV Circuit	10 pcs/box
AN0029	nAPV Circuit w/Pressure Port	10 pcs/box

nMask

15mm Connector

With two level barb designed for easier attachment

Sturdy and Flexible Shell

Soft but steady silicone shell prevents from deformation

Cushioned Rim

Allow full cover around the mouth and nose, especially designed for premature

Babi.Plus® nMask is designed for use with resuscitators and T-piece resuscitation devices. With ergonomic construction, ***Babi.Plus***® nMask seals around the mouth and nose but does not cover the eyes or overlap the chin. The ***Babi.Plus***® nMask is designed to reduce air leakage and skin irritation. 6 sizes of nMasks are available for premature and neonatal patients.

REF	Description	QTY
AN0038	nMask, 25 mm	5 pcs/box
AN0039	nMask, 30 mm	5 pcs/box
AN0040	nMask, 35 mm	5 pcs/box
AN0041	nMask, 40 mm	5 pcs/box
AN0042	nMask, 45 mm	5 pcs/box
AN0043	nMask, 50 mm	5 pcs/box

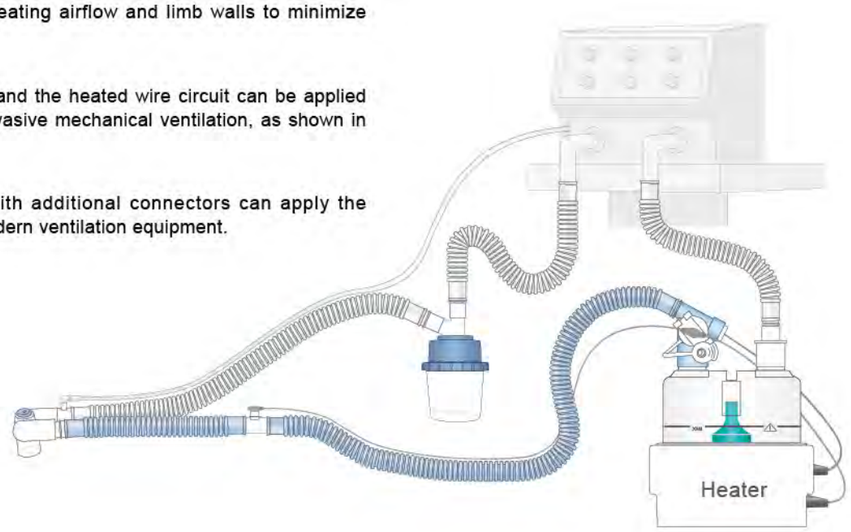
Breathing Circuit System

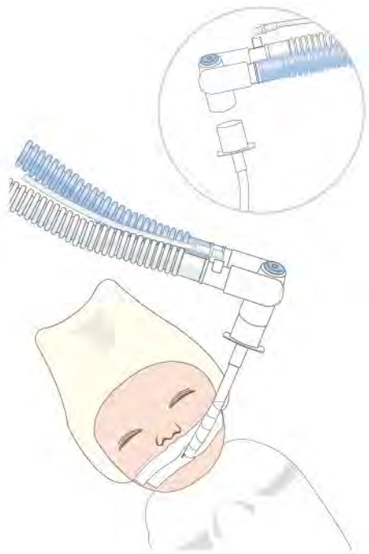
To support the airway function and ventilation of neonatal patients, a complete breathing circuit system includes an active humidification system that can deliver humidified and heated gas.

GaleMed provides a series of single and dual heated wire circuits. All heated limbs have a coiled heated wire structure to provide consistent heating airflow and limb walls to minimize possible rain-out.

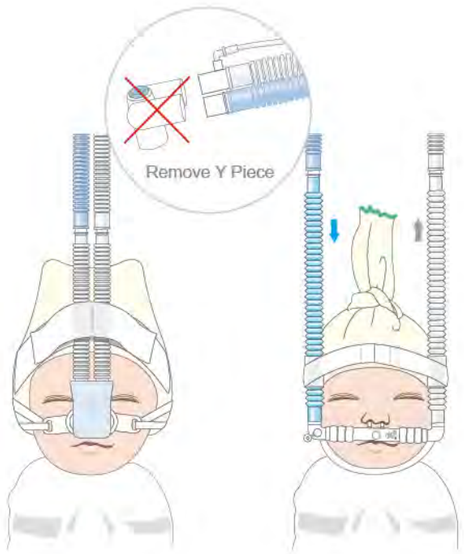
The Y-shaped piece and the heated wire circuit can be applied to invasive or non-invasive mechanical ventilation, as shown in the figure below.

The connector kit with additional connectors can apply the circuit to different modern ventilation equipment.



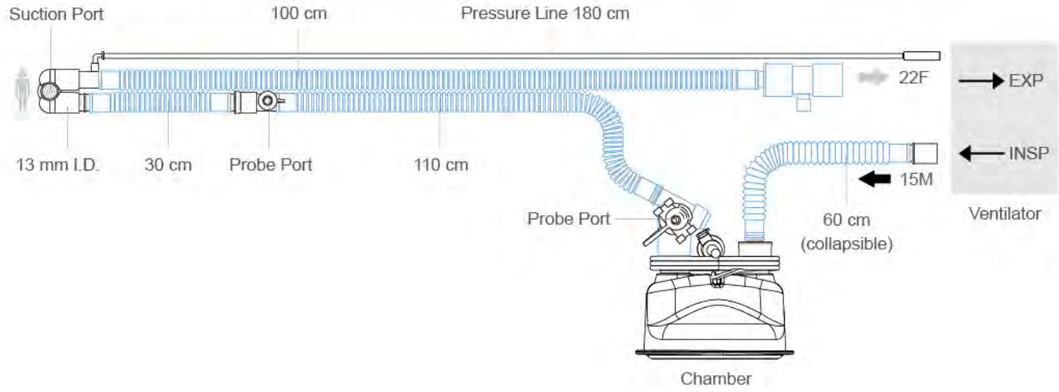


Invasive Mechanical Ventilation



Non-Invasive Mechanical Ventilation

Dual Limb Heated Wire Circuit

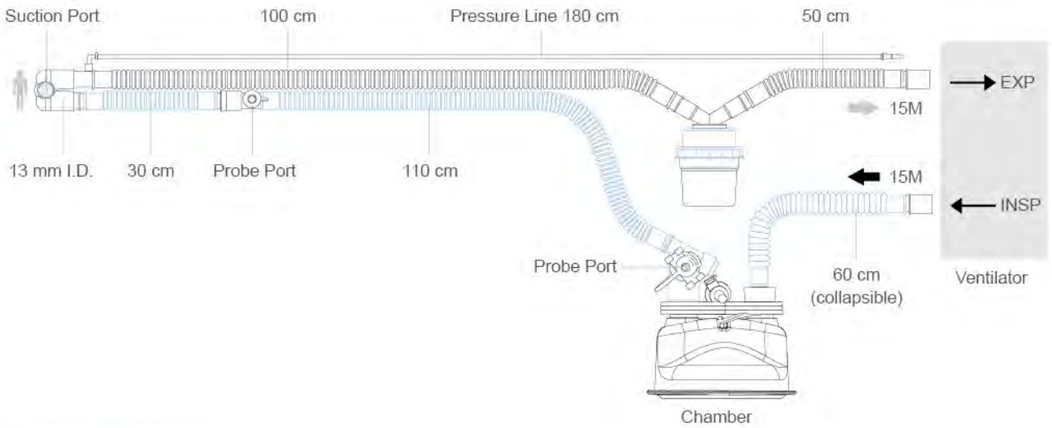


Infant Dual Limb Heated Wire Circuit contains both heated inspiratory limb and heated expiratory limbs, designed to be used with invasive mechanical ventilation (IMV) or non-invasive ventilation (NIV) with or without humidification chamber.

With 10 mm I.D. connectors and a wye connector, the Dual Limb Heated Wire Circuit is available for connection of ***Babi. Plus®*** nCPAP prongs or other applicable products.

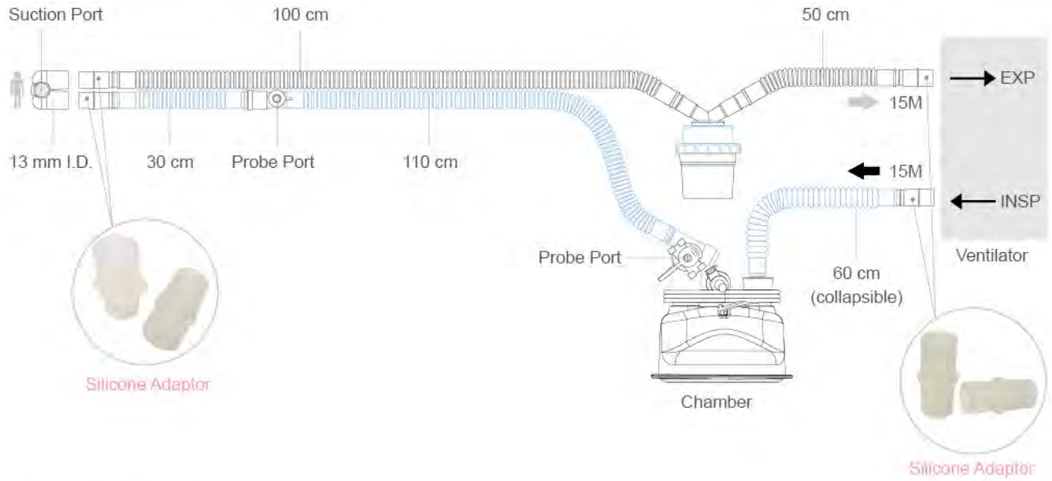
REF	Description	Chamber	QTY
AH0015	HW2 Circuit, Infant	N/A	10 pcs/carton
AH0016	HW2 Circuit, Infant w/Chamber	●	10 pcs/carton

Single Limb Heated Wire Circuit



Standard Type

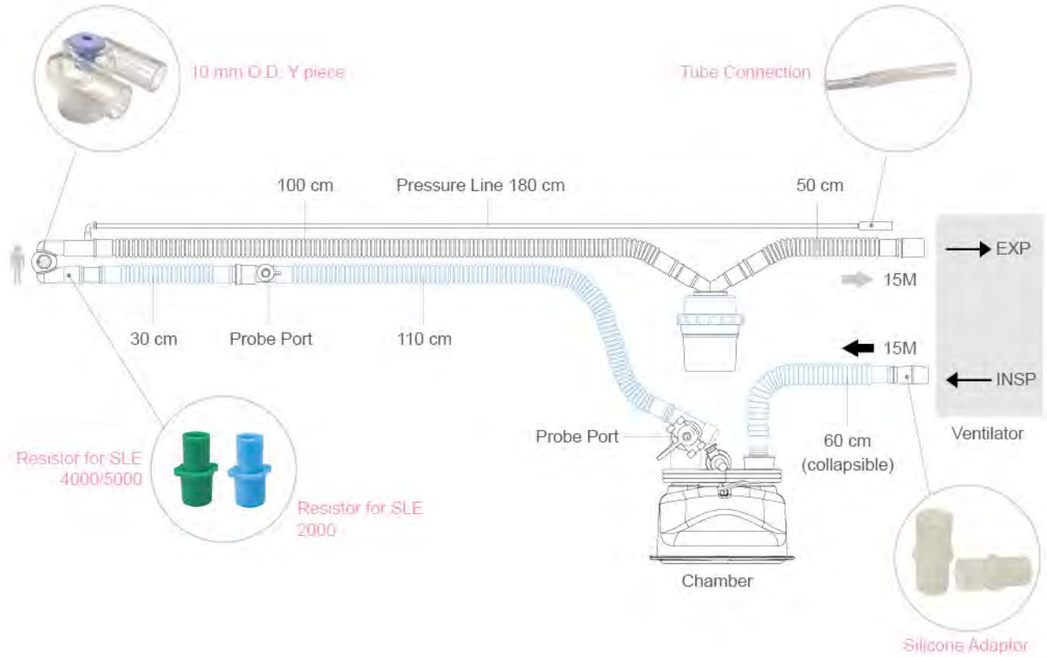
Infant single limb heated wire circuit (standard type) contains a heated inspiratory limb and was designed to be used with invasive mechanical (IMV) or non-invasive ventilation (NIV). With an inner 10 mm ID connector and wye connector, the infant single limb heated wire circuit (standard type) is connected to the ***Babi.Plus***® nBubble CPAP or other applicable products. Infant single limb heated wire circuit can be with or without humidification chamber.



Dräger Type (DR Type)

The DR Type circuit is designed for ***Dräger***™ ventilators. The DR Type circuit contains all silicone adaptors. Due to the design of the ventilator, the pressure line is excluded.

Single Limb Heated Wire Circuit

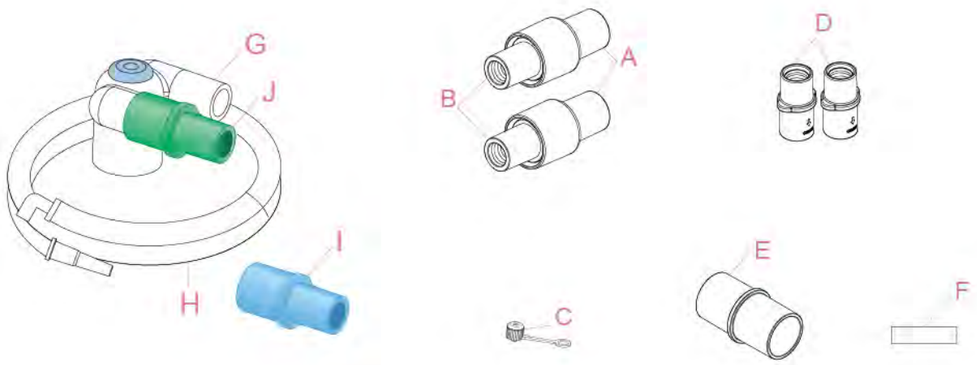


SLE Type

The SLE Type circuit is designed for SLE ventilator. The SLE Type circuit contains adaptors and a resistor.

REF	Description	Application	Chamber	QTY
AH0011	HW1 Circuit, Infant w/WT	Standard	N/A	10 pcs/carton
AH0012	HW1 Circuit, Infant w/WT, Chamber	Standard	●	10 pcs/carton
AH0063	HW1 Circuit, Infant for DR	Dräger Babylog	N/A	10 pcs/carton
AH0013	HW1 Circuit, Infant w/Chamber for DR	Dräger Babylog	●	10 pcs/carton
AH0064	HW1 Circuit, Infant for SLE	SLE 4000/5000	N/A	10 pcs/carton
AH0014	HW1 Circuit, Infant w/Chamber for SLE	SLE 4000/5000	●	10 pcs/carton
AH0070	HW1 Circuit, Infant, SLE	SLE 2000	●	10 pcs/carton

Connector Kit



Two Connector Kit options offer comprehensive solutions for breathing circuit connections with a variety of connectors, tubes, pressure monitoring line, and adaptors. The Connector Kits allow versatility to diverse ventilators and/or anesthesia machines, which feature resistors for specific ventilators (SLE 2000 or 4000/5000) that require resistance conditions.

REF	Description	QTY
AC0231	Connector Kit, Infant w/ Resistor #1, Green	100 pcs/carton
AC0232	Connector Kit, Infant w/ Resistor #0, Blue, Resistor #1, Green	100 pcs/carton

SPECIFICATION

Item	Descriptions	AC0231	AC0232
A	(2) Connector, 22 mm I.D., 15 mm I.D.	●	●
B	(2) Silicone Connector, 10 mm I.D., 12 mm I.D.	●	●
C	(1) Pressure Port Luer Cap, 4.3 mm O.D.	●	●
D	(2) Silicone Connector, 10 mm I.D., 10 mm I.D.	●	●
E	(1) Connector, 22 mm O.D., 22 mm O.D.	●	●
F	(1) Silicone Pressure Line Connector, 5 mm I.D.	●	●
G	(1) Wye Connector, 15 mm I.D., 10 mm O.D., 10 mm O.D.	●	●
H	(1) Pressure Line, 3.5 mm I.D.	●	●
I	(1) Resistor, #1, Green, 10 mm O.D., 10 mm I.D.. Resistance: ≈4.5 cmH_2O @ 2.5 LPM. Applicable on SLE 4000/5000.	●	●
J	(1) Resistor, #0, Blue, 10 mm O.D., 10 mm I.D.. Resistance: ≈6.4 cmH_2O @ 2.5 LPM. Applicable on SLE 2000.	N/A	●

Auto Feeding Chamber

360° Visible Maximum Water Level Indicator
Make it easier to monitor the water level from all angles

Faster Heating
Lower water level needed and larger contact surface for heating to reduce heating time

IV Inlet With Safety Cap Seal
Allow water drainage by means of IV inlet insertion into distilled water bag

Float Valve Mechanism
The water level is maintained with a float valve that closes the water inlet when the optimal level is reached.

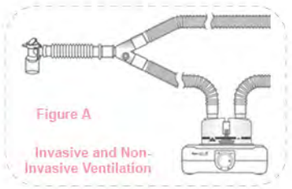
Auto-feeding humidification chamber is an upgrade design of a conventional one to improve the quality of respiratory care. The ***Humi.AIDE™*** Auto Feeding Chamber features a sensitive auto-filling mechanism for accurate water level control, which allows sterile water to fill into the chamber automatically without interruption of airflow and ventilation. It can also reduce the time of frequently monitoring by clinicians and the patients' risk of cross-contamination.

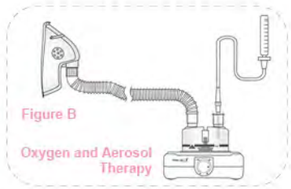
REF	Description	QTY
AH0038	Auto Chamber, Infant	12 pcs/carton

Heated Humidifier (5D and 5A)

Humi.AIDE™ 5D and 5A Humidifiers are the ideal humidification choice for a non-heated wire breathing system. These are easy-to-use devices, especially for homecare and long-term care facilities. ***Humi.AIDE***™ 5D and 5A Humidifiers contain overheat protection to ensure patient safety. Various applications are depicted in Figure A and B.

Humi.AIDE™ 5D: Digital Type



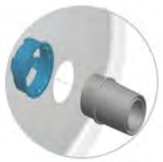


Humi.AIDE™ 5A: Analog Type

REF	Description	Type	Operating Voltage	Frequency	QTY
AQ0019	H5D Humidifier, 120 V	Digital	100-120 V AC	60 Hz	10 pcs/carton
AQ0020	H5D Humidifier, 240 V	Digital	220-240 V AC	50~60 Hz	10 pcs/carton
AQ0002	H5D Temperature Probe, 1.6 m (Accessories, not included in the set)				10 pcs/box
AQ0017	H5A Humidifier, 120 V	Analog	100-120 V AC	60 Hz	10 pcs/carton
AQ0018	H5A Humidifier, 240 V	Analog	220-240 V AC	50~60 Hz	10 pcs/carton

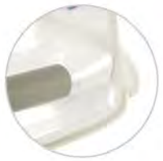
Oxygen Support

Oxi.Hood



Inlet Port Diverter

Prevent direct oxygen flowing onto the baby. 15/22 mm connector is compatible with various types of oxygen supply



Tubing Port

Raised base port allows convenient tubing and line placement

Weight Bar

Provide stable hood fixation by simply placing weight bar in the groove

Padded Neck Hole

Ergonomic design optimally accommodates all ranges of babies' heads

Oxi.Hood features simple operations and functional designs, offering a practical solution for neonatal oxygen administration and temperature maintenance. Transparent hood shell provides a clear view of the baby, ensuring continuous safety monitoring. Weight bar and groove designs secure the hood in position. ***Oxi.Hood*** is available in 3 sizes to provide a better fit for premature and neonate , and each set comes with a hood and two weight bars.

REF	Description	Head (Length x Width x Height)	Neck (Width x Height)	QTY
AO0031	Oxi.Hood, S (included 2 pcs Weight Bar)	19 x18 x 15 cm	7 x 5 cm	10 pcs/box
AO0033	Oxi.Hood, M (included 2 pcs Weight Bar)	19 x 18 x 15 cm	10 x 7 cm	10 pcs/box
AO0034	Oxi.Hood, L (included 2 pcs Weight Bar)	22 x 21 x 18 cm	12 x 10 cm	10 pcs/box
AO0032	Weight Bar for Oxi.Hood (Accessories)	-	-	2 pcs/box

Test Lung

nTest Lung

Pressure Monitoring Port

Connect to the pressure monitoring system for measuring proximal airway pressure

Bracket Test Lung

Bracket creates an approximate 1.0 ml/ cmH_2O compliance and allows test lung to simulate neonate lung with 25 ml tidal volume

Resistance Indicator

4 color-coded indicators easily identify the individual lung resistance. Available resistance of 90, 145, 300 and 600 $cmH_2O/L/s$ at 1 liter per second

Test Lung without Bracket

Without bracket, test lung imitates lung condition with 60 ml tidal volume

Babi.Plus® nTest Lung is an easy test device which simulates pulmonary physiology. It intended for use of demonstration and testing applications with neonatal ventilation systems. Each nTest Lung set includes a strap, two bracket test lungs and a carrying pouch. Various resistance of single test lungs (with or without bracket) are available for assembling the desired lung simulation.

REF	Description	Content	QTY
AN0004	nTest Lung, R145x2	A strap, two bracket test lungs, a carrying pouch	10 pcs/box
AB0051	nTest Lung Module, R90	One test lung without bracket	24 pcs/carton
AB0052	nTest Lung Module, R600	One bracket test lung	24 pcs/carton
AB0053	nTest Lung Module, R300	One bracket test lung	24 pcs/carton
AB0054	nTest Lung Module, R145	One bracket test lung	24 pcs/carton
AB0055	nTest Lung Module, R90	One bracket test lung	24 pcs/carton

Others

Pole Clamp

Dual Pole Clamp

Durable and intend to support a total weight of ≤10 kg of two products on an equipment pole

Single Pole Clamp

Intend to support a weight of ≤3 kg on an equipment pole

Pole Clamps are ISO 19054 compliant and available for poles 2.0 to 3.2 cm in diameter, providing sturdy mounting of the ***Babi.Plus***® Bubble PAP valve, humidifiers or other devices.

REF	Description	QTY
AB0223	ISO Pole Clamp, Dual, Aluminum	10 pcs/mid box
AB0222	ISO Pole Clamp, Single	10 pcs/mid box

Manual Percussor

Manual percussor is an airway management device assisting with chest physiotherapy. It offers a convenient alternative to manual chest percussion via "hand cupping" with unique manual percussor cups, allowing caregivers to perform chest percussion with manual pounding or clapping to loosen secretions.

AW0056 Manual Percussor, S
AW0057 Manual Percussor, M

Package: 48 pcs/carton

GiO™ Manometer

P&H Display
Light up when Peak & Hold is activated and hold the display of peak pressure reading

Power ON/OFF
Press to switch unit of display

P&H Button
Press and hold to activate backlight

Analog Bar Display
Immediate visual feedback

Digital Display
Real-time display of measured pressure

Low Battery Warning
Flashe when low on battery

Unit Display
Measurement in kPa, mbar, cmH_2O

Hydrophobic Filter
Protect ***GiO™*** Manometer from contamination and condensation in the tubing

GB10 ***GiO™*** Manometer is packaged with the following:

- One GB10 ***GiO™*** Manometer with a Lithium Cell
- Two Disposable Pressure Line with Luer-type Connectors
- Two Hydrophobic Filters
- One Additional Lithium Cell
- Two Elbow Connectors
- One Straight Connector
- One Silicone Pressure Line 50 cm

GiO™ Manometer offers a simple method for bedside pressure measurement with real time display in both analogue bar and digital reading. Easy operation starting with only two buttons (Power ON/OFF and P&H Button) brings high efficiency to healthcare. ***GiO™*** Manometer GB10 measures pressure between 0~30 cmH_2O for both non-invasive and invasive infant/neonatal applications.

REF	Description	QTY
AQ0008	GiO Manometer, 0~30 cmH_2O	10 pcs/big box
AF0003	Filter, Hydrophobic, 7.6M, Luer (Accessories)	50 pcs/carton
AC0091	L Connector, 7.6M, 4B, PSF, Amber (Accessories)	5 pcs/box
AC0090	L Connector, 7.6M, 6M, PSF, Amber (Accessories)	5 pcs/box
AC0212	Connector, 7.6M, Luer, PSF (Accessories)	5 pcs/box
AB0061	Gas Sampling Line, 50 cm, 4M, 4M (Accessories)	50 pcs/carton

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AB0054 *	BL1-04	36
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AH0059	H721	12
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AO0033	OH12	34
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AQ0002	HD5-12	32
AQ0008	GB10	39
AQ0017	HA51	32
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AQ0019	HD51	32
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AR0023	H025	22
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AR0025	H050-M	22

* Not Approved by Taiwan Food and Drug Administration

Babi.Plus

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AR0028	MG19	17
AR0039	1098	19
AR0046	1236	20
AR0058	2152	20
AR0062	2162	20
AR0070	2253	18
AR0079	2328	16
AR0080	2329	16
AR0112	2113	19
AR0113	2118	19
AW0056	39200	38
AW0057	39201	38

Clean & Sterilization

MATERIALS USED FOR GALEMED PRODUCTS:

Single patient use or disposable items are prohibited to be reused.
Reusable items are treated as below:

Material	Autoclave 134°C	EtO gas	Liquid Sterilizer
ABS	Distort	Yes	Yes
Polycarbonate (PC)	Distort	Yes	Excellent
Polyethylene (PE)	Marginal to poor	Yes	Excellent
Polypropylene (PP)	Yes	Yes	Excellent
Polysulfone	Excellent	Yes	Excellent
PVC	Marginal to poor	Yes	Distort
Silicone rubber	Yes	Yes	Excellent
Stainless, Aluminum	Excellent	Yes	Excellent
Rubber	Distort	Yes	Yes

CLEANING & STERILIZATION STEPS:

1. Disassemble the product as per the IFU, if necessary.
2. Wash components thoroughly in lukewarm water with a mild detergent which shall be compatible with the material of the device.
3. Rinse the components thoroughly in lukewarm water to remove all traces of detergent.
4. Sterilize the components using one of the following methods:
   a.Autoclaved (max 134°C /273°F).
   b. Ethylene oxide.
   c.The most common disinfecting solution is used the equipment coming from the contact with the patient. Rinse thoroughly with water after sterilization.
5. Dry all components thoroughly after sterilization.
6. Inspect all components prior to usage; if any tear or any damage, please replace it.
7. Repack properly after usage to avoid any contamination.

Symbol Guide For This Catalog

- **Do not reuse** — To indicate that the product is for single use only.
- Latex — Indicates that natural rubber latex was not used in the manufacturing of the product, its container, or its packaging.
- DEHP — Indicates that product that does not contain the phthalate plasticizer DEHP.
- 121 — Sterilizable in a steam sterilizer (autoclave) at temperature 121°C (250°F) will be accepted
- 134 — Sterilizable in a steam sterilizer (autoclave) at temperature 134°C (273°F) will be Sterilizable

Date / /

business card

GaleMed

GaleMed specializes in the design and manufacture of consumable medical devices in the field of respiratory care. Our products cater to the complete patient journey in respiratory care, including neonatal care, emergency care, anesthesia, critical care, and pulmonary rehabilitation. Backed by a team of clinical professionals, we provide customers with the breadth and depth of product solutions.

GaleMed is headquartered in Taiwan and operates manufacturing facilities in Taiwan and Xiamen. With distinct production lines and dedicated marketing teams in both locations, GaleMed has been committed to customers and market needs globally, spanning Europe, America, Southeast Asia, East Asia, and other parts of the world.

With more than 35 years of OEM and OBM experience, GaleMed provides one-stop services, including **Mold Design, Professional Process, Process Validation & Qualification**, and **Automatic Storage Retrieval System**. GaleMed possesses excellent quality control and global logistics capabilities.

GaleMed has an experienced RQA team and ensures that its employees remain properly certified and continuously trained. We possess medical device market approvals and quality system management certifications from multiple countries to keep pace with evolving medical device regulations, including **TFDA, NMPA, FDA, EU MDR, TW-QMS, ISO 13485, MDSAP, JGMP and others**. Thus, our products and services are in line with the latest international standards, helping maintain our customers in a competitive market.

Established in
1987

Business Types
ODM/ OEM manufacturer,
Contract Manufacturer & Exporter

Main Products
- Respiratory Care
  - Critical Care
  - Anesthesia Care
  - Emergency Care
  - Oxygen Therapy
  - Aerosol Therapy
  - Neonatal Care
  - Lung Training

Quality Management System
- ISO 13485
- ISO 9001
- MDSAP
- JAPAN J-GMP
- TAIWAN QMS

Product Certification
- EU MDR Certificate
- FDA Listing and 510K
- China CFDA Registration
- Taiwan TFDA Registration

1st Xiamen Facility

2nd Xiamen Facility

Sales&Service office (Xiamen)

Sales&Service office (Taipei)

I-Lan Facility
(operation headquarter)

GaleMed

Research,
Development
and Manufacture

Since 1986

GaleMed Corporation

www.galemed.com

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