WHO
Neonatal resuscitation manikin technical specifications

WHO medical device technical series

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The WHO neonatal resuscitation manikin: technical specifications was developed under the framework of the World Health Assembly Resolution WHA66.7 *(1)* which is at the foundation of the United Nations Commission on Life-Saving Commodities (UNCLSC) for women and children (Annex 10). The mandate of the UNCLSC is to promote and assure the availability of 13 safe, quality commodities, which include neonatal resuscitation devices.

These specifications are the result of a collaboration of experts from different backgrounds and organizations, including WHO, UNICEF, CHAI, PATH and the members of the Newborn Resuscitation Working Group. The industry survey included in this report was made possible with the support of Global Medical Technology Alliance (GMTA), an NGO in official relations with WHO.

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The following process was followed towards the release of this document. An initial draft of the working document on technical specification was shared with the members of the Newborn Resuscitation Working Group on 20th May 2016 for feedback on the framework. Following the feedback from the group and on consolidating the industry survey, a final draft version of the document was proposed on 16th of June 2016 to partnering organisations UNICEF, CHAI, PATH and with Newborn Resuscitation Working Group. Based on the feedback received, a second draft of the document was shared with the group. The draft was edited and designs were done in 2017. Due to other urgent publications, in 2017 and 2018, this was not updated, until 2019.

The publication was disrupted by the urgency of the COVID-19 response. The document was revised early 2021 to include updates in standards and regulations. In May 2021 a review to ensure market availability for all the products listed was conducted.

This technical specification for neonatal resuscitation manikin was drafted by Einstein Albert Kesi under the supervision of Adriana Velazquez Berumen, with publication support of Daniela Rodriguez Rodriguez and Sihem Halouani.

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Abbreviations

ASTM : American Society for Testing and Materials

CE: Conformité Européenne/European Conformity

CHAI: Clinton Health Access Initiative

FDA: Food and Drug Administration (United States)

GHTF: Global Harmonization Task Force

GMTA: Global Medical Technology Alliance

HIC: High Income Countries

IEC: International Electrotechnical Commission

IMDRF: International Medical Device Regulators Forum

ISO: International Organization for Standardization

LMIC: Low and Middle Income Countries

N/A: Not available

ROHS: Restriction of Hazardous Substances

SoPs: Standard operating procedures

UN: United Nations

UNCLSC: United Nations Commission on Life-Saving Commodities for Women and Children

UNFPA: United Nations Population Fund

UNICEF: United Nations Children's Fund

UNSPSC: United Nations Standard Products and Services Code

USAID: United States of America Agency for International Development

WHA: World Health Assembly

WHO: World Health Organization

Executive summary

The United Nations Commission on Life-Saving Commodities (UNCLSC), launched in 2012, defined 13 health products to be available and used appropriately to end preventable deaths of woman and children. One of those 13 products is the neonatal resuscitator, an indispensable medical device to save newborns from asphyxia at birth. For the efficient use of neonatal resuscitation devices, training of healthcare professionals using neonatal resuscitation manikins is agreed as the most effective approach. This context of critical lifesaving trainings calls for the need of neonatal resuscitation manikins with the right features.

This document is primarily divided in to five parts consisting of scope of the document, technical specifications, industry survey, types of manikins and the conclusion.

The first section briefly explains the context, the intent and thus sets the scope and focus of this document. This is followed by the "Technical specifications" section which covers all the technical aspects of neonatal resuscitation manikin.

The section starts with operational considerations to provide an insight to the operational aspects that cannot be quantified such as ease of use, set up time and other related aspects. These aspects are critical in selection of an appropriate manikin especially for the LMIC context. To further help professionals from nonclinical background, a short description of how to use a neonatal resuscitation manikin is included. This is intended to provide a quick overview of the training context, related operational aspects and also to provide insights to the features needed in a neonatal resuscitation manikin.

To ensure manikins of good quality, the technical specification part includes a section on "Standards and regulatory compliance". This is intended to provide a baseline to all stakeholders on process compliance and material testing standards to ensure good quality neonatal resuscitation manikins for both LMIC as well as HIC markets.

The technical specification part also includes a brief note each on reprocessing, maintenance, packaging and storage of neonatal resuscitation manikins which are integral activities to ensure good functionality of the manikin. These sections provide basic guidelines on decontamination of manikin, day to day maintenance of manikin, packaging for transportation and preparation of manikin for storage after use.

The second part of this document ends with an elaborate table consisting of 50 different elements to guide towards selection of an appropriate neonatal resuscitation manikin.

The third part of this document is the industry survey which has a listing of neonatal resuscitation manikins from some of the leading manufacturers from across the world. This survey provides an overview of to the products available in the market and their respective product features.

The fourth part explains the three major types of manikins that are observed in the survey. This part provides an overview to all three types of neonatal resuscitation manikins. This is intended to provide basic information for selection of an appropriate manikin which suits the working environment and training needs.

The fifth and the final part of the document is the conclusion which states how this technical specification meets UNCLSC's mandate.

The purpose of the WHO Neonatal resuscitation manikin: technical specifications is to provide a minimum standard baseline to meet the increasing demand to procure good quality, affordable, accessible and appropriate neonatal resuscitation manikin. Towards the development of this baseline, this document includes compilation of available scientific evidence from technical literature, international publications, expert reviews and an industry survey which was conducted by WHO medical devices team.

During the COVID-19 pandemic, it becomes indispensable to train health care workers to perform neonatal resuscitation, and to ensure infection prevention measures to ensure no dissemination of diseases when performing or training resuscitation interventions.

These specifications are intended to support policy-makers, managers, procurement officers, regulators and nongovernmental agencies, especially in LMIC to select, procure, use and reprocess appropriate neonatal resuscitation manikins. Product design engineers, manufacturers and dealers may use this specification as a part of technical inputs for design, manufacturing and shipping of good quality, appropriate, affordable and durable neonatal resuscitation manikins. The end goal is to save the children, particularly in low-resource settings.

1. Purpose and scope

This document is prepared based on available literature and scientific evidence. It should be noted that, available literature use the term "manikin" or "mannequin" interchangeably.

It is acknowledged that Neonatal Resuscitation Manikin is an indispensable tool for neonatal resuscitation training. A number of studies have highlighted the effectiveness of neonatal resuscitation manikins for training medical professionals (3,4,5). In order to facilitate effective neonatal resuscitation training in LMIC countries, governments, international aid agencies and non-governmental entities have been involved in sourcing and distribution of neonatal resuscitation manikins from leading manufacturers predominantly based in developed countries and fast developing countries (6,7,8).

The primary intent of this document is to guide procurement officers on good quality, affordable, accessible and appropriate procurement of neonatal resuscitation manikins that meet required performance and design standards. Procurement officers include policy-makers, procurement managers or professional health workers who have responsibility for procuring, supplying and using neonatal resuscitation manikins for all health settings, but particularly in low-resource settings.

International and local manufacturers would benefit from better understanding the product specifications to succeed in low-resource settings and to produce appropriate and quality products (12). Nongovernmental agencies will also be able to find useful information to ensure appropriate and quality neonatal resuscitation manikins are donated or procured (10).

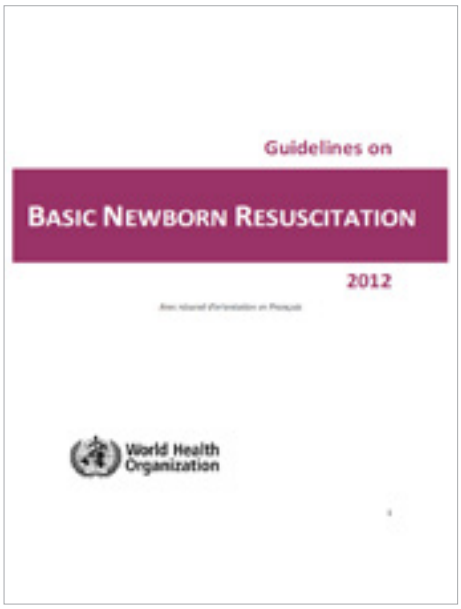
The neonatal resuscitation manikin is a basic priority medical devices that have been named in guidelines and WHO documents, e.g. the Interagency list of medical devices for essential interventions for reproductive, maternal, newborn and child health, published in July 2015.

The neonatal resuscitation manikin should be used to train health care workers. In support of this resuscitation interventions, WHO has also developed the following documents (Fig. 1):

1. WHO Guidelines on basic newborn resuscitation in 2012;

2. WHO-UNICEF Interagency list of essential interventions for reproductive, maternal, newborn and child health, in 2015; and

3. WHO technical specifications for neonatal resuscitation devices in 2016.



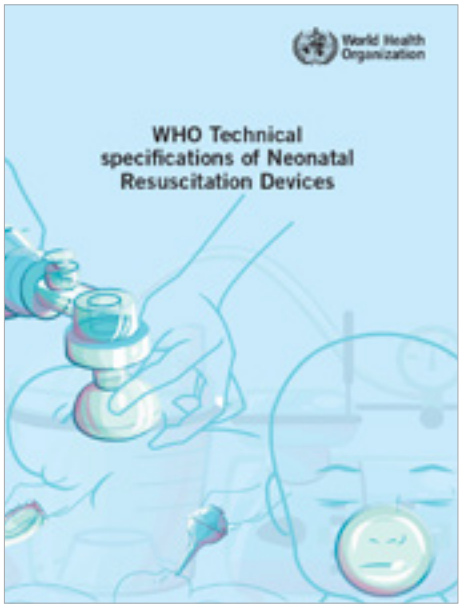


Fig 1. WHO publications related to the neonatal resuscitation medical devices.

2. Technical specifications for neonatal resuscitation manikin

2.1 Description of neonatal resuscitation manikin

Neonatal resuscitation manikin

Neonatal resuscitation manikin is mechanical model that resembles a human newborn baby. This model is used to train healthcare workers on skills required for neonatal Cardio Pulmonary Resuscitation (neonatal CPR). A neonatal resuscitation manikin has similar anatomical landmarks like that of a newborn baby.

Is it important to have a different Manikin for Neonatal CPR?

Neonatal CPR techniques are different from the techniques used for adult CPR. This is due to the difference in the physiology of asphyxia. A neonatal resuscitation manikin has similar anatomical landmarks like that of a newborn baby (25).

2.2 Operational considerations on selection of a neonatal resuscitation manikin

Considering the operational environment the manikin has to address helps in procuring the most appropriate neonatal resuscitation manikin from the many models available in the market. The following points maybe considered

Ease of use & set up time

The time required for preparing the manikin for each training session. This should include the infrastructure and time considerations for disinfecting the manikins (24).

Ease of transport & storage

This is important when the manikins are used for frequent onsite training sessions. Manikins available can be evaluated for their ease of transport and storage by comparing the products weight and size along with the final packaging (24).

Flexibility & simplicity

Consider the possibility to use a simple manikin for multiple neonatal training in addition to neonatal resuscitation. Complex manikins are more difficult to maintain – especially in LMIC context (24).

Durability & maintenance

Evaluate if the manikin is capable of enduring frequent use in the extreme climatic conditions in your region. Ready availability of affordable parts is also good to be considered (24).

Cost of ownership

Evaluate the cost of consumables for disinfection and cost of disposables such as lung bag and minimum order quantity for the same (24).

2.3 Training using a neonatal resuscitation manikin

As indicated in the WHO Guidelines, neonatal resuscitation is recommended to be administered by healthcare professionals who have received adequate resuscitation training using manikins (33).

Training should be done in a continuous way for the staff, to ensure a good resuscitation procedure is done when a newborn baby requires it. The following procedure for neonatal resuscitation training using manikin is only indicative.

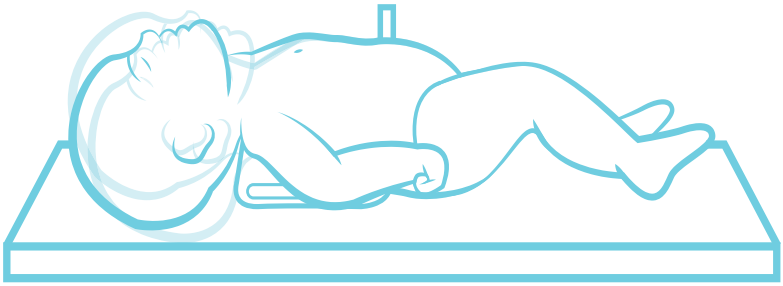


Fig 2: Open the airway by positioning the head of the manikin

To start the neonatal resuscitation training, place the neonatal resuscitation manikin on its back and open the airway by positioning the head of the manikin (Fig 2). The rescuer now positions himself/herself at the side or at the head of the manikin to use the resuscitation bag (Fig 3). It is to be noted that the rescuer has an unobstructed view of the chest movements of the manikin (13, 14).

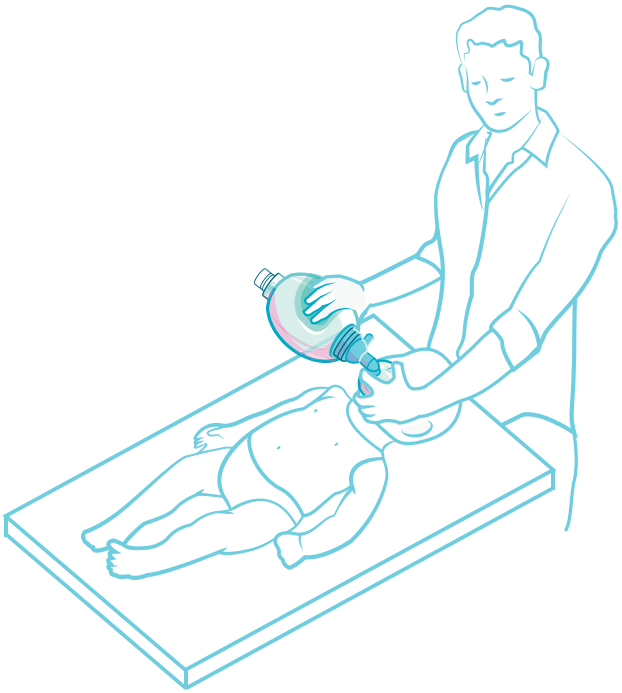


Fig 3: Rescuer position to use the resuscitation bag

Select an appropriate facemask which ensures the nose and mouth of the manikin is covered. Ensure that the tip of the chin rests within the rim of the facemask and that the facemask does not cover or apply pressure on the eyes. Once the facemask is positioned, apply light downward pressure on the mask to form an airtight seal (13, 14). With facemask in position, as per applicable protocols chest compressions can be started on the neonatal resuscitation manikin followed by ventilation by squeezing the bag to deliver breath.

2.4 Standards and regulatory compliance

It should be noted that

- **Following standards are for reference alone, other internationally accepted/national equivalent standard(s) for quality systems or material testing may be used.**
- **It is important to comply as per the local regulatory requirements of the manufacturers and/or customers country as applicable.**

2.4.1 Mechanical components

In the context of manikins being manufactured using a combination of plastics, silicone rubber and metals, for effective product quality, the components shall comply with the following standards (34).

	Temperature range
Material	0^0 to 40^0 Celsius
Silicone Rubber	Considering the proven stable nature of silicone rubber even at extremely negative and positive climatic temperatures with high humidity, manikins completely made of silicone rubber shall provide the proof of raw material qualification certificate from an nationally or internationally approved laboratory.
Plastics	It is good for manikins manufactured completely or partially from plastics to comply with standards such as *ISO 11403-3: Plastics - Acquisition and presentation of comparable multipoint data - Part 3: Environmental influences on properties.
Adhesive Joints	*ISO 14615: Durability of structural adhesive joints - Exposure to humidity and temperature under load

** Other internationally accepted/national equivalent standard(s) for quality systems or material testing may be used.*

It is important to note that, as found in survey results (section 3.1), there are neonatal resuscitation manikin models that qualify for a wider temperature range.

To ensure effective product quality, raw material qualification certificate (for silicon rubber components) or component test certificates that qualify the components to be functional for the claimed temperature range, for required lifespan shall be verified. These tests shall be done in compliance with a relevant internationally accepted/national equivalent standard(s) in a nationally or internationally approved laboratory.

Notes:

1. The above mentioned tests for plastics should be conducted to match the humidity requirements mentioned in point no 32 of the technical specification table under the section 2.8
2. Metal joints if any should be of materials which do not restrict movement of joints due to corrosion.
3. Components made of natural rubber should be avoided.

2.4.2 Process compliance

The manufacturing process should comply to *ISO 9001 quality management systems.

As neonatal resuscitation manikin is not a medical device, *ISO 13485 is not required, however ISO 13485 certified products can be considered for procurement.

2.4.3 General compliance

Guidelines of *ISO/IEC 17050-1 shall be followed by the manufacturer for self-declaration on product safety and quality compliance of manikin and all spare parts.

Guidance for waste disposal and recovery management at end of product life, should be included by the manufacturer in the instruction manual as required by local regulatory agencies. Regional regulatory guidelines on waste disposal and recovery management should be complied by the manufacture/customer as applicable.

Optional: The management system of the manufacturer shall comply with *ISO 45001 standard for occupational health and safety compliance. Note: Latest standard review was conducted in May 2021.

2.5 Reprocessing of neonatal resuscitation manikin

Manikins can act as a medium for spreading infections due to repeated use by a number of students. Hence, national guidelines for disinfection such as CDC guidelines, AS/NZS 4187 or regional directives by healthcare authorities such as NHS Trust guidelines, in the absence of which, guidelines by reputed international organisations such as Red Cross guidelines which specifies disinfection of manikin can be adhered to (17-23). All disposables are to be disposed as suggested by the manufacturer.

It shall be noted that based on the materials used for manufacturing, manufacturers have specific guidelines for decontaminating different models. Hence user instruction manual supplied by the manufacturer have to be referred as the first step.

** Other internationally accepted/national equivalent standard(s) for quality systems or material testing may be used.*

2.6 Maintenance

Besides the use and care of the device, proper reprocessing and assembly, the following points may be noted to ensure long life for the product.

- Handle the neonatal manikins gently and carefully in accordance with humanistic education guidelines (24).
- Maintain clean working environment and ensure that the manikin is cleaned and disinfected after each session as per manufacturer's recommendation. Ensure that harsh abrasives are not used during the cleaning process (18,24).
- Never bring the manikins in contact with ink or printed media as these can stain the manikin (24).
- Never expose manikins to antiseptics, high temperatures or direct sunlight as these may adversely affect the material (24).
- After disinfecting, store them securely in a cool area as instructed by the manufacturer. Do not stack heavy materials on top of the manikin box (24).
- Do mandatory periodic check of the models for tears, wearing out of skin, tightness of the fit of their different parts and function of all moving or jointed parts. Replace damaged parts before further use (24).
- Maintain manikins and models according to instruction manual (24).

2.7 Packaging and storage

Considering the scope for global supply of neonatal resuscitation manikins, to ensure availability of defect free product, it is good for product packaging to be tested to replicate the environmental realities of LMIC countries where products may be stored in ware houses with little or no storage facilities and transportation can be under harsh weather conditions.

In the post training storage context, on completion of the training session, the manikins shall be dismantled as mentioned in the user instruction manual, disinfected as mentioned in section 2.5 of this document, dried and stored as instructed by the manufacturer in a clean place (24). Care should be taken to avoid exposing the manikins to extreme climatic conditions of heat, cold or dampness during storage.

2.8 Technical specifications for neonatal resuscitation manikins

The technical specification for basic type neonatal resuscitation manikin is provided as given below. It may be noted that, there are other types of manikins that are available in the market such as inflatable type and advanced neonatal manikins with simulation capability which are not covered in this document.

Neonatal resuscitation manikin specification		
i	Version no.	3
ii	Date of initial version	2013
iii	Date of last modification	2021
iv	Date of publication	2021
v	Completed/ submitted by	Working group (WHO/UNFPA/UNICEF, CHAI, PATH, GMTA, newborn resuscitation working group)
NAME, CATEGORY AND CODING		
1	WHO category/ code	
2	Generic name	Neonatal training manikin
3	Specific type or variation (optional)	Training manikin/simulator for neonatal resuscitation
4	GMDN name	(to be completed if final user owns valid license or permission)
5	GMDN code	(to be completed if final user owns valid license or permission)
6	GMDN category	(to be completed if final user owns valid license or permission)
7	UMDNS name	(to be completed if final user owns valid license or permission)
8	UMDNS code	(to be completed if final user owns valid license or permission)
9	UNSPS code (optional)	42301503
10	Alternative name/s (optional)	Cardiopulmonary resuscitation training manikins; chest cage manikins; CPR manikins; resusci-anne manikins; resuscitation manikins; resuscitation training manikins; training manikins; anatomical model; teaching aid manikin; training manikin; cardiopulmonary resuscitation manikins; hands on training models
11	Alternative code/s (optional)	MS 38464; S 36326, 10028; S 15666, 15666; S 15309, 15309 or corresponding code/s set by a regional or national authority.
12	Keywords (optional)	CPR, training manikins, resuscitation, neonatal training, neonatal resuscitation
13	GMDN/UMDNS definition (optional)	(to be completed if final user owns valid license or permission)
PURPOSE OF USE		
14	Clinical or other purpose	Designed for use in life-saving treatment training of newborn resuscitation: including cardiopulmonary resuscitation (CPR), rescue breathing, positive air ventilation by using resuscitators and choking first-aid instruction
15	Level of use (if relevant)	Health centre/district hospital/provincial hospital/specialized hospital/nursing schools/midwifery schools/medical schools
16	Clinical department/ ward(if relevant)	Cardiology, emergency medicine, Intensive care unit (Neonatal & other medical speciality ICU's), sick newborn care units, Delivery Ward, internal medicine, materials management, nursing services, pediatrics, pulmonary medicine, respiratory care, midwifery, labor and delivery services.
17	Overview of functional requirements	Molded/stuffed or water/air inflated manikins with realistic chest rise, realistic chest compression resistance.

TECHNICAL CHARACTERISTICS		
18	Detailed requirements	Full size newborn simulator for cardiopulmonary resuscitation training program, Proper head tilt/chin lift to open the airway, Easily accessible chest cavity with realistic rib cage, lungs, safe CPR individual disposable airways or options to decontaminate the airways, umbilical cord stump, lung ventilation, heart and realistic anatomy. Should have full body. Should be free from any hazardous material.
19	Displayed parameters	Nil
20	User adjustable settings	Nil
PHYSICAL/CHEMICAL CHARACTERISTICS		
21	Components (if relevant)	Realistic body color, head tilt/chin lift functionality to open the airway, The texture of the manikin should be as close to the feel of the baby/ adult skin as relevant. Complete unit to be easily washable with mild soap and water without bringing deterioration in the manikin, non-reactive to manufacturer specified disinfectants/ alcohol wipes.
22	Mobility, portability (if relevant)	Portable, ideally realistic weight and size of a newborn baby.
23	Raw materials (if relevant)	Latex free manikins - ideally made of silicone rubber, if not, made of plastics. Hinges or joints if any should be of noncorrodible and durable metals/plastics or silicone rubber. Lubrication for joints or hinges if any should be of non-damaging substances and safe to use chemicals.
UTILITY REQUIREMENTS		
24	Electrical, water and/or gas supply (if relevant)	Relevant fluid specifications for inflatable manikins (fluid type, quantity, temperature etc) **Optional:** Electrical connections as recommended by the manufacturer of manikins for alarms, simulation devices and software's
ACCESSORIES, CONSUMABLES, SPARE PARTS AND OTHER COMPONENTS		
25	Accessories (if relevant)	Standard pack which usually includes detachable face pieces, replaceable airway systems (quantity offered vary from manufacturer to manufacturer) and one carry bag.
26	Sterilization process for accessories (if relevant)	Easily disinfectable by either rubbing vigorously with alcohol wipes or by use of chemical agents, as recommended by the manufacturer and in compliance with regional/organisational regulatory protocols for manikin disinfection. The product should be cleaned by soap and water prior to any disinfection methods.
27	Consumables/ reagents (if relevant)	Disposable airway systems and lungs, alcohol wipes/disinfectants for cleaning the manikin, lubricants (if any), puncture repair patch (for inflatable manikins).
28	Spare parts (if relevant)	Detachable faces, airway systems
29	Other components (if relevant)	Preferably with accessories needed for training purpose such as external umbilical cords, umbilical ties, neonatal mucus sucker, stethoscopes and neonatal resuscitator with two sized masks '0' & '1'.

PACKAGING		
30	Sterility status on delivery (if relevant)	Nil
31	Shelf life (if relevant)	Shelf life of 7 years on storage at 0˚C to +40˚C, relative humidity of 15 to 95%
32	Transportation and storage (if relevant)	Capable of being transported/stored continuously in ambient temperature of -30˚C to +60˚C and relative humidity of 15 to 95%. Capable of operating continuously in ambient temperature of 0˚C to +40˚C and relative humidity of 15 to 95%.
33	Labeling (if relevant)	Cardboard packages should have shipping labels stating the name of manufacturer, model, manufacturer address, product traceability number(s), shipping and storage conditions recommended by the manufacturer. Regional government regulations if any should be adhered to.
ENVIRONMENTAL REQUIREMENTS		
34	Context-dependent requirements	Specify storage and operating temperatures ranges, resistance to dust levels if applicable in the instruction manual (especially for manikins with electronics systems).
TRAINING, INSTALLATION AND UTILISATION		
35	Pre-installation requirements (if relevant)	Nil
36	Requirements for commissioning (if relevant)	Nil
37	Training of user/s (if relevant)	Source of useful information; WHO Guidelines on basic newborn resuscitation https://apps.who.int/iris/handle/10665/75157 WHO technical specifications of neonatal resuscitation devices. https://apps.who.int/iris/handle/10665/206540 **Training of users in handling, disinfection and basic maintenance should be provided:** ASTM F1453 - 92 Standard Guide for Training and Evaluation of First Responders Who Provide Emergency Medical Care (USA). https://www.astm.org/Standards/F1453.htm
38	User care (if relevant)	User manual for handling, instructions for disinfection and basic maintenance should be provided.
WARRANTY AND MAINTENANCE		
39	Warranty	1 year minimum from the date of purchase.
40	Maintenance tasks	Calibration certificate and calibration plan is mandatory for manikins with electronic sensors and alarms/mechanical systems for feedback.
41	Type of service contract	N/A
42	Spare parts availability post-warranty	5 years from the date of purchase or more as per manufacturers offer. List of spares/accessories, relevant part numbers, MOQ and price list to be submitted along with the quotation.
43	Software/ Hardware upgrade availability	Nil
DOCUMENTATION		
44	Documentation requirements	Instruction manual which includes Standard Operating Procedure for using the product, day to day maintenance, maintaining schedule, storage condition, cleaning, calibration, trouble shooting, safety details, warranty details with scope and postal, electronic and telephone contacts of authorised dealer/country representative. Documentation must also show recommended procedures for disposal and any probable hazards to the environment and/or community.

DECOMMISSIONING		
45	Estimated lifespan	5 years and capable of more than 100,000 compressions.
SAFETY AND STANDARDS		
46	Risk classification	**Optional:** Class 1 (if claimed by manufacturer - ie the neonatal resuscitation manikin need not fall under class 1 category of medical devices, unless the manufacturer opts to).
47	Regulatory compliance	Self-declaration on product safety & regulatory compliance of all the spare parts & manikin by the manufacturer and regional regulatory guidelines if any (or other equivalent internationally accepted/national equivalent) **Optional:** CE, USFDA
48	International standards	In the absence of a product standard for manikins, relevant International standards for testing of raw material and/or finished product (or other internationally recognized or national equivalent standards) may be used to qualify the manikins. The qualification approach should be as per base guidelines given in section 2.4 of this document. **Silicone rubber:** The proof of raw material qualification certificate from an Nationally or Internationally approved laboratory. Some standards that are suggested are: **Plastics:** ISO 11403-3: Plastics -- Acquisition and presentation of comparable multipoint data - Part 3: Environmental influences on properties. https://www.iso.org/standard/55462.html **Weathering of adhesive joints:** ISO 14615 : Durability of structural adhesive joints - Exposure to humidity and temperature under load https://www.iso.org/standard/24971.html **Quality management:** ISO 9001 and ISO 45001 (optional), ISO:13485 (not needed, but can be considered). https://www.iso.org/standard/59752.html **General compliance:** ISO/IEC 17050-1: Conformity assessment. Supplier's declaration of conformity. General requirements, regional regulatory guidelines should be complied with for waste disposal and recovery management. https://www.iso.org/standard/29373.html
49	Regional/local standards	Registration under TGA for use in Australia or equivalent, REACH
50	Regulations	Conformity assessment. Supplier's declaration of conformity.

3. Industry survey

The table lists leading manikin manufacturers that manufacture relevant manikin models. The respective neonatal resuscitation models of these companies along with the technical, regulatory, post market support, commercial, desired features and other relevant details of the these models are listed along. It should be noted that only baseline features are compared in detail though models with simulations are also considered. The information presented is based on the survey conducted by WHO medical devices team in May 2016. A review to ensure market availability for all the products listed was conducted in 2021.

Technical details and regulations:

Company name:
Product Family of Neonatal CPR Manikins:
Silicone Rubber / PVC / Mention Others (if any):
Weight of manikin alone:
Provide the range product practically withstands temperature and humidity:
Interlocking of parts by non corroding, durable, self lubricating materials / Interlocking of parts by non lubricating materials or corroding materials or abrasive metal connectors:
Practical number of compression cycles the manikin can withstand with out loosing designed characteristics or getting damaged (face pieces and air way bags excluded):
Decontaminated by: Soap & Water / Autoclaving / Alcohol Swipes / Chemical Agents:
List all Regulatory Compliance your product complies to: CE / USFDA / REACH / RoHS / Others (specify)
List all ISO / EN / DIN / ASTM / IEC or other National / International Standards based on which the product is designed & / or manufactured.

Postmarket information:

Company name:
Product Family of Neonatal CPR Manikins:
Number of years of Spare Support offered
Number of years of warranty offered
Countries where marketed:
Contact details: country and website:
Characteristics: anatomical landmarks:
Function: head tilt and chin lift:
Function: ventilation with bag, valve mask:
Function: visible chest rise:
Simulator Type Wired External Indicators (eg: Wired Monitors) / Wireless Extrenal indicators / Alarm or Lights built in to the manikin
Manikin Type Moulded (ie shell structure with over lays) / Stuffed (ie outer skin supported by internal pressure created by stuffing solid materials) / Inflated (with water or gases)
Carry Bag Is Carry Bag / Case given along with the manikin at no extra cost Yes / No

(*) Disclaimer: The WHO list is not exhaustive, by 2021 other products than the ones submitted to the 2016 survey might be available in the market and were not considered for this publication.

3.1 Technical And Regulatory Compliance

General details		Technical Details						Regulatory	
Manufacturer	Product model	Material(s) used	Weight of the manikin	Temperature & humidity tolerance	Construction of hinges & joints	Compression cycle capacity	Decontaminated by	Regulatory compliance	Compliance to international standards
3B Scientific (with Gaumard partnership)	CPR Newborn no. 1018866	PVC	approx. 4.0 kg	approx. 0°C to +29°C (storage temp.)	non corroding, does not need lubrication	N/A	Soap & water	N/A	ISO 9001:2008 (distributor 3B Scientific)
3B Scientific (with Gaumard partnership)	Newborn CPR Simulator no. 1014570	PVC	approx. 4.5 kg	approx. 0°C to +29°C (storage temp.)	non corroding, does not need lubrication	N/A	Soap & water	N/A	ISO 9001:2008 (distributor 3B Scientific)
3B Scientific (with Gaumard partnership)	CPR Manikin no. 1017247	PVC	approx. 3.0 kg	approx. +7°C to +29°C (storage temp.)	non corroding, does not need lubrication	N/A	Soap & water	N/A	ISO 9001:2008 (distributor 3B Scientific)
KOKEN CO., LTD.	LM-089	Silicone Rubber	about 2,500g	0 - 50 degree less than 80%Rh	N/A	N/A	ph-balanced(neutral) detergent	N/A	ISO9001
KOKEN CO., LTD.	LM-111	Silicone rubber	about 3,000g	0 - 50 degree less than 80%Rh	N/A	N/A	ditto	N/A	ISO9001
Shanghai Honglian Medical Instrument Development Co., Ltd	Full-functional neonatal CPR manikin	PVC	1.72kgs	(-40°C to +60°C)	Non corroding, durable, self lubricating materials	More than tens of thousands of times	Soap & water, alcohol wipes	CE	ISO9001/ISO14001

General details		Technical details						Regulatory	
Manufacturer	Product mdel	Material(s) used	Weight of the Manikin	Temperature & humidity tolerance	Construction of hinges & joints	Compression cycle capacity	Decontaminated by	Regulatory compliance	Compliance to international standards
Laerdal Global Health AS	NeoNatalie Newborn Simulator	PVC, TPU, PP, POM	0.20 kg +/-0.05 kg when inflated with air and 2.2 kg +/-0.2 kg when inflated with water (assembled without tubes and pressure bulbs)	Operating temperature range: +15°C to +40°C, Storage environmental conditions with air: -10°C to +50°C	Continous flexible plastic limbs	no limit set	The manikin shall withstand cleaning with a cloth soaked with mild soapy water.	REACH	N/A
Laerdal Medical AS	Resusci Baby	PVC	2,1 kg	Operating temperature range: 0° to +40°C; Storage temperature: -15° to +50°C	Interlocking of parts by non corroding, durable, self lubricating materials	More than 300,000	Soap & water, alcohol swipes	REACH, RoHS, EC, RCM	EN 60950-1, EN-61000-6-1, EN 61000-6-3
Laerdal Medical AS	SimBaby	PA, PE, POM, ABS, PVC, PP, PC, TPE, silicone rubber, PU-foam, steel, galvanized steel, clothing - cotton, blanket - polyester	4 kg	Operating temperature range: +10° to +40°C, 15-90% RH Storage: -15°C to +50°C, 15-90% RH (non-condensing)	Head and limbs are flexible and movable. Convulsion simulation available	N/A	Soap & water (as the product is not designed for mouth-to-mouth or mouth-to-mask ventilation)	EU/EEA: RoHS, WEEE, EMC, LVD USA: UL/FCC Canada: CSA/IC	EU/EEA: EN 60950-1, EN 55022, EN 55024, EN 61000-3-2, 61000-3-3

General details		Technical details						Regulatory	
Manufacturer	Product model	Material(s) used	Weight of the manikin	Temperature & humidity tolerance	Construction of hinges & joints	Compression cycle capacity	Decontaminated by	Regulatory compliance	Compliance to international standards
Laerdal Medical AS	Baby Anne	Head and limbs in PVC, torso stuffed	1,3 kg	Operating temperature range: 0° to +40°C; Storage temperature: -15° to +50°C	Interlocking of parts by non corroding, durable, self lubricating materials	More than 300,000	Soap & water, alcohol swipes.	N/A	N/A
Laerdal Medical AS	Premature Anne	Silicone rubber / TPU / PC / PUR	435 grams	Operation: +15° to +50°C, 10-90% RH Storage: -15°C to +50°C, 0-90% RH	Head and limbs are limp and flexible (no automatic movements)	> 127000	Soap & water (as the product is not designed for mouth-to-mouth or mouth-to-mask ventilation)	EU/EEA: REACH, RoHS, WEEE, R&TTE (RED) USA: FCC Canada: IC, Aus/ NZ: RCM, Japan: MIC	EU/EEA: EN 60950-1, EN 62311, EN 301 489-1/17, EN 61000-6-1, EN 61000-6-3, EN 300 328
Laerdal Medical AS	Premature Anne Task Trainer	Silicone rubber / TPU / PC / PUR	435 grams	Operation: +15° to +50°C, 10-90% RH Storage: -15°C to +50°C, 0-90% RH	Head and limbs are limp and flexible (no automatic movements)	> 127000	Soap & water (as the product is not designed for mouth-to-mouth or mouth-to-mask ventilation)	REACH	N/A
Laerdal Medical AS	SimNewB	Silicone / PVC / ABS / PUR / nylon / aluminium / brass / Copper / stainless steel	2.8 kg	Operation: +4° to +40°C, 20-90% RH Storage: -15°C to +50°C, 20-90% RH (non-condensing)	Head and limbs are limp and flexible. Automatic movement all limbs: limp, tone, spontaneous, seizure	N/A	Soap & water, 60% isopropanol alcohol (product is not designed for mouth-to-mouth or mouth-to-mask ventilation)	EU/EEA: REACH, RoHS, WEEE, EMC, USA: FCC	EU/EEA: EN 61000-6-1, EN 61000-6-3, IEC 60068-2-6
Ambu A/S	Ambu Baby	PE, PVC hard, PVC soft	1,8 kg	N/A	Yes	N/A	Manual washing / machine wasching / disinfection	REACH / RoHS	N/A

3.2 Post Market Support & Commercial

General Details		Maintenance	Commercials			Desired Features				Other relevant details		
Manufacturer	Product Model	Spare Support (Years)	Manufacturer warranty (years)	Marketed	Contact details	Anatomical landmarks	Head tilt / chin lift	Ventilation with bag valve mask	Visible chest rise	Simulator type	Manikin type	Carry bag
3B Scientific (with Gaumard partnership)	CPR Newborn no. 1018866	5 years from date of delivery	2 Years (offered by 3B Scientific)	Worldwide	Germany, www.3bscientific.com	Yes	Yes	Yes	Yes	N/A	Molded	Yes
3B Scientific (with Gaumard partnership)	Newborn CPR Simulator no. 1014570	5 years from date of delivery	2 Years (offered by 3B Scientific)	Worldwide	Germany, www.3bscientific.com	Yes	Yes	Yes	Yes	Wired external indicators	Molded	Yes
3B Scientific (with Gaumard partnership)	CPR Manikin no. 1017247	5 years from date of delivery	2 Years (offered by 3B Scientific)	Worldwide	Germany, www.3bscientific.com	Yes	Yes	Yes	Yes	Wired external indicators	Molded	Yes
KOKEN CO., LTD.	LM-089	6 years (after the end of sales)	18months after shipping date	Worldwide	Japan, www.kokenmpc.co.jp	Yes	Yes	Yes	Yes	N/A	stuffed with silicone gel	Yes
KOKEN CO., LTD.	LM-111	6 years (after the end of sales)	18months after shipping date	Worldwide, available in EU only in 2017	Japan, www.kokenmpc.co.jp	Yes	Yes	Yes	Yes	Wireless	stuffed with silicone gel	Yes
Shanghai Honglian Medical Instrument Development Co., Ltd	Full-functional neonatal CPR manikin	1 year from date of delivery	1 year	Worldwide	China / http://en.honglian8.com	Yes	Yes	Yes	Yes	Wired external indicators	Molded	Yes
Laerdal Global Health AS	NeoNatalie Newborn Simulator	5 years after end of production	1 year	Worldwide	www.laerdalglobalhealth.com	Yes	Yes	Yes	Yes	N/A	Inflated	Yes

General Details		Maintenance	Commercials			Desired features				Other relevant details		
Manufacturer	Product Model	Spare Support (Years)	Manufacturer warranty (years)	Marketed	Contact details	Anatomical landmarks	Head tilt / chin lift	Ventilation with bag valve mask	Visible chest rise	Simulator type	Manikin type	Carry bag
Laerdal Medical AS	Resusci Baby	5 years after end of production	1 year	Worldwide	www.laerdal.com	Yes	Yes	Yes	Yes	Wired External Indicators	Molded	Yes
Laerdal Medical AS	SimBaby	5 years after end of production	1 year	Worldwide	www.laerdal.com	Yes	Yes	Yes	Yes	Wired External Indicators	Molded	Yes
Laerdal Medical AS	Baby Anne	5 years after end of production	1 year	Worldwide	www.laerdal.com	Yes	Yes	No	Yes	Inbuilt Indicators	Partly molded/ partly stuffed	Yes
Laerdal Medical AS	Premature Anne	5 years after end of production	1 year	EU/EEA, USA, Canada, Japan, Australia, New Zealand, Republic of Korea	www.laerdal.com	Yes	Yes	Yes	Yes	Wireless Extrenal indicators	Stuffed	Yes
Laerdal Medical AS	Premature Anne Task Trainer	5 years after end of production	1 year	Worldwide	www.laerdal.com	Yes	Yes	Yes	Yes	N/A	Stuffed	Yes
Laerdal Medical AS	SimNewB	5 years after end of production	1 year	Worldwide	www.laerdal.com	Yes	Yes	Yes	Yes	Wired External Indicators	Molded	Yes
Ambu A/S	Ambu Baby	10 Years from date of delivery	18 month	Worldwide	www.ambu.com	Yes	Yes	Yes	Yes	N/A	Molded	Yes

4. Types of neonatal resuscitation manikin

The following observations are based on the survey results in section 3.1 and 3.2 of this technical specification for neonatal resuscitation manikins and based on available publications.

Neonatal resuscitation manikins can be broadly classified in to the following three broad categories

1. Basic type neonatal manikin
2. Basic type inflatable neonatal manikin
3. Advanced type neonatal manikin with simulation

As seen in the survey, all three types of manikins are manufactured either from plastics, silicone rubber or from a combination of plastics, silicone rubber and metal. Textiles are used for manufacturing the outer clothing for the manikins.

The market pricing of manikins are closely associated with the type of manikin and then based on the features it offers. Previous studies have found that market price of neonatal resuscitation manikin ranges from US$80 to US$1,500 (8). It is to be noted that with more technological features for simulations getting added to the product every year, the upper price level of neonatal resuscitation manikins have increased multiple times. Good quality products in all three manikin types comply with international process standards such as ISO 9001 and testing standards such as ISO 11403-3 (for environmental testing of plastics) or other internationally accepted equivalent standard(s) based on materials used in manufacturing (16).

4.1 Basic type neonatal manikin

These are basic type neonatal manikins that are manufactured either by molding of an outer shell or by stuffing softer material inside a thick outer skin (Fig 4). Some models are manufactured by using both molding and stuffing processes (30, 31).

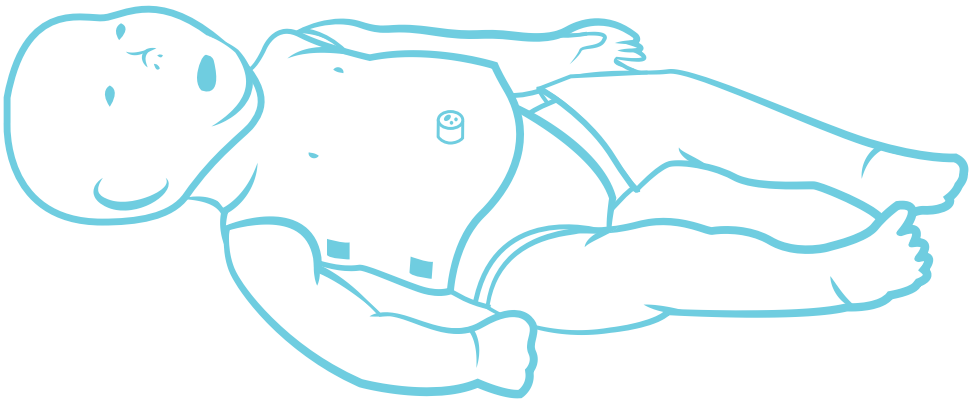


Fig 4: Basic type neonatal manikin

These manikins are either manufactured from plastic or silicone rubber or a combination of plastics, silicone rubber and different metals (34). Basic type neonatal manikins offer the basic

features for neonatal resuscitation training, they are usually heavy for transportation but have comparatively long product life with manufacturers claiming more than 100,000 compressions across lifetime of each manikin.

Due to their rigid construction, basic type neonatal manikins withstand a wider temperature range for storage and operations. Operational and storage temperature range varies from manufacturer to manufacturer based on the materials used for manufacturing (32). Details of temperature tolerance range claimed by some manufacturers can be found in this document under the section 3.1.

4.2 Basic type inflatable neonatal manikin

Basic type inflatable neonatal manikins are like basic type neonatal manikins but are brought to lifelike size by inflating them with air or water (Fig 5). Due to inflatable core, it is good to handle them with care. They are very compact manikins and hence easy for transportation. Like basic type neonatal manikins, inflatable manikins provide only basic features for neonatal resuscitation training. Basic type inflatable neonatal manikins are manufactured from different types of plastics (34).

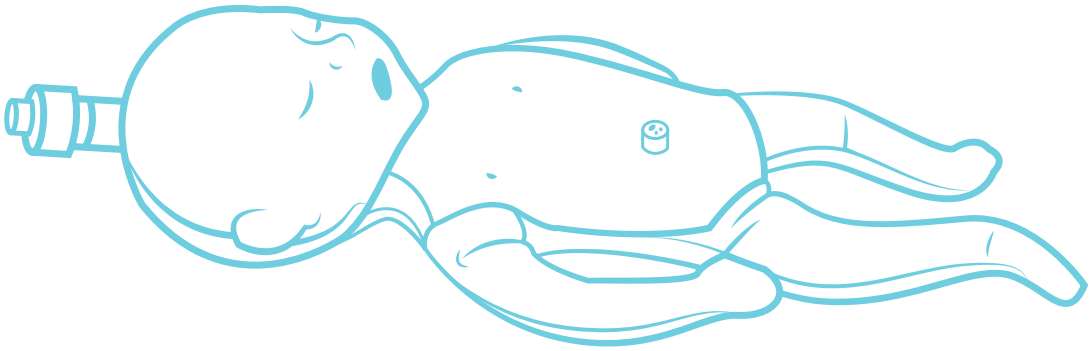


Fig 5: Basic type inflatable neonatal manikin

Inflatable neonatal manikins have a slightly shorter operational temperature range but have an equal or wider storage temperature range than basic type neonatal manikins. Temperature range varies from manufacturer to manufacturer based on the materials used for manufacturing (32).

4.3 Advanced type neonatal manikin with simulation

Advanced Type Neonatal Manikin with simulation is basic type neonatal manikin with extra features such as built-in mechanical alarms, electronic alarms or display systems with built-in and/or externally connected devices to provide audio/visual feedback to students during resuscitation training (Fig 6).

Features offered are dependent on the manufacturer and the models they offer. The features vary from mechanical alarms to notify the correct depth of neonatal CPR compressions to

real-time changes in the neonatal condition due to intervention by the trainee (4). Mechanical manufacturing of these manikins follow the same process as basic type neonatal manikins.

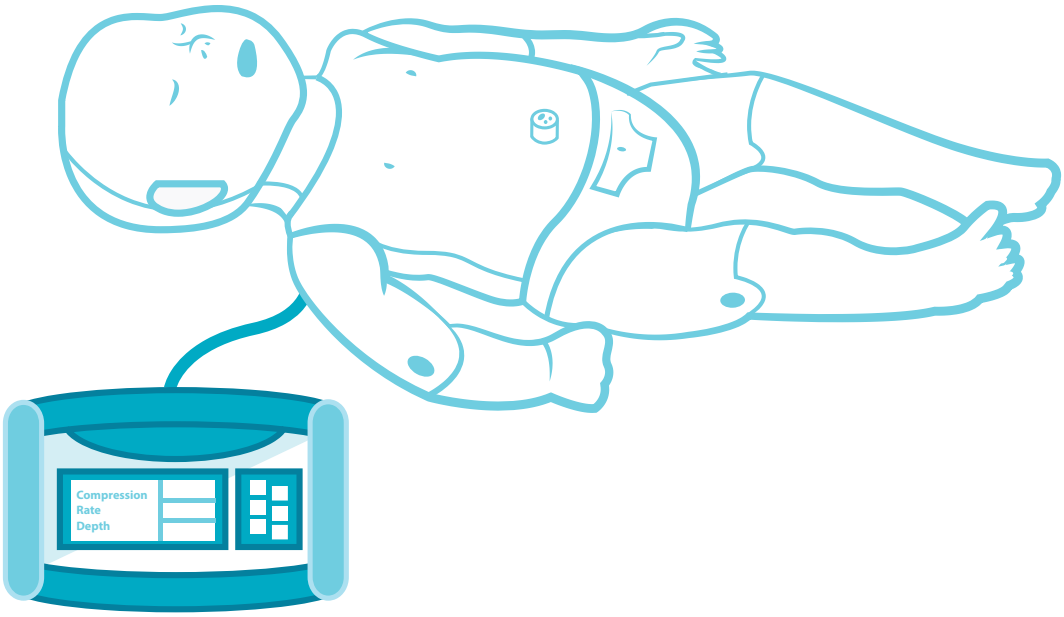


Fig 6: Advanced Type Neonatal Manikin with Simulation

Manikins with inbuilt electronic devices have to comply with international regulations for electrical safety and information technology equipment in addition to mechanical and manufacturing process compliance. Due to inbuilt mechanisms, these manikins can be slightly heavier than basic type neonatal manikins - based on the simulation features offered by the manufacturer. Manikins with electronic sensors and alarm systems need suitable external power supply as recommended by the manufacturer for facilitating the simulation features (24).

Being on the costlier side, advanced type neonatal manikins with simulation are usually designed for a longer product life like basic type neonatal manikins. Due to the sturdy construction required to house and support costly electronics sensors and accessories, like basic type neonatal manikins, in comparison with basic type inflatable neonatal manikins, they withstand a wider temperature range for operations and storage. Operational and storage temperature range varies from manufacturer to manufacturer based on the materials used for manufacturing (32).

5. Concluding statements

Based on the study of available literature and industry survey, the WHO Neonatal resuscitation manikin: technical specifications was developed to fulfil the vision towards reduction in child mortality and towards fulfilling UNCLSC's mandate to promote and assure the availability of 13 safe, quality commodities, which include neonatal resuscitation devices.

It is indispensable to train health care workers on neonatal resuscitation, to have the competency and save lives when it is most required. Manikins play an essential role in this training, and should be of good quality and safe and special infection prevention and control measures should be taken by the users of the maniking to avoid dissemination of diseases. Now a days with the spread of COVID-19, the Infection Prevention and Control (IPC) measures are indispensable also to save the lives of health care workers globally.

Glossary of terms

B

Birth asphyxia: Failure to establish breathing at birth.

C

CPR: Cardio Pulmonary Resuscitation is an emergency procedure in which chest compressions with artificial ventilation in a defined medical sequence is given to a patient to manually preserve brain function intact till natural blood circulation and breathing is restored.

N

Newborn: An infant less than 28 days of age.

R

Resuscitator: A hand-operated device using positive pressure to assist breathing.

S

Silicone: Class of synthetic materials based on chains of alternate silicon and oxygen atoms used to make rubber and plastics.

P

PVC: Commonly known as Polyvinyl chloride, is a polymer used in manufacturing of commonly used plastic goods. PVC can be used for the production of both rigid and flexible products.

POM: Known as Polyoxymethylene is a thermoplastic known for its dimensional stability, abrasion resistance and low friction.

T

Term: Infant born alive after week 37 of pregnancy.

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