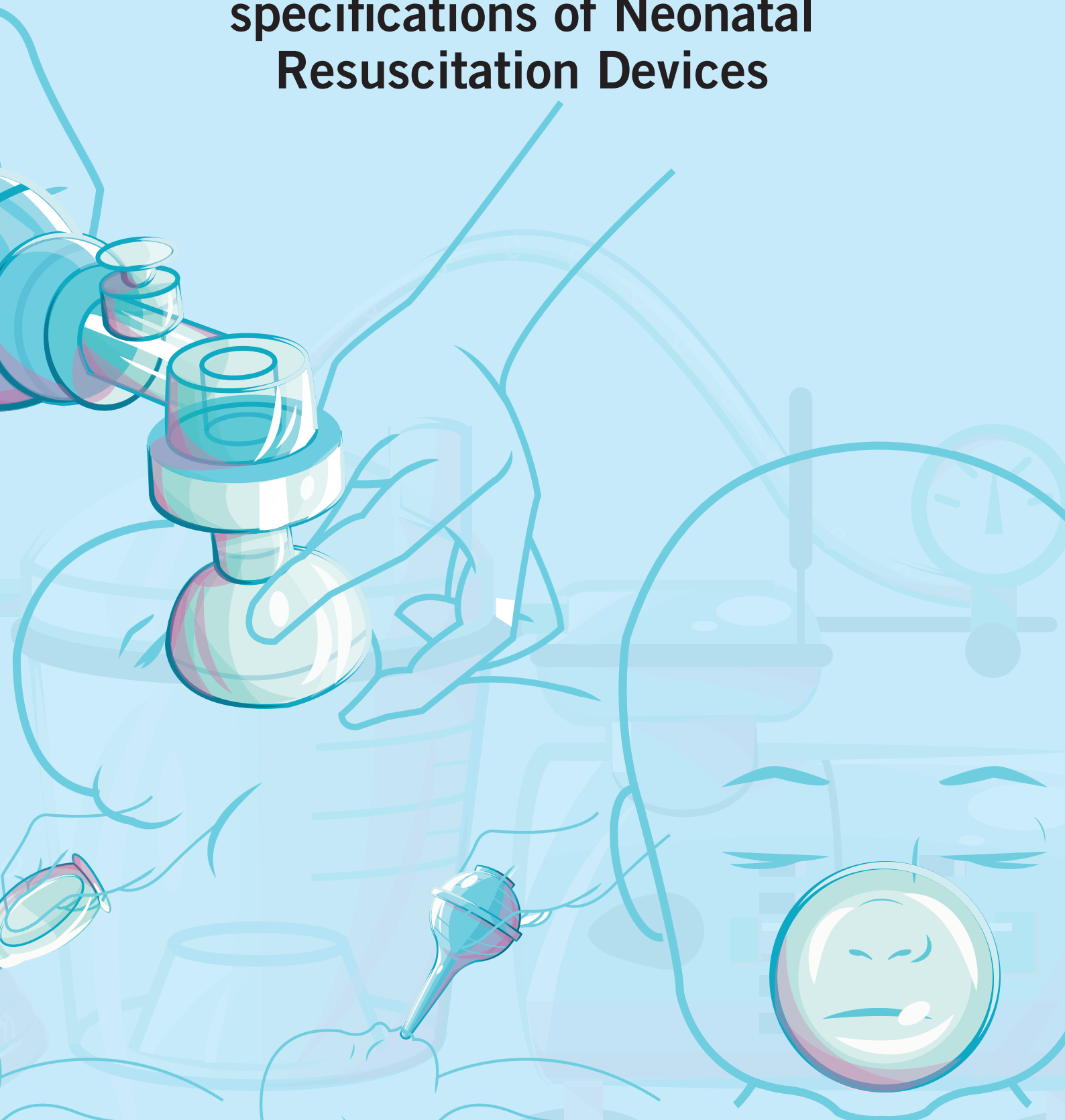


# WHO Technical specifications of Neonatal Resuscitation Devices





# **WHO Technical specifications of Neonatal Resuscitation Devices**

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The *WHO technical specifications of Neonatal Resuscitation Devices* was developed under the framework of the World Health Assembly Resolution WHA66.7,(5) 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 resuscitation devices.

These specifications are the result of a collaboration of experts from different backgrounds and organizations, including WHO, UNICEF, CHAI, PATH and Save the Children, with funding support from the Reproductive, Maternal, Newborn, Child and Adolescent Health (RMNCH) Trust Fund, derived from the UNCLSC.

Cai Long and Didier Mukama drafted this document under the supervision of Adriana Velazquez Berumen, Senior Advisor of Medical Devices at the Policy and Access Unit of the Essential Medicines and Health Products at WHO.

It is noted that in June 2013, an expert group from the Neonatal Resuscitation Group along with representatives from six African countries, gathered at WHO headquarters to discuss for the first time the technical specifications of neonatal resuscitation devices; WHO is grateful to every participant (Annex 9 includes the report of this meeting).

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## Abbreviations

<b>CE</b>	Conformité Européenne/European Conformity
<b>CFR</b>	Code of Federal Regulations – FDA (United States)
<b>CHAI</b>	Clinton Health Access Initiative
<b>Cm</b>	centimetre
<b>cmH<sub>2</sub>O</b>	centimetre of water
<b>EEC</b>	European Economic Commission
<b>EU</b>	European Union
<b>FDA</b>	Food and Drug Administration (United States)
<b>g</b>	gram
<b>GHTF</b>	Global Harmonization Task Force
<b>GMDN®</b>	Global Medical Devices Nomenclature
<b>HLD</b>	high-level disinfection
<b>IEC</b>	International Electrotechnical Commission
<b>IMDRF</b>	International Medical Device Regulators Forum
<b>IMDRF founding member country</b>	Australia, Canada, European Union, Japan, United States
<b>ISO</b>	International Organization for Standardization
<b>JIS</b>	Japanese Industrial Standards
<b>Kg</b>	kilogram
<b>kPa</b>	kilopascal
<b>L</b>	litre
<b>M</b>	metre
<b>MHLW</b>	Ministry of Health, Labour and Welfare - Japan
<b>mL</b>	millilitre
<b>mm</b>	millimetre
<b>mmHg</b>	millimetre of mercury
<b>N</b>	Newton
<b>N/A</b>	not applicable
<b>NIH</b>	National Institutes of Health (United States)
<b>O<sub>2</sub></b>	oxygen
<b>PIP</b>	peak inspiratory pressure
<b>ROHS</b>	Restriction of Hazardous Substances
<b>SoPs</b>	standard operating procedures
<b>UMDNS®</b>	Universal Medical Device Nomenclature System
<b>UN</b>	United Nations
<b>UNCLSC</b>	United Nations Commission on Life-Saving Commodities for Women and Children
<b>UNFPA</b>	United Nations Population Fund
<b>UNICEF</b>	United Nations Children's Fund
<b>UNSPSC</b>	United Nations Standard Products and Services Code
<b>USAID</b>	United States Agency for International Development
<b>WHA</b>	World Health Assembly
<b>WHO</b>	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. This document is part of the work led by WHO to ensure availability of good quality, affordable neonatal resuscitators in every place where a child is born, along with trained health-care workers, in order to help babies breathe and save their lives. This document is a guide for the selection and procurement of neonatal resuscitators, describing the technical specifications as well as providing guidance for correct use.

Neonatal mortality represents approximately 44% of under-5 child deaths, of which one quarter of overall neonatal deaths (around 700 000) is attributed to birth asphyxia, defined as the failure to initiate and sustain breathing at birth. Effective neonatal resuscitation; immediate care, including thorough drying, suction and stimulation after assessment; and positive-pressure ventilation, if needed, can prevent a high number of neonatal deaths (1).

Based on the World Health Organization (WHO) *Guidelines on basic newborn resuscitation* (2012) and the technical meeting on medical devices of the UNCLSC in June 2013, the WHO medical devices team worked in collaboration with neonatal resuscitation experts from PATH, the Clinton Health Access Initiative (CHAI) and the United Nations Children's Fund (UNICEF) to develop technical specifications for neonatal resuscitation devices, which are described in each chapter:

- Chapter 1, neonatal resuscitation self-inflating bag with mask
- Chapter 2, suction machine
- Chapter 3, single and suction device
- Chapter 4, procurement guidance
- Chapter 5, research agenda

The WHO technical specifications for neonatal resuscitation devices were developed based on existing international standards, evidence-based publications from reliable sources and field expert experience. For equipment without prior technical specifications, recommendations were made based on a literature research, depending on quality and significance of evidence.

The purpose of the *WHO technical specifications of Neonatal Resuscitation Devices* is to provide a minimum standard baseline to meet the increasing demand to procure good quality, affordable, accessible and appropriate neonatal resuscitation devices. The specifications are intended to support policy-makers, managers, procurement officers, manufacturers, regulators and nongovernmental agencies, especially in low- and middle-income countries to select, procure, use, reprocess and decommission appropriate neonatal resuscitation equipment. The end goal is to save the children, particularly in low-resource settings.

# Introduction

Neonatal mortality represents approximately 44% of under 5 year old child deaths, of which one quarter of overall neonatal deaths (around 700 000) is attributed to birth asphyxia, defined as the failure to initiate and sustain breathing at birth. About 3–6% of all newborns (about 6 million) require basic neonatal resuscitation (2). A high number of neonatal deaths can be prevented through effective neonatal resuscitation, immediate care including thorough drying, suction, stimulation as needed after assessment, and positive-pressure ventilation if the newborn has not established spontaneous respirations (1). However, lack of commodities is one of the main bottlenecks found in health systems in low-resource settings (3).

To address the above-mentioned health challenges faced in low-resource countries, the World Health Organization (WHO), in conjunction with other United Nations (UN) agencies, has been working on Millennium Development Goals (MDGs) 4, 5 and 6, specifically the under-5 mortality rate and the maternal mortality ratio. In that regard, the UNCLSC was created in 2012 with the goal to increase access to life-saving medicines and health supplies for the world's most vulnerable people by championing efforts to reduce barriers that block access to essential health commodities.

Over 6 million women and children could be saved by 2017 if access to simple, essential and affordable medicines, medical devices and health supplies is provided. The UNCLSC has made 10 recommendations (Table 1) to increase access to 13 essential, overlooked commodities in four categories: reproductive health; maternal health; newborn health; and child health (4). Neonatal resuscitation devices are one of the 13 commodities for newborn.

**Table 1. The UNCLSC recommendations on essential, overlooked commodities**

1. Shaping global market	Reproductive health	Female Condoms Implants Emergency Contraception
2. Shaping delivery markets	Maternal Health	Oxytocin Misoprostol Magnesium sulfate
3. Innovative Financing	Newborn Health	Injectable antibiotics Antenatal Corticosteroid (ANCS) Chlorohexidine Resuscitation Equipment
4. Quality strengthening	Child Health	Amoxicillin Oral Rehydration Salts Zinc
5. Regulation efficiency		
6. Supply and awareness		
7. Demand and awareness		
8. Reaching women and children		
9. Performance & accountability		
10. Product innovation		

Accelerate achievement of MDGs 4 & 5

Source: UNCLSC- brochure. September 2015 (<http://www.lifesavingcommodities.org/>).

In May 2013, resolution WHA66.7 Implementation of the recommendations of the United Nations Commission on Life-Saving Commodities for Women and Children (Annex 10) was approved and requests WHO:

1. to work with UNICEF, UNFPA, the World Bank, UNAIDS, UN Women, national, regional and international regulators, private sector actors and other partners, in order to promote and assure the availability of safe, quality commodities;
2. to work with and support Member States, as appropriate, in improving regulatory efficiency, standardizing and harmonizing registration requirement and streamlining assessment processes, including granting priority to review of the life-saving commodities (5).

The 13 commodities included three related to medical devices that were analysed and discussed at the June 2013 meeting (Annex 9). However, each of these commodities imply other related medical devices, as can be seen in Table 2.

**Table 2. List of the 13 recommended life-saving commodities**

<b>Reproductive health commodities</b>
• Female condom
<b>Injectable antibiotics for newborn sepsis</b>
• Syringe 2mL with needle 23 G 25 mm (with re-use prevention feature)
• Syringe 2mL with needle 23 G 25 mm (without re-use prevention feature)
• Safety box, for used syringes/needles
• Infant scale less than 20 kg
• Clinical thermometer, non-mercury
<b>Resuscitation devices for newborn asphyxia</b>
• Self-inflating neonatal resuscitation bag with masks for pre-term (size 0) and term (size 1) babies
• Electric or foot operated suction machine/pump, negative pressure less than 100mm Hg, with 1 bottle
• Suction catheter, length 50 cm, single use, conical tip, Fr #8
• Single use suction bulb
• Multi-use suction bulb that can be opened, cleaned and sterilized
• Training mannequin/simulator for neonatal resuscitation
• Infant stethoscope

In order to contribute to the access of quality, appropriate life-saving commodities, the medical devices team at WHO, in collaboration with other international organizations, called for technical advisors to support the development of the present publication on technical specifications of neonatal resuscitation devices, specifically: resuscitation bag with masks; suction machine; and single- and suction device. Therefore, these specifications are meant to assist health facilities managers and staffs in low- and middle-income countries in the selection, acquisition and use of appropriate and good quality neonatal resuscitation devices.

With regard to the practice of neonatal resuscitation, WHO published the *Guidelines on basic newborn resuscitation* in 2012, particularly for resource-limited settings countries requiring effective resuscitation. The recommendations (please see details in

Annex 4) in the above-mentioned publication were made based on benefits and harms, quality of evidence, etc. These guidelines, listed in Annex 4, are used as a baseline for neonatal resuscitation recommendations. The *WHO technical specifications of Neonatal Resuscitation Devices* is a complementary support manual on acquisition of the correct and appropriate neonatal resuscitation equipment.

A successful resuscitation programme requires both adequate training and necessary equipment. Moreover, good quality, accessible, acceptable and affordable medical devices play a vital role in efficient neonatal resuscitation. It is, therefore, the role of policy- and decision-makers responsible for health-care delivery to make the essential equipment and supplies as well as training available.

Unique challenges noticed during the development of these technical specifications were:

- discrepancies among existing standards and professional association guidelines;
- lack of evidence-based research for devices in low resource settings.

Strategies, including collaboration with international nongovernmental organizations and associations, internal and external experts advisory, market review and systematic literature review, were used in order to address these challenges and, therefore, provide the most beneficial guide that supports health facility managers in low- and middle-income countries to make the best informative decisions during purchase and selection of neonatal resuscitation devices.

## How to read this document

Each chapter provides information on each specific type of neonatal resuscitation medical device, preceded by a summary of specifications. The detailed WHO standard template technical specifications tables are presented in the annexes. Detailed clarifications are provided for certain technical characteristics when needed.

Technical specifications for the following devices are available in separate chapters:

- neonatal resuscitation bag with mask (reusable)
- suction machine
- single and multi-use suction device.

This is followed by a section on procurement guidance and the final chapter addresses the research agenda.

The annexes include the complete WHO template of technical specifications as well as a report from a consultation to discuss technical specifications and the World Health Assembly resolution related to the implementation of the United Nations Commission on Life-Saving Commodities (UNCLSC).

## Who is this document intended for?

This document is intended primarily for any policy-maker, manager, procurement officer or professional health worker who has responsibility for procuring, supplying and using neonatal resuscitation devices for all health settings, but particularly in low-resource settings.

Manufacturers would benefit from the specifications from this document to produce quality products. Nongovernmental agencies will also be able to find useful information in this document to support the access, whether by in-kind donation or procurement, to quality products that comply with the present specifications.

## Purpose of the document

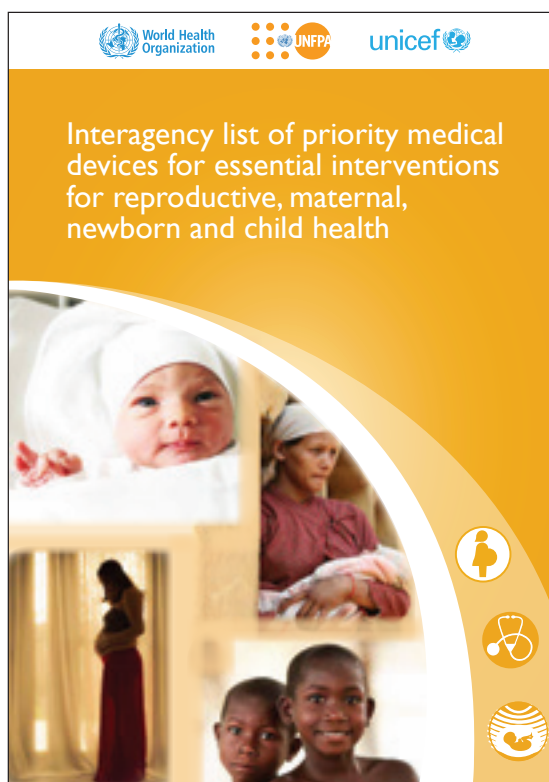
The purpose of this document is to facilitate availability of resuscitation through the introduction of appropriate neonatal resuscitation devices to all levels of health facilities in low-resource setting countries and regions, from health centres to district hospitals, outpatient clinics, ambulances, emergency services and specialized hospitals, wherever neonatal resuscitation is required.

The document provides a technical baseline to meet the increasing demand of procuring affordable, good quality and appropriate neonatal resuscitation devices. These specifications can also be used to assist in the selection, procurement, distribution of medical devices and training of health-care professionals on the safe use of neonatal resuscitation devices to reduce newborn deaths.

## Scope of the document

This document includes available evidence and advice for procurement officers to help them make informed decisions when choosing products that meet performance and design standards; it also includes scientific evidence for manufacturers so that they may better understand the needs in low-resource settings, and may be beneficial for local manufacturers to make local supply products.

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



[http://www.who.int/medical\\_devices/md\\_maternal\\_v12\\_web.pdf](http://www.who.int/medical_devices/md_maternal_v12_web.pdf)

# Chapter 1: Technical specifications for a self-inflating neonatal resuscitation bag with mask

---

## Brief description

A neonatal self-inflating resuscitator is used to ventilate a neonate with a body weight less than 5 kg. Ventilation can be done with ambient air or with oxygen; the device can be totally disassembled and is easy to clean and disinfect. All parts are manufactured with durable and high-quality materials that can withstand a variety of cleaning methods and a range of storage conditions. It is supplied as a complete set with:

- **Non-rebreathing patient valve with a pressure limiting valve** so that airway pressure does not exceed 4.5 kPa (45 cmH<sub>2</sub>O) and can generate an airway pressure of at least 3 kPa (30 cmH<sub>2</sub>O).
  - **Masks:** translucent, in two different sizes: Size 0 (preterm and low-birth-weight baby), round type, outer diameter 35–50 mm; Size 1 (term baby), round type, outer diameter 50–65 mm. Silicone rubber or any material fulfilling at least the standards ISO 10993-1; ISO 10993-5; ISO 10993-10 or equivalent; or classified as USP Class V.
  - **Compressible self-refilling ventilation bag:** silicone rubber or any other material fulfilling the standards. Bag size: 200–320 mL. Intake valve with optional nipple for O<sub>2</sub> tubing: polycarbonate/ polysulfone or other material fulfilling the ISO 10651-4 or equivalent.
- 

## 1.1 Scope

This chapter specifies technical requirements for a reusable neonatal self-inflating resuscitation bag with mask, which uses a self-inflating bag to provide positive pressure to open the neonatal airway as described below. The specifications are mainly based on WHO neonatal resuscitation guidelines (1), international standards and evidence-based research publications. For issues not addressed in standards or reliable sources, recommendations are based on a series of meetings, surveys and reviews with experts and studies by WHO and several nongovernmental organizations and scientific institutions.

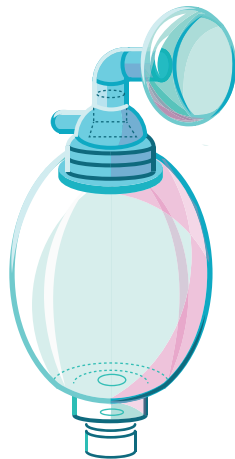
## 1.2 Background for a neonatal resuscitation bag with mask

Every year, 2.9 million newborn babies worldwide die within their first month of life, and more than 1 million die on their first day of life. Almost one quarter of the newborn deaths results from intrapartum hypoxia, also known as birth asphyxia (6). Birth asphyxia is defined as the failure to initiate and sustain breathing at birth. Asphyxia can result from a variety of causes, for example: maternal asphyxia; interruption of blood flow in the cord; fetal anaemia; heart failure, etc. (7). In the WHO *Guidelines on basic newborn resuscitation*, positive-pressure ventilation is recommended to be initiated within 1 minute after birth if the baby has not started breathing after initial steps of resuscitation (1).

A neonatal resuscitation bag with mask is the most standard basic neonatal ventilation device to ventilate a neonate with a body weight less than 5 kg, due to its automatic re-expansion feature and simplicity of use. It can be used without an additional continuous power source or pressurized gas, which is particularly important in low-resource settings. For babies who do not start breathing despite thorough drying and additional stimulation, positive-pressure ventilation using a self-inflating bag and mask should be initiated within 1 minute after birth. WHO recommends starting ventilation with ambient air; if that is not successful, then ventilation should be started with 30% oxygen (1). There should be a source of 100% oxygen and capability to blend the oxygen with air to yield a concentration that produces the desired saturation as measured by pulse oximetry.

The neonatal resuscitator with bag technology in itself is not new, but materials and features have improved over time. The device usually consists of three main parts: a bag; a pressure relief valve; and a facemask (Figures 1 and 2).

**Figure 1. Sample neonatal resuscitation bag with mask**



**Figure 2. How to use a neonatal resuscitation bag with mask**



A neonatal resuscitation bag with mask is recommended to be operated by health-care professionals who have received adequate relevant resuscitation training.

### **1.2.1 Self-inflating bag**

A compressible, self-inflating bag, usually made of silicone rubber or equivalent regulatory approved materials provides positive air pressure required to ventilate an asphyxiated baby.

The immediate spontaneous tidal volume of preterm and term infants after birth ranges from 6.5–7 mL/kg. For babies suffering from asphyxia, it is recommended to maintain a tidal volume from 4–8 mL/kg during resuscitation, at a rate of 40–60 breaths per minute (8–12). A low ventilated volume (tidal volume) might be insufficient to achieve an adequate gas exchange and might cause hypercapnia or atelectotrauma (please



refer to Annex 1 for definition). Animal studies show that excessive ventilation might cause volutrauma (13,14), hence small tidal volumes at the start of ventilation is more adequate than higher volumes (15). According to human factor experiments, “smaller self-inflating bags are more likely to reduce the incidence of excessive tidal volumes and produce better guideline-consistent ventilation for patients” (16).

For the majority of babies weighing less than 5 kg at birth, a bag with a 200–320 mL (Annex 3) size should be adequate to provide ventilation for neonatal resuscitation.

### 1.2.2 Valve

To prevent administering excessive pressure, which can cause lung damage, a pressure relief valve is recommended.

During resuscitation, a 30–40 cmH<sub>2</sub>O initial peak inspiratory pressure (PIP) may be necessary to open term infants’ airways. For preterm infants, 20–25 cmH<sub>2</sub>O may be effective and in some instances, such as the commencement of resuscitation, a positive pressure of more than 40 cmH<sub>2</sub>O may be required to initiate resuscitation (8).

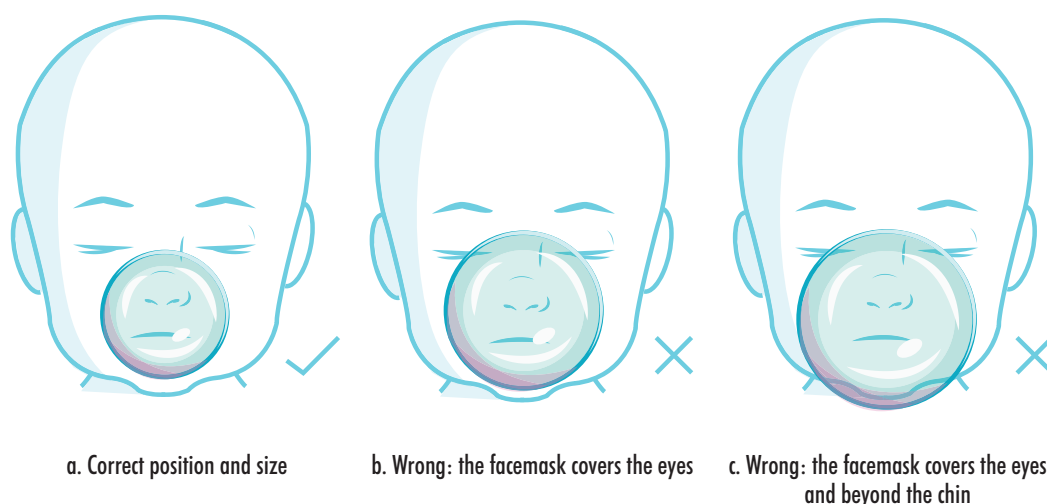
To ensure optimum protection and adequate ventilation, the valve should be able to transmit an airway pressure of at least 30 cmH<sub>2</sub>O, and the maximum pressure for the pressure relief valve is recommended to be 45 cmH<sub>2</sub>O.

The lung compliance is low especially in the initial stages of birth asphyxia and in preterm babies with fluid filled lungs and low surfactant; at times in the early stages, higher pressures or prolonged inflations are required. It is necessary to have the ability to occlude or override the pressure relief valve in these specific circumstances. The user training on the self-inflating neonatal resuscitator should include training on how and when to override the pressure relief valve.

### 1.2.3 Mask

The mask or facemask is connected to the bag and covers the mouth and nose of the newborn who is being resuscitated. A correctly sized mask should cover the mouth and nose, but not the eyes, and should not extend beyond the chin. Using an appropriately sized mask will reduce leakage and is vital for successful effective resuscitation (Figure 3).

Figure 3. Correct use of a neonatal mask





As stipulated by ISO 10651-4:2002, the facemask should have a connecting port that has either a 22 mm female connector or a 15 mm male connector.

For preterm babies, 35 mm or 42 mm diameter facemasks are suitable (17). Based on market review and scientific evidence presented in Annex 2, the proposed ranges for the dimensions of facemasks are:

- Size 0: outer diameter 35–50 mm
- Size 1: outer diameter 50–65 mm.

Ideally, a Size 1 mask is used for term babies and a Size 0 mask for preterm and low-birth-weight babies. However, standards for size are not clearly defined; users should make a note that the mask selected for use in a particular baby should be such that it covers the mouth and nose without covering the eyes or extending over the chin. Manufacturers and users should note that the mask design should provide a good seal and limit air leakage as much as possible. A reusable mask should be able to withstand appropriate reprocessing – pre-clean, disassemble, cleaning and high-level disinfection (HLD)/sterilization, reassemble – and preserve its shape and material properties. Please see Section 1.4.2 for more details on reprocessing.

### 1.3 Standards and regulations compliance

A newborn resuscitation bag with mask should comply with ISO 10651-4:2002 Lung Ventilators – Particular requirements for operator-powered resuscitators or equivalent national or regional standard compliance. For more details with regard to other regional regulations and standards, see the specifications table at the end of the chapter.

### 1.4 Other considerations

#### 1.4.1 How to use a resuscitation bag with mask

The steps below serve as a general guide to trained personnel. The protocol can be customized according to health facilities standards and requirements, but neonatal resuscitator should be prepared and tested for proper functionality before delivery (18). It should be noted that when the resuscitator is used on a newborn, it is important to watch for chest rise, listen to air movement and check for improvement of the newborn's heart rate and colour.

1. Check equipment and select the correct mask.
2. Apply the mask to make a firm seal. Extend the head, place the mask on the chin, then over the mouth and nose. A firm seal permits chest movement when the bag is squeezed.
3. Begin ventilation, practice should follow the WHO *Guidelines on basic newborn resuscitation*.
4. Pre-clean, disassemble, clean, subject equipment to HLD or sterilization, reassemble and assure proper storage before the next use. Please see Section 1.4.2 for more details on reprocessing.

### 1.4.2 Reprocessing

Reusable neonatal resuscitation devices (bag, mask, manual suction device) must be properly reprocessed between patients to avoid infection and the continued functioning of your equipment. Single-use resuscitation devices must be discarded after use as they are not manufactured with materials that are intended to withstand repeated reprocessing and may not be designed to resist to HLD or to sterilization.

The determination of the appropriate reprocessing method for a reusable medical device takes into account the level of infection risk posed by the object. For this, the Spaulding Classification System (19) outlines the risk of infection transmission posed by medical devices and equipment. This risk classification divides equipment and devices into three categories: critical; semi-critical; and noncritical items. Neonatal resuscitation devices fall into the semi-critical class, given that they are objects that come into contact with mucous membranes or non-intact skin, and thus pose a medium level of risk. Before reusing, such objects must be free from all microorganisms, but a small number of bacterial spores are permissible.

Instructions to reprocess neonatal resuscitation devices vary by source and context. Guidelines designed for low-resource settings include selected components of the following process: immediate pre-cleaning; disassembly; cleaning; HLD/sterilization; reassembly; and storage.

Ideally, the manufacturer's instructions, where available, should be followed. Immediate pre-cleaning should be the first step in reprocessing soiled instruments to protect cleaning staff before handling. This step inactivates hepatitis B virus (HBV) and HIV and reduces, but does not eliminate, a number of other microorganisms (21). Pre-cleaning can be done by wiping the outside of the devices with gauze soaked in a 0.5% chlorine solution (19). This first step protects the health worker, but does not achieve a high level disinfection thus the instruments are not ready for reuse yet.

Resuscitation devices should then be disassembled to allow for proper contact of the cleaning and disinfecting agents/methods to reach all surfaces. The next step is cleaning, a process in which visible organic and inorganic material is removed from the devices by washing with soap and water. All the surfaces of the device must be free from any material (such as blood or vernix) and thoroughly rinsed to allow the subsequent disinfecting agent/method to act effectively. Then, resuscitation devices ideally should be sterilized, but otherwise they should be dried and then undergo HLD. HLD can be done by boiling for 20 minutes or by soaking the devices in activated glutaraldehyde or in the 0.5% chlorine solution described above (19). It is important to follow the instructions of the chemical manufacturer regarding exposure time, concentration and solution temperature. After rinsing with clean boiled water, devices should be dried, and then visually inspected for cracks and tears before reassembly. In order to extend the lifetime of your device, it is important to prevent it from overexposure to chemicals and to reprocess it according to the manufacturer's recommendations.

After reassembly, the bag should be checked for correct assembly and proper functioning as recommended by the manufacturer. If the instructions are not available:

- Put the mask on the ventilation bag. Squeeze the bag and look for the valve in the patient outlet to open as you squeeze. This confirms that the device is ready to deliver air to a patient.

- Seal the mask tightly with the palm of the hand and squeeze hard enough to open the pressure release valve. Listen for the sound of air escaping. This demonstrates that air that cannot be delivered safely to the baby will escape through the pressure release valve.
- Maintain the tight seal and check that the bag reinflates after each squeeze. This shows that fresh air will enter the bag through the inlet valve.

If the resuscitator does not function properly, it should either be repaired before use or replaced. The device should then be appropriately packaged and stored to avoid recontamination.

### **1.4.3 Storage and packaging**

ISO 15223-1:2012 Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements should be followed to ensure safe, easy-to-use packaging. Labelling on the primary packaging should include the name and/or trademark of the manufacturer.

The device should always be stored in a clean condition in a clean container on a shelf or on the resuscitation table with the appropriate temperature and humidity to avoid dust and exposure to insects.

### **1.4.4 Maintenance**

Besides the use and care of the device, proper reprocessing and assembly, no other maintenance is required. If a device appears damaged or does not pass the functionality requirements test, it should immediately be taken out of service and replaced.

### **1.4.5 Capacity-building and quality assurance related to the neonatal resuscitator**

Availability of equipment for resuscitation is, on its own, not sufficient; the performance of the user is equally critical. Therefore, competency-based capacity-building of the skilled attendant using the self-inflating bag and mask, based on the standard guidelines, is required not only for use on the baby, but also for reprocessing and maintenance of equipment to prevent infection. Courses on basic resuscitation for low-resource countries are available and cover the required set of skills (18). Moreover, the availability of a training manikin can greatly help in acquiring skills before the attendant actually needs to resuscitate a baby who is not breathing. Ideally, health facilities should have at least one training manikin for training purposes.

It should also be noted that reprocessing of the equipment may or may not be done by the same skilled birth attendant who carries out the resuscitation and who received the training. It is, therefore, essential that the competency is passed onto the appropriate person responsible for the full reprocessing.

Once the resuscitator reaches the facility, it is very important to train the health professionals who will use the resuscitator, making sure supervision of correct and appropriate use is in place, in order to guarantee patient safety and quality of care. Should the device become damaged, or not function properly, then it is indispensable to have good maintenance with qualified professionals who can replace the parts with original manufacturer's parts as needed or have them sent to the manufacturer for repair.

The presences of a training manikin in the facility and motivation to practice frequently have also been shown to help maintain skills (22). The above-mentioned processes should be part of policy support and quality assessment and an improvement framework that should encompass timely procurement of required accessories to avoid out-of-stocks.

## 1.5 Key tender/request for quotation specifications for a neonatal resuscitation bag with masks

Following are the key features that may be noted in a tender or request for quotation; see Annex 5 for detailed standardized WHO technical specifications.

### 1.5.1 Neonatal resuscitation bag with mask specifications

Product	Neonatal resuscitation bag with masks
Key resuscitation bag features	<ul style="list-style-type: none"> <li>• size: 200–320 mL</li> <li>• for full-term babies, preterm and low-weight infants less than 5 kg</li> <li>• reusable</li> <li>• self inflating</li> <li>• hand operated</li> <li>• portable</li> <li>• made of silicone or other materials specified in ISO10651-4 or equivalent</li> <li>• ventilation can be done with ambient air or with oxygen</li> <li>• intake valve with optional nipple for O<sub>2</sub> tubing, material made of polycarbonate/polysulfone or any other material fulfilling ISO 10651-4 or equivalent.</li> </ul>
Key mask features	<ul style="list-style-type: none"> <li>• Size 0 for preterm and low-weight baby, round type, outer diameter 35–50 mm</li> <li>• Size 1 for term baby, round type, outer diameter 50–65 mm</li> <li>• translucent</li> <li>• fulfilling ISO 10993-1:2009; ISO 10993-5:2009; ISO 10993-10:2010 or USP Class V (or equivalents)</li> </ul>
Bundling instructions	<p>Resuscitator bag and masks supplied as a complete set along with the following:</p> <ul style="list-style-type: none"> <li>• non-rebreathing patient valve with a pressure limiting valve so that the airway pressure does not exceed 4.5 kPa (45 cmH<sub>2</sub>O) and can generate an airway pressure of at least 3 kPa (30 cmH<sub>2</sub>O)</li> </ul>
Materials	<ul style="list-style-type: none"> <li>• all parts manufactured from high-strength, long-life materials that require no special maintenance or storage conditions and comply to with national standards</li> <li>• the mask is made of silicone rubber or any material fulfilling ISO 10993-1:2009; ISO 10993-5:2009; ISO 10993-10:2010 or equivalent or USP Class V</li> <li>• the bag is made of silicone and valve of polycarbonate/polysulfone or any materials fulfilling ISO10651-4 or equivalent.</li> </ul>

Packaging	<ul style="list-style-type: none"> <li>• primary packaging: unit of use; one resuscitator set in a plastic bag + box with manufacturer's instruction for use</li> <li>• labelling on the primary packaging: name and/or trademark of the manufacturer; manufacturer product reference; type of product and main characteristics</li> <li>• if the packaging is not transparent, it must bear a diagram (preferably actual size) showing the essential parts of the product and indicating the position of the product in the packaging</li> <li>• lot number prefixed by the word "LOT" (or equivalent harmonized symbol)</li> <li>• information for particular storage conditions (temperature, pressure, light, humidity, etc.) as appropriate (or equivalent harmonized symbol)</li> <li>• information for handling, if applicable (or equivalent harmonized symbol)</li> </ul>
Language	<ul style="list-style-type: none"> <li>• English and/or any language preferred by users</li> </ul>
Assembly and reassembly instructions	<ul style="list-style-type: none"> <li>• resuscitator can be totally disassembled</li> <li>• clear instructions/diagrams for assembly and reassembly instructions must be included in and/or on the packaging</li> </ul>
Cleaning instructions	<ul style="list-style-type: none"> <li>• easy to clean, disinfect and sterilize</li> <li>• clear instructions/diagrams for cleaning instructions must be included in and/or on the packaging</li> </ul>
Warranty	<ul style="list-style-type: none"> <li>• minimum 1 year</li> </ul>
Reference to International standards	<ul style="list-style-type: none"> <li>• ISO 13485:2012 Medical devices – Quality management systems – Requirements for regulatory purposes</li> <li>• ISO 10651-4:2002* Lung ventilators – Part 4: Particular requirements for operator-powered resuscitators (*EN 13544-2 implied), oxygen related clauses are optional</li> <li>• For facemask (if not made of silicone):</li> <li>• ISO 10993-1:2009 Biological evaluation of medical devices – Part 1: Evaluation and testing for mask</li> <li>• ISO 10993-5:2009 Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity</li> <li>• ISO 10993-10:2009 Biological evaluation of medical devices – Part 10: Tests for irritation and delayed-type hypersensitivity (or classified as USP class V):</li> <li>• Optional:</li> <li>• ISO 14971:2012 Medical devices – Application of risk management to medical devices</li> <li>• ISO 5356-1:2004 Anaesthetic and respiratory equipment – Conical connectors – Part 1: Cones and sockets</li> <li>• BS EN 980:2008 Graphical symbols for use in the labelling of medical devices</li> <li>• ISO 15223-1:2012 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements</li> <li>• BS EN 1041:2008 Information supplied by the manufacturer with medical devices</li> </ul>
Regulatory approvals	<ul style="list-style-type: none"> <li>• To comply with the regulatory requirements of the National Regulatory Agency; or</li> <li>• registered in country of import, if applicable; or</li> <li>• approval from the National Regulatory Agency of the manufacturer's country; or</li> <li>• FDA registration (United States); or</li> <li>• CE Mark (EU) for class IIa, with notified body number, or</li> <li>• approval from other regulatory body in an IMDRF founding member country</li> </ul>

# Chapter 2: Technical specifications for a suction machine

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## Brief description

A portable, hand-held, battery-powered/hand- or foot-operated suction equipment designed to enable an adult to gently suction and clear excessive mucus from the airway (nasal or oral) passages of a newborn or an infant to facilitate easier breathing, with following technical requirements:

- AC line or battery-powered with rechargeable battery;
  - maximum vacuum: 100 mmHg (20 kPa);
  - collection bottle (one or two): 1L (disposable bag or collection jar);
  - bottle(s) with an automatic cut off when full, to prevent ingress of fluid to the pump; filter and overflow valve incorporated to prevent cross-contamination (e.g. shatterproof material; overflow protection system); should be either disposable or autoclavable;
  - tubing to the patient is a minimum of 0.5 m long, noncollapsible type.
- 

## 2.1 Scope

This chapter defines technical specifications for a suction machine, also known as an airway/nasal aspirator. Suction machines are used to gently suction and clear excessive mucus from the airway passages of a newborn or an infant, in order to facilitate easier breathing. They can be electrical, manual or foot operated. Suction machines used for newborns are classified as low-flow suction machines (with airflow less than 20 L/minute).

## 2.2 Background for a suction machine

When a newborn is unable to breathe enough in the first few minutes of life, birth asphyxia may occur. One way that this occurs is when the infant still has fluid in the airway. Suction can, therefore, in this case assist in removing the fluid and clear the airway to allow the newborn to breathe easily or to decrease respiratory resistance. However, as suction can cause bradycardia in certain circumstances, it is recommended to carry it out only in cases where the newborn has obvious airway obstruction that prevents spontaneous breathing. WHO recommends suctioning only if the newborn has meconium-stained amniotic liquid or when either the mouth or nose is blocked with secretions (23).

Moreover, it also has been evidenced that a few inexpensive practices can save newborn lives. One of these practices is immediate drying and stimulation at birth (24). In addition, clearing of the newborn's airways, where indicated, may also help in improving

breathing. The suction machine is used to clear the airways, allowing the newborn to breathe properly and prevent asphyxia.

However, high vacuum pressures can be harmful to the newborn airway tissues. Therefore, the most important characteristic of the aspirator is its regulated negative pressure that sucks the obstructing fluids from the buccal cavity and the nasal airways. Negative pressure regulates the vacuum created in the airways. Published airway suction guidelines recommend a negative pressure level of 80-100 mmHg for newborns (25,26). Negative pressure recommended in these specifications for a newborn nasal aspirator is a maximum of 100 mmHg. Moreover, ISO recommends that a low-flow device should have a vacuum less than 20 kPa (150 mmHg).

## 2.3 Equipment requirement

### 2.3.1 Electrical suction machine

The equipment is electrically powered and portable, thus there must be an electric power source (220V or 120V, according to different national standards) in the room to allow battery charging. The user should be trained on how to operate the machine and how to clean and maintain the equipment. The user should wear protective gear such as gloves, as a self-protection measure during the use and care of the equipment (Figure 4). More details on the equipment requirements are available in the technical specifications tables in Annex 6.

An electrical suction machine consists of the following.

#### 2.3.1.1 POWER SOURCE/MAINS

In this case, a rechargeable battery-operated electric circuit powers the pump. The line power cord allows connection to the battery and recharging of the battery. The device should be able to run intermittently for a minimum duration of 30 minutes on the battery, under maximum free airflow of not less than 20 L/minute and a vacuum of not less than 20 kPa below atmospheric pressure. The device should have audible and visible alarms indicating a low battery. This part should fulfil Clause 7 of IEC6061-1:1998 or equivalent.

#### 2.3.1.2 VACUUM SOURCE

The vacuum source is the pump. It should be durable and require limited maintenance, produce a maximum vacuum of 100 mmHg and a flow of 20 L/minute, and be able to produce 20 kPa below atmospheric pressure in 10 seconds. The pump should cease to operate when the collection container is full; or, if it continues to operate, the device should have an overflow means. The device should stop working when a maximum of 5 mL of liquid passes downstream of the overflow device. The suction machine should have the means to prevent the pump from contamination.

#### 2.3.1.3 COLLECTION BOTTLE

The collection container can be either a disposable bag or collection jar, with a capacity of 1 L and should be transparent in order to see the level of the contents. The usable volume should be marked in millilitres, by no less than 50 mL and no more than 250 mL graduations. The container should have inlet and outlet ports clearly indicated (26).

#### 2.3.1.4 SUCTION TUBING

The inner diameter of the suction tubing should be no less than 6 mm. The degree of collapse is indicated in ISO 10079-2:2014. The minimum length of the tubing to the patient should be not less than 0.5 m. The airline to the pump must incorporate a bacterial filter (hydrophobic). Both tubings should be a noncollapsible type, reusable and made of silicone (26).

#### 2.3.1.5 CONNECTORS

The inlet port and the outlet port of the suction device are to have different inner diameters and it must not be possible to connect the suction tubing to the outlet port. The inner diameter of the inlet port should be 6–12 mm, while the minimum inner diameter of the outlet port is 14 mm, to avoid the risk of incorrect connections (26).

#### 2.3.1.6 VACUUM GAUGE AND VACUUM REGULATOR

The vacuum gauge indicates the level of the vacuum pressure and should have an accuracy of  $\pm 0\%$ . The vacuum regulator should adjust the suction from 0–100 mmHg.

**Figure 4. Electrical suction machine with a canister**



## 2.4 How to use an electrical suction machine

It should be noted that the device must be available in the room and ready to be used before the baby is born.

1. Wash hands thoroughly with water and soap, dry thoroughly and put on gloves.
2. Place the suction machine on a sturdy surface.
3. Position the baby in a comfortable position with his/her head supported.
4. Connect the catheter with the connecting tubing to the suction tubing.
5. Turn on the suction machine (refer to the device user manual).
6. Set the suction unit to the appropriate suction pressure, a range 50–100 mmHg, or according to the health facility's standard operating procedures (SoPs).
7. Insert the suction catheter according to the SoPs. If not available, mouth should be suctioned first.



8. Start suctioning. Proceed as required by the SoPs. It is advised to not use more than 10 seconds for every suction and to provide some time between suction passes (approximately 30 seconds or as required by the SoPs guideline) to allow for the infant to catch its breath.
9. Clean (clear by suctioning some sterile water) the catheter after each pass (according to the SoPs).
10. Repeat steps 7, 8 and 9 until the mucus is cleared in the mouth or nose.
11. Disconnect the tubings and catheter. Discard the catheter appropriately after use or if reusable, then clean and sterilize before using on another baby. Discard patient tubing or catheter if not reusable or damaged.
12. Dismantle and clean (remove body fluids, wash with detergent, rinse and dry), disinfect and reassemble as described in user manual.
13. Use disinfectant solutions such as 0.5% chlorine and avoid exposing the electric parts to this solution to clean the suction machine.

### 2.4.1 Manual/foot-operated suction machines

A manual/foot-operated machine, in contrast with the electrical suction machine, generates a vacuum by direct human effort, the foot in this case (Figures 5 and 6). The specifications in the previous paragraph on a vacuum source, collection bottle, vacuum gauges and regulators also apply to manual/foot-operated suction machines. Foot-operated devices have the special advantage in that they free up the hands for other aspects of care of the baby.

**Figure 5. Sample foot-operated suction machine**



**Figure 6. Sample manual-operated suction machine**



#### 2.4.1.1 POWER SOURCE

The device is actuated by hand or feet. A foot-operated suction machine should require less than 350 N (approximately 35 kg) to activate the device. Hand-operated suction equipment should not require more than 45 N (approximately 4.5 kg).

## 2.5 Standards and regulations compliance

The electrical suction machine must comply with the product standards as mentioned in the technical specifications sheet: ISO 10079-1:1999 Medical suction equipment – Part 1: Electrically powered suction equipment – Safety requirements as a minimum standard or equivalent; as well as ISO 5359: 2014 or equivalent. Details of other regulations and standards, regional or international, can be found in the technical specifications table at the end of the chapter.

## 2.6 Other considerations

### 2.6.1 Reprocessing

Table 3 provides an overview of different parts of a suction machine and its cleaning methods in case no SOPs are available. It is advised to follow the health facility's SOPs. The suction catheter is a single-use item and must be discarded after use, as noted above.

**Table 3. Suction pump user maintenance chart**

No.	Part	Clean	Disinfect	Sterilize
1	Pump	X	X	
2	Collection bottle	X	X	
3	Suction tubing (patient)	X	X	X
4	Vacuum regulators and vacuum gauges	X	X	
5	Connectors	X	X	

### 2.6.2 Maintenance

The electrical suction pump should require the least maintenance possible except for the user care: cleaning; disinfection; and sterilization. Where maintenance is required, it should be as minimal as possible and the internal parts of the device should be easily reachable. Before performing maintenance tasks, it is advised to prevent the likelihood of infection by ensuring sterilization of the machine before any maintenance task. Care should be taken to wear gloves and clean hands after maintenance tasks or use of the machine. Generic regular checks on suction devices include:

1. On a daily basis, clean, wipe dust off the exterior and cover the equipment after each use.
2. Wash the bottle and patient tubing as previously indicated.
3. Check if all fittings and accessories are mounted correctly.
4. Check if the filter is clean; and check for leaks and crack.
5. Check for the level of suction. A lower level indicates that there are leakages. Check that parts are fitted tightly (the lid on the bottle, the sealing washer and tube connections on the bottle or on the pump) and replace any broken tubes or damaged bottle or washer. If after these two procedures suction is still weak,

it might be caused by an internal fault. To check for an internal fault, remove the tubing from the pump outlet; block the outlet while the device is on. The suction gauge indicator should reach the maximum level. If it does not, then the problem is internal (assuming all other checks mentioned earlier have been done and are satisfactory). A qualified biomedical technician must then open the pump to check if the pump's diaphragm (if it is a diaphragm pump) does not have a hole or is broken or has any other fault.

6. Always check if the device functions well after maintenance and repair before returning it to service.

### 2.6.3 Suction catheter

Single-use, Fr #8 catheters with a length of 50 cm should be used during neonatal resuscitation. They are single-use or reusable and should have a soft conical tip to reduce damaging mucus membranes.

## 2.7 Key tender/request for quotation specifications for a suction machine, electrically operated

Following are the key features that may be noted in a tender or request for quotation; detailed standardized WHO technical specifications can be found in Annex 6.

### 2.7.1 Suction machine specifications

Product	Suction machine, electrically operated
Key features	<ul style="list-style-type: none"> <li>• low vacuum, low flow, oil-free vacuum pump</li> <li>• electrically powered or battery-powered with rechargeable battery</li> <li>• maximum vacuum: 100 mmHg</li> <li>• collection bottle (one or two): 1 L (disposable bag or collection jar); with an automatic cut off when full to prevent ingress of fluid to the pump; a filter and overflow valve incorporated to prevent cross-contamination (e.g. shatterproof material, overflow protection system); either disposable or autoclavable</li> <li>• airline to the pump incorporating a bacterial filter</li> <li>• tubing to the patient a minimum of 0.5 m long, a noncollapsible type; all parts manufactured from high-strength, durable material that does not require specific maintenance or storage conditions and are approved by national regulatory agencies</li> <li>• pump that can be disassembled entirely, is easy to disinfect and clean</li> <li>• pressure gauge that displays the level of suction generated</li> <li>• adjustment of suction delivered to the patient</li> <li>• unit surface that is hard and corrosion resistant; pump handle/pedal that is spring loaded to return to the "up" position after each stroke</li> <li>• mounted on a robust board with a carrying handle</li> <li>• supplied with: spare filters: 10 sets; spare suction bottle: one unit; seals: two pairs for each storage jar</li> <li>• additional documents from supplier: <ul style="list-style-type: none"> <li>› a list of other spare parts anticipated during one year's operation, with costs</li> <li>› user and maintenance manuals</li> </ul> </li> </ul>
Language	<ul style="list-style-type: none"> <li>• <i>English and/or any language preferred by final users</i></li> <li>• packaging of the set depends on the shipment type; at a minimum, per Annex C: Clause 12.1 of Part 1 of ISO 15500:2004 or equivalent</li> <li>• symbols used according to ISO 15223 or equivalent</li> </ul>

Warranty	<ul style="list-style-type: none"> <li>• <i>duration of warranty clearly stated</i></li> <li>• minimum 1 year, with specific inclusions and exclusions listed and contact details of the manufacturer, supplier and local service agent provided</li> </ul>
Reference to International standards	<ul style="list-style-type: none"> <li>• ISO 10079-1:1999 Medical suction equipment – Part 1: Electrically powered suction equipment – Safety requirements or equivalent</li> <li>• ISO 13485:2003 Medical devices – Quality management systems – Requirements for regulatory purposes (Australia, Canada, EU) or equivalent</li> <li>• IEC 60601-1-2 Ed. 3.0:2014 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests or equivalent</li> <li>• ISO 14971:2012 Medical devices – Application of risk management to medical device</li> </ul>
Regulation requirement	<p>To comply with the regulatory requirements of the national regulatory agency</p> <p>Optional:</p> <ul style="list-style-type: none"> <li>• registered in country of import, if applicable; or</li> <li>• approval from the national regulatory agency of the manufacturer's country; or</li> <li>• FDA registration (United States); or</li> <li>• CE Mark (EU) for class IIa, with notified body number,</li> </ul> <p>or approval from other regulatory body in an IMDRF founding member country</p>

# Chapter 3: Technical specifications for a suction device

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## Brief description

A suction device is a portable, hand-held, manual suction device designed to suck gently and clear excessive mucus from the airway of a newborn to facilitate easier breathing (Figures 7 and 8). Both single-use and multi-use suction devices are used in clinical settings. Single-use bulbs must be discarded after use and reusable suction devices need to be opened and subjected to pre-cleaning, cleaning, HLD/sterilization and proper storage until subsequent use.

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## 3.1 Scope

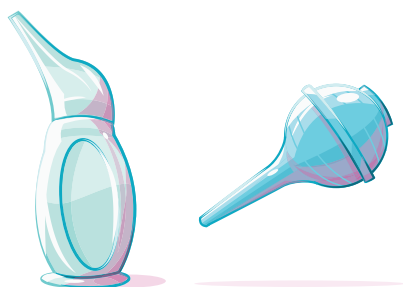
This chapter specifies technical requirements for suction devices for neonatal resuscitation. Both single-use and multi-use suction devices are approved to be clinically efficient to clear excessive mucus to facilitate breathing. The specifications are based on WHO neonatal resuscitation guidelines and international standards (see Section 3.3).

## 3.2 Background

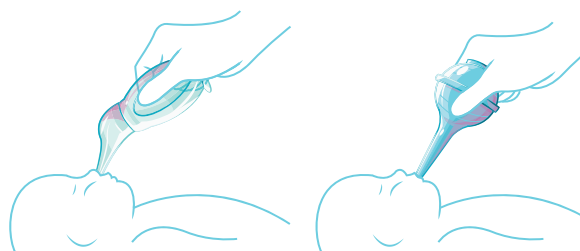
Neonates who do not start breathing after thorough drying and stimulation require suctioning before ventilation, if the mouth or nose is blocked with secretions. When mechanical equipment to perform suction is not available, a suction device (single-use or reusable) is recommended (1). A suction device is a portable, hand-held, manual suction device designed to suck gently and clear excessive mucus from the airway of the newborn to facilitate easier breathing.

A suction device should be able to withstand appropriate reprocessing (pre-cleaning, cleaning and HLD/sterilization).

**Figure 7. Sample suction devices**



**Figure 8. Suction device being used on a baby**



### 3.3 Standards and regulations compliance

Although no specific industry reference standards are available for newborn suction devices, the standards noted in the following resources (or other equivalent standards) are suggested to ensure quality:

ISO 13485:2003 Medical devices – Quality management systems – Requirements for regulatory purposes

ISO 14971:2007 Medical devices – Application of risk management to medical devices

ISO 11135-1:2007 Sterilization of health-care products – Ethylene oxide – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices

ISO 11135:2014 Sterilization of health-care products – Ethylene oxide – Requirements for the development, validation and routine control of a sterilization process for medical devices

ISO 8836:2007 or ISO 8836:2014 Suction catheters for use in the respiratory tract

### 3.4 Reprocessing

It is essential to be able to easily dispose of single-use suction bulbs without causing harm to the environment.

Reusable Suction devices must be able to be easily opened, pre-cleaned, cleaned and subjected to HLD/sterilization after each use. Although suction devices can be difficult to clean sometimes, note that they can become a source of cross-infection if not cleaned properly.

Manufacturer's instructions and international guidelines should be followed to ensure appropriate HLD/sterilization.

### 3.5 Maintenance

Besides pre-cleaning, cleaning, HLD/sterilization and proper storage after each use no other maintenance is required.

### 3.6 Capacity-building and quality assurance related to the suction devices

Health workers involved in resuscitation need to have the competence to use the suction device and suction bulb.

Training, supervision and motivation are needed to use the suction device in a safe and effective manner, and to avoid infection. Single-use bulbs must be discarded after use and reusable suction devices need to be opened and subjected to pre-cleaning, cleaning, HLD/sterilization, and proper storage until subsequent use.

Follow-up supervision and mentoring for quality of care should be carried out as described for the bag and mask.

### 3.7 Key tender/request for quotation specifications for a suction bulb

Following are the key features that may be noted in a tender or request for quotation; detailed standardized WHO technical specifications can be found in Annex 7 and Annex 8.

#### 3.7.1 Single-use suction bulb specifications

Product	Suction machine, electrically operated
Key features	<ul style="list-style-type: none"> <li>• oral, nasal</li> <li>• manual or handheld</li> <li>• compressible bulb with a tip that can be inserted into the nares</li> </ul>
Clinical purpose	<ul style="list-style-type: none"> <li>• evacuate secretions and liquids from the nasal cavity or from high infant airways</li> </ul>
Materials	<ul style="list-style-type: none"> <li>• non-latex</li> </ul>
Packaging	<ul style="list-style-type: none"> <li>• ensure the device is clean and in a sealed package</li> <li>• note any special markings/information required on the packaging</li> </ul>
Colour	<ul style="list-style-type: none"> <li>• any</li> </ul>
Reference to International standards	<ul style="list-style-type: none"> <li>• ISO 13485:2003 Medical devices – Quality management systems – Requirements for regulatory purposes or equivalent</li> </ul>
Regulation requirement	<p>Approval to comply with the regulatory requirements from the national regulatory agency</p> <p>Optional:</p> <ul style="list-style-type: none"> <li>• registered in country of import, if applicable</li> <li>• approval by regulatory body of the country of the manufacturer</li> <li>• FDA registration (United States), CE Mark (EU)</li> </ul>

### 3.7.2 Suction device specifications

Product	Suction machine, electrically operated
Key features	<ul style="list-style-type: none"> <li>• oral, nasal</li> <li>• manual or handheld</li> <li>• compressible bulb with a tip that can be inserted into the nares</li> </ul>
Clinical purpose	<ul style="list-style-type: none"> <li>• evacuate secretions and liquids from the nasal cavity or from high infant airways</li> </ul>
Materials	<ul style="list-style-type: none"> <li>• silicone or any material fulfilling ISO 10993-4:2002 and USP Class V or equivalent</li> <li>• latex free</li> </ul>
Packaging	<ul style="list-style-type: none"> <li>• insert any relevant information regarding packaging and labelling of packaging</li> </ul>
Colour	<ul style="list-style-type: none"> <li>• any</li> </ul>
Cleaning	<ul style="list-style-type: none"> <li>• can be subjected to boiling HLD and sterilization, including autoclaving</li> <li>• clear instructions/diagrams for cleaning instructions must be included in and/or on the packaging</li> </ul>
Reference to International standards	<ul style="list-style-type: none"> <li>• ISO 13485:2003 Medical devices – Quality management systems – Requirements for regulatory purposes (Australia, Canada, EU) or equivalent.</li> <li>• ISO 10079-2:1999 Medical suction equipment – Part 2: Manually powered suction equipment or ISO 10079-2:2014 or equivalent</li> </ul>
Regulation requirement	<p>Approval to comply with the regulatory requirements from the national regulatory agency</p> <p>Optional:</p> <ul style="list-style-type: none"> <li>• registered in country of import, if applicable</li> <li>• approval by regulatory body of the country of the manufacturer</li> <li>• FDA registration (United States), CE Mark (EU)</li> </ul>



## Chapter 4: Procurement guidance for neonatal resuscitation devices

There are a number of neonatal resuscitation devices on the market, but not all of them adhere to a high standard of quality. Although specifications should be selected to suit the needs of the end users, the key specifications that can be included in a tender in order to help managers and procurement personnel to purchase the correct product are described in each corresponding chapter.

A request for information that is also useful to include in a tender/request for quotation may include the following:

- lead-time from receipt of contract/purchase order;
- delivery date;
- method of shipment;
- shipping route;
- INCOTERMS (ensure it is clear who is paying customs clearance charges, import duties and taxes, final delivery costs, etc.);
- shipment/delivery costs, if applicable;
- weight and dimension of shipment;
- validity of quotation;
- payment terms;
- general and any special terms and conditions that will appear on the contract and/or the purchase order;
- copy of ISO certificates;
- copy of quality assurance certificates such as those from the United States Food and Drug Administration (FDA), CE certificate or other regulatory body approval certificates;
- copy of the certificate of conformity, where applicable;
- copy of proof of registration in the country of import, where applicable.

It is also important to mention that medical devices are regulated in some countries and there both the device and manufacturer must be registered in order for the medical devices to be imported into the country. In the absence of a registered product/manufacturer, an importer can often work with the Ministry of Health to apply for an import waiver. An import waiver, however, is only issued on a per shipment basis thus it is important to work with manufacturers to ensure that they apply to the local regulatory authority in order to become registered for future procurements. In some countries, the registration process can take from one to three years so the earlier the manufacturer applies, the better.

More procurement information for neonatal resuscitation devices can be found in the Neonatal Resuscitation Commodities Procurement Toolkit (27). A detailed key tender/request for quotation specification for each device type can be found at the end of each chapter.

## Chapter 5: For further research

Technical specifications play a vital role in procuring good quality, appropriate, affordable neonatal resuscitation devices. In collaboration with the United Nations Children's Fund (UNICEF), the United States Agency for International Development (USAID), PATH and the Clinton Health Access Initiative (CHAI), WHO has gathered internal and external experts to determine and develop technical specifications. The challenges faced during this process are:

- discrepancies among existing standards and professional association guidelines;
- lack of international standards for certain technical specifications for life-saving essential health technologies, specifically for mask sizes and bag sizes;
- lack of information and research for life-saving essential health technologies;
- making unbiased optimal recommendations in a smaller market with limited vendors.

For example, there is a gap between physiology and available equipment specifications: although the goal is to ventilate with an adequate tidal volume, current devices are calibrated in terms of pressure. Active research and development is required in this area.

Also, as stated in Chapter 2, the mask size has not been standardized in international standards, which leads manufacturers to use different dimensions. From users and procurers' perspective, this greatly increases the barrier to supply appropriate products for health facilities and creates confusion.

Some manufacturers from low-income countries find it difficult to comply with ISO, the prevalent international standards, as they are not publically available. It is difficult for these countries to make affordable devices for health facilities in low-resource settings, while following those standards. It is, therefore, recommended to conduct further research on standards for appropriate technology for low-resource settings or availability of international standards to improve compliance

There is a lack of evidence and data on the safe use of life-saving devices in low-income settings. Further actions on this can help manufacturers make more efficient devices. Attention should be raised towards life-saving essential health technologies, including encouraging scientific research and evidence-based clinical reports.

## Annex 1. Glossary of terms

### -A-

**Amniotic fluid:** A clear, slightly yellowish liquid that surrounds the unborn baby (fetus) during pregnancy. It is contained in the amniotic sac. While in the womb, the baby floats in the amniotic fluid. The amount of amniotic fluid is greatest at about 34 weeks (gestation) into the pregnancy, when it averages around 800 mL.

**Apnoea:** Temporary cessation of breathing.

**Atelectotrauma:** Occurs when there is ventilation that causes atelectasis. Atelectasis is a complete or partial collapse of a lung or lobe of a lung that occurs when the tiny air sacs (alveoli) within the lung deflate.

### -B-

**Birth asphyxia:** Failure to establish breathing at birth.

**Blender:** An oxygen blender is a device used to control the oxygen-air mix according to patients' needs.

### -C-

**CE:** From the French “Conformité Européenne” or “European Conformity”. It is a mark on products. It indicates that the product complies with the essential requirements of the relevant European health, safety and environmental protection legislation.

### -H-

**HLD:** High-level disinfectant. It is a type of germicide that inactivates all microbial pathogens in (or on) a container for a short contact time.

**Hypercapnia:** Presence of too much carbon dioxide in the blood.

### -I-

**Inner diameter:** The length from one interior edge to the other of a round shape facemask.

**Intrapartum hypoxia:** Lack of oxygen in the fetus during labour, due pinching of the umbilical cord. It is also called fetal hypoxia.

### -L-

**Lung compliance:** Change in lung volume for a given change in pressure.

### -M-

**Meconium:** Earliest stool of a newborn. It is viscous, sticky-like tar; its colour is usually a very dark olive green or can appear in various shades of green, brown or yellow. It is completely passed by the end of the first few days after birth.

### **-N-**

**Negative pressure:** Pressure that is less than ambient atmospheric pressure. It is also called vacuum.

**Newborn:** An infant less than 28 days of age.

### **-O-**

**Oral intercommissural distance:** Mouth width at rest, measured from one corner of the mouth to the other.

**Oxygen concentrator:** A device used to produce and provide oxygen to patients.

**Oxygen saturation:** A measurement that derives the amount of oxygen in the blood.

### **-P-**

**Peak inspiratory pressure (PIP):** Highest proximal airway pressure reached during inspiration.

**Philtrum length:** The distance from under the nose to the lowest point of the mid-Cupid's bow (tip of mouth).

**Positive-pressure ventilation:** Pressure that is higher than ambient atmospheric pressure.

**Preterm:** Newborn who is born alive before week 37 of pregnancy.

**Pulse oximetry:** Non-invasive method for monitoring a person's O<sub>2</sub> saturation. A pulse oximeter is a sensor device placed usually on the fingertip or earlobe or, in the case of an infant, across a foot.

### **-R-**

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

### **-S-**

**Self-inflating bag:** Stiff plastic bag, squeezed to deliver its gas contents into the patient's airway; when the pressure is released, it is reinflated from the atmosphere or an attached oxygen supply.

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

**Single-use 50 cm length, Fr #8 catheter:** Accessory used for the removal of secretions from the trachea and bronchial tubes to keep the airway clear. Fr #8 refers to French size 8.

**Suction machine:** Device used to clear the airways, to allow proper breathing and prevent asphyxia.

**Suction regulator:** Component of a suction machine that is used to control the negative pressure or suction pressure.

## **-T-**

**Term:** Infant born alive after week 37 of pregnancy.

**Tidal volume:** Normal lung volume of air displaced between normal inhalation and exhalation without extra effort.

**Tracheal:** From “trachea”. The main trunk of respiratory system tubes that connects the mouth and nose to the lungs.

## **-U-**

**UNSPSC:** United Nations Standard Products and Services Code. It is an open, global, multi-sector standard for efficient, accurate classification of products and services.

## **-V-**

**Vacuum/suction:** See negative pressure.

**Valve:** Component of a facemask that controls inlet or outlet airflow and protects against too much pressure in the airways.

**Vernix:** Also called vernix caseosa; the waxy, white substance found covering the skin of newborns.

**Volutrauma:** Damage to the lung caused by excessive high tidal volume.

## Annex 2. Facemask size discussion

As seen in Table A2.1, the manufacturer example does not classify the facemask sizes as Size 0, Size 1, etc., as is the case with most manufacturers, though many other details are provided. Size M (outer diameter 50 mm) corresponds to masks for newborns less than 2.5 kg, which compares to Size S (outer diameter 42 mm) masks for preterm newborns, and Size L (outer diameter 60 mm) masks for term newborns. It was also found that, based on studies on the oral inter-commissural distance, the mentioned distances range from 17 mm to 33 mm (28).

**Table A2.1 Sample facemask sizes in terms of inner diameter from one manufacturer**

	Micro-premature (XS)	Premature (S)	Neonatal (M)	Infant (L)	Paediatric (XL)
Diameter (inner)	35 mm (1.38 inches)	42 mm (1.65 inches)	50 mm (1.97 inches)	60 mm (2.36 inches)	72 mm (2.83 inches)
Suggested weight range	400 g–1 kg (2.3 pounds)	<1.5 kg (3.3 pounds)	<2.5 kg (5.5 pounds)	<5 kg (11 pounds)	<10 kg (22 pounds)
	Extremely low-birth-weight (ELBW)	Very low-birth-weight (VLBW)	Low-birth-weight (LBW)	Term	

## Annex 3. Bag size review – resuscitation bag with mask

### A3.1 Overview

A literature review has been completed by searching “neonatal resuscitation”, “neonatal ventilator”, “neonatal resuscitator” and other related or referenced articles. The outcome of the literature review is listed in the section below as evidences.

### A3.2 Summary of evidences

Two kinds of scientific evidences are listed below for further discussion, including physiological facts that scientists have found about infants, especially their breathing pattern; and human factor considerations for the bag size and mask ventilation process.

#### A3.2.1 Physiological evidence

Recommended beginning pressure is 30 cmH<sub>2</sub>O for term infants; for preterm infants it is 20–25 cmH<sub>2</sub>O, at a rate of 40–60 breaths per minute (1,2).

The immediate spontaneous tidal volumes of preterm and term infants after birth are found to be 6.5–7 mL/kg (3).

It is recommended to maintain a tidal volume of 4–8 mL/kg during resuscitation (1,6). Animal studies show that a low ventilated volume (tidal volume) might be insufficient to achieve adequate gas exchange and might cause hypercapnia or atelectotrauma, while excessive ventilation might cause volutrauma (7,8). The Australia Resuscitation Association recommends starting resuscitation with a smaller tidal volume (6).

#### A3.2.2 Human factor evidence

Studies show that mask leak usually has a range of 45±20% (1).

It has been found that smaller self-inflating bags reduce the incidence of overzealous tidal volumes and produce greater guideline-consistent results for cardiac arrest patients (8).

**Table A3.1 Discussion on required bag size**

	Maximum	Majority (97%)
Infant weight	Less than 7 kg	2.4–4.5 kg
Optimum tidal volume	28–56 mL	10–36 mL
Average	42 mL	23 mL
Stroke volume needed with 45% leakage	63–126 mL	22–80 mL
Average	95 mL	51 mL

From the table it is shown that for the majority infant size, up to 80 mL of air is needed to compress into the lung, which only takes less than one third of the total volume of 250 mL.

Researchers have agreed that a self-inflating neonatal resuscitation bag with about 250 mL will be more than adequate to inflate a baby’s lungs. If inadequate, then it must be due to a very large leakage (greater than 90%) between the mask and the face.

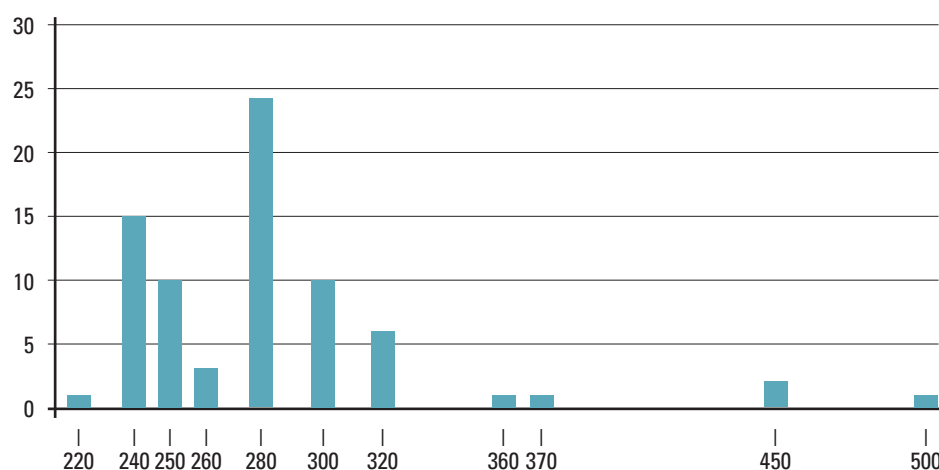
### A3.3 Market review

WHO conducted a web search of bag sizes available on market based on a field guide of practical selection of neonatal resuscitators by PATH (29). The results showed that almost all of the manufacturers are using bag sizes between 240 mL and 320 mL for infants and 500 mL for children (Table A3.1) and two had a maximum stroke volume of 150 mL.

**Table A3.2 Self-inflating neonatal and child resuscitator bag sizes**

Manufacturer	Bag size (mL)	Note
Zeal Medical	250	Infant
	500	Child
Shinmed	280	Infant
BIS system	320	Infant
	900	Child
Laerdal	220/240	Infant (up to 5 kg)
	320	Infant (up to 10 kg)
	500	Child
Besmed	280	Infant
	500	Child
Kaycoindia	240	Infant
	500	Child
Ambu	220	Infant (up to 10 kg)

**Table A3.3 Estimated percentage of neonatal resuscitation bag sizes (mL) on the market (research conducted by PATH)**





## Annex 4. 2012 WHO Guidelines on basic newborn resuscitation

No.	Recommendation	Strength of recommendation	Quality of evidence
Immediate care after birth			
1.	<p>In newly born term or preterm babies who do not require positive-pressure ventilation, the cord should not be clamped earlier than 1 minute after birth.</p> <p>When newly born term or preterm babies require positive-pressure ventilation, the cord should be clamped and cut to allow effective ventilation to be performed.</p>	<p>Strong</p> <p>Weak</p>	<p>High to moderate</p> <p>Guidelines Development Group consensus in absence of published evidence</p>
2.	Newborn babies who do not breathe spontaneously after thorough drying should be stimulated by rubbing the back two to three times before clamping the cord and initiating positive-pressure ventilation.	Weak	Guidelines Development Group consensus in absence of published evidence
3.	<p>In neonates born through clear amniotic fluid who start breathing on their own after birth, suctioning of the mouth and nose should not be performed.</p> <p>In neonates born through clear amniotic fluid who do not start breathing after thorough drying and rubbing the back two to three times, suctioning of the mouth and nose should not be done routinely before initiating positive-pressure ventilation. Suctioning should be done only if the mouth or nose is full of secretions.</p>	<p>Strong</p> <p>Weak</p>	<p>High</p> <p>Guidelines Development Group consensus in absence of published evidence</p>
4.	In the presence of meconium-stained amniotic fluid, intrapartum suctioning of the mouth and nose at the delivery of the head is not recommended.	Strong	Low
5.	<p>In neonates born through meconium-stained amniotic fluid who start breathing on their own, tracheal suctioning should not be performed.</p> <p>In neonates born through meconium-stained amniotic fluid who start breathing on their own, suctioning of the mouth or nose is not recommended.</p> <p>In neonates born through meconium-stained amniotic fluid who do not start breathing on their own, tracheal suctioning should be done before initiating positive-pressure ventilation.</p> <p>In neonates born through meconium-stained amniotic fluid who do not start breathing on their own, suctioning of the mouth and nose should be done before initiating positive-pressure ventilation.</p>	<p>Strong</p> <p>Weak</p> <p>Weak (in situations where endotracheal intubation is possible)</p> <p>Weak</p>	<p>Moderate to low</p> <p>Guidelines Development Group consensus in absence of published evidence</p> <p>Very low</p> <p>Guidelines Development Group consensus in absence of published evidence</p>

6.	In settings where mechanical equipment to generate negative pressure for suctioning is not available and a newly born baby requires suctioning, a bulb syringe (single-use or easy-to-clean) is preferable to a mucous extractor with a trap in which the provider generates suction by aspiration.	Weak	Very low
Positive-pressure ventilation			
7.	In newborn babies who do not start breathing despite thorough drying and additional stimulation, positive-pressure ventilation should be initiated within 1 minute after birth.	Strong	Very low
8.	In newborn term or preterm (>32 weeks gestation) babies requiring positive-pressure ventilation, ventilation should be initiated with air.	Strong	Moderate
9.	In newborn babies requiring positive-pressure ventilation, ventilation should be provided using a self-inflating bag and mask.	Weak	Very low
10.	In newborn babies requiring positive-pressure ventilation, ventilation should be initiated using a facemask interface.	Strong	Based on limited availability and lack of experience with nasal cannulae, despite low-quality evidence for benefits
11.	In newborn babies requiring positive-pressure ventilation, adequacy of ventilation should be assessed by measurement of the heart rate after 60 seconds of ventilation with visible chest movements.	Strong	Very low
12.	In newly born babies who do not start breathing within 1 minute after birth, priority should be given to providing adequate ventilation rather than to chest compressions.	Strong	Very low
Stopping resuscitation			
13.	In newly born babies with no detectable heart rate after 10 minutes of effective ventilation, resuscitation should be stopped.	Strong	Low
	In newly born babies who continue to have a heart rate less than 60/minute and no spontaneous breathing after 20 minutes of resuscitation, resuscitation should be stopped.	Weak (relevant to resource-limited settings)	Very low

## Annex 5. Technical specifications for a self-inflating neonatal resuscitation bag with masks

Medical device specifications		
I	Version No.	1
II	Date of initial version	25 June 2013
III	Date of last modification	11 December 2015
IV	Date of publication	30 December 2015
V	Completed/submitted by	Working group (WHO/UNFPA/UNICEF)
Name, category and coding		
1	WHO Category/code	(under development)
2	Generic name	Resuscitator, hand operated neonatal, reusable.
3	Specific type or variation (optional)	Multi-use self-inflating neonatal resuscitation bag with masks for preterm and full-term babies and low-birth-weight infants (less than 5 kg).
4	GMDN© name	Manual pulmonary resuscitator, reusable and resuscitator facemask, reusable.
5	GMDN© code	17591 and 17170
6	GMDN© category	02 Anaesthetic and respiratory devices, 09 Reusable devices
7	UMDNS© name	Resuscitators, pulmonary, manual [13-367]; resuscitators, pulmonary, manual, reusable [17-591].
8	UMDNS© code	13-367 17-591
9	UNSPS code	42272303
10	Alternative name/s	Resuscitation kit, resuscitation cabinets; CPR emergency kit; emergency kit, cardiopulmonary resuscitation, resuscitation bag and masks.
11	Alternative code/s	S 37507; S 16161
12	Keywords	resuscitation bag, mask, resuscitator, reusable devices, valves
13	GMDN©/UMDNS© definition	<p>"Manual pulmonary resuscitator, reusable [17591] A hand-operated device designed to provide or assist ventilation in patients who are apnoeic or exhibit inadequate respiration. It typically employs entrained ambient air and includes a large flexible chamber that is hand ventilated, a gas reservoir, tubing, and a connector for attachment to a mask or endotracheal (ET) tube; oxygen (O<sub>2</sub>) from an O<sub>2</sub> source may also be connected when necessary. It is used by emergency medical services (EMS) in ambulances, intensive care units (ICU), during internal patient transfer, accident and emergency (A&amp;E), mass casualty incidents (MCI), and is generally placed strategically throughout a hospital. This is a reusable device."</p> <p>"Resuscitator facemask, reusable [17170] A flexible, form-shaped device that is placed over a patient's nose and mouth to direct ambient air, or medical oxygen (O<sub>2</sub>) and air, from a resuscitator to the upper airway and lungs. It is typically made of non-conductive sterilisable materials (e.g. silicone) that will create a gas-tight seal against the face. It will typically include a 15 mm and/or 22 mm connector and is available in a range of sizes (baby to adult). It will be directly attached to the resuscitator and held in place on the patient's face by the operator. This device is intended for use with a breathing resuscitator but may be used for the delivery of anaesthesia gases. This is a reusable device."</p>

Purpose of use		
14	Clinical or other purpose	Provide positive air pressure ventilation to newborn babies with asphyxia, babies who experience respiratory arrest, apnoea or respiratory distress requiring assisted ventilation, and babies who require assisted ventilation during procedures.
15	Level of use (if relevant)	Health centre/district hospital/provincial hospital/specialized hospital/other health facilities that include maternity services.
16	Clinical department/ward (if relevant)	Nursing services, surgery, paediatrics, emergency medicine, obstetrics, intensive care unit, labour and delivery room.
17	Overview of functional requirements	The resuscitator is used to ventilate newborns with a body weight less than 5 kg. The resuscitator can be used to efficiently maintain ventilation, or as resuscitation in other critical situations.
Technical characteristics		
18	Detailed requirements	<p>A resuscitator is used to ventilate a neonate with a body weight of less than 5 kg. It is operated by hand and ventilation can be done with ambient air or with oxygen. A resuscitator can be totally disassembled, and is easy to clean and disinfect. All parts are manufactured from high-strength, long-life materials that require no special maintenance or storage conditions. A resuscitator is supplied as a complete set with:</p> <ul style="list-style-type: none"> <li>• non-rebreathing patient valve with a pressure limiting valve so that airway pressure does not exceed 4.5 kPa (45 cmH<sub>2</sub>O) and can transmit an airway pressure of at least 3 kPa (=30 cmH<sub>2</sub>O);</li> <li>• masks, translucent, in two different sizes: Size 0 (preterm and low-birth-weight baby), round type, outer diameter 35–50 mm; Size 1 (term baby), round type, outer diameter 50–65 mm silicone rubber or any material fulfilling at least the standards ISO 10993-1:2009; ISO 10993-5:2009; ISO 10993-10:2010, or equivalent; or classified as USP Class V;</li> <li>• compressible self-refilling ventilation bag: silicone rubber or any other material fulfilling ISO 10651-4;</li> <li>• bag size: 200–320 mL; intake valve with an optional nipple for O<sub>2</sub> tubing: polycarbonate/polysulfone or any other material fulfilling the ISO 10651-4 or any other equivalent;</li> <li>• bag made of silicone and valve made of polycarbonate or polysulfone or any other sterilizable material complying with ISO 10651-4 or equivalent</li> <li>• material: polycarbonate/polysulfone or any other sterilizable material fulfilling at least ISO 10651-4.</li> </ul>
19	Displayed parameters	N/A
20	User adjustable settings	
Physical/chemical characteristics		
21	Components (if relevant)	Self-inflating neonatal resuscitation bag with masks for preterm and term babies. Patient valves with pressure relief valves o 45 cmH <sub>2</sub> O.
22	Mobility, portability (if relevant)	Portable and mobile.
23	Raw materials (if relevant)	Recommended material is silicone rubber for the bag and mask and polycarbonate/polysulfone for the valves. Any material fulfilling ISO 10993-1:2009; ISO 10993-5:2009; ISO 10993-10:2010 or equivalent or USP Class V is also recommended.
Utility requirements		
24	Electrical, water and/or gas supply (if relevant)	N/A
Accessories, consumables, spare parts and other components		
25	Accessories (if relevant)	Masks for preterm, low-birth-weight babies (Size 0) and term babies (Size 1) (see Section 18 of this table for details).
26	Sterilization process for accessories (if relevant)	The resuscitator and mask must be cleaned and disinfected after each use; following the manufacturer's instruction is recommended.
27	Consumables/reagents (if relevant)	N/A

28	Spare parts (if relevant)	N/A
29	Other components (if relevant)	N/A
<b>Packaging</b>		
30	Sterility status on delivery (if relevant)	Cleaned and disinfected before use.
31	Shelf life (if relevant)	N/A
32	Transportation and storage (if relevant)	Primary packaging: unit of use. One resuscitator set in a plastic bag + box with the manufacturer's instruction for use. Labelling on the primary packaging: name and/or trademark of the manufacturer. Manufacturer's product reference. Type of product and main characteristics. If the packaging is not transparent, it must bear a diagram (preferably actual size) showing the essential parts of the product and indicating the position of the product in the packaging. Lot number prefixed by the word "LOT" (or equivalent harmonized symbol) (if applicable). Information for particular storage conditions (temperature, pressure, light, humidity, etc.) as appropriate (or equivalent harmonized symbol). Information for handling, if applicable (or equivalent harmonized symbol).
33	Labelling (if relevant)	Symbols used according to ISO 15223 standards.
<b>Environmental requirements</b>		
34	Context-dependent requirements	N/A
<b>Training, installation and utilization</b>		
35	Pre-installation requirements (if relevant)	N/A
36	Requirements for commissioning (if relevant)	N/A
37	Training of user/s (if relevant)	The resuscitator should only be operated someone who has received adequate basic training in resuscitation technique.
38	User care (if relevant)	After each dismantling and cleaning, the resuscitator must be reassembled and tested to make sure that it works correctly. In view of its use, the item is considered an "emergency resuscitation item", which means that it must always be readily available and in a good working condition. Following the manufacturer's instructions manual is recommended.
<b>Warranty and maintenance</b>		
39	Warranty	Minimum 1 year.
40	Maintenance tasks	N/A
41	Type of service contract	N/A
42	Spare parts availability post-warranty	N/A
43	Software/hardware upgrade availability	N/A
<b>Documentation</b>		
44	Documentation requirements	The resuscitator is supplied in a box as a complete set, with clear instructions/diagrams for use and assembly in the language of the user and a list of accessories/parts. The resuscitator is supplied with instructions and diagrams covering its functionality, how to use it, how to dismantle and assemble it, and how to clean, disinfect and sterilize it. It is supplied with an instruction manual covering item descriptions and functionality, including usage, maintenance and a list of spare parts.

Decommissioning		
45	Estimated lifespan	5 years.
Safety and standards		
46	Risk classification	Class B (GHTF Rule 6), Class II a (EU, Australia), Class II (Canada, Japan).
47	Regulatory approval/certification	Optional: <ul style="list-style-type: none"> <li>• registered in country of import, if applicable;</li> <li>• approval from the national regulatory agency of the manufacturer's country;</li> <li>• FDA registration (United States); or</li> <li>• CE Mark (EU) for class IIa, with notified body number, or approval from other regulatory body in an IMDRF founding member country.</li> </ul>
48	International standards (for reference)	<p>ISO 13485:2012 Medical devices - Quality management systems – Requirements for regulatory purposes:  ISO 10651-4:2002 Lung ventilators -- Part 4: Particular requirements for operator-powered resuscitators (EN 13544-2 implied). For devices not intended to be used with oxygen, oxygen related clauses are optional</p> <p>For facemask (if not made of silicone):  ISO 10993-1:2009 Biological evaluation of medical devices – Part 1: Evaluation and testing for mask  ISO 10993-5:2009 Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity  ISO 10993-10:2009 Biological evaluation of medical devices – Part 10: Tests for irritation and delayed-type hypersensitivity  or classified as USP class V</p> <p>Optional:  ISO 14971:2012 Medical devices – Application of risk management to medical devices  ISO 5356-1:2004 Anaesthetic and respiratory equipment – Conical connectors - Part 1: Cones and sockets  BS EN 980:2008 Graphical symbols for use in the labelling of medical devices  ISO 15223-1:2012 Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements  BS EN 1041:2008 Information supplied by the manufacturer with medical devices</p>
49	Regional/local standards	Any national standards equivalent/harmonized to International standards.
50	Regulations	<p>Directive 93/68/EEC (CE Mark)  Directive 2001/104/EC  Directive 2007/47/EC</p> <p>Japan regulations:  MHLW Ministerial Ordinance No. 169  17591000 Reusable manually operated pulmonary resuscitator  Or any other national or regional regulation equivalent/harmonized to the above mentioned</p>

## Annex 6. Technical specifications for a suction machine, electrically operated

Medical device specification (including information on the following where relevant/appropriate, but not limited to)		
I	Version No.	1
II	Date of initial version	25 June 2013
III	Date of last modification	11 December 2015
IV	Date of publication	December 2015
V	Completed/submitted by	WHO and revision of neonatal resuscitation of the UNCLSC group (UNICEF, CHAI, and PATH).
Name, category and coding		
1	WHO Category/code	(under development)
2	Generic name	Electrical or hand/foot-operated portable suction machine/pump.
3	Specific type or variation (optional)	Infant suction system with negative pressure less than 100 mmHg, with one bottle.
4	GMDN© name	Nasal aspirator, electric.
5	GMDN© code	56647
6	GMDN© category	09 Reusable devices.
7	UMDNS© name	Aspirators; aspirators, infant; aspirators, nasal; aspirators, thoracic; aspirators, tracheal.
8	UMDNS© code	10208; 10214; 10216; 10218; 10219
9	UNSPS code (optional)	42142400
10	Alternative name/s (optional)	Aspirator for medical use; compressors; aspirator; evacuators; pumps, aspirator; pumps, suction; suction pumps; suction units; sump pumps; vacuum pumps.
11	Alternative code/s (optional)	MS 43699, 120400001
12	Keywords (optional)	compressors, aspirator, evacuators pumps, suction pumps, vacuum pumps
13	GMDN©/UMDNS© definition (optional)	A portable hand-held, either electrical, battery-powered or hand- or foot-operated suction device designed to enable an adult to gently suction and clear excessive mucus from the nasal passages of an infant or child to facilitate easier breathing. It consists of a handgrip that contains the batteries, a small electric pump that creates the suction, and typically a silicone nozzle attached to a detachable, washable, collection cup at the distal end. It is designed for domestic use and is typically applied superficially to the nasal opening (i.e. not inserted into the nasal cavity). This is a reusable device.
Purpose of use		
14	Clinical or other purpose	Devices designed to evacuate gas, fluid, tissue or foreign materials from the high airways by means of vacuum suction.
15	Level of use (if relevant)	District hospital, provincial hospital, specialized hospital.
16	Clinical department/ward (if relevant)	Emergency medicine, gynecology, intensive care unit, nursing services, obstetrics, paediatrics.
17	Overview of functional requirements	Electrically operated, biohazard disposal and negative pressure less than 100 mmHg.

Technical characteristics		
18	Detailed requirements	<ul style="list-style-type: none"> <li>• low vacuum, low flow, oil-free vacuum pump;</li> <li>• battery powered with rechargeable battery;</li> <li>• maximum vacuum: 100 mmHg;</li> <li>• collection bottle (one or two): 1 L (disposable bag or collection jar); bottle(s) with an automatic cut off when full to prevent ingress of fluid to pump, a filter and overflow valve incorporated to prevent cross-contamination (e.g. shatterproof material, overflow protection system), and either disposable or autoclavable;</li> <li>• airline to the pump to incorporate a bacterial filter;</li> <li>• tubing to the patient a minimum of 0.5 m long, noncollapsible type;</li> <li>• all parts manufactured from high-strength, durable material that does not require specific maintenance or storage conditions;</li> <li>• pump can be disassembled entirely and is easy to clean, disinfect and sterilize;</li> <li>• any necessary greasing/oiling is simple, accessible and possible by normal clinical operator.</li> </ul>
19	Displayed parameters	Pressure gauge displays the suction generated.
20	User adjustable settings	User settable adjustment of suction delivered to the patient.
Physical/chemical characteristics		
21	Components (if relevant)	Unit surface is hard and corrosion resistant. Pump handle/pedal is spring loaded to return to the "up" position after each stroke. Supplied mounted on robust board with carrying handle.
22	Mobility, portability (if relevant)	Portable.
23	Raw materials (if relevant)	N/A
Utility requirements		
24	Electrical, water and/or gas supply (if relevant)	Line power AC and/or rechargeable battery (optional).
Accessories, consumables, spare parts and other components		
25	Accessories (if relevant)	Suction tubes and soft conical tip.
26	Sterilization process for accessories (if relevant)	The collection canister and the aspirating tube must be cleaned and disinfected after each use. All parts can be sterilized in a steam sterilizer. All parts can be autoclaved at 121 °C.
27	Consumables/reagents (if relevant)	Tubing, collection canisters. Supplier to describe detailing shelf life and number of uses.
28	Spare parts (if relevant)	Spare filters: 10 sets. Spare suction bottle: one unit. Seals: two pairs for each storage jar. To provide list of other spare parts anticipated during one year's operation, with costs.
29	Other components (if relevant)	N/A
Packaging		
30	Sterility status on delivery (if relevant)	N/A
31	Shelf life (if relevant)	N/A
32	Transportation and storage (if relevant)	Unit supplied protectively packed for safe onward shipping. Labelling on the primary packaging under local regulations.
33	Labelling (if relevant)	Symbols used according to ISO 15223 standards.



Environmental requirements		
34	Context-dependent requirements	Capable of being stored continuously in ambient temperature of 0–50 °C and relative humidity of 15–90%. Capable of operating continuously in ambient temperature of 10–40 °C and relative humidity of 15–90%.
Training, installation and utilization		
35	Pre-installation requirements (if relevant)	Supplier to perform installation, safety and operation checks before handover. Local clinical staff to confirm completion of installation and training if necessary.
36	Requirements for commissioning (if relevant)	N/A
37	Training of user/s (if relevant)	Training of users in operation and basic maintenance is provided. Local clinical users need to be trained in neonatal resuscitation.
38	User care (if relevant)	Collection canisters should be monitored and emptied if they come close to capacity. Suction regulators must be accurate; suction levels that are too high can cause tissue damage. A pump containing aspirated fluid can be a source of contamination; changing or cleaning the suction tip during surgeries or other use can help reduce infection risk. Operators should follow universal precautions, including wearing gloves, face shields or masks and gowns. After dismantling and cleaning, the pump must be reassembled and tested to make sure that it works correctly.
Warranty and maintenance		
39	Warranty	Duration of warranty clearly stated, minimum 1 year. Specific inclusions and exclusions listed. Contact details of manufacturer, supplier and local service agent provided.
40	Maintenance tasks	List of equipment and procedures required for local routine user maintenance is provided. Advanced maintenance tasks required are documented.
41	Type of service contract	Costs and types of post-warranty service contract available are described.
42	Spare parts availability post-warranty	Guaranteed time period of availability of spare parts post-warranty is described.
43	Software/hardware upgrade availability	Guaranteed time period of support availability post-warranty is described.
Documentation		
44	Documentation requirements	User and maintenance manuals are supplied in English or local language specified by the purchaser. Supplier to describe any materials contained in the device that are classified as hazardous under local regulations.
Decommissioning		
45	Estimated lifespan	Supplier to describe estimated lifetime of fully maintained device.
Safety and standards		
46	Risk classification	Class B (GHTF Rule 11); Class II a (EU, Australia), Class II (Canada, Japan).
47	Regulatory approval/certification	To comply with the regulatory requirements of the national regulatory agency.  Optional: <ul style="list-style-type: none"> <li>• registered in country of import, if applicable;</li> <li>• approval from the national regulatory agency of the manufacturer's country;</li> <li>• FDA registration (United States); or</li> <li>• CE Mark (EU) for class IIa, with notified body number, or approval from other regulatory body in an IMDRF founding member country.</li> </ul>

48	International standards (for reference)	<p>ISO 10079-1:1999 Medical suction equipment – Part 1: Electrically powered suction equipment – Safety requirements. or equivalent  ISO 13485:2003 Medical devices – Quality management systems – Requirements for regulatory purposes (Australia, Canada, EU); or equivalent  ISO 14971:2007 Medical devices – Application of risk management to medical devices  IEC 60601-1-2 Ed. 3.0:2007 (or later version) Medical electrical equipment – Part 1–2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests</p> <p>The set packaging depends on the shipment type.  At a minimum, as per Annex C: Clause 12.1 of Part 1 of IS 15500:2004.  ROHS compliant.</p>
49	Regional/local standards	<p>JIS T 7111:2006 Hose assemblies for use with medical gas systems (Japan).</p> <p>Any national standards equivalent/harmonized to international standards.</p>
50	Regulations	<p>United States regulations:  21 CFR part 820; 21CFR Section 878.4780 pump, portable, aspiration (manual or powered) (United States)</p> <p>EU regulations:  Council Directive 93/42/EEC  Directive 93/68/EEC (CE Mark)  Directive 2007/47/EC</p> <p>Japan regulations:  MHLW Ministerial Ordinance No. 169  34860010 Low pressure suction unit; 34860020 Electrically powered low pressure suction unit 36616030 Electrically powered transportable suction unit (Japan)</p> <p>Any national regulation equivalent/harmonized to those above.</p>

## Annex 7. Technical specifications for a single-use suction device

Medical device specification (including information on the following where relevant/appropriate, but not limited to)		
I	Version No.	1
II	Date of initial version	25 June 2013
III	Date of last modification	11 December 2015
IV	Date of publication	30 December 2015
V	Completed/submitted by	Working group (WHO/UNFPA/UNICEF)
Name, category and coding		
1	WHO Category/code	(under development)
2	Generic name	Suction bulb.
3	Specific type or variation (optional)	Single-use suction bulb.
4	GMDN© name	Nasal aspirator, manual.
5	GMDN© code	41826
6	GMDN© category	09 Reusable devices (GMDN© has no single-use term).
7	UMDNS© name	Suction kits.
8	UMDNS© code	13846
9	UNSPS code (optional)	42142400
10	Alternative name/s (optional)	Aspirators infant, infant nasal aspirators, paediatric nasal aspirators, toddler nasal aspirators.
11	Alternative code/s (optional)	N/A
12	Keywords (optional)	suction, aspirator
13	GMDN© generic definition (optional)	A collection of items intended for suctioning secretions from a patient; this is a single-use device.
Purpose of use		
14	Clinical or other purpose	Evacuate secretions and liquids from the nasal cavity or from high infant airways.
15	Level of use (if relevant)	Health centre, district hospital, province hospital, specialized hospital ambulances.
16	Clinical department/ward (if relevant)	Obstetrics, paediatrics, surgery.
17	Overview of functional requirements	Device that provides the suction in a manually operated bulb that draw mucus out of the child's nose.
Technical characteristics		
18	Detailed requirements	<ul style="list-style-type: none"> <li>• Ensure the device is clean and in a sealed package.</li> </ul>
19	Displayed parameters	N/A
20	User adjustable settings	N/A
Physical/chemical characteristics		
21	Components (if relevant)	N/A
22	Mobility, portability (if relevant)	Portable and mobile.
23	Raw materials (if relevant)	N/A

Utility requirements		
24	Electrical, water and/or gas supply (if relevant)	N/A
Accessories, consumables, spare parts and other components		
25	Accessories (if relevant)	N/A
26	Sterilization process for accessories (if relevant)	N/A
27	Consumables/reagents (if relevant)	N/A
28	Spare parts (if relevant)	N/A
29	Other components (if relevant)	N/A
Packaging		
30	Sterility status on delivery (if relevant)	N/A
31	Shelf life (if relevant)	N/A
32	Transportation and storage (if relevant)	Required to keep the product clean and in a sealed package.
33	Labelling (if relevant)	N/A
Environmental requirements		
34	Context-dependent requirements	As per manufacturer recommendations.
Training, installation and utilization		
35	Pre-installation requirements (if relevant)	N/A
36	Requirements for commissioning (if relevant)	N/A
37	Training of user/s (if relevant)	N/A
38	User care (if relevant)	Ensure the pressure is not too high when working with the device, avoid trauma from deep or aggressive suctioning or stimulation of vagal reflexes, which produce bradycardia.
Warranty and maintenance		
39	Warranty	N/A
40	Maintenance tasks	N/A
41	Type of service contract	N/A
42	Spare parts availability post-warranty	N/A
43	Software/hardware upgrade availability	N/A

Documentation		
44	Documentation requirements	N/A
Decommissioning		
45	Estimated lifespan	N/A
Safety and standards		
46	Risk classification	Class B (GHTF Rule 5-6); Class II a (EU, Australia); Class II (Canada, Japan), Class I (United States).
47	Regulatory approval/certification	FDA approval (United States) or CE Mark (EU).
48	International standards (for reference)	ISO 13485:2003 Medical devices – Quality management systems – Requirements for regulatory purposes (Australia, Canada, EU); or equivalent
49	Regional/local standards	<p>To comply with the regulatory requirements of the national regulatory agency.</p> <p>Optional:</p> <ul style="list-style-type: none"> <li>• registered in country of import, if applicable;</li> <li>• approval from the national regulatory agency of the manufacturer's country;</li> <li>• FDA registration (United States); or</li> <li>• CE Mark (EU) for class IIa, with notified body number, or approval from other regulatory body in an IMDRF founding member country.</li> </ul> <p>Any national standards equivalent/harmonized to international standards.</p>
50	Regulations	<p>United States regulations: 21 CFR part 820 21CFR Section 868.68106 tracheal suction set (kit) (United States)</p> <p>EU regulations: Council Directive 93/42/EEC, Directive 2007/47/EC</p> <p>Japan regulations: MHLW Ministerial Ordinance No. 169:  <ul style="list-style-type: none"> <li>• 34860010 Low pressure suction unit</li> <li>• 36616010 Manually operated transportable suction unit</li> </ul> </p> <p>Or any other national or regional regulation equivalent/harmonized to the above mentioned.</p>

## Annex 8. Technical specifications for a reusable suction device

Medical device specification (including information on the following where relevant/appropriate, but not limited to)		
I	Version No.	1
II	Date of initial version	25 June 2013
III	Date of last modification	11 December 2015
IV	Date of publication	30 December 2015
V	Completed/submitted by	Working group (WHO/UNFPA/UNICEF)
Name, category and coding		
1	WHO Category/code	(under development)
2	Generic name	Suction bulb.
3	Specific type or variation (optional)	Multi-use suction bulb that can be opened cleaned and sterilized.
4	GMDN© name	Nasal aspirator, manual.
5	GMDN© code	41826
6	GMDN© category	Categories: 09 Reusable devices.
7	UMDNS© name	Aspirators, airway, nasal, infant.
8	UMDNS© code	10214
9	UNSPS code (optional)	42142400
10	Alternative name/s (optional)	Aspirators infant, infant nasal aspirators, paediatric nasal aspirators, toddler nasal aspirators.
11	Alternative code/s (optional)	
12	Keywords (optional)	suction, aspirator
13	GMDN© generic definition (optional)	A portable, hand-held, manual suction device designed to enable an adult to gently suction and clear excessive mucus from the nasal passages of an infant or child to facilitate easier breathing. It is available in a variety of forms, including a compressible bulb with a tube that is inserted into the nares, or a syringe with a small bulb at its distal end that is applied to the nasal opening. It is designed for domestic use. This is a reusable device.
Purpose of use		
14	Clinical or other purpose	Evacuate secretions and liquids from the nasal cavity or from high infant airways.
15	Level of use (if relevant)	Health centre, district hospital, province hospital, specialized hospital.
16	Clinical department/ward (if relevant)	Obstetrics, paediatrics, surgery. Delivery room.
17	Overview of functional requirements	Device that provides the suction in a manually operated bulb that draw mucus out of the newborn's mouth and nose.
Technical characteristics		
18	Detailed requirements	The top part can be opened to permit easier cleaning, can be subjected to boiling (HLD) and sterilization, including autoclaving, and can be translucent. It does not contain latex.

19	Displayed parameters	N/A
20	User adjustable settings	N/A
<b>Physical/chemical characteristics</b>		
21	Components (if relevant)	N/A
22	Mobility, portability (if relevant)	Mobile and portable
23	Raw materials (if relevant)	N/A
<b>Utility requirements</b>		
24	Electrical, water and/or gas supply (if relevant)	N/A
<b>Accessories, consumables, spare parts and other components</b>		
25	Accessories (if relevant)	N/A
26	Sterilization process for accessories (if relevant)	Subjected to boiling (HLD) and sterilization, including autoclaving.
27	Consumables/reagents (if relevant)	N/A
28	Spare parts (if relevant)	N/A
29	Other components (if relevant)	N/A
<b>Packaging</b>		
30	Sterility status on delivery (if relevant)	Following the sterilization process.
31	Shelf life (if relevant)	N/A
32	Transportation and storage (if relevant)	Required to keep the product clean.
33	Labelling (if relevant)	N/A
<b>Environmental requirements</b>		
34	Context-dependent requirements	N/A
<b>Training, installation and utilization</b>		
35	Pre-installation requirements (if relevant)	N/A
36	Requirements for commissioning (if relevant)	N/A
37	Training of user/s (if relevant)	N/A
38	User care (if relevant)	Clean and sterilize before use according to the stability process.
<b>Warranty and maintenance</b>		
39	Warranty	N/A
40	Maintenance tasks	N/A
41	Type of service contract	N/A
42	Spare parts availability post-warranty	N/A
43	Software/hardware upgrade availability	N/A
<b>Documentation</b>		
44	Documentation requirements	N/A

Decommissioning		
45	Estimated lifespan	N/A
Safety and standards		
46	Risk classification	Class B (GHTF Rule 11); Class II a (EU, Australia); Class II (Canada, Japan, United States).
47	Regulatory Approval/certification	To comply with the regulatory requirements of the national regulatory agency. Optional: <ul style="list-style-type: none"> <li>• registered in country of import, if applicable;</li> <li>• approval from the national regulatory agency of the manufacturer's country;</li> <li>• FDA registration (United States); or</li> <li>• CE Mark (EU) for class IIa, with notified body number, or,</li> <li>• approval from other regulatory body in an IMDRF founding member country.</li> </ul>
48	International standards (for reference)	ISO 13485:2003 Medical devices – Quality management systems – Requirements for regulatory purposes (Australia, Canada, EU) ISO 10079-2:1999 Medical suction equipment – Part 2: Manually powered suction equipment or equivalent
49	Regional/local standards	To comply with the regulatory requirements of the national regulatory agency. Optional: <ul style="list-style-type: none"> <li>• registered in country of import, if applicable;</li> <li>• approval from the national regulatory agency of the manufacturer's country;</li> <li>• FDA registration (United States); or</li> <li>• CE Mark (EU) for class IIa, with notified body number, or approval from other regulatory body in an IMDRF founding member country.</li> </ul> Any other national standards equivalent/harmonized to international standards.
50	Regulations	United States regulations: 21 CFR part 820 21CFR Section 878.4780 pump, portable, aspiration (manual or powered) (United States)  EU regulations: Council Directive 93/42/EEC Directive 93/68/EEC (CE Mark) Directive 98/79/EC Directive 2001/104/EC Directive 2007/47/EC  Japan regulations: MHLW Ministerial Ordinance No. 169; 36616010 Manually operated transportable suction unit (Japan)  Or any other national or regional regulation equivalent/harmonized to the above mentioned.



# Annex 9. Meeting Report - Consultation for technical specifications for procurement and regulatory pathway of medical devices determined by the United Nations Commission on Life Saving Commodities (June 10-12, 2013)

## **DRAFT V1 MEETING REPORT**

Consultation for technical specifications for procurement and regulatory pathway of medical devices determined by the United Nations Commission on Life Saving Commodities

**WORLD HEALTH ORGANIZATION – HEADQUARTERS  
GENEVA, SWITZERLAND**

June 10-12, 2013

Diagnostic Imaging and Medical Device Unit  
Essential Medicines and Health Products Department  
Health Systems and Innovation Cluster

## BACKGROUND

As a way to increase the actions towards reaching the Millennium Development Goals 4, 5 and 6, the UN Commission on Life Saving commodities was launched in March 2012 (<http://www.everywomaneverychild.org/resources/un-commission-on-life-saving-commodities/about>) and developed 10 recommendations in order to increase the access to 13 essential commodities.

The 10 recommendations are the following:

### **I. Improved markets for life-saving commodities:**

1. Shaping global markets;
2. Shaping local delivery markets;
3. Innovative financing;
4. Quality strengthening: By 2015, at least three manufacturers per commodity are manufacturing and marketing quality-certified and affordable products;
5. Regulatory efficiency: By 2015, all EWEC countries have standardized and streamlined their registration requirements and assessment processes for the 13 live-saving commodities with support from stringent regulatory authorities, the World Health Organization and regional collaboration.

### **II. Improved national delivery of life-saving commodities:**

6. Supply and awareness;
7. Demand and utilization;
8. Reaching women and children;
9. Performance and accountability.

### **III Improved integration of private sector and consumer needs.**

10. Product innovation.

Note that WHO is fully responsible of recommendations 4 and 5, and participates in others as Needed.

The 13 commodities involve 3 specific types of medical devices: female condom, neonatal resuscitation (mask, valve and bag, suction bulb or aspirator) and supportive medical devices for injectable antibiotics (syringes, needle,) that are part of the commodities defined by the UNCoLSC.

Further references:

<http://www.everywomaneverychild.org/resources/un-commission-on-lifesaving-commodities/life-saving-commodities> and

<http://www.everywomaneverychild.org/resources/un-commission-on-life-saving-commodities>.

World Health Organization

Considering the resolution WHA66.7 approved in May 2013, named “Implementation of the recommendations of the United Nations Commission on Life Saving Commodities for Women and Children.”

Requests WHO:

“(1) to work with UNICEF, UNFPA, the World Bank, UNAIDS, UN Women, national, regional and international regulators, private sector actors and other partners in order to promote and assure the availability of safe, quality commodities;

(2) to work with and support Member States, as appropriate, in improving regulatory efficiency, standardizing and harmonizing registration requirements and streamlining assessment processes, including granting priority to review of the life-saving commodities”

(See annex 1 on WHA66.7)

## CONSULTATION

Will specifically focus on: recommendations 4 and 5 which are responsibility of WHO:

4. Quality strengthening: By 2015, at least three manufacturers per commodity are manufacturing and marketing quality-certified and affordable products;
5. Regulatory efficiency: By 2015, all EWEC countries have standardized and streamlined their registration requirements and assessment processes for the 13 life-saving commodities with support from stringent regulatory authorities, the World Health Organization and regional collaboration.

The three essential commodities that involve medical devices:

1. For Reproductive Health: Female Condoms
2. For Newborn Health: Neonatal Resuscitation Equipment
3. For New born and child: Injectable antibiotics (syringes and other medical devices)

## MEETING OBJECTIVES

1. To develop the three essential commodities technical specifications of in order to have quality affordable and developed products in the market, as stated in recommendation 4 on quality strengthening.
2. To establish a regulatory pathway of those commodities including a harmonized registration requirements and the assessment process, as indicated in the recommendation 5 on regulatory efficiency.
3. To disseminate these requirements to the regulatory authorities and to the procurement agencies that belong to the Member States, NGOs and UN agencies, in furtherance to increase the access to the commodities mentioned before.

## PARTICIPANTS

- a. The lead conveners for each of this commodities group.
- b. The health technology focal points, (for medical devices management, selection, procurement or regulation) or the person designated by the Ministry of Health of the countries where the actions are being implemented in the first phase. (Path finder countries).
- c. WHO Advisors in technical specifications.

- d. WHO Advisors in medical devices regulations.
- e. NGOs and UN agencies involved with procurement of these products.
- f. The WHO staff related to recommendations: 4 on quality of product and 5 on regulatory process. (For specific details, please see list of participants at the end section of this document)

## APPOINTMENTS

**Co-Chairs:** June 10, 2013: Mr Sam S.B. Wanda  
 June 11, 2013: Dr Jean Bosco Ndiokubwayo and Ms Bidia Deperthes  
 June 12, 2013: Ms Adriana Velazquez and Mr Keith Neroutsos

**Rapporteurs:** Ms Alejandra Velez, Dr Yukiko Nakatani. Support from interns : Mr Nathan Lo, Ms Jacintha Leyden, Ms Samantha Mendoza and Ms Daria Istrate.

## MEETING MINUTES

Following is an overview of discussions and inputs generated on each day of the meeting. (All presentations are in annex 3)

### Day 1: June 10, 2013

Day 1 program was aimed to discuss objectives and background of the meeting and WHO's Medical Devices Unit and during the afternoon focused on discussion of the Female Condom's commodity.

#### Introduction and background

- Participants were greeted and the meeting objectives were presented by Ms. Velazquez.
- The UN Commission on Life Saving Commodities was presented by Dr. Kristensen.
- Presentation of the on-going projects within WHO's Medical Devices Unit:
  - › Available publications.
  - › Global challenges on medical devices.
  - › Results on the country survey of medical devices.
  - › Local production and technology transfer to increase access to medical device
  - › Compendium of innovative health technologies for low-resource settings.
  - › H4+ Interagency list of essential medical devices for reproductive maternal and newborn health.

#### Country Assessments Tools for Procurement and Regulatory Agency and Commodity Status Survey

For the purpose of collecting country information for the recommendation 4 and 5, on regulatory and procurement process of the 13 commodities described in the UNCoLSC, an automated version using a WHO tool named datacol was discussed. This Country Assessments Tools for Procurement and Regulatory Agency and Commodity Status Survey, Sections 7a, 7b, 8a and 8b were presented by Ms. Barragan.

- General discussion on the Country Assessment Tools:
- As the first concern: countries usually do not have information about specific devices, instead of this information they normally know how much do they invest by group of devices for each specialty, in this case maternal/newborn.
- Mr. Wanda suggested that even the survey information could be provided by different departments inside the country, which would be useful for filter and standardize it.
- Dr. Nagesh suggested the establishment of a specific period of time for answering the survey.
- Important to get information of the final user
- Source of funding: that can come different sources, for each commodity for instance: UN agencies, NGO's, donations, world bank, etc.
- Furthermore depending on the origin of the founding, the process of procurement and regulating would be.

### **Generic specifications on the Commodity: Female Condom**

Dr. Festin presented a current situation of policies that are related to Family Planning at WHO. Also, specific characteristics, use and provision of the female condoms. The need of training people in the correct use of the female condom was emphasized.

Ms Deperthes and Ms Traeger, from UNFPA, presented the generic specifications, pre-qualification process and guidelines for procurement of female condom. Additionally statistics, and efforts for marketing and distribution. They presented how pre-qualification process analyses if the manufacturing site and the product is developed with acceptable standards and if they have the ability to produce according with the specifications. The list of prequalified products are publicly available on the UNFPA and WHO website data. It was also mentioned that the ISO qualification is different for male and female condoms.

- General discussion on prequalification of female condoms:
  - › Standards are not available online, it is needed to increase the access to them.
  - › The high price of female condom compare with the male condom's price.
  - › Not enough promotion, training and funds guided for female condom programming.
  - › Low availability: 1 female condom for 8 women in Sub Saharan Africa.
  - › Not enough knowledge and information for women and men in reproductive age regarding the use and benefit of the female condom for safer sex.
  - › It was mentioned by Mr Neroutsos that if manufacturers are required to get a re-qualification every two years, the product could be continually tested.
  - › It was recommended by Mr Nado that once the product is pre-qualified, into a country level they register the product on a fast track.
  - › Ms Deperthes recommended a review of the essential medicines list, then countries can easily include female condoms in its essential medicines list, the distribution is still insufficient.

### **Country considerations:**

#### **Malawi:**

- Ms Deperthes commented that Malawi is one of the success stories; they went from 150 thousand to 1.5 million female condoms.

- The Government was delegated to decide whether they want to register the condom or not, and also to define the minimum criteria that the local government authorities should have.

#### **Sierra Leone by Mr Kabia:**

- Female condoms are not very popular.
- Procurement of medical devices in general:
  - › Biomedical engineers are not involved in procurement developed by the Ministry of Health.
  - › There is no regulation authority for Medical Equipment.

#### **Tanzania by Mr Mvanga and Ms Mariki:**

- Different NGO's are working on condoms promotion, mostly about the FC2.
- Female condoms usability is low, because the purpose of usability is not well understood.
- Great need of training, motivation and promotion.
- The Ministry of Health through the Tanzanian FDA regulates medicine, cosmetics, medical devices and food.
- Female condoms are registered as single use devices and follow ISO standards.
- Two procedures: screening phase for 60 days and payment of fees for different classes of products (B-USD 500, C-USD 750, D-USD 1,000) and 270 working days for class C products to be released in Tanzania, almost one year, samples need to be submitted also and they usually contract out the testing of these samples to South Africa or other countries.
- Tanzanian FDA has types of evaluation: full and abridged. If the applicant is pre-qualified by WHO or is released in other developed countries, it could be evaluated in the abridged form, otherwise it needs to be evaluated fully.
- Tanzania's regulatory model could be used in the region.
- Ms Deperthes proposed to first see how the condoms would be accepted in the specific countries, then define what is needed and then register a product as soon as possible.

#### **Uganda by Mr Wanda:**

- NDA – regulators since 1983, added food and medical devices as a small department.
- NACME – since 1989, the Ministry of Health said they needed a committee of experts with advisory role that are sitting on NDA and UNBS.
- Currently no national specifications for female condoms, but both FC2 and Cupid are available in the country; but are much more expensive than the male condoms. There is a high need to promote its use.
- Ms Deperthes addressed that sometime ago there was a request to provide Uganda with 1 million Cupid condoms, however UNFPA rejected this idea because it is important to have an overview to make sure that people could accept these condoms, to receive some samples to show them to the population. She also commented that when providing a country of a high quantity of condoms is useless if this action is just done for 2-3 years and then discontinue the product. The use of this commodity is based on education.
- South Africa and Uganda are countries where Cupid is already distributed; it is needed to create competition between Cupid and FC2.

## **H4+ Interagency List of Essential Medical Devices for Maternal and Newborn Health**

Ms Velez presented the section on Family Planning and Reproductive Health of the draft book H4+ Interagency List of Essential Medical Devices for Maternal and Newborn Health, and the challenges confronted during the whole project.

### **Day 2: June 11, 2013**

Day 2 program was aimed to discuss injectable antibiotics for newborn and thus the medical devices required for the delivery of these antibiotics.

#### **Injectable antibiotics for neonatal sepsis:**

Dr Wall from Save the Children, who leads the injectable antibiotics group of the UNCoLSC, presented a current situation and key activities for priority injectable antibiotics. Also, critical points which we should consider: the difficulties to select antibiotics, neonatal formulations, promoting appropriate use, and the lack of distribution and local production. In terms of medical devices, he suggested to develop technical specifications of all related products.

Dr Weerasuriya, from WHO, presented the background and current work concerning the WHO Essential Medicines List (EMLc) for children, and the difficulties in supply due to small maker size.

Dr Qazi presented WHO documents on dosage of antibiotics for neonatal sepsis, diagnostic, treatment and management for neonatal infections and sepsis. At the view of clinical use for neonatal treatment, 2 ml syringes with 23G needle are required medical devices to delivery antibiotics to neonates.

- General discussion on Injectable antibiotics for neonatal sepsis
  - › As dosage of antibiotics determined by weight of babies, infant scale is also required as essential medical device.
  - › Alcohol and swabs are also suggested to be available always for injections.
  - › Consider to innovation products (e.g. autodisable injection, re-use prevention, single dose(Uniject™), micro-needle patches).

#### **Patient safety and Injection safety on injectable antibiotics for neonatal sepsis:**

Ms Allegranzi presented WHO considerations on patient safety and recommendations on avoidance, prevention and amelioration of adverse events in healthcare system. In terms of injection, injuries, infection were some of typical adverse events due to incorrect use of medical devices on injection. Unnecessary injection was also problem considering the risk for patients. She mentioned it was quite important the training for health workers at each level of facility in each country.

Dr Khamassi presented Injection safety topics. Reuse, overuse, unsafe disposal, unsafe collection are major problems. As intended in survey on year 2000, up to 70% of injections were done by reused syringes. Transmission of blood borne pathogens, abscess and nerve damage were associated risks with injections. The WHO injection

safety program includes patients, health workers, and community safety (seven steps of safe injection) A big problem is the training of service providers, given the high turnover. Waste management such as sharps management is very important and broader health system approach is needed. For example, high temperature incineration or other options are selected by the country.

- General discussion on Patient safety and Injection safety
  - › Important for WHO to promote safety issues related to the use of medical devices (e.g. the right dose, the right management of adverse events).
  - › The system causes adverse events primarily, not the individual and medical devices as part of this system (e.g. health care workers are not sufficiently trained to manage those medical devices).
  - › Checklists can be a solution to delivery antibiotics. Nevertheless the correct use requires quite a lot of effort for the education of the health care workers, but it is very effective.
  - › Tools for training individuals to sustain their learned skills:
  - › Training given by highly respected and constant leader
  - › Do training the trainer.
  - › Standard Operating Procedures posted on the wall.
  - › Advocacy to manufacturers to change vial labels to distinguish between medications.
  - › Denmark has specific systems to manage invisible waste (as medicines that go throw the pipes).

### **General specifications on injection medical devices:**

Dr Maire presented WHO PQS Prequalification System including background, databases, methods of qualification and prequalified injection devices. The WHO databases of prequalified medical products covers laboratory, company, eight categories of medical devices. Over 30 syringes and 10 safety boxes are prequalified by WHO. The type of syringes are 2 piece, 3 piece, auto-disable (AD) syringes, re-use prevention (RUP) syringes. The mechanism of syringes are Serrated plunger, Piston with hook, Ring on barrel and Claw on plunger. Risk classification of single use syringe is medical devices Class IIa. For the prequalification of syringes, dossier requirements contain information on manufacturing, product, material, mechanism, label, volume, laboratory test report, compliance with ISO, 20 samples, and other regulatory requirements.

Dr Moller from Supply division of UNICEF presented the UNICEF Supply Catalogue which provides technical specifications on needles, syringes including RUP, safety box, etc. UNICEF also procures AD syringes only prequalified by WHO. UNICEF procurement has to consider supply chain, clearance through the ports, and distribution campaign, etc. Sometimes UNICEF has to delivery medical devices different from medicines.

Dr Nakatani presented the draft book of the H4+ Interagency List of Essential Medical Devices for Reproductive, Maternal and Newborn Health, a section on Newborn Health. The draft tables of medical devices related to diagnostics and interventions for neonatal sepsis, which was containing normal syringes, syringes with RUP, needles, cannula, safety box, etc. In the draft book, the management and treatment for neonatal sepsis is available in District hospital and Referral Hospital.



- General discussion on specifications of injectable antibiotics
  - › Suggest linking the UN Commission on Life Saving Commodities with the H4+ Interagency List of Essential Medical Devices for Maternal and Newborn Health.
  - › Debates on what antibiotics should be accessible at what level of care. Agreement is to define procedures conducted at each level, then to define necessary devices.

### **Country presentations:**

Each of the invited countries presented their current status, needs and challenges regarding injectable antibiotics, patient safety, prequalification, procurement of medical devices on the country level. These presentations were followed by an open discussion.

#### **Malawi by Mr Mkukuma:**

- Chemical engineer, works for MoH, management and procurement of medical equipment.
- Hospitals responsible for procurement.
- Cites four types of needles for procurement.
- Syringes and needles are procured by the hospital themselves, they are also responsible for the specifications.
- The Government recently procured 4 types of needles and three sizes of syringes.

#### **Sierra Leone by Mr Kabia:**

- All procurement is done by UNICEF.
- District Health Facilities program – procurement was done by UNFPA.
- Believes children are forgotten in medical device procurement (e.g. lack of scale, incubator).
- Cites major problem with donation of equipment on lack of training or on lack of maintenance.

#### **Senegal by Mr Nado:**

- All procurement is done by UN agencies. Syringes and vaccines are coming from UNICEF.

#### **India by Dr Nagesh:**

- Public-private partnerships to improve health.
- A lot of coordination and centralization from the Ministry of Health, but different states have different budgets and policies.
- Procurement funding available through the government, but still a long way to go, as opposed to the private sector that is moving much faster.
- Single use syringes available for immunization in public and private sector.
- Newborn is the biggest challenges: lack of equipment and personnel

#### **Tanzania by Mr Mvanga and Ms Mariki:**

- Syringes, AD one the only ones used.
- UNICEF, Jhpiego, and others support procurement.
- Cash program to train community health worker to help with procedures.
- Private facility may gain funding from public since it has capacity not available in public hospitals.
- Western medical products may be present, but not operational.

- Got contract with Netherlands to build incinerators for waste management of syringes.
- Regulatory pathway: syringes are Class II device.
- Post-market surveillance, started with sterile syringes and gloves.
- Permit system, medical devices should not be procured without permit.
- Guideline for disposal of waste.

#### **Uganda by Mr Wanda:**

- The responsibility of the Ministry of Health to make sure that the requirements and needs of their country are met.
- Newborns need specific sizes for needles, the right dilution and calculations of medicines.
- Collect waste with funding from USAID.
- General Discussion on country presentation
  - › For babies, size of needle must be adjusted.
  - › Weighing scale, calibrated weekly is needed to calculate the dose.
  - › Incubators also needed for neonatal care in hospitals.
  - › Use technical specification if qualification from PQS system.
  - › Large proportion of those giving injections are not trained.
  - › How to deal with RUP advocacy against drug users who are allowed to reuse on themselves.
  - › Waste both visible and invisible (health waste put into water source, cannot be captured at purification point)

### **Day 3: June 12, 2013**

Day 3 program was aimed to discuss neonatal resuscitation devices

Dr Bahl presented the WHO Neonatal Resuscitation Guidelines:

- Differences between adult and baby resuscitation. In babies is more important to recover breathing than circulation.
- Procedures for ventilation, suction, etc.
- Recommendation, not to use 100% oxygen for resuscitation. If available, blender to provide maximum 30%.
- There is no WHO guideline for minimum resuscitation conditions in terms of number of weeks of pregnancy for newborn. It depends on too many factors/ context and legal issues – decided to go with national level decision.

Dr Narayanan presented an overview of Neonatal Resuscitation of the UNCLSC:

- Core package for the basic facility/peripheral centers – give priorities to centers that have deliveries above a certain threshold.
- In Tanzania it is compulsory to practice the steps of resuscitation, with checklist on the wall with steps that need to be undertaken.
- Specifications for manufacturers – how many of them could produce the models, by closely defining what we need.
- Presented advantages and disadvantages of different types of neonatal resuscitators.

- Provide the basic requirements for suction device should have: easy to be cleaned, translucent, not hard/plastic edge, etc. Training also in the sterilization/cleaning method for these devices.
- Mannequins are very expensive but she proposed that they should be available for training purposes.
- Temperature control during neonatal resuscitation is an important issue.
- Market and regulatory perspective must be considered.
- For high level medical devices, we should try to prioritize between different items, based on evidence guidelines.

Ms Velazquez presented background and the current status of H4+ Interagency List for reproductive, maternal and newborn health (RMNH), and current WHO activities on medical devices. WHO already has provided the list of medical devices by health care facilities, e.g. health post, health centre, district hospital, specialized hospital, but the list is not linked to interventions. H4+ Interagency List for RMNH is integrated with cross-matching tables by interventions, level of healthcare facility, and medical devices. The basic list of medical devices includes over 500 medical devices.

## **Country presentations**

Each of the invited countries presented their current status, needs and challenges regarding resuscitation for newborn, procurement of related medical devices on the country level. These presentations were followed by an open discussion.

### **Malawi by Mr Mkukuma:**

- Only four biomedical engineers in charge of all the medical devices at ministry of health.
- As donated medical equipment come from different brands, engineers are not usually prepared in the maintenance skills neither with enough consumables to operate the equipment.

### **Sierra Leone by Mr Kabia:**

- Big challenge: scarce of medical equipment and skills,
- It is needed to bring trainers from other Western African countries to train them.
- Statistics presented are based on empirical evidence, no database.
- Experienced in many events against safety patient.

### **Tanzania by Mr Mvanga and Ms Mariki:**

- Country receives donations of medical equipment and they just distribute in the health facilities without previous strategic planning.
- Oxygen concentrators can only adjust volume and pressure and alarms when oxygen is less than 72%.
- For example, in health facilities usually do not receive breathing circuits for children, just for adults.
- Most of the patient deaths are inside the health centers or during the transportation to referral level.

**Uganda by Mr Wanda:**

- Using Masks, Valves and Bags for the newborn asphyxia in Uganda.
- Bags as Ambu, masks were size 0 for prenatal and size 1 for full-natal babies.
- Masks had upright or horizontal bag, but preferred upright type because of better seal, fewer parts to clean and assemble, and lower cost.
- Resuscitation set contained a transparent "penguin" suction bulb which was openable for cleaning, boilable for disinfection, easily checked for readiness, highly durable and affordable.
- Resuscitation set contained stethoscope, warm clothes and cord ties.

**Other general discussions:**

- Due to procurement that is not standardized, there are not only several brands for the same medical device but also not enough training, spare parts, manuals, etc.
- There is no way to track down the equipment at the hospital because there is no an asset registry.
- Safe use of medical devices – not a very specific initiative on addressing the high mortality due to unsafe use of medical devices and high risk ones in particular,
- Participants interested in the safe use of medical devices book that will be prepared by WHO as part of the medical devices technical series.

**DELIVERABLES and WAY FORWARD**

Based on the meeting objectives and the expected outcomes, following are the list of deliverables:

1. In Table 1. is the list of the precise medical devices associated to the commodities discussed.

**Table 2. List of the 13 recommended life-saving commodities**

Reproductive health commodities
• Female condom
Injectable antibiotics for newborn sepsis
• Syringe 2 mL with needle 23 G 25 mm (with re-use prevention feature)
• Syringe 2 mL with needle 23 G 25 mm (without re-use prevention feature)
• Safety box, for used syringes/needles
• Infant scale less than 20 kg
• Clinical thermometer, non-mercury
Resuscitation devices for newborn asphyxia
• Self-inflating neonatal resuscitation bag with masks for pre-term(size 0) and term(size 1) babies
• Electric or foot operated suction machine/pump, negative pressure less than 100mm Hg, with 1 bottle

• Suction catheter, length 50 cm, single use, conical tip, Fr# 8
• Single use suction bulb
• Multi-use suction bulb that can be opened, cleaned and sterilized
• Training mannequin/simulator for neonatal resuscitation
• Infant stethoscope

2. In Annex A, are the thirteen technical specifications in WHO Template for the medical devices listed on Table 1. For review by the participants of the consultation. Response due 31 July, 2013.
3. The survey launched by WHO to assess the status of the 13 life –saving commodities in country level, in sections 7a, 7b, 8a and 8b has been updated according to the comments received during this meeting and to the list of devices in Table 1. The link to this survey will be provided to all participants. And will be distributed in Senegal meeting and also to other EWEC countries. Results will be expected end of August, 2013.
4. The definition of Harmonized Registration technical requirements and Assessment tool to improve the quality assurance in countries and the national delivery on those devices, is being developed with the assistance of other regulators and will be shared with the members of this consultation before the end of August.
5. In Annex B, Provisional Programme of Work.
6. Attached all PowerPoint presentation in the meeting, to be used as reference of this report.

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## Annex 10. Sixty-Sixth World Health Assembly Implementation of the recommendations of the United Nations Commission on Life- Saving Commodities for Women and Children (WHA66.4)

The Sixty-sixth World Health Assembly,

Having considered the report on follow-up actions to recommendations of the high-level commissions convened to advance women's and children's health;

Recalling resolution WHA63.15 on monitoring of the achievement of the health-related Millennium Development Goals and resolution WHA65.7 on implementation of the recommendations of the United Nations Commission on Information and Accountability for Women's and Children's Health;

Recalling also that the United Nations Secretary-General called upon the global community through the Global Strategy for Women's and Children's Health to work together to save 16 million lives by 2015;

Acknowledging the pledges and commitments made by a large number of Member States and partners to the United Nations Secretary-General's Global Strategy for Women's and Children's Health;

Recognizing that millions of women and children die needlessly every year from conditions that are easily prevented by the use of existing, inexpensive medical commodities;

Recognizing also the need urgently to address and overcome the barriers that prevent women and children from accessing and using appropriate commodities;

Welcoming the report of the United Nations Commission on Life-Saving Commodities for Women and Children, which estimates that six million lives can be saved within five years by improving access to 13 specific, overlooked commodities and related products (see Annex);

Welcoming also the actions recommended by the United Nations Commission on Life-Saving Commodities for Women and Children and the implementation plan to deliver the actions;

Acknowledging that the actions recommended by the United Nations Commission on Life-Saving Commodities for Women and Children's Health will also increase access to a broader set of commodities;

Acknowledging also the need to promote, establish or support and strengthen the health services needed by women and children from before pregnancy to delivery, during the immediate post-delivery period, and childhood;

Reaffirming the importance of facilitating technology transfer on mutually agreed terms between developed and developing countries as well as among developing countries, as appropriate;

Acknowledging the role of the independent Expert Review Group in reviewing the progress made in implementing the recommended actions,

**1. URGES Member States to put into practice, as appropriate, the implementation plan on lifesaving commodities for women and children, including:**

1. improving the quality, supply and use of the 13 life-saving commodities and other essential commodities for reproductive, maternal, newborn and child health, under the supervision and guidance of health care professionals, where needed, and building upon information and communication technology best practices for making these improvements;
2. developing plans to implement at scale appropriate interventions in order to increase demand for and utilization of health services, particularly among underserved populations;
3. facilitating universal access for all members of society, in particular the poorest, to the 13 life-saving commodities as well as to other essential commodities for reproductive, maternal, newborn and child health;
4. improving regulatory efficiency by harmonizing registration requirements and streamlining assessment processes, including granting priority to review of the life-saving commodities;
5. implementing proven mechanisms and interventions to ensure that health care providers are knowledgeable about the latest national guidelines for maternal and child health;

**2. REQUESTS the Director-General:**

1. to work with UNICEF, UNFPA, the World Bank, UNAIDS, UN Women, national, regional and international regulators, private sector actors and other partners in order to promote and assure the availability of safe, quality commodities;
2. to work with and support Member States, as appropriate, in improving regulatory efficiency, standardizing and harmonizing registration requirements and streamlining assessment processes, including granting priority to review of the life-saving commodities;


3. to provide support to the independent Expert Review Group on Information and Accountability for Women's and Children's Health in its work on assessing the progress made in the implementation of the United Nations Secretary-General's Global Strategy for Women's and Children's Health, as well as in the implementation of the recommendations of the United Nations Commission on Life-Saving Commodities for Women and Children;
4. to report annually until 2015, through the Executive Board, to the World Health Assembly on progress achieved in the follow-up of the recommendations of the Commission on Life-Saving Commodities for Women and Children, in connection with the agenda item concerning promoting health through the life course.

## ANNEX

### Commodities by life stage


<b>Maternal health commodities</b>
Oxytocin – post partum haemorrhage (PPH)
Misoprostol – post-partum haemorrhage
Magnesium sulfate – eclampsia and severe pre-eclampsia
<b>Newborn health commodities</b>
Injectable antibiotics – newborn sepsis
Antenatal corticosteroids (ANCs) – preterm respiratory distress syndrome
Chlorhexidine – newborn cord care
Resuscitation devices – newborn asphyxia
<b>Child health commodities</b>
Amoxicillin – pneumonia
Oral rehydration salts – diarrhoea
Zinc – diarrhea
<b>Reproductive health commodities</b>
Female condoms
Contraceptive implants – family planning/contraception
Emergency contraception – family planning/contraception

# Annex 11. UNCLSC Poster – Second Global Forum on Medical Devices



WHO/EMPI PAU Medical Devices

Second Global Forum on Medical Devices (Geneva 22-24 Nov. 2013)



## United Nations commission Life-Saving Commodities

### Objectives

As a way to reach Millennium Development Goals 4, 5 and 6, the **United Nations Commission on Life-Saving commodities** was launched in March 2012. It developed **10 recommendations** in order to increase the access to **13 essential commodities (WHA 66.7)** "Implementation of the recommendations of United Nations Commission on Life-Saving Commodities for Women and Children")

**Commission's Recommendations**

**4. Quality strengthening:** By 2015, at least three manufacturers per commodity are manufacturing and marketing quality-certified and affordable products;

**5. Regulatory efficiency:** By 2015, all EWEC countries have standardized and streamlined their registration requirements and assessment processes for the 13 life-saving commodities with support from stringent regulatory authorities, the World Health Organization and regional collaboration.

**WHA 60.29:** "To provide support to Member States with vulnerable health-care systems so as to identify and put in place appropriate health technologies in particular medical devices that facilitate access to quality services in primary health care"



### ANNEX of WHA 66.7, Commodities by life stage

Maternal health commodities	
1 Oxytocin	Post-Partum Haemorrhage
2 Misoprostol	Post-Partum Haemorrhage
3 Magnesium sulfate	Eclampsia and Severe Pre-Eclampsia
Newborn health commodities	
4 Injectable antibiotics	Newborn Sepsis
5 Antenatal Corticosteroid (ANC)	Profound Respiratory Distress Syndrome
6 Chlorhexidine	Newborn Cord Care
7 Resuscitation Equipment	Newborn Asphyxia
Child health commodities	
8 Amoxicillin	Pneumonia
9 Oral Rehydration Salts (ORS)	Diarrhea
10 Zinc	Diarrhea
Reproductive health commodities	
11 Female Condoms	Family planning/Contraception
12 Contraceptive Implants	Family planning/Contraception
13 Emergency Contraception	Family planning/Contraception

### Packages of medical devices

WHO organized a consultation with UN agencies and focal points from African countries, and proposed packages for three medical devices based on existing WHO guidelines.




WHO has been developing technical specifications for each device in this package. (Please see WHO Poster on "Technical Specifications")

WHO Guidelines

### Proposed packages for three commodities

Reproductive health commodities	Resuscitation devices for newborn asphyxia
Female condom	Self-inflating neonatal resuscitation bag with masks for pre-term (size 0) and term (size 1) babies
Injectable antibiotics for newborn sepsis	Electric or foot operated suction machine/pump, negative pressure less than 100mm Hg, with 1 bottle
Syringe 2 ml, with needle 23 G 25 mm (with re-use prevention feature)	Suction catheter, length 50 cm, single use, conical tip, Fr 8 B
Syringe 2 ml, with needle 23 G 25 mm (without re-use prevention feature)	Single use suction bulb
Sharps container, for used syringes/needles	Multi-use suction bulb that can be opened, cleaned and sterilized
Infant scale less than 20 kg	Training manikin/simulator for neonatal resuscitation
Clinical thermometer, non-mercury	Infant stethoscope

### Country survey for RMNCH

**1.2.1 National coordination mechanism for procurement and supply chain management (N=8)**

No 38% Yes 62%

**1.2.2 Requirement of evidence of QMS for medical devices (ISO 13485) of manufacturers (N=7)**


No 14% Yes 86%

**1.3.2 System for registration of medical devices (N=9)**

No 56% Yes 44%

**1.3.2 System for post-market surveillance for medical devices (N=8)**

No 63% Yes 37%



WHO Datacol

Data Source: Website "Every Woman Every Child", WHO meeting report and survey Poster Production: Medical Devices Team [http://www.who.int/medical\\_devices/en/](http://www.who.int/medical_devices/en/)

WHO does not endorse any of the selected technologies.

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