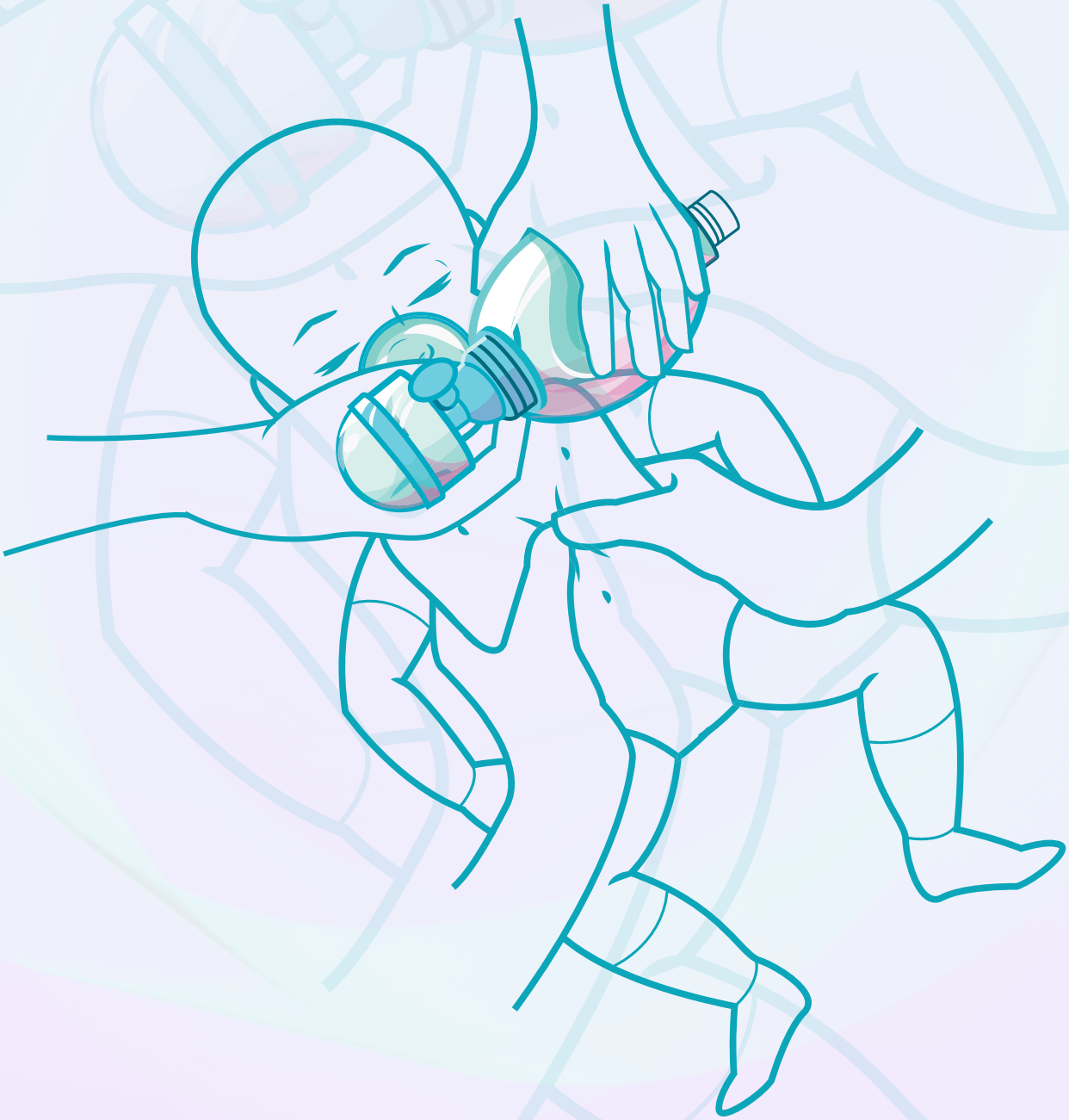
WHO
Neonatal resuscitation manikin technical specifications

WHO medical device technical series



World Health Organization

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WHO neonatal resuscitation manikin: technical specifications

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Acknowledgements

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

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

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

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

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

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Abbreviations

ASTM : American Society for Testing and Materials

CE: Conformité Européenne/European Conformity

CHAI: Clinton Health Access Initiative

FDA: Food and Drug Administration (United States)

GHTF: Global Harmonization Task Force

GMTA: Global Medical Technology Alliance

HIC: High Income Countries

IEC: International Electrotechnical Commission

IMDRF: International Medical Device Regulators Forum

ISO: International Organization for Standardization

LMIC: Low and Middle Income Countries

N/A: Not available

ROHS: Restriction of Hazardous Substances

SoPs: Standard operating procedures

UN: United Nations

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

UNFPA: United Nations Population Fund

UNICEF: United Nations Children's Fund

UNSPSC: United Nations Standard Products and Services Code

USAID: United States of America Agency for International Development

WHA: World Health Assembly

WHO: World Health Organization

Executive summary

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

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

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

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

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

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