

Training for essential birthing manoeuvres*

Country of origin		China
Primary use		Healthcare provider education and training
Category		Training manikin

Commercial information _____

List price (USD): 555

Year of commercialization: 2021

Number of units distributed: 4700

Currently marketed in: Globally

Model: MamaBirthie CS Birthing and Safe C-Section Simulator

Product description _____

MamaBirthie CS is ideal for training in birthing assessment and can be used for basic skill acquisition and competency development for all stages of labour

Product details _____

Accessories: Placenta with umbilical cord and membranes, BabyBirthie newborn manikin, cervix inserts (4, 6, and 8 cm dilatation), USB with instructional videos, pinard stethoscope, table clamp, syringe, urine catheter, 2 blankets, 2 packs gloves, fetal fontanelle skull, carry bag, caesarian section uterus.

Consumables: N/A

Warranty duration: 1 year

Lifetime: 3 years shelf life

Energy requirements: N/A

Facility requirements: N/A

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* Information reported by manufacturer, October 2023



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WHO assessment**

Clinical



Clinical



Recommended

The technology is a birth simulator that enables health-care professionals to gain competency and confidence in vaginal and operative births. It can be used to train birth-assisting skills such as abdominal and vaginal examinations, normal birth, shoulder dystocia and vaginal breech.

It has a specific module to train in caesarian section and abdominal suturing (i.e., B-Lynch suture for postpartum haemorrhage).









Overall, this technology is significantly useful in training health-care professionals, from medical students, residents, and other doctors in training to nurses and midwives, particularly in LMICs, where simulation-based education can be limited or absent.

Comparison with WHO technical specifications

Cannot be verified.


















The manufacturer provides the necessary detailed technical specifications, supporting their declarations with different technical documentation. At the time of this report's creation, WHO technical specifications documents were not available to compare this type of technology, while UNICEF has technical specifications for different childbirth simulators.

Regulatory

 Pre-market assessment	 N/A Not applicable
 Post-market assessment	 N/A Not applicable
 Quality system assessment	 Proceed
 Security	 Proceed

This product is not a medical device, and hence not applicable to assess it based on medical device regulatory requirements.

Health technology assessment

Indicators	Evidence assessment	Innovation
 Medical		
 Safety		
 Economy		
 Organizational		
 Legal		<p>The technology is an innovative birth and caesarean section simulator made of neoprene, polypropylene, and textile materials (lycra) without the need for electrical power. The product is safe, and the innovator has conducted quality management according to ISO13485 and ISO9001 and security management as per ISO/IEC 27001 with all relevant documentation provided.</p> <p>The simulator can be used as a tabletop attachment or worn by the trainer, which is ideal for simulating reality in provider-client communication. It facilitates the practice of all essential skills required during birth and postpartum, such as abdominal and vaginal examination, normal childbirth, anatomical rotation at birth, assisted breech and vacuum delivery, shoulder dystocia, bladder catheterization, and B-lynch suture in the management of severe postpartum bleeding.</p> <p>The product is intended for use in in-service training and pre-service education programmes of undergraduate medical doctors, obstetrics and gynaecology residents, non-physician emergency surgical officers, and comprehensive emergency obstetrics. It is highly suitable for basic skill acquisition and competency development for all stages of labour especially for caesarean section training; it is an indispensable, life-saving intervention for women and newborns who require, safe, prompt interventions. The simulator trains students in skills with case scenarios before entering clinical practice, significantly enhancing the quality of care they offer to patients. Adequate training contributes to competent and confident medical doctors, midwives, and nurses, ensuring access to safe caesarean section procedures in LMICs.</p>
 Social		
 Ethical		
 Green environment		

Technology readiness level **9**

Technology evidence assessment **Recommended**

Health technology management



-  Durability
-  Ease of Use
-  Ease of maintenance
-  Environmental conditions
-  Affordability
-  Local access to technical support
-  Ease of cleaning
-  Infrastructure requirements



Health-care delivery platform






By providing safe, realistic simulations, the MamaBirthie can play a significant role in enhancing the skills and confidence of health-care providers, leading to improved maternal and neonatal outcomes. The manufacturer has completed durability testing, which indicated wear and tear on product fabrics after a set number of simulated caesarian sections were completed. The stage of improvement of the current product is unclear. No evidence of commonly used hospital chemicals resistance tests has been submitted.



Preventive and corrective maintenance training was not available in the manufacturer submission. Multiple beta tests for 'usability' testing were completed; however, detailed protocols for these tests have not been submitted. At 555 USD, the MamaBirthie is a significant investment, particularly for training institutions with limited budgets and health facilities trying to implement on-the-job orientation programmes with already stretched budgets. Although this price point is competitive with those of other products on the market landscape, continued price optimization is key to making it accessible to a broader range of users.



Intellectual property and local production

-  Technology transferability
-  Open source/ access
-  Local production



Intellectual property: This technology is protected by copyrights and trade secrets. The use of all intellectual property will require clearance.



Local production: The product has a compliant manufacturing process. Due to the import dependency of the raw materials and the low rate of growth of global requirements, the product has a moderate business case. As the product is currently manufactured in an optimal cost region, further cost reduction may be challenging.

