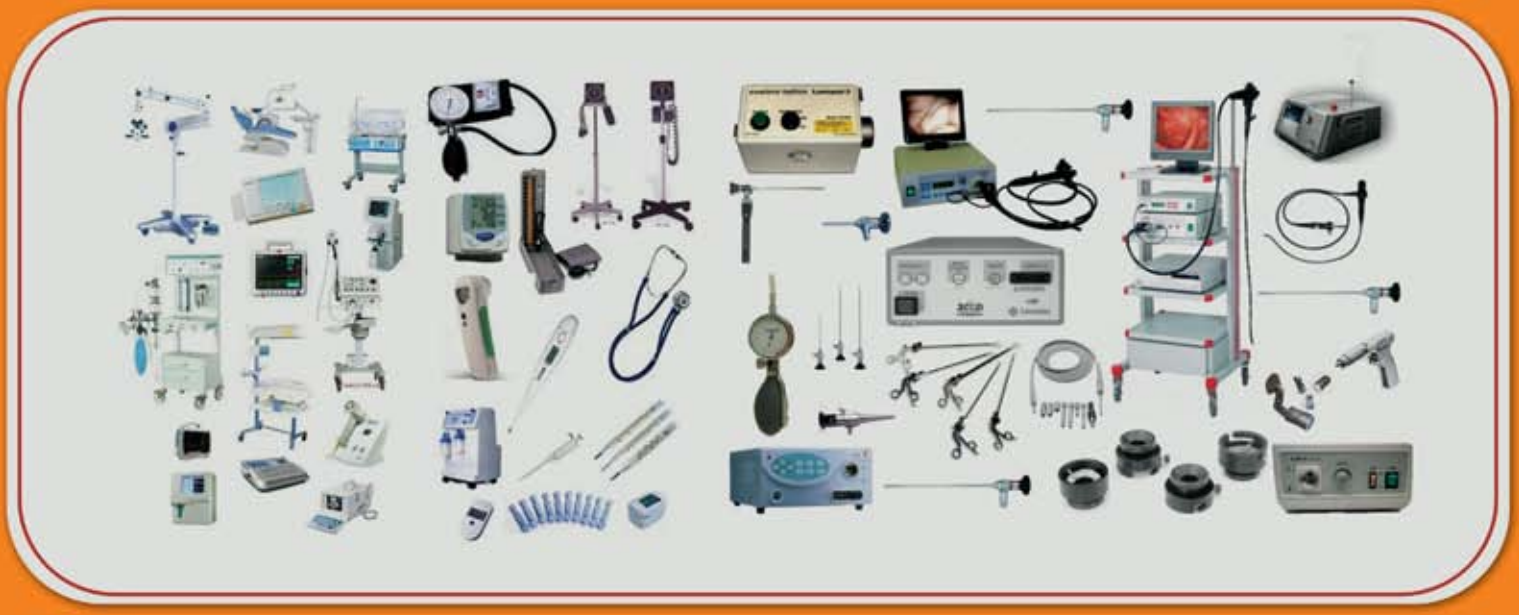
सत्यमेव जयते

NATIONAL HEALTH MISSION
राष्ट्रीय स्वास्थ्य मिशन

Ministry of Health and Family Welfare
Government of India



Technical Specifications of Medical Devices for **Skill Laboratories**

सत्यमेव जयते

NATIONAL HEALTH MISSION
राष्ट्रीय स्वास्थ्य मिशन

Ministry of Health and Family Welfare
Government of India

Technical Specifications of Medical Devices for **Skill Laboratories**

NATIONAL HEALTH MISSION
राष्ट्रीय स्वास्थ्य मिशन
भानु प्रताप शर्मा
सचिव
B.P. SHARMA
Secretary

सत्यमेव जयते

भारत सरकार
स्वास्थ्य एवं परिवार कल्याण विभाग
स्वास्थ्य एवं परिवार कल्याण मंत्रालय
Government of India
Department of Health and Family Welfare
Ministry of Health and Family Welfare

Dated : 29th April, 2015

MESSAGE

Ministry of Health and Family Welfare in its endeavor to achieve highest standards of health for the people has undertaken several programmatic and institutional strengthening measures. National Health Mission is one such programmatic intervention aimed at improved overall health with special focus in energizing rural health infrastructure and services. Providing essential medical equipment is a critical component of strengthening health infrastructure. However, rapidly changing technologies, complexity associated with medical equipment and high costs of procurement - all these make selection of appropriate and cost effective equipment a challenging task. I am happy to note that National Health Systems Resource Centre (NHSRC) under the guidance of experts and with active participation of stakeholders have developed technical specifications of commonly procured medical devices to facilitate procurements by State / UT Governments. I am sure that you will find these very helpful. The specifications are suggestive and we have tried to keep them generic. However, we would welcome any suggestions for further improvement in these specifications.

(B.P. Sharma)

कमरा नं 156, ए-स्कंध, निर्माण भवन, नई दिल्ली-110011
Room No. 156, A-Wing, Nirman Bhawan, New Delhi-110011
Tele : (O) 011-23061863, Fax : 011-23061252, E-mail : secyhfw@gmail.com

NATIONAL HEALTH MISSION
राष्ट्रीय स्वास्थ्य मिशन

C.K. Mishra, IAS
Additional Secretary &
Mission Director, NHM
Telefax : 23061066, 23063809
E-mail : asmd-mohfw@nic.in

भारत सरकार
स्वास्थ्य एवं परिवार कल्याण मंत्रालय
निर्माण भवन, नई दिल्ली - 110011
GOVERNMENT OF INDIA
MINISTRY OF HEALTH & FAMILY WELFARE
NIRMAN BHAVAN, NEW DELHI-110011

MESSAGE

Under National Health Mission, support is being provided to all States/UTs for improving quality of health services and improving necessary infrastructure including medical equipment. Providing for adequate, safe and appropriate medical equipment at all levels of public health facilities remains a focus for the Government. Given the challenges of procurement it is necessary to have generic specifications for medical equipment. Cost, utility, availability in domestic market, maintenance and patient safety are crucial issues to be considered while procuring medical devices. I am pleased to note that these have been adequately considered by NHSRC while preparing the specifications. Keeping them as reference specifications while undertaking procurement will reduce costs of procurement, maintenance problems and procurement lead time. I am happy to note that NHSRC, has filled in an important technical gap by providing these specifications and I am sure that technical specifications suggested here will serve as a reference for procurement of medical devices under the National Health Mission.

We would be happy to have your valuable suggestion on improving these.

(C.K. Mishra)

New Delhi
29th April, 2015

NATIONAL HEALTH MISSION
राष्ट्रीय स्वास्थ्य मिशन

Manoj Jhalani, IAS
Joint Secretary
Telefax : 23063687
E-mail : manoj.jhalani@nic.in

भारत सरकार
स्वास्थ्य एवं परिवार कल्याण मंत्रालय
निर्माण भवन, नई दिल्ली – 110011
GOVERNMENT OF INDIA
MINISTRY OF HEALTH & FAMILY WELFARE
NIRMAN BHAVAN, NEW DELHI - 110011

31st April 2015

MESSAGE

National Health Systems Resource Centre which is also a WHO collaborating centre for priority medical devices & health technology policy; in consultation with users, care providers, engineers, medical technologists and representatives from medical devices manufacturers association has formulated technical specifications for commonly used medical devices. Specifications are suggestive in nature and any specific requirement needs to be incorporated at the time of procurement. However having well deliberated specification at one place should considerably reduce the procurement cost & time and improve quality of procurement.extensively. The specifications suggested herein are an outcome of several rounds of consultations with experts, user clinicians & care providers, medical technologists & engineers and industry stake holders. While effort has been made to make the specifications as generic as possible and consensus and technical appropriateness has been the corner stone of this technical exercise. We would welcome suggestions from the States.

(Manoj Jhalani)

Acknowledgement

Medical devices are a very important part of health care and their use is increasing by the day. Technical specifications play an important role in identification, selection and procurement of appropriate and cost effective medical devices. Consistency and standardization in technical specifications promotes positive competition and reduces effective costs. It also promotes uniformity in user training and smooth maintenance of equipment. In order to address the variation in technologies many of which could be add-ons, separate exercises were undertaken for specific categories of medical devices procured under National Health Mission. The experts consulted for specifications formulation exercises included clinicians, medical technologists, maintenance experts and also representatives from manufactures' industry associations. Specifications for medical devices for Special Neonatal Care Units, Neonatal and Pediatric Care Units, Ambulances, Operation Theatre for district sub-district levels, Rashtriya Bal Suraksha Karyakaram, Laboratory & Radiology equipment, Skill laboratory program are an outcome of intense participation, deliberation, technical research and inputs from experts. These include experts from prestigious institutions such as AIIMS, PGIMER-Chandigarh, RML Hospital, Safdarjung Hospital, Sree Chitra Institute of Medical Sciences & Technology, Central Scientific Instrument Organisation, Hindustan Life Care Limited, IITs, to name a few. Overall review by DGHS provided further validation to the technical work. Division of Healthcare Technology, NHSRC being the technical secretariat for this work played a pivotal role and names of following professionals deserve special mention: Jitendar Sharma, Mohammad Ameel, Anurag, Swati Barwala, Prabhat Arora, Kavita Kachroo, Akriti Chahar, Pankaj Parashar, Prashant Tiwari, Ashfaq Ashraf, Anjanaya, Himanshu Bhushan, Prashant KS, Anil K, Sonia Luna and Ajit Singh. I am sure that specifications confirming to adequate standards of safety and accuracy shall be immensely useful for the states in undertaking appropriate and cost effective procurement of medical devices.

Dr. Sanjiv Kumar
Executive Director

ABDOMINAL PALPATION MANNEQUIN FOR LEOPOLD MANEUVERS DURING PREGNANCY

Version no. :		1.0
Date:		7/4/2014
Done by : (name/institution)		HCT/ NHSRC
NAME AND CODING		
GMDN name		**NA**
GMDN code		1816
GMDN definition		Lower adult female torso with anatomical features capable of demonstrating various stages of pregnancy (5th, 7th and term)
GENERAL		
1. USE		
1.1	Clinical purpose	To demonstrate Leopold maneuvers during pregnancy
1.2	Used by Clinical Department	Skill labs
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific to this type of device)**	1. The material of mannequin should be of polyvinyl or silicone rubber, free from any hazardous materials. 2. The texture of the mannequin should be as close to the feel of the baby/ adult skin as relevant. 3. The Internal parts of the mannequin must be realistically sculpted, anatomically accurate and feel must be smooth/resilient/bony as relevent and suitable for simulation. 4. The abdominal palpation model should have full size adult female torso (abdomen and pelvis) 5. The abdominal palpation mannequin should have one-piece full term fetus with palpable frontanelles, spine, shoulders, elbows and knees. 6. The abdominal palpation mannequin should have a mechanism to adjust the firmness of the abdomen in respect to the weeks of pregnancy i.e. 12, 24, 36, 42 gestational age models. 7. The abdominal mannequin should be able to accomodate the fetus in vertex, breech, or transverse positions.
2.2	**Settings**	NA
2.3	**User's interface**	NA
2.4	**Software and/or standard of communication (where ever required)**	NA
3. PHYSICAL CHARACTERISTICS		
3.1	**Dimensions (metric)**	NA
3.2	**Weight (lbs, kg)**	NA
3.3	**Configuration**	NA
3.4	**Noise (in dBA)**	NA
3.5	**heat dissipation**	NA
3.6	Mobility, portability	Yes, Portable

4. ENERGY SOURCE (Electricity, UPS, Solar, Gas, Water, CO_2 ....)		
4.1	**Power Requirements**	NA
4.2	**Battery operated**	NA
4.3	**Tolerance (to variations, shutdowns)**	NA
4.4	**Protection**	NA
4.5	**Power consumption**	NA
4.6	**Other energy supplies**	NA
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	**Accessories & spare parts**	Fetus size-5th, 7th and term flexible enough to fit inside abdominal palpation mannequin.
5.2	**Consumables/reagents (open, closed system)**	NA
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS		
6.1	**Atmosphere/Ambiance (air conditioning, humidity, dust ...)**	Capable of being stored continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90%. Capable of operating continuously in ambient temperature of 10 to 40 deg C and relative humidity of 15 to 90%.
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	Complete unit to be easily washable with mild soap and water without bringing deterioration in the mannequin.
7. STANDARDS AND SAFETY		
7.1	**Certifications**	BS EN ISO/IEC 17050-1:2010 Conformity assessment. Supplier's declaration of conformity. EMC Directive:2004/108/EC.
8. TRAINING AND INSTALLATION		
8.1	**Pre-installation requirements: nature, values, quality, tolerance**	NA
8.2	**Requirements for sign-off**	Demonstration to the user while delivering the product.
8.3	**Training of staff (medical, paramedical, technicians) OPTIONAL (Depending upon scope of work order)**	Training of users in handling and basic maintenance shall be provided.
9. WARRANTY AND MAINTENANCE		
9.1	**Warranty**	3 years against functionality excluding asthetics.
9.2	**Maintenance tasks**	maintainance manual detailing complete maintaining schedule.
9.3	**Service contract clauses, including prices**	Local clinical staff/authorized officer on behalf of purchaser to affirm completion of installation.
10. DOCUMENTATION		
10.1	**Operating manuals, service manuals, other manuals**	Advanced maintenance tasks required shall be documented User manuals to be supplied in english/hindi language along with machine diagrams. List to be provided of equipment and procedures required for local calibration and routine maintenance Once a year visit to site, within warranty period including training of user on maitenance.
10.2	**Other accompanying documents**	List to be provided of important spares and accessories, with their part numbers and cost. Certificate of calibration and inspection to be provided.
11. NOTES		
11.1	**Service Support Contact details (Hierchy Wise; including a toll free/landline number)**	NA
11.2	**Recommendations or warnings**	Any recommendations for best use and supplimentary warning for safety should be declared.

ADULT CPR MANNNEQUIN

Version no. :		1.0
Date:		5/8/2013
Done by : (name/institution)		HCT/ NHSRC
NAME AND CODING		
GMDN name		**Simulators (Resuscitation training model)**
GMDN code		CT1817, CT254
GMDN definition		A specially-constructed doll with simulated respiratory and cardiovascular functions designed to demonstrate and teach resuscitation techniques that include chest compressions [cardiopulmonary resuscitation (CPR)].
GENERAL		
1. USE		
1.1	**Clinical purpose**	It is used to demonstrate nose pinch required for ventilation techniques. Head tilt/chin lift and jaw thrust allowing students to currently practice all manoeuvers necessary when resuscitating a real victim.
1.2	**Used by clinical department**	Skill lab
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific to this type of device)**	1. The material of mannequin should be of polyvinyl or silicone rubber, free from any hazardous materials. 2. The texture of the mannequin should be as close to the feel of the baby/ adult skin as relevant. 3. The Internal parts of the mannequin must be realistically sculpted, anatomically accurate and feel must be smooth/resilient/bony as relevent and suitable for simulation. 4. It should have features to demonstrate opening of airway, head tilt/chin tilt and jaw thrust techniques. 5. Adult CPR Mannequin should have disposable airways. 6.Adult CPR Mannequins should have removable, reusable faces. 7. Adult CPR mannequin should have an indicator which confirms correct chest compression technique. 8. It should have compression spring for consistent resistance.
2.2	**Settings**	NA
2.3	**User's interface**	NA
2.4	**Software and/or standard of communication (where ever required)**	NA
3. PHYSICAL CHARACTERISTICS		
3.1	**Dimensions (metric)**	adult torso
3.2	**Weight (lbs, kg)**	NA
3.3	**Configuration**	NA
3.4	**Noise (in dBA)**	NA
3.5	**heat dissipation**	NA
3.6	**Mobility, portability**	Yes, portable

4. ENERGY SOURCE (Electricity, UPS, Solar, Gas, Water, CO_2 ....)		
4.1	**Power Requirements**	NA
4.2	**Battery operated**	NA
4.3	**Tolerance (to variations, shutdowns)**	NA
4.4	**Protection**	NA
4.5	**Power consumption**	NA
4.6	**Other energy supplies**	NA
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	**Accessories & spare parts**	10 nos.reusable mannequin faces. 10 nos. reusable airways. 50 nos mannequin wipes.
5.2	**Consumables/reagents (open, closed system)**	NA
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS		
6.1	**Atmosphere/Ambiance (air conditioning, humidity, dust ...)**	Capable of being stored continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90%. Capable of operating continuously in ambient temperature of 10 to 40 deg C and relative humidity of 15 to 90%.
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	Complete unit to be easily washable with mild soap and water without bringing deterioriation in the mannequin.
7. STANDARDS AND SAFETY		
7.1	**Certifications**	BS EN ISO/IEC 17050-1:2010 Conformity assessment. Supplier's declaration of conformity. EMC Directive:2004/108/EC.
8. TRAINING AND INSTALLATION		
8.1	**Pre-installation requirements: nature, values, quality, tolerance**	NA
8.2	**Requirements for sign-off**	Demonstration to the users while delivering the product.
8.3	**Training of staff (medical, paramedical, technicians) OPTIONAL (Depending upon scope of work order)**	Training of users in handling and basic maintenance shall be provided.
9. WARRANTY AND MAINTENANCE		
9.1	**Warranty**	3 years against functionality excluding asthetics.
9.2	**Maintenance tasks**	maintainance manual detailing complete maintaining schedule.
9.3	**Service contract clauses, including prices**	Local clinical staff/authorized officer on behalf of purchaser to affirm completion of installation.
10. DOCUMENTATION		
10.1	**Operating manuals, service manuals, other manuals**	Advanced maintenance tasks required shall be documented User, technical and maintenance manuals to be supplied in english/hindi language along with visit log sheet. List to be provided of equipment and procedures required for local calibration and routine maintenance Once a year visit to the site within warranty period including training of users on maitenance.
10.2	**Other accompanying documents**	List to be provided of important spares and accessories, with their part numbers and cost. Certificate of calibration and inspection to be provided.
11. NOTES		
11.1	**Service Support Contact details (Hierchy Wise; including a toll free/landline number)**	NA
11.2	**Recommendations or warnings**	Any recommendations for best use and supplimentary warning for safety should be declared

CHILD BIRTH SIMULATOR ALONG WITH ATTACHMENT FOR CERVICAL DIALATATION(CLOSED OS, 4CM, 6CM, 8CM, FULLY DILATED CERVIX)

Version no. :		1.0
Date:		7/4/2014
Done by : (name/institution)		HCT/ NHSRC
NAME AND CODING		
GMDN name		**Simulators and associated devices**
GMDN code		CT2372
GMDN definition		Lower female torso with anatomical features of pregnancy capable of demonstrating child birth
GENERAL		
1. USE		
1.1	**Clinical purpose**	Should be able to demonstrate Leopold maneuver
1.2	**Used by Clinical Department/Ward**	skill labs
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific to this type of device)**	1. The material of mannequin should be of polyvinyl or silicone rubber, free from any hazardous material. 2. The texture of the mannequin should be close to the feel of the baby/ adult skin. 3. The Internal parts of the mannequin must be realistically sculpted, anatomically accurate and feel must be smooth/resilient/bony as relevent and suitable for simulation. 4. Should have pelvis structure of adult female with anatomical landmarks like pelvic cavity, spine etc.Should have manual birthing system to enable the user to control the rotation and speed of fetus delivery etc. 5. Should have fetal baby with movable joints. 6. Should be versatile to change the position of the fetus during the process of birth including descent, flexion, extension, internal and external rotation, restitution. 7. Should have features for training normal and breech deliveries. 8. Should have features to demonstrate cord prolapse. 9. Shall allow demonstration and practice of placenta previa. 10. Should have cervical dialatation attachment for closed os, 4cm, 6cm, 8cm and fully dilated cervix.
2.2	**Settings**	NA
2.3	**User's interface**	NA
2.4	**Software and/or standard of communication (where ever required)**	NA
3. PHYSICAL CHARACTERISTICS		
3.1	**Dimensions (metric)**	standard female pelvic structure
3.2	**Weight (lbs, kg)**	NA

3.3	**Configuration**	NA
3.4	**Noise (in dBA)**	NA
3.5	**heat dissipation**	NA
3.6	**Mobility, portability**	Yes, Portable
	4. ENERGY SOURCE (Electricity, UPS, Solar, Gas, Water, CO_2 ....)	
4.1	**Power Requirements**	NA
4.2	**Battery operated**	NA
4.3	**Tolerance (to variations, shutdowns)**	NA
4.4	**Protection**	NA
4.5	**Power consumption**	NA
4.6	**Other energy supplies**	NA
	5. ACCESSORIES, SPARE PARTS, CONSUMABLES	
5.1	**Accessories & spare parts**	1. fetal baby with moving joints. 2. 2 detachable abdominal pads. 3. 2 nos placentas. 4. 6 nos umbilical cords. 5. 2 sets cervical dilatation attachment for closed Os, 4cm, 6cm, 8cm and fully dilated cervix.
5.2	**Consumables/reagents (open, closed system)**	NA
	6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS	
6.1	**Atmosphere/Ambiance (air conditioning, humidity, dust ...)**	Capable of being stored continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90%. Capable of operating continuously in ambient temperature of 10 to 40 deg C and relative humidity of 15 to 90%.
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	Complete unit to be easily washable with mild soap and water.
	7. STANDARDS AND SAFETY	
7.1	**Certifications**	BS EN ISO/IEC 17050-1:2010 Conformity assessment. Supplier's declaration of conformity. EMC Directive:2004/108/EC .
	8. TRAINING AND INSTALLATION	
8.1	**Pre-installation requirements: nature, values, quality, tolerance**	NA
8.2	**Requirements for sign-off**	Demonstration to user while delivering the product.
8.3	**Training of staff (medical, paramedical, technicians) OPTIONAL (Depending upon scope of work order)**	Training of users in handling and basic maintenance shall be provided.
	9. WARRANTY AND MAINTENANCE	
9.1	**Warranty**	3 years against functionality excluding asthetics.
9.2	**Maintenance tasks**	maintainance manual detailing complete maintaining schedule.

9.3	**Service contract clauses, including prices**	Local clinical staff/authorized officer on behalf of purchaser to affirm completion of installation.
	10. DOCUMENTATION	
10.1	**Operating manuals, service manuals, other manuals**	Advanced maintenance tasks required shall be documented User, technical and maintenance manuals to be supplied in english/hindi language along with visit log sheet. List to be provided of equipment and procedures required for local calibration and routine maintenance Once a year visit to site within warranty period including training of users on maintenance.
10.2	**Other accompanying documents**	List to be provided of important spares and accessories, with their part numbers and cost. Certificate of calibration and inspection to be provided.
	11. NOTES	
11.1	**Service Support Contact details (Hierchy Wise; including a toll free/landline number)**	NA
11.2	**Recommendations or warnings**	Any recommendations for best use and supplimentary warning for safety should be declared

ADULT IV TRAINING ARM KIT

Version no. :		1.0
Date:		7/4/2014
Done by : (name/institution)		HCT/ NHSRC
NAME AND CODING		
GMDN name		Infusion/injection training model
GMDN code		CT254 (Healthcare training)
GMDN definition		A synthetic replica of a human arm designed for instructing intravenous (IV) line placement, injections, infusions and intravenous. It simulates the anatomy of an arm with blood vessels, tissues, and skin produced in soft, rubber-like materials.
GENERAL		
1. USE		
1.1	**Clinical purpose**	It is ideal for practicing:intravenous injections, correct punture of peripheral veins for blood sampling.Puncturing of arm veins.Positioning of a butterfly cannula.
1.2	**Used by Clinical Department**	Skill lab
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific to this type of device)**	1. The material of mannequin should be of polyvinyl or silicone rubber, free from any hazardous materials. 2. The texture of the mannequin should be close to the feel of the baby/ adult skin as relevant. 3. The Internal parts of the mannequin must be realistically sculpted, anatomically accurate and feel must be smooth/resilient/bony as relevent and suitable for simulation. 4. Adult IV training Arm should have full adult arm with clenched/open fist. 5. Adult IV arm should be suitable for practicing IV injections. 6. Adult IV training arm should have prominent venous network. 8. Adult IV trainning arm should have anatomically located venous grooves, fitted with soft tubes, closely simulating consistency of human veins. 7. Adult IV training arm must have a pliable translucent skin stretched over venous network. 8. Adult IV training arm should have veins in dorsum of hand. 9. Adult IV training arm should feature 'realistic feel' as needle enters vein. 10. Adult IV training arm veins and skin must be replaceable. 11. IV training arm should have cephalic, basic, antecubital, radial and ulnar veins. 12. IV training arm must have base and metal stand to hold the mannequin and accessories as required.

2.2	**Settings**	NA
2.3	**User's interface**	NA
2.4	**Software and/or standard of communication (where ever required)**	NA
	3. PHYSICAL CHARACTERISTICS	
3.1	**Dimensions (metric)**	Adult arm
3.2	**Weight (lbs, kg)**	NA
3.3	**Configuration**	NA
3.4	**Noise (in dBA)**	NA
3.5	**heat dissipation**	NA
3.6	**Mobility, portability**	Yes, Portable
	4. ENERGY SOURCE (Electricity, UPS, Solar, Gas, Water, CO_2 ....)	
4.1	**Power Requirements**	NA
4.2	**Battery operated**	NA
4.3	**Tolerance (to variations, shutdowns)**	NA
4.4	**Protection**	NA
4.5	**Power consumption**	NA
4.6	**Other energy supplies**	NA
	5. ACCESSORIES, SPARE PARTS, CONSUMABLES	
5.1	**Accessories & spare parts**	1. 2 packs of red colour concentrate/powder, with tubing and connector. 2. 25 sets of replacement skin.
5.2	**Consumables/reagents (open, closed system)**	NA
	6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS	
6.1	**Atmosphere/Ambiance (air conditioning, humidity, dust ...)**	Capable of being stored continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90%. Capable of operating continuously in ambient temperature of 10 to 40 deg C and relative humidity of 15 to 90%.
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	Complete unit to be easily washable with mild soap and water without bringing deterioration in the mannequin.
	7. STANDARDS AND SAFETY	
7.1	**Certifications**	BS EN ISO/IEC 17050-1:2010 Conformity assessment. Supplier's declaration of conformity. EMC Directive:2004/108/EC.
	8. TRAINING AND INSTALLATION	
8.1	**Pre-installation requirements: nature, values, quality, tolerance**	NA
8.2	**Requirements for sign-off**	Demonstration to the user while delivering the product.
8.3	**Training of staff (medical, paramedical, technicians) OPTIONAL (Depending upon scope of work order)**	Training of users in handling and basic maintenance shall be provided.
	9. WARRANTY AND MAINTENANCE	
9.1	**Warranty**	3 years against functionality excluding asthetics.
9.2	**Maintenance tasks**	maintainance manual detailing complete maintaining schedule.

9.3	**Service contract clauses, including prices**	Local clinical staff/authorized officer on behalf of purchaser to affirm completion of installation.
	10. DOCUMENTATION	
10.1	**Operating manuals, service manuals, other manuals**	Advanced maintenance tasks required shall be documented User, manuals to be supplied in english language along with visit log sheet. List to be provided of equipment and procedures required for local calibration and routine maintenance Once a year visit to site within warranty period including training of users on maintenance.
10.2	**Other accompanying documents**	List to be provided of important spares and accessories, with their part numbers and cost. Certificate of calibration and inspection to be provided.
	11. NOTES	
11.1	**Service Support Contact details (Hierchy Wise; including a toll free/landline number)**	NA
11.2	**Recommendations or warnings**	Any recommendations for best use and supplimentary warning for safety should be declared.

EPISIOTOMY SUTURING TRAINER

Version no. :		1.0
Date:		7/4/2014
Done by : (name/institution)		HCT/ NHSRC
NAME AND CODING		
GMDN name		Episiotomy suturing unit, reusable.
GMDN code		CT342 (sutures and associated devices).
GMDN definition		Model of female external pudendum with episiotomy and episiotomy with tears.Suitable for training of episiotomy suturing.
GENERAL		
1. USE		
1.1	**Clinical purpose**	The models demonstrate the different types of episiotomies and permits episiotomy suturing.
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific to this type of device)**	1. The material of mannequin should be of polyvinyl or silicone rubber, free from any hazardous materials. 2. The texture of the mannequin should be as close to the feel of the baby/ adult skin as relevant. 3. The Internal parts of the mannequin must be realistically sculpted, anatomically accurate and feel must be smooth/resilient/bony as relevent and suitable for simulation. 4. Should enable use of chromic sutures. 5. Should have one model featuring standard episiotomy with tears in labia minora (medio-lateral) on left and right side. 6. It may have features to attach with child birth simulator and episiotomy with tears. (desirable).
2.2	**Settings**	NA
2.3	**User's interface**	NA
2.4	**Software and/or standard of communication (where ever required)**	NA
3. PHYSICAL CHARACTERISTICS		
3.1	**Dimensions (metric)**	NA
3.2	**Weight (lbs, kg)**	NA
3.3	**Configuration**	NA
3.4	**Noise (in dBA)**	NA
3.5	**heat dissipation**	NA
3.6	**Mobility, portability**	Yes, portable

4. ENERGY SOURCE (Electricity, UPS, Solar, Gas, Water, CO_2 ....)		
4.1	**Power Requirements**	NA
4.2	**Battery operated**	NA
4.3	**Tolerance (to variations, shutdowns)**	NA
4.4	**Protection**	NA
4.5	**Power consumption**	NA
4.6	**Other energy supplies**	NA
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	Accessories & spare parts	If episiotomy part is replaceable, quote for 100 sets may be given.
5.2	Consumables/reagents (open, closed system)	NA
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS		
6.1	**Atmosphere/Ambiance (air conditioning, humidity, dust ...)**	Capable of being stored continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90%. Capable of operating continuously in ambient temperature of 10 to 40 deg C and relative humidity of 15 to 90%.
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	Complete unit to be easily washable with mild soap and water without bringing deterioration in the mannequin.
7. STANDARDS AND SAFETY		
7.1	Certifications	BS EN ISO/IEC 17050-1:2010 Conformity assessment. Supplier's declaration of conformity. EMC Directive:2004/108/EC.
8. TRAINING AND INSTALLATION		
8.1	**Pre-installation requirements: nature, values, quality, tolerance**	NA
8.2	**Requirements for sign-off**	Demonstration to user while delivering the product.
8.3	**Training of staff (medical, paramedical, technicians) OPTIONAL (Depending upon scope of work order)**	Training of users in handling and basic maintenance shall be provided.
9. WARRANTY AND MAINTENANCE		
9.1	**Warranty**	3 years against functionality excluding asthetics.
9.2	**Maintenance tasks**	maintainance manual detailing complete maintaining schedule.
9.3	**Service contract clauses, including prices**	Local clinical staff/authorized officer on behalf of purchaser to affirm completion of installation.
10. DOCUMENTATION		
10.1	**Operating manuals, service manuals, other manuals**	Advanced maintenance tasks required shall be documented User manuals to be supplied in english/hindi language along witth visit log sheet. List to be provided of equipment and procedures required for local calibration and routine maintenance Once a year visit to site within warranty period including training of users on maintenance.
10.2	**Other accompanying documents**	List to be provided of important spares and accessories, with their part numbers and cost. Certificate of calibration and inspection to be provided.
11. NOTES		
11.1	**Service Support Contact details (Hierchy Wise; including a toll free/landline number)**	NA
11.2	**Recommendations or warnings**	Any recommendations for best use and supplimentary warning for safety should be declared

FEMALE LOWER TORSO MANNEQUIN WITH NORMAL AND POSTPARTUM UTERUS AND ACCESSORIES

Version no. :		1.0
Date:		7/4/2014
Done by : (name/institution)		HCT/ NHSRC
NAME AND CODING		
GMDN name		Gynaecologic trainer
GMDN code		CT1817
GMDN definition		A model of female adult lower body with relevant internal anatomical landmarks suitable for intended palpation and inspection of female pelvic organ.The model should also permit practice of IUD insertion and removal and use of other female contraceptive devices.
GENERAL		
1. USE		
1.1	**Clinical purpose**	used for teaching/practicing bi-manual pelvic examination, vaginal examination, PPIUCD (postpartum intrauterine contraceptive device).
1.2	**Used by Clinical Department/ Ward**	Skill labs
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific to this type of device)**	1. The material of mannequin should be of polyvinyl or silicone rubber, free from any hazardous materials. 2. The texture of the mannequin should be as close to the feel of the baby/ adult skin as relevant. 3. The Internal parts of the mannequin must be realistically sculpted, anatomically accurate and feel must be smooth/resilient/bony as relevent and suitable for simulation. 4. Should have full size adult female lower torso with relevant internal landmarks and post-partum uterus. 5. Should have palpable normal and pregnant uteri with realistically sculpted and anatomically accurate ovaries and fimbriae. 6. Should have normal and abnormal crevices. 7. Should be suitable for teaching/practicing bi-manual pelvic examination. 8. Should be suitable for vaginal examination, including insertion of speculum, uterine sounding and IUD insertion and removal and PPIUCD (postpartum intrauterine contraceptive device). 9. Should have distal end of vagina to facilitate introduction of a female condom. 10. Should have detachable and attachable cervix.
2.2	**Settings**	NA
2.3	**User's interface**	NA

2.4	**Software and/or standard of communication (where ever required)**	NA
	3. PHYSICAL CHARACTERISTICS	
3.1	**Dimensions (metric)**	NA
3.2	**Weight (lbs, kg)**	NA
3.3	**Configuration**	NA
3.4	**Noise (in dBA)**	NA
3.5	**heat dissipation**	NA
3.6	**Mobility, portability**	Yes, Portable
	4. ENERGY SOURCE (Electricity, UPS, Solar, Gas, Water, CO_2 ....)	
4.1	**Power Requirements**	NA
4.2	**Battery operated**	NA
4.3	**Tolerance (to variations, shutdowns)**	NA
4.4	**Protection**	NA
4.5	**Power consumption**	NA
4.6	**Other energy supplies**	NA
	5. ACCESSORIES, SPARE PARTS, CONSUMABLES	
5.1	**Accessories & spare parts**	1. One normal and abnormal uterus. 2. One set of normal and abnormal cervices. 3. One anteverted and retroverted uterus. 4. One set of postpartum uterus with duckbill cervix and fallopian tubes. 5. 3 sets of 6 different types of cervices.
5.2	**Consumables/reagents (open, closed system)**	NA
	6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS	
6.1	**Atmosphere/Ambiance (air conditioning, humidity, dust ...)**	Capable of being stored continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90%. Capable of operating continuously in ambient temperature of 10 to 40 deg C and relative humidity of 15 to 90%.
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	Complete unit to be easily washable with mild soap and water without bringing deterioration in he mannequin.
	7. STANDARDS AND SAFETY	
7.1	**Certifications**	BS EN ISO/IEC 17050-1:2010 Conformity assessment. Supplier's declaration of conformity. EMC Directive:2004/108/EC.
	8. TRAINING AND INSTALLATION	
8.1	**Pre-installation requirements: nature, values, quality, tolerance**	NA
8.2	**Requirements for sign-off**	Demonstration to the user while delivering the product.
8.3	**Training of staff (medical, paramedical, technicians) OPTIONAL (Depending upon scope of work order)**	Training of users in handling and basic maintenance shall be provided.
	9. WARRANTY AND MAINTENANCE	
9.1	**Warranty**	3 years against functionality excluding asthetics.
9.2	**Maintenance tasks**	maintainance manual detailing complete maintaining schedule.

9.3	**Service contract clauses, including prices**	Local clinical staff/authorized officer on behalf of purchaser to affirm completion of installation.
	10. DOCUMENTATION	
10.1	**Operating manuals, service manuals, other manuals**	Advanced maintenance tasks required shall be documented User manuals to be supplied in english language along with visit log sheet. List to be provided of equipment and procedures required for local calibration and routine maintenance Once a year visit to site within warranty period including training of users on maintenance.
10.2	**Other accompanying documents**	List to be provided of important spares and accessories, with their part numbers and cost. Certificate of calibration and inspection to be provided.
	11. NOTES	
11.1	**Service Support Contact details (Hierchy Wise; including a toll free/landline number)**	NA
11.2	**Recommendations or warnings**	Any recommendations for best use and supplimentary warning for safety should be declared.

NORMAL NEW BORN BABY SIMULATION MODEL

Version no. :		1.0
Date:		7/4/2014
Done by : (name/institution)		HCT/ NHSRC
NAME AND CODING		
GMDN name		Simulators
GMDN code		CT602, CT152 (Peadiatrics).
GMDN definition		Synthetic or rubber replica of human baby to demonstrate Kangaroo mother care (KMC).
GENERAL		
1. USE		
1.1	**Clinical purpose**	It is used to demonstrate the characteristics and examination of new born baby and Kangaroo mother care (KMC).
1.2	**Used by Clinical Department**	Skill labs
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific to this type of device)**	1. The material of mannequin should be of polyvinyl or silicone rubber, free from any hazardous materials. 2. The texture of the mannequin should be as close to the feel of the baby/ adult skin as relevant. 3. New born baby mannequin should weigh close to the normal newborn. 4. Should have actual size showing external development and growth. 5. Should be close to normal skin colour, texture and bony feel. 6. Should have moving head, flexible upper and lower limbs. 7. Should have KMC clothes compatible with the size of the mannequins.
2.2	**Settings**	NA
2.3	**User's interface**	NA
2.4	**Software and/or standard of communication (where ever required)**	NA
3. PHYSICAL CHARACTERISTICS		
3.1	**Dimensions (metric)**	NA
3.2	**Weight (lbs, kg)**	NA
3.3	**Configuration**	NA
3.4	**Noise (in dBA)**	NA
3.5	**heat dissipation**	NA
3.6	**Mobility, portability**	Yes, Portable
4. ENERGY SOURCE (Electricity, UPS, Solar, Gas, Water, CO_2 ....)		
4.1	**Power Requirements**	NA

4.2	Battery operated	NA
4.3	**Tolerance (to variations, shutdowns)**	NA
4.4	**Protection**	NA
4.5	**Power consumption**	NA
4.6	**Other energy supplies**	NA
	5. ACCESSORIES, SPARE PARTS, CONSUMABLES	
5.1	**Accessories & spare parts**	NA
5.2	**Consumables/reagents (open, closed system)**	NA
	6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS	
6.1	**Atmosphere/Ambiance (air conditioning, humidity, dust ...)**	Capable of being stored continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90%. Capable of operating continuously in ambient temperature of 10 to 40 deg C and relative humidity of 15 to 90%.
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	Complete unit to be easily washable with mild soap and water without bringing deterioration to the mannequin.
	7. STANDARDS AND SAFETY	
7.1	**Certifications**	BS EN ISO/IEC 17050-1:2010. Conformity assessment. Supplier's declaration of conformity. EMC Directive:2004/108/EC.
	8. TRAINING AND INSTALLATION	
8.1	**Pre-installation requirements: nature, values, quality, tolerance**	NA
8.2	**Requirements for sign-off**	Demonstration to user while delivering the product.
8.3	**Training of staff (medical, paramedical, technicians) OPTIONAL (Depending upon scope of work order)**	Training of users in handling and basic maintenance shall be provided.
	9. WARRANTY AND MAINTENANCE	
9.1	**Warranty**	3 years aginst functionalityexcluding asthetics.
9.2	**Maintenance tasks**	maintainance manual detailing complete maintaining schedule.
9.3	**Service contract clauses, including prices**	Local clinical staff/authorized officer on behalf of purchaser to affirm completion of installation.
	10. DOCUMENTATION	
10.1	**Operating manuals, service manuals, other manuals**	Advanced maintenance tasks required shall be documented User manuals to be supplied in english/hindi language along with visit log sheet List to be provided of equipment and procedures required for local calibration and routine maintenance Once a year visit to site within warranty period including training of user on maintenance.
10.2	**Other accompanying documents**	List to be provided of important spares and accessories, with their part numbers and cost. Certificate of calibration and inspection to be provided.
	11. NOTES	
11.1	**Service Support Contact details (Hierchy Wise; including a toll free/landline number)**	NA
11.2	**Recommendations or warnings**	Any recommendations for best use and supplimentary warning for safety should be declared.

PEADIATRIC IV ARM KIT

Version no. :		1.0
Date:		7/4/2014
Done by : (name/institution)		HCT/ NHSRC
NAME AND CODING		
GMDN name		Infusion/injection training model.
GMDN code		CT1816 (Anatomical training models).
GMDN definition		A synthetic replica of a human arm designed for instructing intravenous (IV) line placement, injections, and intravenous infusions. It simulates the anatomy of an arm with blood vessels, tissues, and skin produced in soft, rubber-like materials.
GENERAL		
1. USE		
1.1	**Clinical purpose**	It is ideal for practicing: intravenous injections, correct puncture of peripheral veins for blood sampling, puncturing the veins of upper limb including positioning of butterfly cannula.
1.2	**Used by Clinical Department**	Skill labs
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific to this type of device)**	1. The material of mannequin should be of polyvinyl or silicone rubber, free from any hazardous material. 2. The texture of the mannequin should be close to the feel of the baby/ adult skin as relevant. 3. The Internal parts of the mannequin must be realistically sculpted, anatomically accurate and feel must be smooth/resilient/bony as relevent and suitable for simulation. 4. Should have pediatric arm. 5. Should have simulated blood pack. 6. Should have blood bag with tubing and connector. 7. Should have clamp and hook. 8. Should have mannequin lubricant, if required. 9. Should have replacement skin and multi-vein system.
2.2	**Settings**	NA
2.3	**User's interface**	NA
2.4	**Software and/or standard of communication (where ever required)**	NA
3. PHYSICAL CHARACTERISTICS		
3.1	**Dimensions (metric)**	NA
3.2	**Weight (lbs, kg)**	NA
3.3	**Configuration**	NA
3.4	**Noise (in dBA)**	NA
3.5	**heat dissipation**	NA
3.6	**Mobility, portability**	Yes

4. ENERGY SOURCE (Electricity, UPS, Solar, Gas, Water, CO_2 ....)		
4.1	**Power Requirements**	NA
4.2	**Battery operated**	NA
4.3	**Tolerance (to variations, shutdowns)**	NA
4.4	**Protection**	NA
4.5	**Power consumption**	NA
4.6	**Other energy supplies**	NA
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	**Accessories & spare parts**	Replaceable skin sets-25 Lubricant to be provided, if the type of mannequin requirs it for effective fnctioning.
5.2	**Consumables/reagents (open, closed system)**	NA
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS		
6.1	**Atmosphere/Ambiance (air conditioning, humidity, dust ...)**	Capable of being stored continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90%. Capable of operating continuously in ambient temperature of 10 to 40 deg C and relative humidity of 15 to 90%.
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	Complete unit to be easily washable with mild soap and water without bringing deteriorities in the mannequin.
7. STANDARDS AND SAFETY		
7.1	**Certifications**	BS EN ISO/IEC 17050-1:2010 Conformity assessment. Supplier's declaration of conformity. EMC Directive:2004/108/EC
8. TRAINING AND INSTALLATION		
8.1	**Pre-installation requirements: nature, values, quality, tolerance**	NA
8.2	**Requirements for sign-off**	Demonstration to user while delivering the product.
8.3	**Training of staff (medical, paramedical, technicians) OPTIONAL (Depending upon scope of work order)**	Training of users in handling and basic maintenance shall be provided.
9. WARRANTY AND MAINTENANCE		
9.1	**Warranty**	3 years against functionlity excluding asthetics.
9.2	**Maintenance tasks**	maintainance manual detailing complete maintaining schedule.
9.3	**Service contract clauses, including prices**	Local clinical staff/authorized officer on behalf of purchaser to affirm completion of installation.
10. DOCUMENTATION		
10.1	**Operating manuals, service manuals, other manuals**	Advanced maintenance tasks required shall be documented User manuals to be supplied in english language along with visit log sheet. List to be provided of equipment and procedures required for local calibration and routine maintenance. Once a year visit to site, within warranty period including training of user on maintenance.
10.2	**Other accompanying documents**	List to be provided of important spares and accessories, with their part numbers and cost. Certificate of calibration and inspection to be provided.
11. NOTES		
11.1	**Service Support Contact details (Hierchy Wise; including a toll free/landline number)**	NA
11.2	**Recommendations or warnings**	Any recommendations for best use and supplimentary warning for safety should be declared

UTERINE MODEL

Version no. :		1.0
Date:		7/4/2014
Done by : (name/institution)		HCT/ NHSRC
NAME AND CODING		
GMDN name		Uterine Cavity Simulator
GMDN code		CT1816
GMDN definition		Rubber or synthetic model with anatomical structures capable of demonstrating insertion of IUD.
GENERAL		
1. USE		
1.1	**Clinical purpose**	Based on real anatomy of female genitalia, this model is designed and used for demonstration of insertion or removal of IUD.
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific to this type of device)**	1. The material of mannequin should be of polyvinyl or silicone rubber, free from any hazardous materials. 2. The texture of the mannequin should be as close to the feel of the baby/ adult skin as relevant. 3. The Internal parts of the mannequin must be realistically sculpted, anatomically accurate and feel must be smooth/resilient/bony as relevent and suitable for simulation. 4. Anatomically accurate sagittal or coronal section of uterus and vagina suitable for demonstration of insertion and removal of IUCDs. 5. Should have uterus, ovaries and fimbria. 6. Model should have a transparent window for easy view of cavity.
2.2	**Settings**	NA
2.3	**User's interface**	NA
2.4	**Software and/or standard of communication (where ever required)**	NA
3. PHYSICAL CHARACTERISTICS		
3.1	**Dimensions (metric)**	NA
3.2	**Weight (lbs, kg)**	NA
3.3	**Configuration**	NA
3.4	**Noise (in dBA)**	NA
3.5	**heat dissipation**	NA
3.6	**Mobility, portability**	Yes
4. ENERGY SOURCE (Electricity, UPS, Solar, Gas, Water, CO_2 ....)		
4.1	**Power Requirements**	NA
4.2	**Battery operated**	NA

4.3	**Tolerance (to variations, shutdowns)**	NA
4.4	**Protection**	NA
4.5	**Power consumption**	NA
4.6	**Other energy supplies**	NA
	5. ACCESSORIES, SPARE PARTS, CONSUMABLES	
5.1	**Accessories & spare parts**	NA
5.2	**Consumables/reagents (open, closed system)**	NA
	6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS	
6.1	**Atmosphere/Ambiance (air conditioning, humidity, dust ...)**	Capable of being stored continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90%. Capable of operating continuously in ambient temperature of 10 to 40 deg C and relative humidity of 15 to 90%.
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	Complete unit to be easily washable with mild soap and water without bringing deterioration in the mannequin.
	7. STANDARDS AND SAFETY	
7.1	**Certifications**	BS EN ISO/IEC 17050-1:2010 Conformity assessment. Supplier's declaration of conformity. EMC Directive:2004/108/EC.
	8. TRAINING AND INSTALLATION	
8.1	**Pre-installation requirements: nature, values, quality, tolerance**	NA
8.2	**Requirements for sign-off**	Demonstration to the user while delivering the product.
8.3	**Training of staff (medical, paramedical, technicians) OPTIONAL (Depending upon scope of work order)**	Training of users in handling and basic maintenance shall be provided.
	9. WARRANTY AND MAINTENANCE	
9.1	**Warranty**	3 years against functionality excluding asthetics.
9.2	**Maintenance tasks**	maintainance manual detailing complete maintaining schedule.
9.3	**Service contract clauses, including prices**	Local clinical staff/authorized officer on behalf of purchaser to affirm completion of installation.
	10. DOCUMENTATION	
10.1	**Operating manuals, service manuals, other manuals**	Advanced maintenance tasks required shall be documented User manuals to be supplied in english/hindi language along with visit log sheet. List to be provided of equipment and procedures required for local calibration and routine maintenance Once a year visit to the site within warranty period including training of users on maintenance.
10.2	**Other accompanying documents**	List to be provided of important spares and accessories, with their part numbers and cost. Certificate of calibration and inspection to be provided.
	11. NOTES	
11.1	**Service Support Contact details (Hierchy Wise; including a toll free/landline number)**	NA
11.2	**Recommendations or warnings**	Any recommendations for best use and supplimentary warning for safety should be declared.

ESSENTIAL NEW BORN CARE AND RESUSCITATION MANNEQUIN

Version no. :		1.0
Date:		7/4/2014
Done by : (name/institution)		HCT/ NHSRC
NAME AND CODING		
GMDN name		Simulators and associated devices
GMDN code		CT2372
GMDN definition		Human neonate model for the demonstration of ENBC and practice of cleaning of airway and ventilation as part of neonatal resuscitation
GENERAL		
1. USE		
1.1	**Clinical purpose**	To demonstrate and practice neonatal resuscitation
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific to this type of device)**	1. The material of mannequin should be of polyvinyl and silicone rubber, free from any hazardous material. 2. The texture of the mannequin should be close to the feel of the baby/ adult skin as relevant. 3. The Internal parts of the mannequin must be realistically sculpted, anatomically accurate and feel must be smooth/resilient/bony as relevent and suitable for simulation. 4. Newborn mannequin should have features for training essential newborn care (ENBC) and newborn resuscitation. 5. Newborn Mannequin should facilitate effective bag and mask ventilation, chest must rise only with correct technique. 6. The newborn mannequin should include the following: Squeeze bulbs for simulation of cord pulsation, spontaneous breathing, auscultation of heart sound and cry. 7. The new born mannequin should demonstrate clearing of airways, perform suction;monitoring of ventilation and pulsation.
2.2	**Settings**	NA
2.3	**User's interface**	NA
2.4	**Software and/or standard of communication (where ever required)**	NA
3. PHYSICAL CHARACTERISTICS		
3.1	**Dimensions (metric)**	NA
3.2	**Weight (lbs, kg)**	NA
3.3	**Configuration**	NA
3.4	**Noise (in dBA)**	NA
3.5	**heat dissipation**	NA
3.6	**Mobility, portability**	Yes, Portable

4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ....)		
4.1	**Power Requirements**	NA
4.2	**Battery operated**	NA
4.3	**Tolerance (to variations, shutdowns)**	NA
4.4	**Protection**	NA
4.5	**Power consumption**	NA
4.6	**Other energy supplies**	NA
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	**Accessories & spare parts**	1. 10 units-device for suction of nose and mouth. 2. 4 external umbilical cords and 6 umbilical ties. 3. 2 neonatal mucus sucker (easy to open, clean, autoclave and reusable). 4. 2 training stethoscopes.
5.2	**Consumables/reagents (open, closed system)**	NA
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS		
6.1	**Atmosphere/Ambiance (air conditioning, humidity, dust ...)**	Capable of being stored continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90%. Capable of operating continuously in ambient temperature of 10 to 40 deg C and relative humidity of 15 to 90%.
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	Complete unit to be easily washable with mild soap and water without bringing deterioration in the mannequin.
7. STANDARDS AND SAFETY		
7.1	**Certifications**	BS EN ISO/IEC 17050-1:2010 Conformity assessment. Supplier's declaration of conformity. EMC Directive:2004/108/EC.
8. TRAINING AND INSTALLATION		
8.1	**Pre-installation requirements: nature, values, quality, tolerance**	NA
8.2	**Requirements for sign-off**	Demonstration to the user while delivering the product.
8.3	**Training of staff (medical, paramedical, technicians) OPTIONAL (Depending upon scope of work order)**	Training of users in handling and basic maintenance shall be provided.
9. WARRANTY AND MAINTENANCE		
9.1	**Warranty**	3 years against functionality excluding asthetics.
9.2	**Maintenance tasks**	maintainance manual detailing complete maintaining schedule.
9.3	**Service contract clauses, including prices**	Local clinical staff/authorized officer on behalf of purchaser to affirm completion of installation.
10. DOCUMENTATION		
10.1	**Operating manuals, service manuals, other manuals**	Advanced maintenance tasks required shall be documented User, technical and maintenance manuals to be supplied in english/hindi language along with visit log sheet. List to be provided of equipment and procedures required for local calibration and routine maintenance Once a year visit to site within warranty period including training of users on maintenance.
10.2	**Other accompanying documents**	List to be provided of important spares and accessories, with their part numbers and cost. Certificate of calibration and inspection to be provided.
11. NOTES		
11.1	**Service Support Contact details (Hierchy Wise; including a toll free/landline number)**	NA
11.2	**Recommendations or warnings**	Any recommendations for best use and supplimentary warning for safety should be declared

FEMALE CATHETERIZATION MANNEQUIN

Version no. :		1.0
Date:		7/4/2014
Done by : (name/institution)		HCT/ NHSRC
NAME AND CODING		
GMDN name		Cervical Dialatation catheter, Indwelling Catheterization kit.
GMDN code		CT154 (Obstretics/Gynecology).
GMDN definition		Rubber or synthetic model depicting normal uro-genital system capable of demonstrating insertion of urinary catheter for drainage of urine.
GENERAL		
1. USE		
1.1	**Clinical purpose**	This simulator allows the students to feel the pressure and resistance when a catheter is passed through the urethra and sphincter into the bladder.When the catheter enters the bladder, artificial urine (water) will flow through the catheter.
1.2	**Used by clinical departments/ wards**	Skill labs
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific to this type of device)**	1. The material of mannequin should be of polyvinyl or silicone rubber, free from any hazardous mateials. 2. The texture of the mannequin should be close to the feel of the baby/ adult skin as relevant. 3. The Internal parts of the mannequin must be realistically sculpted, anatomically accurate and feel must be smooth/resilient/bony as relevent and suitable for simulation. 4. Should have adult female lower torso with realistic vulval area and urethral opening. 5. Female catheterization mannequin should have reservoir bladder. 6. Should have replaceable urethral valve to prevent fluid leakage. 7. Should have removable urinary assembly.
2.2	**Settings**	NA
2.3	**User's interface**	NA
2.4	**Software and/or standard of communication (where ever required)**	NA
3. PHYSICAL CHARACTERISTICS		
3.1	**Dimensions (metric)**	NA
3.2	**Weight (lbs, kg)**	NA
3.3	**Configuration**	NA
3.4	**Noise (in dBA)**	NA
3.5	**heat dissipation**	NA
3.6	**Mobility, portability**	Yes

4 ENERGY SOURCE (Electricity, UPS, Solar, Gas, Water, CO_2 ....)		
4.1	**Power Requirements**	NA
4.2	**Battery operated**	NA
4.3	**Tolerance (to variations, shutdowns)**	NA
4.4	**Protection**	NA
4.5	**Power consumption**	NA
4.6	**Other energy supplies**	NA
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	**Accessories & spare parts**	2 bladder tanks, 6 urethra valves
5.2	**Consumables/reagents (open, closed system)**	NA
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS		
6.1	**Atmosphere/Ambiance (air conditioning, humidity, dust ...)**	Capable of being stored continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90%. Capable of operating continuously in ambient temperature of 10 to 40 deg C and relative humidity of 15 to 90%.
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	Complete unit to be easily washable with mild soap and water without bringing deterioration to the mannequin.
7. STANDARDS AND SAFETY		
7.1	Certifications	BS EN ISO/IEC 17050-1:2010 Conformity assessment. Supplier's declaration of conformity. EMC Directive:2004/108/EC
8. TRAINING AND INSTALLATION		
8.1	**Pre-installation requirements: nature, values, quality, tolerance**	NA
8.2	**Requirements for sign-off**	NA
8.3	**Training of staff (medical, paramedical, technicians) OPTIONAL (Depending upon scope of work order)**	Training of users in handling and basic maintenance shall be provided
9. WARRANTY AND MAINTENANCE		
9.1	**Warranty**	3 years against functionality excluding asthetics.
9.2	**Maintenance tasks**	maintainance manual detailing complete maintaining schedule.
9.3	**Service contract clauses, including prices**	Local clinical staff/authorized officer on behalf of purchaser to affirm completion of installation.
10. DOCUMENTATION		
10.1	**Operating manuals, service manuals, other manuals**	Advanced maintenance tasks required shall be documented User, manuals to be supplied in english/hindi language along with visit log sheet. List to be provided of equipment and procedures required for local calibration and routine maintenance Once a year visit to site within warranty period including training of users on maintenance.
10.2	**Other accompanying documents**	List to be provided of important spares and accessories, with their part numbers and cost. Certificate of calibration and inspection to be provided.
11. NOTES		
11.1	**Service Support Contact details (Hierchy Wise; including a toll free/landline number)**	NA
11.2	**Recommendations or warnings**	Any recommendations for best use and supplimentary warning for safety should be declared.

INTRAMUSCULAR INJECTION TRAINING MANNEQUIN

Version no. :		1.0
Date:		7/4/2014
Done by : (name/institution)		HCT/ NHSRC
NAME AND CODING		
GMDN name		Infusion/injection training mode (Anatomical Training Models).
GMDN code		CT1816
GMDN definition		A synthetic replica of lower torso for demonstrating IM injections in gluteal region.
GENERAL		
1. USE		
1.1	**Clinical purpose**	It is designed to simulate the actual sensation of the human skeletal structure required to determine the correct injection site. It helps users to practice a range of injection procedures, including needle puncture and infusion of simulated injection fluid (water).
1.2	**Used by clinical department**	Skill labs
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific to this type of device)**	1. The material of mannequin should be of polyvinyl or silicone rubber, free from any hazardous materials. 2. The texture of the mannequin should be as close to the feel of the baby/ adult skin as relevant. 3. The Internal parts of the mannequin must be realistically sculpted, anatomically accurate and feel must be smooth/resilient/bony as relevent and suitable for simulation. 4. Intramuscular injection training model should have lifelike human torso with intramuscular injection site in upper outer quadrant of palpable gluteal region on both side (left and right). 5. Should have intramuscular injection in ventrogluteal site below iliac crest on both side (left and right).
2.2	**Settings**	NA
2.3	**User's interface**	NA
2.4	**Software and/or standard of communication (where ever required)**	NA
3. PHYSICAL CHARACTERISTICS		
3.1	**Dimensions (metric)**	NA
3.2	**Weight (lbs, kg)**	NA
3.3	**Configuration**	NA
3.4	**Noise (in dBA)**	NA
3.5	**heat dissipation**	NA
3.6	**Mobility, portability**	Yes, Portable

4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ....)		
4.1	**Power Requirements**	NA
4.2	**Battery operated**	NA
4.3	**Tolerance (to variations, shutdowns)**	NA
4.4	**Protection**	NA
4.5	**Power consumption**	NA
4.6	**Other energy supplies**	NA
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	**Accessories & spare parts**	NA
5.2	**Consumables/reagents (open, closed system)**	NA
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS		
6.1	**Atmosphere/Ambiance (air conditioning, humidity, dust ...)**	Capable of being stored continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90%. Capable of operating continuously in ambient temperature of 10 to 40 deg C and relative humidity of 15 to 90%.
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	Complete unit to be easily washable with mild soap and water without bringing deterioration to the mannequin.
7. STANDARDS AND SAFETY		
7.1	**Certifications**	BS EN ISO/IEC 17050-1:2010. Conformity assessment. Supplier's declaration of conformity. EMC Directive:2004/108/EC.
8. TRAINING AND INSTALLATION		
8.1	**Pre-installation requirements: nature, values, quality, tolerance**	NA
8.2	**Requirements for sign-off**	Demonstration to user while delivering the product.
8.3	**Training of staff (medical, paramedical, technicians) OPTIONAL (Depending upon scope of work order)**	Training of users in handling and basic maintenance shall be provided.
9. WARRANTY AND MAINTENANCE		
9.1	**Warranty**	3 years against functionality excluding asthetics.
9.2	**Maintenance tasks**	maintainance manual detailing complete maintaining schedule.
9.3	**Service contract clauses, including prices**	Local clinical staff/authorized officer on behalf of purchaser to affirm completion of installation.
10. DOCUMENTATION		
10.1	**Operating manuals, service manuals, other manuals**	Advanced maintenance tasks required shall be documented. User manuals to be supplied in english/hindi language along with visit log sheet. List to be provided of equipment and procedures required for local calibration and routine maintenance. Once a year visit to site within warranty period including training of users on maintenance.
10.2	**Other accompanying documents**	List to be provided of important spares and accessories, with their part numbers and cost. Certificate of calibration and inspection to be provided.
11. NOTES		
11.1	**Service Support Contact details (Hierchy Wise; including a toll free/landline number)**	NA
11.2	**Recommendations or warnings**	Any recommendations for best use and supplimentary warning for safety should be declared.

OG TUBE INSERTION SIMULATION MODEL

Version no. :		1.0
Date:		7/4/2014
Done by : (name/institution)		HCT/ NHSRC
NAME AND CODING		
GMDN name		Gastric feeding tube
GMDN code		CT2268 (Gastrointestinal tubes and associated devices)
GMDN definition		An infant simulation model to practise insertion of nasal and oral tubes for the purpose of suction and feeding
GENERAL		
1. USE		
1.1	**Clinical purpose**	This model can be used to practice the insertion of suction catheters into oral cavity as well suction procedures, oral tube feeding, and gastrostomy care procedures, routinely applied in the nursing and caregiving fields.
1.2	**Used by Clinical Department**	Skill labs
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific to this type of device)**	1. The material of the mannequin should be of Polyvinyl and silicone rubber, free from any hazardous material. 2. The texture of the mannequin should be close to the feel of baby/adult skin as relevant. 3. The Internal parts of the mannequin must be realistically sculpted, anatomically accurate and feel must be smooth/resilient/bony as relevant and suitable for simulation. 4. Should look like 0-8 weeks old 5.should have soft and flexible and replaceable face skin and upper body skin, 6. placing NP/OP tubes must be possible, 8.should have markings for ear canal, should have removable internal parts.
2.2	**Settings**	NA
2.3	**User's interface**	NA
2.4	**Software and/or standard of communication (where ever required)**	NA
3. PHYSICAL CHARACTERISTICS		
3.1	**Dimensions (metric)**	NA
3.2	**Weight (lbs, kg)**	NA
3.3	**Configuration**	NA
3.4	**Noise (in dBA)**	NA
3.5	**heat dissipation**	NA
3.6	**Mobility, portability**	Yes, Portable

4. ENERGY SOURCE (Electricity, UPS, Solar, Gas, Water, CO_2 ....)		
4.1	**Power Requirements**	NA
4.2	**Battery operated**	NA
4.3	**Tolerance (to variations, shutdowns)**	NA
4.4	**Protection**	NA
4.5	**Power consumption**	NA
4.6	**Other energy supplies**	NA
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	**Accessories & spare parts**	NA
5.2	**Consumables/reagents (open, closed system)**	NA
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS		
6.1	**Atmosphere/Ambiance (air conditioning, humidity, dust ...)**	Capable of being stored continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90%. Capable of operating continuously in ambient temperature of 10 to 40 deg C and relative humidity of 15 to 90%.
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	Complete unit to be easily washable with mild soap and water without bringing deterioration in the mannequin.
7. STANDARDS AND SAFETY		
7.1	**Certifications**	BS EN ISO/IEC 17050-1:2010. Conformity assessment. Supplier's declaration of conformity. EMC Directive:2004/108/EC.
8. TRAINING AND INSTALLATION		
8.1	**Pre-installation requirements: nature, values, quality, tolerance**	NA
8.2	**Requirements for sign-off**	Demonstration to the user while delivering the product.
8.3	**Training of staff (medical, paramedical, technicians) OPTIONAL (Depending upon scope of work order)**	Training of users in handling and basic maintenance shall be provided.
9. WARRANTY AND MAINTENANCE		
9.1	**Warranty**	3 years against functionality excluding asthetics.
9.2	**Maintenance tasks**	maintainance manual detailing complete maintaining schedule.
9.3	**Service contract clauses, including prices**	Local clinical staff/authorized officer on behalf of purchaser to affirm completion of installation.
10. DOCUMENTATION		
10.1	**Operating manuals, service manuals, other manuals**	Advanced maintenance tasks required shall be documented User manuals to be supplied in english/hindi language along with visit log sheet. List to be provided of equipment and procedures required for local calibration and routine maintenance Once a year visit to site within warranty period including training of user on maintenance.
10.2	**Other accompanying documents**	List to be provided of important spares and accessories, with their part numbers and cost. Certificate of calibration and inspection to be provided.
11. NOTES		
11.1	**Service Support Contact details (Hierchy Wise; including a toll free/landline number)**	NA
11.2	**Recommendations or warnings**	Any recommendations for best use and supplimentary warning for safety should be declared.

POSTPARTUM HEMORRHAGE SIMULATION MODEL

Version no. :		1.0
Date:		7/4/2014
Done by : (name/institution)		HCT/ NHSRC
NAME AND CODING		
GMDN name		NA
GMDN code		NA
GMDN definition		A synthetic or rubber model which simulates Postpartum hemorrhage (PPH), which demonstrates different methods of prevention and management.
GENERAL		
1. USE		
1.1	**Clinical purpose**	It is used for teaching simulation of postpartum bleeding and allows students to practice fundal massage techniques.
1.2	**Used by clinical department**	Skill labs
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific to this type of device)**	1. The material of mannequin should be of polyvinyl or silicone rubber, free from any hazardous materials. 2. The model should be highly realistic for simulating postpartum hemorrhage. 3. The model should have features to manually control the amount of bleeding.
2.2	**Settings**	NA
2.3	**User's interface**	NA
2.4	**Software and/or standard of communication (where ever required)**	NA
3. PHYSICAL CHARACTERISTICS		
3.1	**Dimensions (metric)**	NA
3.2	**Weight (lbs, kg)**	NA
3.3	**Configuration**	NA
3.4	**Noise (in dBA)**	NA
3.5	**heat dissipation**	NA
3.6	**Mobility, portability**	Yes, Portable
4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ....)		
4.1	**Power Requirements**	NA
4.2	**Battery operated**	NA
4.3	**Tolerance (to variations, shutdowns)**	NA
4.4	**Protection**	NA
4.5	**Power consumption**	NA
4.6	**Other energy supplies**	NA

5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	**Accessories & spare parts**	The mannequin should have the following : 1. Full term fetus with placenta and umbilical cord 2. Red fluid Concentrate 3. Fluid Collection tray 4. Fluid drain 5. Urine catheter 6. 20 ml syringe 7. carrying bag
5.2	**Consumables/reagents (open, closed system)**	NA
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS		
6.1	**Atmosphere/Ambiance (air conditioning, humidity, dust ...)**	Capable of being stored continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90%. Capable of operating continuously in ambient temperature of 10 to 40 deg C and relative humidity of 15 to 90%.
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	Complete unit to be easily washable using mild soap and water without bringing deterioration in the mannequin.
7. STANDARDS AND SAFETY		
7.1	**Certifications**	BS EN ISO/IEC 17050-1:2010 Conformity assessment. Supplier's declaration of conformity. EMC Directive:2004/108/EC.
8. TRAINING AND INSTALLATION		
8.1	**Pre-installation requirements: nature, values, quality, tolerance**	NA
8.2	**Requirements for sign-off**	Demonstration to user while delivering the product.
8.3	**Training of staff (medical, paramedical, technicians) OPTIONAL (Depending upon scope of work order)**	Training of users in handling and basic maintenance shall be provided. Training features to include complete and incomplete placenta delivery, oxytocin injection, and controlled cord traction.
9. WARRANTY AND MAINTENANCE		
9.1	**Warranty**	3 years against functionality excluding asthetics.
9.2	**Maintenance tasks**	maintainance manual detailing complete maintaining schedule.
9.3	**Service contract clauses, including prices**	Local clinical staff/authorized officer on behalf of purchaser to affirm completion of installation.
10. DOCUMENTATION		
10.1	**Operating manuals, service manuals, other manuals**	Advanced maintenance tasks required shall be documented User manuals to be supplied in english language along with visit log sheet. List to be provided of equipment and procedures required for local calibration and routine maintenance Once a year visit to site within warranty period including training of user on maintenance.
10.2	**Other accompanying documents**	List to be provided of important spares and accessories, with their part numbers and cost. Certificate of calibration and inspection to be provided.
11. NOTES		
11.1	**Service Support Contact details (Hierchy Wise; including a toll free/landline number)**	NA
11.2	**Recommendations or warnings**	Any recommendations for best use and supplimentary warning for safety should be declared

Notes

Notes

Notes

NATIONAL HEALTH MISSION
Ministry of Health and Family Welfare
Government of India
website : www.nrhm.gov.in