



Ministry of Health and Family Welfare Government of India



Technical Specifications of Medical Devices for Skill Laboratories





Ministry of Health and Family Welfare Government of India

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भारत सरकार रवारथ्य एवं परिवार कल्याण विभाग स्वारथ्य 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)



C.K. Mishra, IAS Additional Secretary & Mission Director, NHM

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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



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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 subdistrict 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

Versio	on no. :	1.0		
Date:		7/4/2014		
Done by : (name/institution)		HCT/ NHSRC		
		NAME AND CODING		
	N name	NA		
GMDI	N code	1816		
GMDI	N definition	Lower adult female torso with anatomical features capable of demonstrating		
		various stages of pregnancy (5th, 7th and term)		
		GENERAL		
1 1	Clinian I manusara	1. USE		
1.1	Clinical purpose	To demonstrate Leopold maneuvers during pregnancy Skill labs		
1.2	Used by Clinical Department	TECHNICAL		
		2. TECHNICAL CHARACTERISTICS		
2.1	To do			
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.		
		 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. AC	CESSORIES, 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. ENVIRON	MENTAL 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 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		
10.2	Other accompanying	warranty period including training of user on maitenance. List to be provided of important spares and accessories, with their part		
	documents	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		
GMD	N name	Simulators (Resuscitation training model)		
	N code	CT1817, CT254		
GMD	N 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.		
		 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		
	,, por taxinity	L		

	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. AC	CESSORIES, 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. ENVIRON	MENTAL 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
GMDI	N name	Simulators and associated devices
GMDI	N code	CT2372
GMDI	N 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	
		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 S	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. AC	CESSORIES, 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. ENVIRON	MENTAL 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

Versio	on no. :	1.0
Date:		7/4/2014
Done by : (name/institution)		HCT/ NHSRC
		NAME AND CODING
GMDI	N name	Infusion/injection training model
GMDI	N 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 S	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. AC	CESSORIES, 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. ENVIRON	MENTAL AND DEPARTMENTAL CONSIDERATIONS
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
		CESSORIES, 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. ENVIRON	MENTAL 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.
	5	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	 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.
	 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.
	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).
	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. AC	CESSORIES, 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. ENVIRON	MENTAL 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,	Complete unit to be easily washable with mild soap and water without
	Disinfection & Sterility issues	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

Versio	on no. :	1.0		
Date:		7/4/2014		
Done by : (name/institution)		HCT/ NHSRC		
Done	NAME AND CODING			
GMDI	N name	Simulators		
GMDI	N code	CT602, CT152 (Peadiatrics).		
GMDI	N 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) 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) 6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS 6.1 Atmosphere/Ambiance (air conditioning, humidity, Capable of being stored continuously in ambient temperature of 0 to 5 C and relative humidity of 15 to 90%. Capable of operating continuously		
shutdowns) 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) 6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS 6.1 Atmosphere/Ambiance (air Capable of being stored continuously in ambient temperature of 0 to 5		
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 Capable of being stored continuously in ambient temperature of 0 to 5		
4.6 Other energy supplies NA 5. ACCESSORIES, SPARE PARTS, CONSUMABLES 5.1 Accessories & spare parts NA 5.2 Consumables/reagents (open, closed system) 6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS 6.1 Atmosphere/Ambiance (air Capable of being stored continuously in ambient temperature of 0 to 5		
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6.1 Atmosphere/Ambiance (air Capable of being stored continuously in ambient temperature of 0 to 5		
conditioning, humidity, C and relative humidity of 15 to 90%. Capable of operating continuously		
dust) ambient temperature of 10 to 40 deg C and relative humidity of 15 to 9	-	
6.2 User's care, Cleaning, 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: NA nature, values, quality, tolerance		
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 functionality excluding as the tics.		
9.2 Maintenance tasks maintainance manual detailing complete maintaining schedule.		
9.3 Service contract clauses, 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 be provided of equipment and procedures required for local calibration and routine maintenance Once a year visit to site within warranty periodicular including training of user on maintenance.	to 1	
10.2 Other accompanying List to be provided of important spares and accessories, with their part		
documents numbers and cost. Certificate of calibration and inspection to be provided	ed.	
11. NOTES		
11.1 Service Support Contact NA details (Hierchy Wise; including a toll free/landline number)		
11.2 Recommendations or Any recommendations for best use and supplimentary warning for safe	ty	

PEADIATRIC IV ARM KIT

Version no.:		1.0	
Date:		7/4/2014	
Done by : (name/institution)		HCT/ NHSRC	
	NAME AND CODING		
GMDI	N name	Infusion/injection training model.	
GMDI	N 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	
	Tarana a	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	1. The material of mannequin should be of polyvinyl or silicone rubber, free	
	(specific to this type of device)	from any hazardous material.	
		The texture of the mannequin should be close to the feel of the baby/ adult skin as relevant.	
		 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 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	

4.1 Power Requirements NA 4.2 Battery operated NA 4.3 Tolerance (to variations, shutdowns) 4.4 Protection NA 4.5 Power consumption NA 4.6 Other energy supplies NA 5. Accessories & spare parts Replaceable skin sets-25 Lubricant to be provided, if the type of mannequin requires the for effective frictioning. 5.1 Accessories & spare parts Replaceable skin sets-25 Lubricant to be provided, if the type of mannequin requires the for effective frictioning. 6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS 6. Atmosphere/Ambiance (air conditioning, humidity, dust) 6. User's care, Cleaning, Disinfection & Sterility issues 7. Tannopard Ambiance with the temperature of 0 to 50 dec (Cand relative humidity of 15 to 90%. Capable of operating continuously in ambient temperature of 10 to 40 deg Cand relative humidity of 15 to 90%. Capable of operating continuously in ambient temperature of 10 to 40 deg Cand relative humidity of 15 to 90%. Capable of operating continuously in ambient temperature of 10 to 40 deg Cand relative humidity of 15 to 90%. Capable of operating continuously in ambient temperature of 10 to 40 deg Cand relative humidity of 15 to 90%. Capable of operating continuously in ambient temperature of 10 to 40 deg Cand relative humidity of 15 to 90%. Capable of operating continuously in ambient temperature of 10 to 40 deg Cand relative humidity of 15 to 90%. Capable of operating continuously in ambient temperature of 10 to 40 deg Cand relative humidity of 15 to 90%. Capable of operating continuously in ambient temperature of 10 to 40 deg Cand relative humidity of 15 to 90%. Capable of operating continuously in ambient temperature of 10 to 40 deg Cand relative humidity of 15 to 90%. Capable of operating on the temperature of 10 to 40 deg Cand relative humidity of 15 to 90%. Capable of operating on the temperature of 10 to 40 deg Cand relative humidity of 15 to 90%. Ca	4. ENERGY SOURCE (Electricity, UPS, Solar, Gas, Water, CO ₂)		
4.2 Battery operated 4.3 Tolerance (to variations, shutdowns) 4.4 Protection 4.5 Power consumption 4.6 Other energy supplies 5. Accessories & spare parts 5. Accessories & spare parts 6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS 6. Consumables/reagents (open, closed system) 6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS 6.1 Atmosphere/Ambiance (air conditioning, humidity, dast) 6.2 User's care, Cleaning, Disinfection & Sterility issues 7. SANDARDS AND SAFETY 7.1 Certifications 8 SE NI SOJIEC 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 8.2 Requirements for sign-off 8.3 Training of staff (medical, paramedical, technicians) OPTIONAL (Depending upon scope of work order) 9.1 Warranty 9.2 Warranty 9.3 Service contract clauses, including prices 10.1 Operating manuals, service manuals, other manuals 10.1 Operating manuals, service manuals, other manuals 10.2 Other accompanying documents 11.1 Service Support Contact details (Hierchy Wise; including a toll free/andline number) 11.1 Service Support Contact details (Hierchy Wise; including a toll firee/andline number) 11.1 Service Support Contact details (Hierchy Wise; including a toll firee/andline number) 11.2 Service Support Contact details (Hierchy Wise; including a toll firee/andline number) 11.3 Service Support Contact details (Hierchy Wise; including a toll firee/andline number) 11.4 Service Support Contact details (Hierchy Wise; including a toll firee/andline number) 11.5 Service Support Contact details (Hierchy Wise; including a toll firee/andline number)	<u>4</u> 1		·
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S.1 Accessories & spare parts Replaceable skin sets-25 Lubricant to be provided, if the type of mannequin requirs it for effective finctioning.	4.6	Other energy supplies	NA
Feeding of Start (Certifications Certifications Start (Certifications Certifications		5. AC	CESSORIES, SPARE PARTS, CONSUMABLES
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11.2 Recommendations or warnings Any recommendations for best use and supplimentary warning for safety	11.1	details (Hierchy Wise; including	
should be declared	11.2	Recommendations or warnings	· · · · · · · · · · · · · · · · · · ·

UTERINE MODEL

Version no. :		1.0
Date:		7/4/2014
Done by : (name/institution)		HCT/ NHSRC
		NAME AND CODING
GMDI	N name	Uterine Cavity Simulator
GMDI	N code	CT1816
GMDI	N 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.
		 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, 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. AC	CESSORIES, SPARE PARTS, CONSUMABLES
5.1	Accessories & spare parts	NA
5.2	Consumables/reagents (open, closed system)	NA
	6. ENVIRON	MENTAL 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;	NA
	including a toll free/landline number)	

ESSENTIAL NEW BORN CARE AND RESUSCITATION MANNEQUIN

Version no. :	1.0	
Date:	7/4/2014	
Done by : (name/institution)	HCT/ NHSRC	
Bone by . (name, institution)	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 dev	The material of mannequin should be of polyvinyl and silicone rubber, free from any hazardous material.	
	The texture of the mannequin should be close to the feel of the baby/ adult skin as relevant.	
	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.	
	 Newborn mannequin should have features for training essential newborn care (ENBC) and newborn resuscitation. 	
	Newborn Mannequin should facilitate effective bag and mask ventilation, chest must rise only with correct technique.	
	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 or communication (where every required)		
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	

A.1 Power Requirements	4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2)		
4.2 Battery operated 4.3 Tolerance (to variations, shutdowns) 4.4 Protection 4.5 Power consumption 5. ACCESSORIES, SPARE PARTS, CONSUMABLES 5.1 Accessories & spare parts 5. 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) 6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS 6. Introsphere/Ambiance (air conditioning, humidity, dust) 6. User's care, Cleaning, Disinfection & Sterility issues 7. STANDARDS AND SAFETY 7.1 Certifications 8. SENISO/IEC 17050-1:2010 Conformity assessment. Supplier's declaration of conformity. 8. Pre-installation requirements: nature, values, quality, tolerance 8. Requirements for sign-off 8.3 Training of staff (medical, paramedical, technicians) OPTIONAL (Depending upon scope of work order) 9. Warranty 9. Wa	4.1	T T	
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	11.1	Service Support Contact	
		details (Hierchy Wise; including	
a toll free/landline number)		a toll free/landline number)	
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warnings should be declared	11.2	Recommendations or	

FEMALE CATHETERIZATION MANNEQUIN

Version	on no ·	1.0
Version no. : Date:		7/4/2014
Done by : (name/institution)		HCT/ NHSRC
2 00	by (claime, motitudies),	NAME AND CODING
GMDI	N name	Cervical Dialatation catheter, Indwelling Catheterization kit.
	N code	CT154 (Obstretics/Gynecology).
	N 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/	Skill labs
	wards	
		TECHNICAL
	1	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. 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	NA
	required)	
		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. AC	CESSORIES, SPARE PARTS, CONSUMABLES	
5.1	Accessories & spare parts	2 bladder tanks, 6 urethra valves	
5.2	Consumables/reagents (open, closed system)	NA	
	6. ENVIRON	MENTAL 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.	
	I	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

Date: 7/4/2014 Done by : (name/institution) HCT/ NHSRC NAME AND CODING	Versio	on no. :	1.0		
Done by : (name/institution)					
Infusion/Injection training mode (Anatomical Training Models).					
GMDN name	2 01.10	, , , , , , , , , , , , , , , , , , , ,			
GMDN code GMDN definition A synthetic replica of lower torso for demonstrating IM injections in gluteal region. GENERAL 1. USE 1.1 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). TECHNICAL 2. TECHNICAL CHARACTERISTICS 2.1 Technical characteristics (specific to this type of device) Siblication of simulated injection fluid (water). TECHNICAL 2. TECHNICAL CHARACTERISTICS 3. The material of mannequin should be of polyvinyl or silicone rubber, free from any hazardous materials. 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 is 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). 7. Should have intramuscular injection in ventrogluteal site below iliac crest on both side (left and right). 8. PHYSICAL CHARACTERISTICS 3.1 Dimensions (metric) 3.2 Weight (lbs, kg) 3.3 Configuration 3.4 Noise (in dBA) NA 3.5 heat dissipation NA	GMD	N name			
A synthetic replica of lower torso for demonstrating IM injections in gluteal region. Continuous	GMD	N code			
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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	2.4	communication (where ever	NA		
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3.3ConfigurationNA3.4Noise (in dBA)NA3.5heat dissipationNA	3.1	Dimensions (metric)	NA		
3.4 Noise (in dBA) NA 3.5 heat dissipation NA	3.2	Weight (lbs, kg)	NA		
3.5 heat dissipation NA	3.3	Configuration	NA		
	3.4	Noise (in dBA)	NA		
3.6 Mobility, portability Yes, Portable	3.5	heat dissipation	NA		
	3.6	Mobility, portability	Yes, Portable		

	4 ENEDGY C	SOURCE (electricity, UPS, solar, gas, water, CO2)
4.1	Power Requirements	NA
4.1	Battery operated	NA NA
4.3	Tolerance (to variations,	NA NA
4.5	shutdowns)	IVA
4.4	Protection	NA
4.5	Power consumption	NA
4.6	Other energy supplies	NA
		CESSORIES, SPARE PARTS, CONSUMABLES
5.1	Accessories & spare parts	NA
5.2	Consumables/reagents (open, closed system)	NA
	•	MENTAL AND DEPARTMENTAL CONSIDERATONS
6.1	Atmosphere/Ambiance (air	Capable of being stored continuously in ambient temperature of 0 to 50 deg
	conditioning, humidity,	C and relative humidity of 15 to 90%. Capable of operating continuously in
	dust)	ambient temperature of 10 to 40 deg C and relative humidity of 15 to 90%.
6.2	User's care, Cleaning,	Complete unit to be easily washable with mild soap and water without
	Disinfection & Sterility issues	bringing deterioration to the mannequin.
7.1	Cautification	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:	NA
	nature, values, quality, tolerance	
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,	Local clinical staff/authorized officer on behalf of purchaser to affirm
	including prices	completion of installation.
		10. DOCUMENTATION
10.1	Operating manuals, service	Advanced maintenance tasks required shall be documented.
	manuals, other manuals	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	Any recommendations for best use and supplimentary warning for safety

OG TUBE INSERTION SIMULATION MODEL

Version no. :	1.0		
Date:	7/4/2014		
Done by : (name/institution)	HCT/ NHSRC		
Done by . (name/institution)	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		
dividit delimition	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		

		SOURCE (Electricity, UPS, Solar, Gas, Water, CO2)		
4.1 Po	Power Requirements	NA		
	Battery operated	NA NA		
4.3 T o	olerance (to variations, hutdowns)	NA NA		
	Protection	NA		
	ower consumption	NA		
4.6 O	Other energy supplies	NA		
	5. AC	CESSORIES, SPARE PARTS, CONSUMABLES		
5.1 A	Accessories & spare parts	NA		
	Consumables/reagents (open, closed system)	NA		
	6. ENVIRON	MENTAL AND DEPARTMENTAL CONSIDERATONS		
co	Atmosphere/Ambiance (air conditioning, humidity, lust)	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%.		
	Jser'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 C	Certifications	BS EN ISO/IEC 17050-1:2010. Conformity assessment. Supplier's declaration of conformity. EMC Directive:2004/108/EC.		
	8. TRAINING AND INSTALLATION			
	Pre-installation requirements: nature, values, quality, tolerance	NA		
8.2 R	Requirements for sign-off	Demonstration to the user while delivering the product.		
p: O	raining of staff (medical, paramedical, technicians) OPTIONAL (Depending upon cope of work order)	Training of users in handling and basic maintenance shall be provided.		
·		9. WARRANTY AND MAINTENANCE		
9.1 W	Varranty	3 years against functionality excluding asthetics.		
9.2 M	Maintenance tasks	maintainance manual detailing complete maintaining schedule.		
	Service contract clauses, ncluding prices	Local clinical staff/authorized officer on behalf of purchaser to affirm completion of installation.		
		10. DOCUMENTATION		
	Operating manuals, service nanuals	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.		
	Other accompanying	List to be provided of important spares and accessories, with their part		
d	locuments	numbers and cost. Certificate of calibration and inspection to be provided. 11. NOTES		
d _e in	Service Support Contact details (Hierchy Wise; ncluding a toll free/landline number)	NA		
	Recommendations or varnings	Any recommendations for best use and supplimentary warning for safety should be declared.		

POSTPARTUM HEMORRHAGE SIMULATION MODEL

Date: 7/4/2014 Done by : (name/institution) HCT/ NHSRC NAME AND CODING GMDN name NA GMDN code NA	Versio	on no.:	1.0		
Done by : (name/institution) HCT/ NHSRC NA					
MAME AND CODING GMDN name GMDN code 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 TECHNICAL TECHNICAL 2. TECHNICAL CHARACTERISTICS 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. 3. The model should have features to manually control the amount of bleeding. 3. The model should have features to manually control the amount of communication (where ever required) 3. PHYSICAL CHARACTERISTICS 3.1 Dimensions (metric) 3. PHYSICAL CHARACTERISTICS 3.1 Dimensions (metric) 3. PHYSICAL CHARACTERISTICS 3.1 Dimensions (metric) NA 3.2 Weight (lbs, kg) 3.3 Configuration NA 3.4 Noise (in dBA) 3.5 heat dissipation NA 3.6 Mobility, portability 4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2) 4.1 Power Requirements NA 4.2 Battery operated NA 7. Olerance (to variations, shutdowns) NA 4.4 Protection NA Power consumption NA			., ,,==		
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. Skill labs TECHNICAL 2. TECHNICAL CHARACTERISTICS 2.1 Technical characteristics (specific to this type of device) 5. The model should be highly realistic for simulating postpartum hemorrhage. 3. The model should be highly realistic for simulating postpartum hemorrhage. 3. The model should have features to manually control the amount of bleeding. 3. The model should have features to manually control the amount of bleeding. 3. The model should have features to manually control the amount of bleeding. 3. PHYSICAL CHARACTERISTICS 3. PHYSICAL CHARACTERISTICS 3. PHYSICAL CHARACTERISTICS 3. Dimensions (metric) NA 3. PHYSICAL CHARACTERISTICS 3. PHYSICAL CHARACTERISTICS	Done	by . (name, mateution,			
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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. Skill labs TECHNICAL 2. TECHNICAL 2. TECHNICAL CHARACTERISTICS 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) 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 7.4 Protection NA NA NA NA NA NA NA Power consumption NA NA NA NA NA Power consumption NA NA NA NA NA NA NA NA NA N	GMDI	N code			
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3.4 Noise (in dBA) 3.5 heat dissipation 3.6 Mobility, portability 4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2) 4.1 Power Requirements 4.2 Battery operated 4.3 Tolerance (to variations, shutdowns) 4.4 Protection NA NA NA NA NA NA NA NA NA N	3.2	Weight (lbs, kg)	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) 4.4 Protection NA 4.5 Power consumption NA	3.3	Configuration	NA		
3.6 Mobility, portability 4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2) 4.1 Power Requirements NA 4.2 Battery operated NA 1.3 Tolerance (to variations, shutdowns) 4.4 Protection NA NA NA NA NA NA NA NA	3.4	Noise (in dBA)	NA		
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 4.1 Power Requirements NA 4.2 Battery operated NA 4.3 Tolerance (to variations, shutdowns) 4.4 Protection NA 4.5 Power consumption NA 	3.6	Mobility, portability	Yes, Portable		
4.2 Battery operated NA 4.3 Tolerance (to variations, shutdowns) 4.4 Protection NA 4.5 Power consumption NA	4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2)				
4.3 Tolerance (to variations, shutdowns) 4.4 Protection NA 4.5 Power consumption NA	4.1	Power Requirements	NA		
shutdowns) 4.4 Protection NA 4.5 Power consumption NA	4.2	Battery operated	NA		
4.5 Power consumption NA	4.3		NA		
·	4.4	Protection	NA		
4.6 Other energy supplies NA	4.5	Power consumption	NA		
	4.6	Other energy supplies	NA		

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) 6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS 6.1 Atmosphere/Ambiance (air conditioning, humidity, dust) 6.2 User's care, Cleaning, Disinfection & Sterility issues 7. STANDARDS AND SAFETY 7.1 Certifications 8.2 Experiments for sign-off staff (medical, paramedical, technicians) 9.1 OPTIONAL (Depending upon scope of work order) 9.2 Warranty 9.3 Maintenance tasks 8.4 Service contract clauses, including prices 10. DOCUMENTATION 10. Operating manuals, service manuals, other manuals Accessories & spare parts 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 7. carrying bag 7. carrying bag 8. Capable of being stored continuously in ambient temperature of 0 to 10 to 40 deg C and relative humidity of 15 to 10 to 40 deg C and relative humidity of 15 to 10 to 40 deg C and relative humidity of 15 to 15 to 90%. Capable of operating continuously in ambient temperature of 0 to 10 to 40 deg C and relative humidity of 15 to 10 to 40 deg C and relative humidity of 15 to 15 to 90%. Capable of operating ontinuously in ambient temperature of 10 to 2 deg C and relative humidity of 15 to 15 to 90%. Capable of operating continuously in ambient temperature of 10 to 2 deg C and relative humidity of 15 to 15 to 90%. Capable of poperating ontinuously in ambient temperature of 10 to 2 deg C and relative humidity of 15 to 15 to 90%. Capable of perating ontinuously in ambient temperature of 10 to 2 deg C and relative humidity of 15 to 15 to 10 to 40 deg C and relative humidity of 15 to 15 to 10 to 40 deg C and relative humidity of 15 to 15 to 15 to 15 to 10 to 40 deg C and relative humidity of 15 to 15 to 15	5. ACCESSORIES, SPARE PARTS, CONSUMABLES			
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· · · ·			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. NOTES	
11.1 Service Support Contact NA details (Hierchy Wise; including a toll free/landline number)		details (Hierchy Wise; including		
11.2 Recommendations or warnings Any recommendations for best use and supplimentary warning for safe should be declared			Any recommendations for best use and supplimentary warning for safety should be declared	

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