

PROMPT Birthing Simulator Force Monitoring



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Declaration of Conformity

We affirm that the electrical equipment manufactured by us fulfils the requirements of the Low Voltage Directive (LVD) 73/23/EEC amended by directive 93/68/EEC, and the Directive of Electromagnetic Compatibility (EMC) 89/336/EEC amended by directives 91/263/EEC, 92/31/EEC, 93/68/EEC and 93/97/EEC.

Name of manufacturer	Limbs & Things Ltd.
Manufacturer contact details	Sussex Street St Philips Bristol BS2 0RA Tel. 0117 311 0500 Fax. 0117 311 0501
Description of product	Birthing trainer – USB interface.
Trade name & model, part number, and serial number of the product	"PROMPT Birthing Trainer - Force Monitoring" Part No: 80005 Every unit's assembly has been registered in our database.

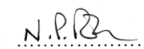
The products accordance with the LVD has been verified through our technical documentation TN_LAT003_05 (22-02-06).

The product fulfils the relevant requirements of the EMC Directive according to our technical documentation TN_LAT003_05 (22-02-06). The technical documentation has been verified to be correct by the competent body PaniK Technology Unit 10 Avon Business Park, Lodge Causeway, Bristol BS16 3JP.

The construction of the product is in accordance with the afore-mentioned directives as detailed in the Technical Construction File.

The appliance is CE-marked 2006.

Limbs & Things Ltd.

 (signature)

Nic RILEY (name), Managing Director



In order for this equipment to satisfy CE requirements then this equipment must only be used with CE-marked equipment.

This is NOT a toy and must only be operated by a competent person. It is for professional training purposes only.

Never modify the equipment or an accessory under any circumstances.

Do not operate this equipment in environments containing explosive materials or vapours.

This equipment is designed for indoor use only. Do not expose to rain or moisture.

The affixed manufacturer labels must not be removed, changed or obscured in any way.

Do not remove the cover or disassemble in any way. No user serviceable parts inside. Refer servicing to Limbs & Things Ltd.

Do not use if the equipment appears damaged or faulty. Refer servicing to Limbs & Things Ltd.

If the overload indicator is or has been on then the equipment must be returned to Limbs & Things Ltd for servicing.

Introduction

The PROMPT Birthing Simulator provides a platform for the teaching and acquisition of the practical skills required for the successful management of childbirth. It has been developed for multi professional training, in conjunction with midwives and obstetricians from Southmead Hospital, Bristol (UK) and Gloucestershire Royal Hospital (UK). It is an integral part of the PROMPT (PRactical Obstetric Multi-Professional Training) course.

Affectionately known as 'Nellie' during its development, the PROMPT Birthing Simulator incorporates a number of features which enhance training: an anatomically correct bony pelvis in the mother (modelled from CT scan data), silicone pelvic floor musculature and a stretchable perineum. The baby is of newborn size and weight, is fully articulated, and features the correct anatomical landmarks such as fontanelles, clavicles and scapulae.

In addition to being an all-round birthing simulator for all levels of trainee, this product was specifically designed to enable doctors and nurses to learn and practise the manoeuvres required to manage shoulder dystocia, an unpredictable and largely unpreventable obstetric emergency. Annual drill training for the management of shoulder dystocia is a requirement for the maternity Clinical Negligence Scheme for Trusts (CNST) level II in the UK, and is recommended by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) in the USA.

Obstetric brachial plexus injury (OBPI) is a serious neonatal complication of shoulder dystocia which may be associated with excessive traction applied during delivery¹. The unique force monitoring baby incorporates a strain gauge linked to a computer for the measurement and recording of the force applied to the baby by the *accoucheur* during delivery.

The PROMPT Birthing Simulator, with its force monitoring capability, has been used for a UK Department of Health funded study, SaFE (Simulation and Fire-drill Evaluation), to investigate training for obstetric emergencies. During the product development stage, midwives and obstetricians, who received training using a prototype, demonstrated a significant objective improvement in the management of simulated shoulder dystocia².

In addition to training for deliveries complicated by shoulder dystocia, this high fidelity birthing simulator realistically simulates normal delivery, in semi-recumbent and 'all fours' positions, as well as vaginal breech and instrumental (forceps and ventouse) deliveries.

¹ *Risk Factors for Shoulder Dystocia: an engineering study of clinician-applied forces* Allen R, Sorab J, Gonik B. Dept of Mechanical Engineering, University of Delaware, Newark. Obstet Gynecol. 191 Mar;77 (3) :352-5

² *Shoulder dystocia training using a new birth training mannequin*

Joanna F Crofts, Georgios Attilakos, Mike Read, Thabani Sibanda, Timothy J Draycott. RCOG 2005 BJOG: an International Journal of Obstetrics and Gynaecology 112, pp. 1-3



Normal delivery



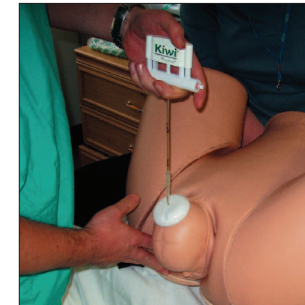
Delivery of posterior arm with Shoulder Dystocia



Forceps delivery



Delivery of placenta



Ventouse delivery



Breech delivery



Mother on 'all fours' delivery

PROMPT Birthing Simulator - Force Monitoring

Part No: **80005**

This version of the Simulator includes the force monitoring baby which is fitted with an electronic strain gauge allowing for the measurement of force applied to the baby as it is delivered.

Skills

- Normal delivery
- Breech delivery
- Delivery on all fours
- Shoulder dystocia management
- Vacuum delivery
- Forceps delivery: traction and rotational deliveries
- Delivery of placenta

Features

Baby

- Fully articulated body
- Force monitoring system including computer software package for simultaneous force display, measurement and recording of data
- Weight 2.3 kg
- Palpable fontanelles and suture lines
- Palpable clavicles and scapulae
- Detachable placenta with cord

Mother

- Movable legs: semi-recumbent, lithotomy position, McRoberts' position and 'all fours' position
- Realistic pelvis modelled from CT scan data
- Detachable abdominal and perineal skin to enable clear view of internal manoeuvres and foetal positioning during training
- Durable, stretchy silicone skin and perineal musculature
- Detachable base with securing straps to allow fixing to table or delivery bed
- Patient actor can be integrated with birthing mother for training sessions

Package supplied

- 1 **Lubricant (250ml)** Part No: **50181**
- 1 **Birthing Placenta** Part No: **80023**
- 1 **Birthing Baby - Force Monitoring** Part No: **80022**
- 1 **Birthing Mother** Part No: **80020**
 - 1 **Birthing Abdomen & Perineum Skin** Part No: **80024**
 - 1 **Birthing Perineal Muscles** Part No: **80026**
 - 1 lower torso with removable base & straps
- 1 carry case

Components



Birthing Mother

Part No: **80020**



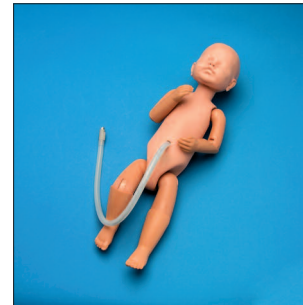
Birthing Perineal Muscles

Part No: **80026**



Birthing Abdomen & Perineum Skin

Part No: **80024**



Birthing Baby - Force Monitoring

Part No: **80022**

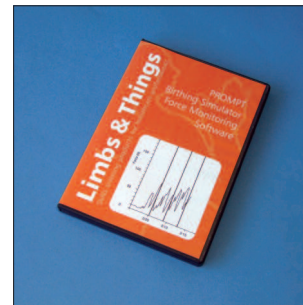


Force Monitoring Interface Unit



Computer leads:

- PS2 baby lead
- USB computer lead



Force Monitoring Software CD-ROM



Birthing Placenta

Part No: **80023**



Birthing Lubricant (250ml)

Part No: **50181**

Unpacking/packing

1



To remove the product from the case, securely and easily: with one hand grasp the torso end whilst supporting the buttocks with the other hand. Lift the Mother out from the case.

The Baby case is underneath.

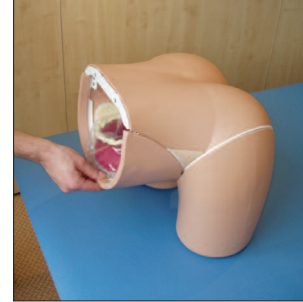
2



Note
When repacking, the Baby case should be put in first: it supports the abdomen of the Mother.

Preparing the Birthing Mother

1



Place the Mother on the work surface in the all fours position.

Use the Baby case as a support under the abdomen.

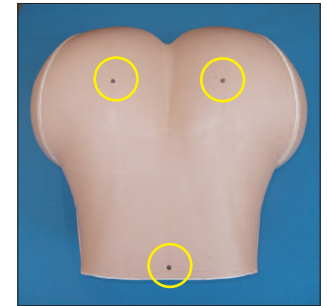
2



Remove any other items from inside the Mother.

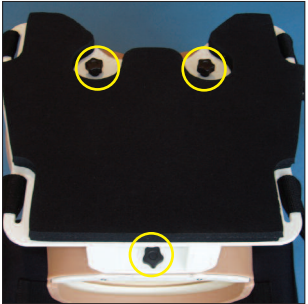
Place the Base upside down on the back of the Mother, aligning the holes.

3



The three holes in the Base should line up with those on the back of the Mother.

4



Fix the Base in position by tightening the single turn knob.

Secure the Base in place by tightening the remaining two. Ensure all three turn knobs are secure.

Note
Do not overtighten the knobs.

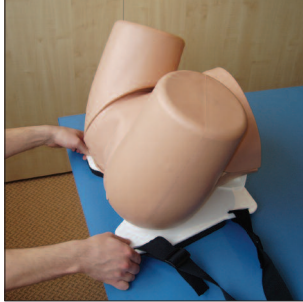
5



Remove the Baby case from under the abdomen.

Tilt the Mother towards to the edge of the work surface.

6



Turn the Mother over and place on the work surface. Adjust the position, ensuring that the Mother is close to the edge for easy access whilst training.

Line up the black securing straps ensuring that they run parallel with each other and that they hang over the sides of the work surface or delivery bed.

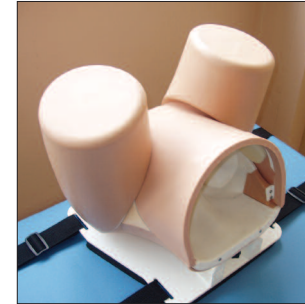
7



Draw the ends of one of the pair of straps together underneath the work surface and clip together.

Tighten by pulling the loose end.

8



Ensure both sets of straps are fully tightened.

The Mother should now be firmly secured to the work surface and ready to use.

Accessing the pelvis

1



The Abdomen & Perineum Skin can be removed easily to facilitate correct positioning of the Baby within the pelvis. Ensure the legs are lying flat.

Peel the Skin away from the support hoop. Start at one end and work along it until it is completely free.

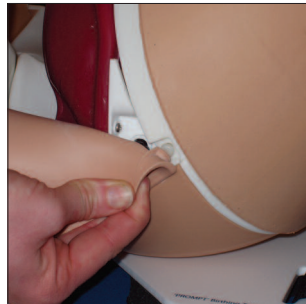
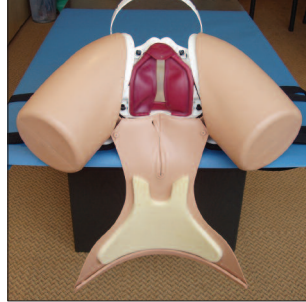
2



Lift away from hoop.

Pull back over the pubic symphysis.

3



Ensure that the perineal muscles are completely exposed. The Mother is now ready to be set up for a procedure.

Note
When reattaching the Skin the 2 corner studs should be engaged.

Connecting the Placenta to the Baby

1



To attach the Baby to the Placenta align the ends of the leads so that the flat faces with the double arrows are towards you.

Gently push together.

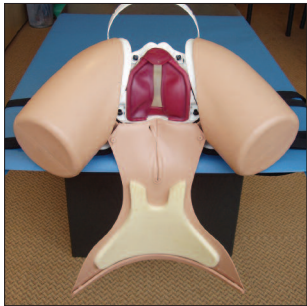


To identify the type of Baby:

The Force Monitoring Baby has a serial number and a red band on the end of the connector.

The Standard Baby has a green band on the connector.

Normal delivery



Remove the Abdomen & Perineum Skin before continuing with the setup. For full instructions on how to do this see the section 'Accessing the pelvis' on page 10.

1



Using the lubricant provided, spray the perineal muscles 2 or 3 times.

Spread the lubricant evenly over the surfaces of the muscles, both front and back.

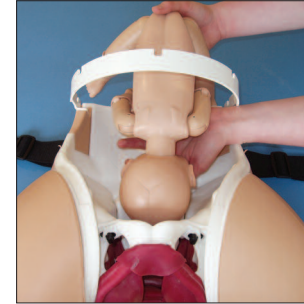
2



Spray the Baby 2 or 3 times.

Spread the lubricant over the head and upper body.

3



With the Baby's arms and legs fully extended, position the Baby face down (OA) in the pelvis.

Advance the head until it is engaged in the pelvis. Ensure the shoulders are in the oblique position.

4



Replace the Skin. The Simulator is now ready for use. To conduct a normal delivery the trainer needs to push the Baby through the pelvis, rotating the Baby as appropriate to mimic the mechanism of normal delivery.

Note
When you have finished with the Simulator, remove any lubricant from the Mother and Baby using the supplied wipes.

Extended breech delivery



Remove the Abdomen & Perineum Skin before continuing with the setup. For full instructions on how to do this see the section 'Accessing the pelvis' on page 10.

1



Using the lubricant provided, spray the perineal muscles 2 or 3 times.

Spread the lubricant evenly over the surfaces of the muscles, both front and back.

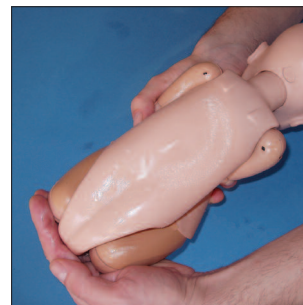
2



For an extended breech delivery extend the Baby's legs and flex the arms.

Spray the Baby's back and bottom 2 or 3 times.

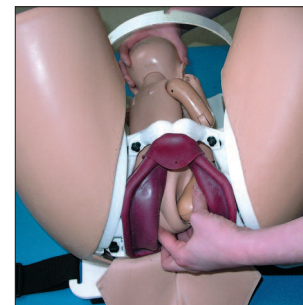
3



Spread the lubricant evenly over the back and bottom.

Load the Baby, with the Baby's sacrum in the oblique diameter, into the pelvis.

4



Pull the Baby into the pelvis from below so the buttocks present through the perineal muscles.

Reattach the Skin.

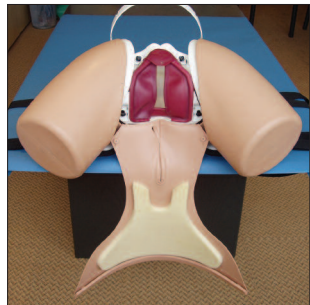
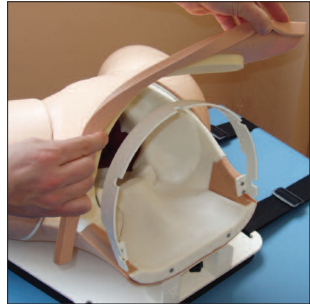
5



Push on the head from above (picture shown with Skin removed) to simulate contractions and maternal effort. Ensure the Baby's arms remain flexed during the delivery (unless nuchal arms are required for training).

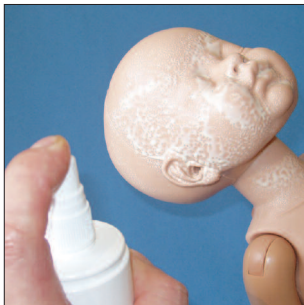
Note
When you have finished with the Simulator, remove any lubricant from the Mother and Baby using the supplied wipes.

Shoulder dystocia



Remove the Abdomen & Perineum Skin before continuing with the setup. For full instructions on how to do this see the section 'Accessing the pelvis' on page 10.

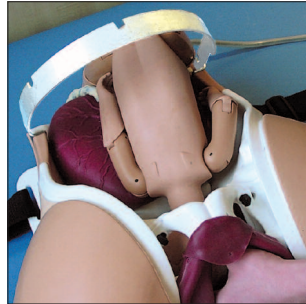
1



Using the lubricant provided, spray the perineal muscles 2 or 3 times. Spread the lubricant evenly over the surfaces of the muscles, both front and back.

Spray the Baby's head 2 or 3 times. Spread the lubricant evenly over the head. Any excess lubricant can be applied to the Baby's shoulders.

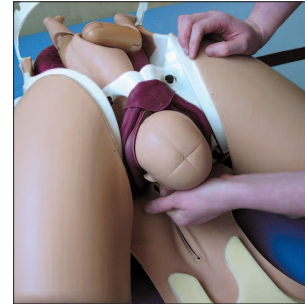
2



The Placenta can be placed inside the Mother to cushion the trainer's hand whilst holding the Baby in position during training.

Place the Baby's head into the pelvis in the OA position.

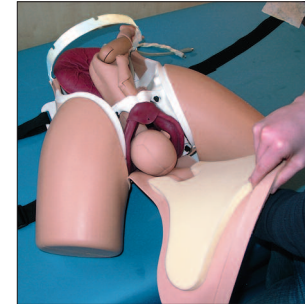
3



Deliver the Baby's head through the perineal muscles by flexion from below.

Ensure that the anterior shoulder of the Baby is wedged behind the symphysis pubis, the baby must be held in this position by the trainer when delivery commences.

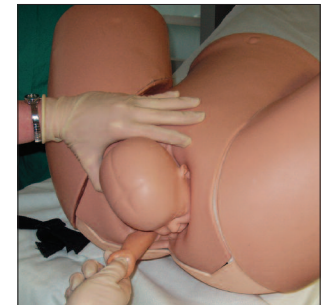
4



Pull the Skin over the Baby's head.

Pull the head through the vaginal opening.

5



Fasten the Skin. The Simulator is ready to use.

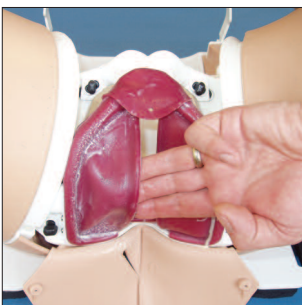
Note
The Baby will need to be held in the shoulder dystocia position until the trainee has performed appropriate manoeuvres to facilitate delivery. You may decide to hold the Baby in position only until McRoberts or suprapubic pressure has been performed, or continue holding until all the correct internal manoeuvres have been performed.

Instrumental delivery - forceps

1



Remove the Abdomen & Perineum Skin before continuing with the setup. For full instructions on how to do this see the section 'Accessing the pelvis' on page 10.



Using the lubricant provided, spray the perineal muscles 2 or 3 times.

Spread the lubricant evenly over the surfaces of the muscles, both front and back.

Note
Do not lubricate the baby too much as lubrication may prevent the forceps from grasping securely.

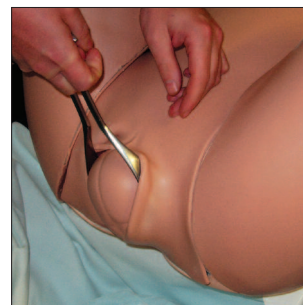
2



Load the Baby in to the pelvis in the position required for teaching such as OA, ROT, OP. Reattach the Skin.

The trainer/patient needs to gently hold the first blade in place from within the pelvis until the second blade has been applied and the forceps have been locked together. (Shown with Skin removed).

3



The placement of the forceps blades can be seen by peeling back the Skin. Whilst the Baby's head is being delivered make sure the shoulders enter the Mother's pelvis in the oblique or AP diameter. If a rotational instrumental delivery is performed, the trainer should ensure the appropriate rotation of the Baby's body in relation to the Baby's head within the pelvis.

The Simulator is now ready to use.

Note
When you have finished with the Simulator, remove any lubricant from the Mother and Baby using the supplied wipes.

Instrumental delivery - vacuum device

1



Remove the Abdomen & Perineum Skin before continuing with the setup. For full instructions on how to do this see the section 'Accessing the pelvis' on page 10.



Using the lubricant provided, spray the perineal muscles 2 or 3 times.

Spread the lubricant evenly over the surfaces of the muscles, both front and back.

Note
Do not lubricate the Baby too much as lubrication may prevent the vacuum device from attaching securely.

2



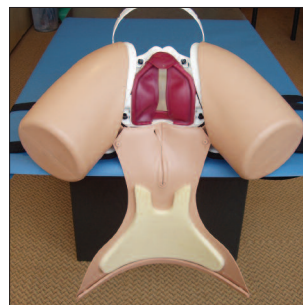
Load the Baby in the Mother's pelvis in the position required for teaching such as OA, ROT, OP. Reattach the Skin.

Apply vacuum device to the Baby's head. Whilst the Baby's head is being delivered make sure the Baby's shoulders enter the Mother's pelvis in the oblique or AP diameter.

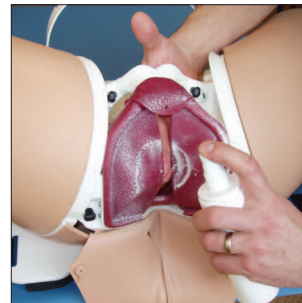
Note
When you have finished with the Simulator, remove any lubricant from the Mother and Baby using the supplied wipes.

Delivery on all fours

1



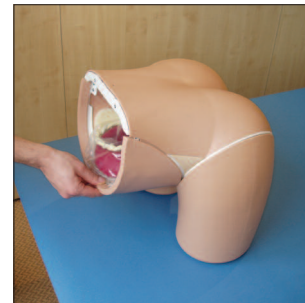
Remove the Abdomen & Perineum Skin before continuing with the setup. For full instructions on how to do this see the section 'Accessing the pelvis' on page 10.



Using the lubricant provided, spray the perineal muscles 2 or 3 times.

Spread the lubricant evenly over the surfaces of the muscles, both front and back. Reattach the Skin.

2



Place the Mother onto the work surface in the all fours position.

To support the Mother rest the abdomen on something soft such as the Baby case or pillows. The angle of the Mother's torso and pelvis can be changed by placing a higher support under the abdomen.

3



Spray the Baby's head 2 or 3 times.

Spread the lubricant evenly over the head.

4



Position the Baby inside the Mother as seen in the 'Normal delivery' section, stages 3 & 4 (page 12).

To conduct a normal delivery the trainer should push the Baby through the pelvis, rotating the Baby as appropriate to mimic the mechanism of normal delivery.

5

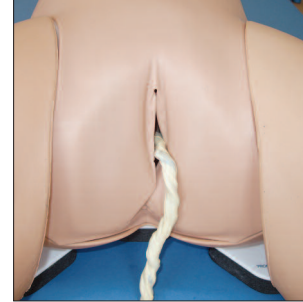


The Simulator is now ready to use.

Note
When you have finished with the Simulator, remove any lubricant from the Mother and Baby using the supplied wipes.

Management of 'Third stage'

1

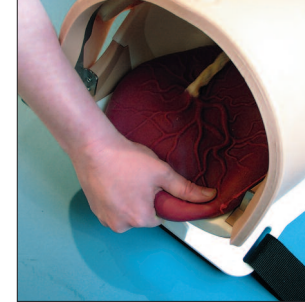


Ensure that the umbilical cord is partially delivered.



Cord traction can be practised to establish if separation of the Placenta has occurred.

2



The trainer can hold the Placenta in situ to represent an attached Placenta or it can be left free to represent a placenta that has separated.

Note
When you have finished with the Simulator, remove any lubricant from the Mother and Placenta using the supplied wipes.



Replacing the Abdomen & Perineum Skin

1



Ensure the legs are lying flat.

Peel the abdominal end of the Abdomen & Perineum Skin away from the support hoop. Start at one end and work along until it is completely free.

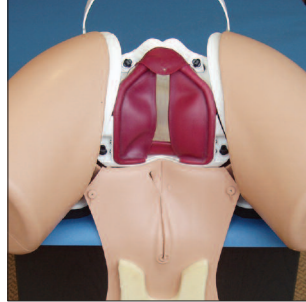
2



Lift the Skin away from the hoop.

Pull it back over the pubic symphysis until only the perineal end is attached.

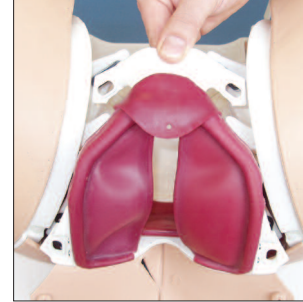
3



The Perineal Muscle frame must be detached to allow access to the perineal end of the skin.

Release the frame from the pelvis by turning the four black clips.

4



Remove the frame.

Note
During reassembly, the bottom of the frame is inserted between the lower perineal muscle and the perineal end of the skin.

5



The studs securing the perineal end of the Skin are now exposed.

Starting from one end, gently pull the Skin off.

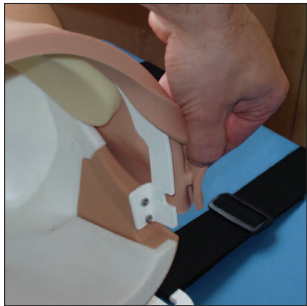
6



The Mother is now ready to have a new Abdomen & Perineum Skin fitted. Reverse the stages for fitting.

Replacing the Perineal Muscles

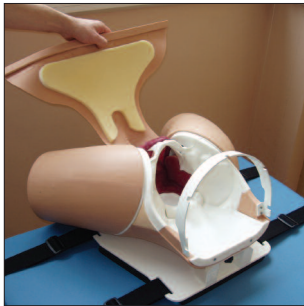
1



Ensure the legs are lying flat.

Peel the abdominal end of the Abdomen & Perineum Skin away from the support hoop. Start at one end and work along until it is completely free.

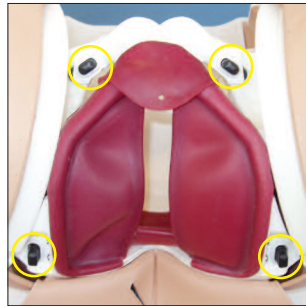
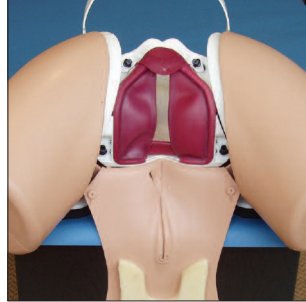
2



Lift the Skin away from the hoop.

Pull it back over the pubic symphysis until only the perineal end is attached.

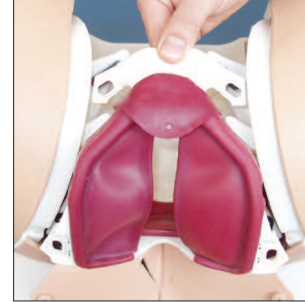
3



The Perineal Muscle frame must be detached to allow access to the perineal end of the skin.

Release the frame from the pelvis by turning the four black clips.

4



Remove the frame. Reverse the stages for fitting replacement Perineal Muscles.

Note
During reassembly, the bottom of the frame is inserted between the lower perineal muscle and the perineal end of the Skin.

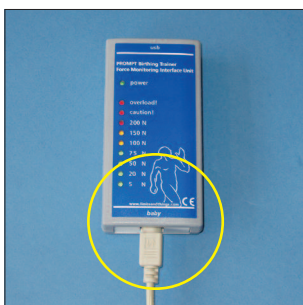
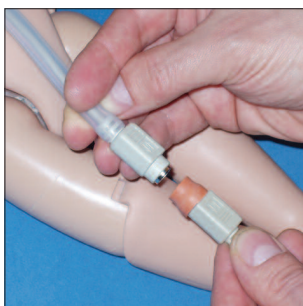
Hardware & software quick start guide

Ensure that the computer meets the minimum system requirements:
 Operating system:
 - Windows 2000 / XP
 Hardware:
 - USB 1.1 port
 - CD-ROM drive
 Monitor:
 - 800 x 600 pixels in 16-bit (65536 colours)
 Start up the computer.



PS2 baby lead.
 USB computer lead.

1

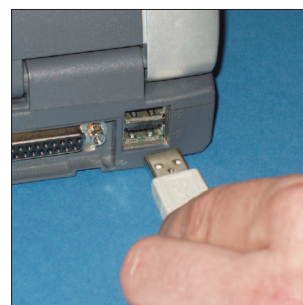
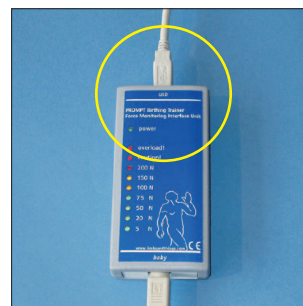


If you have a PROMPT Birthing Simulator - Value Set and need to identify which Baby you are connecting, see the section 'Connecting the Placenta to the Baby' on page 11.

Connect the end of the PS2 baby lead, with the orange ring, to the umbilical cord on the Baby.

Connect the other end of the PS2 baby lead to the socket on the Force Monitoring Interface Unit marked 'baby'.

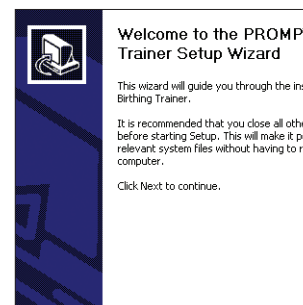
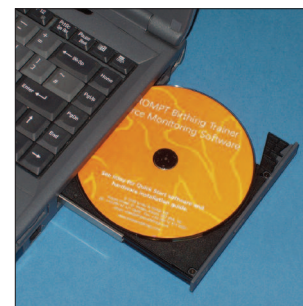
2



Connect the 'square' end of the USB computer lead to the socket on the Interface Unit marked USB.

Connect the 'flat' end of the USB lead to a spare USB socket on the computer. The computer should report that it has found the Birthing Simulator, and will install new hardware for it. (Reboot the computer if requested to do so.)

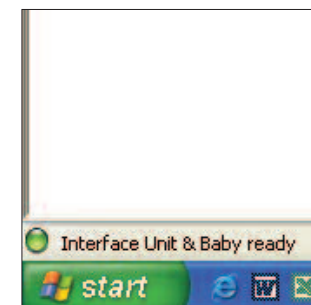
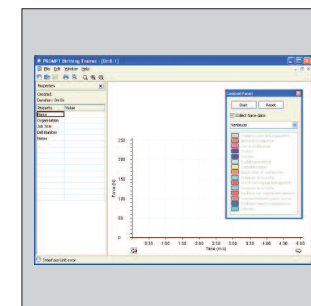
3



Insert the software CD-ROM into the drive. The CD browser program should automatically run. (If it does not, use Windows Explorer to navigate to the CD-ROM drive. Double click **cdstart.exe** to launch the CD browser program).

To install the Force Monitoring Software, click on the install button and follow the instructions in the installation wizard.

4



Launch the application.
 Check that the computer recognises the attached hardware: the Status Bar in the bottom left hand corner of the program window displays 'Interface Unit & Baby ready' and a green light.
 See the separate user guide supplied with the Force Monitoring Baby for detailed instructions on how to use the application.