SIMone™

P80/1

BIRTH SIMULATOR OPERATING INSTRUCTIONS

SIMone™

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› 1. OVERVIEW

1.1 Summary

The SIM*one*™ birth simulator is used to simulate birth processes interactively. During a birth scenario, the user assesses the birth process, makes decisions and implements measures, and discusses them with a trainer at the end of the process. During a simulation, the participants practice – depending on the scenario – the correct use of the instruments used for an operative vaginal delivery and the management of complications during childbirth.

1.2 Overview of the birth simulator

PC with touchscreen interface

Torso of the female abdomen

Mobile base with height adjustment

Figure 1: Overview of the birth simulator

› 2. GENERAL INFORMATION

2.1 Information on the operating instructions
These operating instructions contain important information on the safe and efficient use of the simulator. They are an integral part of the simulator and must be kept in its immediate vicinity and accessible at all times for staff working on or with it. Staff must have carefully read and understood these operating instructions before beginning any work. A basic prerequisite for safe operation is compliance with all instructions concerning safety and use. In addition, the local accident prevention regulations and general safety provisions applicable at the location at which the simulator is used must also be followed.
The illustrations in this document are designed to provide a basic understanding and may differ from the actual design of the simulator. Claims cannot be derived from them.

2.2 Explanations of symbols

Warnings
For the purpose of practicing a realistic birth simulation, the SIMone™ uses an electric motor with moment of torque sensor. For this reason, both the simulator and the operating instructions are marked with warnings and symbols. They are also preceded by signal words used to indicate the degree of hazard.

• Always follow all instructions.
• Always exercise caution when working to prevent personal injury and damage to property.

> **WARNING!**
> • Indicates a potential or immediate hazardous situation that can cause serious injury or even death if not avoided.
> • Indicates a potential hazardous situation that can lead to slight or minor injury if not avoided.
> • Indicates a potential hazardous situation that can lead to damage to property if not avoided.

> **NOTE:**
> ...Highlights useful tips and recommendations, as well as information for efficient and trouble-free operation.

Specific safety instructions
To draw attention to specific hazards, the following symbols are used in the operating instructions in conjunction with safety instructions.

> **WARNING!**
> ...Indicates hazards caused by electric power. Failing to follow the safety instructions can result in serious injury or death.

> **Note on height adjustment:**
> ...There is a particular crush hazard when adjusting the height. Failing to follow the safety instructions can result in serious injury.
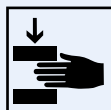
> **Note on transport position:**
> ...Indicates that the simulator must be in the designated transport position for any planned transport.

2.3 Limitation of liability
All information and instructions in this guide have been compiled in accordance with the applicable standards and regulations, the best available technology and our many years of experience.
The manufacturer assumes no liability for damage due to:
• Non-compliance with all parts of the full documentation
• Use for purposes other than those intended
• Operation by unauthorized persons
• Unauthorized conversions or unauthorized technical changes
• Use of unauthorized replacement parts
The person responsible for this damage is fully and exclusively liable for it.
The obligations agreed in the delivery contract, the general terms and conditions, the manufacturer's terms of delivery and the legal provisions in place at the time of contract conclusion apply.

2.4 Warranty provisions
The warranty provisions are contained in the manufacturer's general terms and conditions.

2.5 Customer service
For technical information, our customer service is at your disposal. Information on the contact persons responsible for each region is available at any time by phone, fax, e-mail or on the Internet (address ➙ back page of this guide).
In addition, our staff are always interested in new information and experiences arising from the use of the simulator that may be valuable for the improvement of our products.

2.6 Copyright protection
The operating instructions are protected by copyright. Transfer of these instructions to third parties, reproduction of any kind – including extracts – as well as utilization and/or impartation of their contents are prohibited without the written permission of the manufacturer.
Infringement will result in liability for damages. All other rights reserved.

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2.7 Definition of terms
These operating instructions contain technical terms associated with
obstetrics and birth assistance, explained as follows:

TERM	MEANING
Acupuncture	Therapeutic method against functional disorders and for the treatment of pain derived from the Chinese medicine.
Amniotomy	Instrumental opening of the amniotic sac.
Analgesia	Elimination of pain through reduction or interruption of stimuli or through medicinal intervention.
Antibiotics (ceftriaxone 1000 mg)	The normal dose has no effect if the case does not indicate its administration. At a higher dose than the normal dose (more than 2 g/12 hrs, more than 4 g/24 hrs), the transaminase value increases to GOT > 70, GPT > 70. Overdose (more than 3 g/12 hrs, more than 6 g/24 hrs): the leukocytes fall to 4, the thrombocytes fall to 100, hemoglobin falls to 10, GOT increases to over 80, GPT increases to over 90 and the simulation ends after 40 minutes.
Antihypertensives (methyldopa 250 mg)	The normal dose has no effect if the case does not indicate its administration. At a higher dose than the normal dose (more than 2 pills/6 hrs, between 4-8 pills/24 hrs), the transaminase value increases to GOT > 70, GPT > 70 and the blood pressure falls to approximately 80/60 mmHg. In the event of overdose (more than 8 pills/12 hrs), the transaminase value increases to GOT > 80, GPT > 90, the blood pressure falls to approximately 70/50 mmHg and the simulation ends after 30 minutes with a liver failure of the mother.
EFM / Electronic Fetal Monitor	Instrument-based recording of fetal heart rate and maternal uterine activity.
Epidural anesthetic	Has an anesthetic effect and relieves the pain felt by the mother, allowing the fetus to move more easily through the birth canal and shortening the duration of the birth depending on the parity of the mother.
Episiotomy	Procedure to relieve pressure on the perineum and speed up the birth. This reduces the pressure on the fetal head.
Fetal scalp blood analysis (FSBA)	Acid-base balance analysis; a blood sample is taken from the fetus to determine pH value, pCO_2, pO_2, bicarbonate and base excess.
Forceps	The delivery forceps.
Forceps extraction	Forceps delivery; operative vaginal end of the birth process.
Position	The deepest point entered by the fetus into the maternal pelvis is set in relation to the interspinal line and this distance is estimated in centimeters. The interspinal line is defined with zero (in the direction of the pelvic inlet: minus values, after passing the interspinal line: plus values).
Infusion – Ringer's solution or NaCl	After administration of the normal dose for a patient with fever, the patient is hydrated and the body temperature falls by about 0.3°C, leading to moderate improvements of the fetal heart rate.
Presenting part	The lowest, presenting part of the fetus in the birth canal, e.g. forehead, occiput or buttocks.
Misoprostol (50 µg), prostaglandin pessary (10 mg), prostaglandin gel (1 mg)	If these are administered before dilation of the cervix of 4 cm, the birth process is accelerated; the frequency of contractions, duration and amplitude of contractions and basal tone are increased. The pause between contractions becomes constant. If more than one prostaglandin is administered at the same time, uterine hyperstimulation in the mother occurs. Each has different effects on the maturation / dilation of the cervix, and therefore on the progress of the birth.
Opiates, opioids	The term opiates denotes all substances obtained from the milk-like sap of the unripe seed vessels of the opium poppy. The sap contains about 25 alkaloids, including morphine, codeine and thebaine. Given their sedative effect and in particular the respiratory depression effect on the newborn, the systemic use of opioids should be limited to the early opening phase, so that their effectiveness is completed before birth.

TERM	MEANING
Oxytocin	Hormone used to stimulate the contraction of the uterine muscles. Has the effect of inducing contractions; increases the frequency and amplitude of contractions and the basal tone. The duration of contractions is increased only when more than 10 U/min is administered. The pause between contractions is less variable. Depending on the case, the delivery is also accelerated. If the dose administered is higher than the case requires, 30 minutes of hyperstimulation occur during which the student can stabilize the mother's contractions through a reduction of the oxytocin dose and a tocolysis. If the student cannot stabilize the mother's contractions, 20 minutes of hyperstimulation occur without a possibility of recovery with the exception of an emergency C-section. If prostaglandins is administered simultaneously with oxytocin, this causes hyperstimulation. Can be administered safely 3 hours after administration of misoprostol. Can be administered safely 30 minutes after the administration of the prostaglandin pessary. Can be administered safely 6 hours after the administration of the prostaglandin gel.
Paracetamol 500 mg	The normal dose has no effect if the case does not indicate its administration. At a higher dose than the normal dose (more than 2 pills/6 hrs), the transaminase value increases to GOT > 70, GPT > 70. In the event of overdose (more than 8 pills/12 hrs), the transaminase value increases to GOT > 80, GPT > 90 and the simulation ends after 15 minutes with a liver failure of the mother.
Partogram	A simple tool for the documentation of progress in the form of a graph in which the elapsed time of birth is entered on the x-axis, and the y-axis records cervical dilation on the one hand and the position of the presenting part on the other.
Peridural anesthetic (PDA)	In peridural anesthesia, a local anesthetic and/or opioid is introduced into the peridural space (epidural space) at the level of the intervertebral space L2/3 or L3/4 using either the "single-shot" technique or the catheter technique.
Pudendal block	The blockade of the pudendal nerve including its branches relieves perineal pain and relaxes the muscles of the pelvic floor. A local anesthetic is injected through the vagina on both sides in the pudendal nerve region.
Caesarean section	Abdominal operation to end the pregnancy.
Tocolysis	Medicinal inhibition of contractions; indicated in the event of premature contractions in order to extend the pregnancy for small premature infants. May also be of help during the birth in the event that uterine activity is too high but ineffective. It also helps the fetus recover from immediate hypoxia if carried out within 30 minutes of the onset of hypoxia.
Vacuum extraction	Vacuum extraction delivery; operative vaginal acceleration of the birth.
General anesthetic	General anesthetics are used only in the last moments before C-section. The simulation is therefore terminated if the student does not perform a C-section under general anesthetic in less than 5 minutes after administration. If the student performs the C-section under local anesthetic after the administration of the general anesthetic, the simulation ends with undesirable results.

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❯ 3. SAFETY

This section provides an overview of all important safety aspects for optimum protection of staff as well as safe and trouble-free operation.

Failure to follow the handling instructions set out in these operating instruction can result in significant hazards.

3.1 Intended use
The simulator is designed and constructed exclusively for the intended use described here.

NOTE:
The SIM*one*™ birth simulator may only be used for the simulation of births. Depending on the simulation in question, the utilization of medical devices used during childbirth is permitted.

WARNING!
Danger from improper use!
Any use extending beyond or other than the intended use of the simulator can lead to dangerous situations.
Therefore:
• Use the simulator only as intended.
• Strictly adhere to all information in the operating instructions.
In particular, refrain from the following uses, which are considered improper use:
• Insertion of body parts or objects into the simulator's birth canal that are not used for the simulation of a determination of position or operative vaginal delivery.
• Use of medical devices other than those used in childbirth.
• Manipulation of safety equipment.
• Conversion, refitting or modification of the construction or individual pieces of equipment.

3.2 Responsibilities of the operator
The operator of the simulator is subject to the statutory obligations governing safety at work.
In addition to the safety instructions in these operating instructions, the rules governing safety, accident prevention and environmental protection applicable to use of the simulator must also be followed.
In particular, the operator must:
• Be informed about the applicable health and safety regulations.
• Undertake a risk assessment to determine the additional hazards that arise from the special working conditions at the simulator's location.
• Set out the necessary behavioral requirements for the operation of the simulator at its location in operating instructions.
• Check regularly during the entire period of use of the simulator to ensure that the operating instructions as drawn up correspond to the current status of the regulations.
• Adapt the operating instructions – where necessary – to new provisions, standards and operating conditions.
• Clearly define the responsibilities for installation, operation, maintenance and cleaning of the simulator.
• Ensure that all employees working on or with the simulator have read and understood the operating instructions. In addition, staff must be trained at regular intervals in working with the simulator and informed about the potential hazards.
• Provide staff tasked with working with the simulator with the required and recommended safety equipment.

The operator is also responsible for ensuring that the simulator is:
• Always in perfect technical condition.
• Maintained in accordance with the specified maintenance intervals.
• Regularly checked to ensure that all safety equipment is complete and working properly.

3.3 Responsibilities of staff
Staff are subject to the statutory obligations governing safety at work.
In addition to the safety instructions in these operating instructions, the rules governing safety, accident prevention and environmental protection applicable to use must also be followed.
In particular, staff must:
• Be informed about the applicable health and safety regulations.
• Comply with the behavioral requirements for the operation of the simulator at its location set out in the operating instructions.
• Properly observe the assigned responsibilities for the operation, maintenance and cleaning of the simulator.
• Have read and understood the operating instructions before starting work.
• Use the required and recommended safety equipment.

In addition, all staff working on or with the simulator are to varying degrees responsible for ensuring that the simulator is:
• Always in perfect technical condition.
• Maintained in accordance with the specified maintenance intervals.
• Regularly checked to ensure that all safety equipment is complete and working properly.

3.4 Staff requirements

Core requirements
For the various activities, use only persons who can be expected to carry out their work reliably and in accordance with the specified requirements in each case.
In addition, always observe the specific provisions relating to age and occupation applicable at the location when selecting staff.

Qualification

WARNING!
Risk of injury in the event of inadequate qualification!
Improper handling can lead to injury or damage to property.
Therefore:
All work must be carried out by qualified persons only.

Teachers
For the operation of the simulator, a person trained in obstetric and operation of the simulator is required.

Students
Students may work on the simulator only after training and in compliance with the safety instructions.

Electrician
Allowed to carry out all work on the electrical system of this simulator.

With technical training, knowledge and experience and familiarity with the relevant standards and provisions, the electrician is qualified to carry out work on electrical systems properly, independently recognize potential hazards and prevent the occurrence of injury or damage to property through preventive action.

Training
Before commencing work, all persons must be instructed by the operator in the activities entrusted to them and potential hazards associated with the work.
• Repeat training courses at regular intervals.
• All staff training must be documented.

> **NOTE:**
> An option is available to have training conducted by employees of 3B Scientific. For more information, please contact your authorized distributor or manufacturer (address ➜ back of this guide).

Unauthorized persons

> **WARNING!**
> **Danger for unauthorized persons!**
> Persons who are not trained are unaware of the hazards in the work area and are considered unauthorized.
> Therefore:
> • Keep unauthorized persons away from the work area.
> • In case of doubt, approach the persons and send them away from the work area.
> • Interrupt work while there are unauthorized persons in the work area.

Persons whose ability to respond is influenced for example by drugs, alcohol or medications also cannot meet the described requirements and are therefore also considered unauthorized. They are not permitted in the work area and in no case allowed to carry out work.

3.5 Specific hazards
The following section sets out residual risks determined on the basis of a hazard analysis.
The instructions listed here and the safety instructions in the other sections of this guide must be followed at all times in order to reduce potential health hazards, particularly during maintenance work, and avoid hazardous situations.

Electric power

> **WARNING!**
> **Risk of death due to electrical current!**
> Contact with live parts poses an immediate danger to life. Damage to insulation or individual components can be life-threatening.
> Therefore:
> • In the event of damage to insulation, switch off the power supply immediately and have it repaired.
> • Work on the electrical system may only be carried out by qualified electricians.
> • Before carrying out maintenance, cleaning and repair work, switch off the power supply and secure it against being switched back on by pressing EMERGENCY STOP and unplugging the power plug. Otherwise, there is a risk of the motor inside the machine suddenly starting the mechanical equipment or that where insulation is damaged, contact with live parts cannot be excluded.
> • Never bridge or disable fuses.
> • When replacing fuses, ensure that the amperage is correct.
> • Keep moisture away from live parts, as it can lead to a short circuit.

Electrical cables and supply lines

> **WARNING!**
> **Risk of death due to defective cables!**
> Cable defects can cause electric shock and may lead to death.
> Therefore:
> • All electrical connections must be fixed in place and free of corrosion.
> • Use appropriate cables only for their intended use.
> • Always choose conductor cross-sections of sufficient strength in accordance with the current drain.
> • Ensure that the protective conductor is properly connected.
> • Protect cables and lines from heat, oil, dust and aggressive media.
> • Lay cables and lines so that there is no trip hazard. Do not run them along sharp edges or corners. Avoid chafing, kinks and pinching.
> • When in use, do not leave cables wound up on rolls, drums or in loops.
> • Never use cables to carry equipment or tools.
> • Do not pull plugs from the power outlet with the cable.
> • Check cables and plugs before use to ensure that they are in good condition. In the event of damage, do not use them. Have them repaired or replaced by a specialist immediately.
> • Always secure live cables and lines so that they cannot cause hazards, cannot cause injury and cannot be damaged.

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Moving components

> **WARNING!**
> **Risk of injury from moving components!**
> Moving parts can cause injury.
> To avoid this risk during operation:
> - Do not insert body parts or objects into the birth canal that are not used for the simulation of a determination of position or operative vaginal delivery.
> - Use only medical devices commonly used for childbirth.
> - Never operate the simulator with the cover/housing removed.
> - Before opening the simulator, switch off the device at the main switch and secure it against being switched back on by pressing the emergency stop button and unplugging the power plug.
> - Do not deactivate, disable or bypass safety equipment and/or functions.
> - Never let the simulator run without closed covers or fully functional safety equipment.
> - Never reach into moving equipment.
> - When carrying out set-up and maintenance work and correcting errors, always work with particular care and attention to crush points.

> **WARNING!**
> When adjusting the height of the table, ensure that there are no objects or people in the movement area.
> When lowering the table in particular, ensure that there are no objects such as chairs or a person sitting on a chair below the body. There is a risk of severe crushing.

Dirt and objects lying around

> **CAUTION!**
> **Trip hazard due to dirt and objects lying around!**
> Dirt and objects lying around are a slip and trip hazard that can cause considerable injury.
> Therefore:
> - Always keep the work area clean.
> - Clean up spilled lubricant immediately.
> - Remove any items that are no longer needed.

3.6 Safety equipment

> **WARNING!**
> **Risk of injury from malfunctioning safety equipment!**
> Your safety is guaranteed only when the safety equipment is intact.
> Therefore:
> - Before starting work, check to ensure that all safety equipment is installed and working properly.
> - Never override safety equipment.
> - Ensure that the safety equipment is freely accessible at all times.

Emergency stop button
Pressing the emergency stop button triggers an emergency stop.
To enable a restart, the emergency stop button must be unlocked by turning it (the red button jumps out of the locked position).

Figure 2: Emergency stop button on the right side of the simulator

> **WARNING!**
> **Risk of injury due to uncontrolled restart!**
> An uncontrolled restart can cause serious injury.
> Therefore:
> - Before switching back on, ensure that the cause of the emergency stop has been corrected and that all safety equipment is in place and working properly.
> - Do not unlock the emergency stop button until there is no further danger.

Before putting the device into operation, the local mains voltage must be set to 115 / 230 V on the voltage selection switch.

Main switch

The main switch is also designed as an emergency stop button. Switching the main switch to the "0" position shuts off the power supply immediately, triggering an emergency stop.

Figure 3: Main switch on the back of the simulator

> **WARNING!**
> **Risk of injury due to uncontrolled restart!**
> An uncontrolled restart can cause serious injury.
> Therefore:
> • Before switching back on, ensure that the cause of the emergency stop has been corrected and that all safety equipment is in place and working properly.

Safety limit switch / housing circuit breaker as access protection

The interior of the simulator's casing is equipped with safety limit switches, so-called housing circuit breakers (Figure 4, Figure 5, Figure 6/1, 2). They prevent the motor from starting when safety equipment is open. Opening safety equipment, for example removing the housing during operation, brings the device to an immediate stop.

Figure 4: Safety limit switch 1
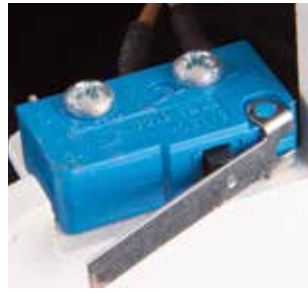
Figure 5: Safety limit switch 2
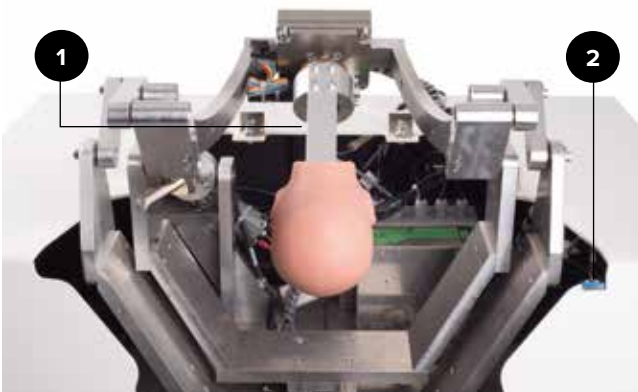
Figure 6: Position of the safety limit switch

3.7 Securing against restart

> **WARNING!**
> **Risk of injury due to unauthorized restart!**
> When working on individual assemblies or components, there is a risk of the power supply being switched on by an unauthorized person, causing injury to those in the danger zone.
> Therefore:
> • Before all work, use the following procedure to secure the device against a restart:
>   1. Switch off the device at the main switch.
>   2. Press EMERGENCY STOP to lock.
>   3. Secure the device against being switched back on by unplugging the power plug. (The device is not properly disconnected from the power supply until the power plug is disconnected).

3.8 Securing against unintentional movement

Figure 7: Operation of the brakes

> **WARNING!**
> **Risk of injury from unintentional movement!**
> Before using the simulator, always apply the brakes on the rollers.

3.9 Securing during transport

> **NOTE:**
> Please ensure that the simulator's height adjustment unit is in the designated transport positionduring transport.

Figure 8: Finger on control panel

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3.10 Procedure in the event of danger or accident

If not already defined in the in-house accident prevention regulations, always ensure the following in the event of danger or accident:

Preventive measures
• Always be prepared for accident or fire.
• Keep first aid equipment (first aid kit, blankets etc.) and fire extinguishers close at hand.
• Familiarize staff with accident reporting, first aid and rescue facilities.
• Keep access routes for emergency services free.

Just in case: Do the right thing
• Trigger an emergency stop immediately.
• Initiate first aid measures.
• Rescue people from the danger zone.
• Inform those responsible on site.
• Alert doctor and/or fire department.
• Clear access routes for emergency services.

3.11 Environmental protection

The birth simulator is operated using its integrated application software. 3B Scientific will continue to develop the software, so that future application options can be acquired while retaining the existing mechanical systems. In the event that individual components or the device as a whole is to be withdrawn from service, please note the following.

> **CAUTION!**
> **Environmental hazard due to incorrect handling!**
> Handling environmentally hazardous substances incorrectly or improper disposal can cause considerable damage to the environment.
> Therefore:
> • Please pay particular attention to the following instructions.

The following are environmentally hazardous substances:

Electronic components
Electronic components (touchscreen PC, motors, electronics box, switching power supply, sensors) must be treated as hazardous waste. They must be disposed of by a specialist waste management company.

Remaining components
In the design of the simulator, 3B Scientific has made every effort to use recyclable materials and machine parts. Send the electronic components removed from the mechanical equipment to a metal recycling company.
All other components of the simulator can be disposed of as normal household waste.
Local municipal authorities and waste management companies can provide information on environmentally responsible disposal.

3.12 Signs

You will find the following signs and symbols in the work area. They relate to the immediate vicinity in which they are displayed.

> **WARNING!**
> **Risk of injury due to illegible symbols!**
> Over time, signs and labels can become dirty or illegible in some other way.
> Therefore:
> • Always keep all safety, warning and operating instructions in a clearly legible condition.
> • Replace damaged signs or labels immediately.

Electric height adjustment
When adjusting the height of the table, ensure that there are no objects or people in the movement area.

When lowering the table in particular, ensure that there are no objects such as chairs or a person sitting on a chair below the body. There is a risk of crushing.

Setting the transport position
• Press and hold down the arrow key (▼) to move the simulator to the lowest position (height adjustment unit stops automatically).
• Release the key for a moment (about 1 second).
• Press and hold down the arrow key (▼) for another 10 seconds until the simulator locks into the transport position.

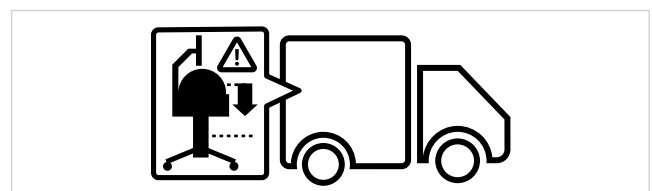Figure 9: Signs on the outside of device 1

Figure 10: Signs on the outside of device 2

3.13 Replacement parts

> **WARNING!**
> **Risk of injury due to incorrect replacement parts!**
> Incorrect or faulty replacement parts can result in damage, malfunctions or total failure and seriously compromise safety.
> Therefore:
> • Use original replacement parts.

Original replacement parts can be purchased from authorized distributors or directly from the manufacturer (address ➞ back of this guide).

› 4. TECHNICAL DATA

4.1 Dimensions

Specification	Value
Weight	115 kg
Weight (with packaging)	150 kg
Table top height adjustment	84 – 104 cm
Length	80 cm
Width	85 cm
Height	155 – 175 cm
Length packaged	80 cm
Width packaged	120 cm
Height packaged	130 cm

4.2 Connection values

Electrical

Specification	Value
Supply voltage	110 / 230 ± 10 %
Frequency	50 – 60 Hz
Power consumption, maximum	150 W
Phase protection	2 x 5 A (delay-action)

Power cord with safety plug type E/F and adapter
for connector types B, D, E, F, G/BS1363, I, J, L and M (150 countries).

4.3 Operating conditions

The device may only be operated indoors and in compliance with the following operating conditions:

Work area

Specification	Value
Temperature range	10 – 50 °C
Relative humidity	20 – 70 %
Non-condensing	
Max permissible voltage fluctuations in the power supply network	± 10 %
Protection class	I
Contamination level	2
Terms	Protect device components from sunlight and heat Avoid direct moisture, dust and frost

Operating time

Specification	
Continuous operation, max	Suitable for continuous operation
Power-on pause	Not required
Service life	Unlimited

4.4 Nameplate
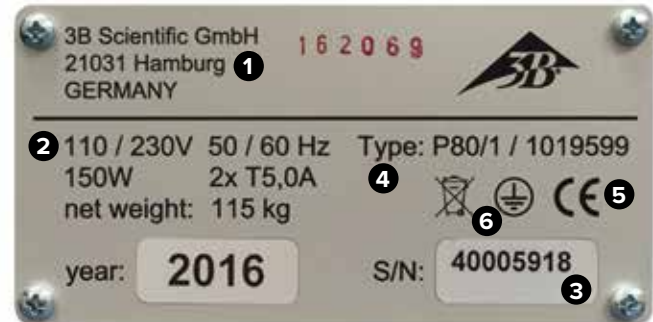
Figure 11: Nameplate

The nameplate is located on the back of the simulator next to the main switch and includes the following information:
1 Manufacturer
2 Power supply and fuse protection
3 Serial number
4 Type designation of the device
5 Certification marks (CE, FCC, UL etc.)
6 Protective conductor connection (protection class I)

4.5 Requirements for the installation location

Installation conditions
Install the simulator so that:
• A secure footing is guaranteed.
• The brakes are applied and the rollers blocked.
• Escape routes and rescue equipment are freely accessible.
• The safety of staff is guaranteed.
• Adequate lighting is available.
• All parts of the simulator are easily accessible and there is sufficient clearance for maintenance work and measures to eliminate errors.

When installing, observe the requirements of the regional or national regulations at the installation location in terms of incidence of light on the monitor, spaces to be kept clear and escape routes. For viewing the monitor, a lateral incidence of light is recommended.

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› 5. LAYOUT AND FUNCTION

5.1 Summary

The SIMone™ birth simulator is used to simulate birth processes and procedures. Selectable scenarios show a range of complex birth processes. SIMone™ supports the work process for case history, examination, diagnosis and intervention.
It is also used to practice the proper handling of medical devices as they are used in actual births with realistic haptics.

5.2 Scope of delivery

5.2.1 Main device

A simulator with a haptic, visual and audio interface as a training module for use of the instruments used for operative vaginal delivery. SIMone™ is supplied with:
• Simulator mechanics with a fetal head in a model of the abdomen of the mother
• Application software with scenarios for model-based training in instrumental delivery and problem-based learning of birth management
• 19" touchscreen PC and stylus (pen for touchscreen operation)
• Power cord type E/F with plug adapter
• Height-adjustable table with drawers for accessories

> **NOTE:**
> For the individual components in the consignment, see also "Figure 14: Components of the consignment".
> For replacement parts, see section "13 Accessories and replacement parts".

5.2.2 Accessories included in delivery
• 1 suction cup (XP803)
• 1 vacuum pump 0 – 1,000 mbar (XP804)
• 1 forceps (XP805)
• 2 x 100 ml lubricant (XP806)
• Latex-free disposable gloves, size M/L (XP807-M/L)
• 1 replacement insert for the genitals (XP811)
• 1 stylus (XP813)
• Assembly tool (XP816)
• Lubricant OKS 470 allround grease 100 g (XP817)
• Operating instructions (XP818xx*)

* xx acts here as a placeholder for the language version and stands for the two-letter country code as per ISO 3166

5.3 Display, controls and connections

5.3.1 On the simulator

The simulator is operated using the connected touchscreen.

On the back of the simulator, you will find:
1 Main switch
2 Acknowledge button
3 Power cord for the power supply
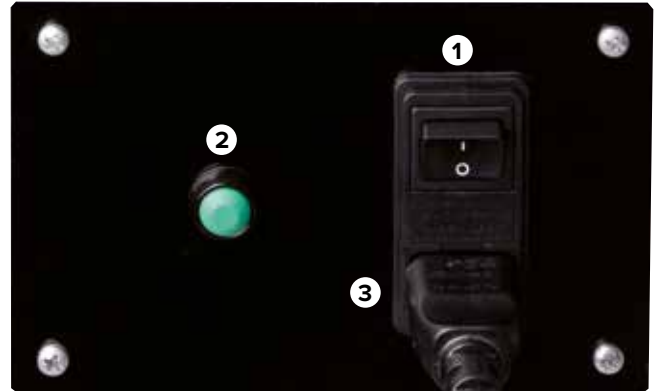
Figure 12: Main switch

5.3.2 On the touchscreen
Below the screen are the buttons for setting the PC itself.
These are described below:

Figure 13: Controls on the monitor

Button	Function
LCD power	Opens the PC menu
Brightness control	Sets the required brightness
Volume control	Sets the required volume

› 6. TRANSPORT, PACKAGING, STORAGE

→ NOTE:
Have the installation and initial start-up carried out by a representative of the operator as described in these operating instructions (see section 7 "Installation and initial start-up").

6.1 Transport inspection
Upon receipt, check the delivery without delay for completeness and transport damage.
In the event of visible external damage, proceed as follows:
• Do not accept the delivery or accept it only under reserve.
• Make a note of the extent of the damage on the transport documents or on the carrier's delivery note.
• Submit a complaint.

→ NOTE:
Submit a complaint about each defect detected. Claims for damages can only be asserted within the applicable period for complaints.

6.2 Safety instructions for transport

Improper transport

❗ CAUTION!
Damage due to improper transport!
Improper transport can lead to significant damage to property.
Therefore:
• When unloading the packages and transporting them internally, always proceed with the utmost care and caution.
• Note the symbols on the packaging.
• Use only the attachment points provided.
• Do not remove packaging until immediately before starting assembly.

Staff
Internal transport without the help of supervised lifting or handling equipment and installation on site may only be carried out by trained personnel.
Transport with supervised lifting or handling equipment may only be carried out by trained personnel.

Personal protective equipment
Always wear personal protective equipment during transport:

Protective work clothing
Closely fitting work clothes with low tear strength, tight sleeves and no protruding parts. Used mainly to protect against becoming entangled in moving machine parts. Do not wear rings, necklaces or other jewelry.

Protective gloves
Used to protect the hands against friction, abrasion, pricks or deeper injuries, and against contact with hot surfaces.
Safety shoes for protection against heavy falling parts and slipping on slippery surfaces.

Safety shoes
Used to protect against heavy falling parts and slipping on slippery surfaces.

6.3 Transport
The factory shipment consists of a single unit on a pallet.
The dimensions of the pallet are:
• H: 130 cm
• W: 120 cm
• D: 80 cm
The weight is 150 kg.
The package can be transported with a forklift, pallet truck etc.

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6.4 Symbols on the packaging

The symbols on the outside of the packages must always be observed during transportation and storage.

NOTE:
If you plan to transport the equipment again after unpacking or at a later date, keep the original packaging, including symbols and labels, and use it again.

Also ensure that you:
- Keep the original packaging at least until the end of the warranty period and for any return deliveries that may be necessary.
- Note the contents of each of the individual package before final disposal of the packaging: type, size and shape, including the filler materials and attached symbols.
- For future transport of the equipment, either keep the original packaging as described above or make suitable transport containers similar to the original packaging. Where necessary, the manufacturer can supply shipping materials for a fee.
- Always ensure that the required symbols and labels are again clearly visible on the outside of the packages.

Explanation of symbols

Fragile
Identifies packages with fragile or delicate contents. Handle the package with care, do not drop or expose to shocks.

6.5 Transport and storage

About the packaging
The individual packages are packaged according to the expected transport conditions. Only environmentally friendly materials were used for the packaging.
The packaging is designed to protect the individual components from transport damage, corrosion and other damage until assembly. You should therefore not destroy the packaging and remove it properly only shortly before assembly.

Transport of pallets
Packages that are secured on pallets can be transported with an industrial truck under the following conditions:
- The truck must be designed to take the weight of the transport units.
- The driver must be authorized to drive the truck.
- Always ensure that pallets with an off-center center of gravity cannot overturn.

Handling of packaging materials
Dispose of packaging materials in accordance with the applicable legal requirements and local regulations.

CAUTION!
Environmental damage due to incorrect disposal!
Packaging materials are valuable raw materials that can be re-used in many cases or reconditioned and recycled for other purposes.
Therefore:
- Dispose of packaging materials in an environmentally-friendly manner.
- Follow the locally applicable disposal regulations. Assign disposal to a specialist company where necessary.

Storage of packages
Store packages under the following conditions:
- Do not store outdoors.
- Store in a dry and dust free place.
- Do not expose to corrosive media.
- Protect against direct sunlight.
- Avoid mechanical shocks.
- Storage temperature: 15 to 35 °C
- Relative humidity: Max 60%.
- If storing for longer than 3 months, regularly check the general condition of all parts and the packaging. If necessary, refresh or replace the packaging.

NOTE:
In some circumstances, the package contains instructions for storage that go beyond the requirements listed here. These instructions should also be followed.

› 7. INSTALLATION AND INITIAL START-UP

7.1 Safety core requirements

⚠ **WARNING!**
Risk of injury due to improper installation and initial start-up!
Improper installation and initial start-up can lead to serious injury or damage to property.
Therefore:
- All work related to installation and initial start-up may only be carried out by qualified personnel who have been authorized and trained by the operator.
- Before starting work, ensure that there is sufficient space for assembly.
- Ensure that the assembly location is clean and tidy. Loosely stacked or scattered components and tools are sources of accidents.

During assembly, ensure that:
- The components are arranged correctly and properly in place.
- Install all fastening elements correctly.
- Before switching on, ensure that all covers and protective devices are correctly installed and working properly.

Electrical equipment

⚠ **WARNING!**
Risk of death due to electrical current!
Contact with live components poses a danger to life. Switched on electrically operated components can start moving uncontrollably and cause very severe injury.
Therefore:
- Before starting work, switch off the device at the main switch and secure it against being switched back on by pressing EMERGENCY STOP and unplugging the power plug.
- All work on the electrical system, on individual electrical components and on the connections may only be carried out by qualified electricians.
- Connect the device only to a properly grounded power outlet with a protective ground contact.
- Use the device only as intended and follow these instructions at all times.

Securing against restart

⚠ **WARNING!**
Risk of death due to unauthorized restart!
When working on individual assemblies or components, there is a risk of the power supply being switched on by an unauthorized person, causing injury to those in the danger zone.
Therefore:
- Before all work, use the following procedure to secure the device against a restart:
  1. Switch off the device at the main switch.
  2. Press EMERGENCY STOP to lock.
  3. Secure the device against being switched back on by unplugging the power plug. (The device is not properly disconnected from the power supply until the power plug is disconnected).

Personal protective equipment
When installing and assembling, always wear:

Protective work clothing
Closely fitting work clothes with low tear strength, tight sleeves and no protruding parts. Used mainly to protect against becoming entangled in moving machine parts. Do not wear rings, necklaces or other jewelry.

Protective gloves
Used to protect the hands against friction, abrasion, pricks or deeper injuries, and against contact with hot surfaces.
Safety shoes for protection against heavy falling parts and slipping on slippery surfaces.

7.2 Preparation for assembly
Before starting assembly, check for:
- Conformity of the local power supply with the information on the nameplate and the specifications in the technical data.
- Compliance with the specified installation conditions (→ 4.5 Requirements for the installation location).
- Compliance with local environmental conditions (→ 4.3 Operating conditions).
- Definition of the responsibilities for installation and initial start-up.
- Completeness and good condition of the required tools and aids.
- Compliance with local safety regulations.

7.3 Space requirements at the installation location
When assembled, 1 m² of space is required. The height of the monitor bar is 1.75 m. In a simulation scenario, the student stands in front of the simulator. For the unpacking and assembly of the simulator, a ceiling height of 2.70 m is recommended to allow the required freedom of movement, especially when unpacking.

→ **NOTE:**
When the simulator is being used for training, there are often several people around the device. For didactic reasons, a space of at least 6 m² is therefore recommended.

7.4 Installation and connection

→ **NOTE:**
Two people are needed to unpack and assemble the simulator. For any questions or problems that are not answered by these instructions, please get in touch with your authorized dealer or the manufacturer (address → back of this guide).

Unpacking the simulator components
1. Remove the securing straps.
2. Cut open the cardboard box at the taped areas.
3. Remove the filler material.
4. Raise the upper transport box out (two people).
5. Remove any additional filler material and protective foil around the table.

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NOTE:
When unpacking the simulator, lift at the base lift, not at the handle.

Table with birth mechanics
Touchscreen PC
Monitor column
Mounting holder
Replacement genital insert
Stylus
2x lubricant
Suction cup with vacuum pump
Forceps
Screwdriver
Gloves size M
Gloves size L
Adapter
Lubricant OKS 470
allround grease

Figure 14: Components of the consignment

NOTE:
For the exact scope of delivery, including accessories, see sections "5.2.2 Accessories included in delivery" and "13 Accessories and replacement parts".

NOTE:
Before assembling the column and the PC, ensure that the roller brakes are applied.

Installing the PC

Assemble the column

- There is a screw protruding from the middle of the base, behind the abdominal torso.
- Place the two washers on the screw.

- Screw the column to it.
- Align the column so that the opening, which is used later for fixing the cables, is pointing to the rear.

- Slide the holder onto the column.

- Fix holder and attachment.
- Fit the cover cap into place.

Install the PC

- To mount the PC, open the flap on the holder.

- Lift the PC into the holder from above.

- Close the flap on the holder.

Install the cables

- There are two cables extending outwards form the base.
- Plug in the cable with the power plug.

- Plug in the USB cable.

- Run the two cables into the opening in the column and secure with the clips.
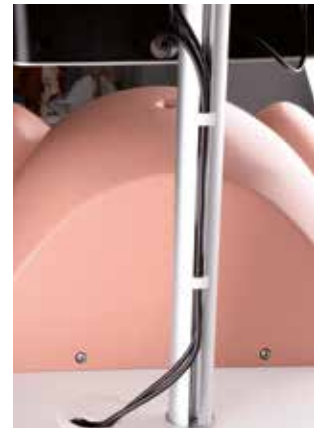
Figure 15: Emergency stop button on the right side of the simulator table

Emergency stop button
- Check whether the head of the emergency stop button is pressed in, and unlock by turning it if necessary.
- Plug the power cord into a power outlet and ensure that the cable is fitted to the simulator.

> **NOTE:**
> If the button has been pressed during assembly work, the software boots when you switch on the simulator, but the mechanical equipment is not supplied with power.

The SIMone™ birth simulator is now ready for use.

Figure 16: Simulator in use

8.1 Safety Core requirements

! **WARNING!**
Risk of injury due to improper operation!
Improper operation can lead to serious injury or damage to property.
Therefore:
• The device may only be operated by sufficiently qualified personnel who have been authorized and trained by the operator.
• Perform all operating steps as set out in the instructions in this guide.
• Before starting work, ensure that all covers and protective devices are correctly installed and working properly.
• Never override safety equipment during operation.
• Ensure that the work area is clean and tidy. Loosely stacked or scattered items such as medical devices, tools, cleaning equipment or dirt are sources of accidents.

8.2 Personal protective equipment
During birth simulation, disposable gloves must be worn in order to:
• Create a realistic situation.
• Prevent skin contact with the lubricant.
• Help to prevent soiling of the model.

Disposable gloves
Must always be worn during the simulation. Used to protect the simulator's genital insert from dirt and to protect the hands from contact with the lubricant.

8.3 Starting the simulator

8.3.1 Switching on
To switch on, proceed as follows:
1. Insert the mains plug into the power outlet.
2. Check the position of the emergency stop button. If necessary, unlock it by turning to the right.
3. Switch on the main switch (1).
4. Press the green acknowledge button (2).

Figure 17: Emergency stop button on the right side of the simulator table
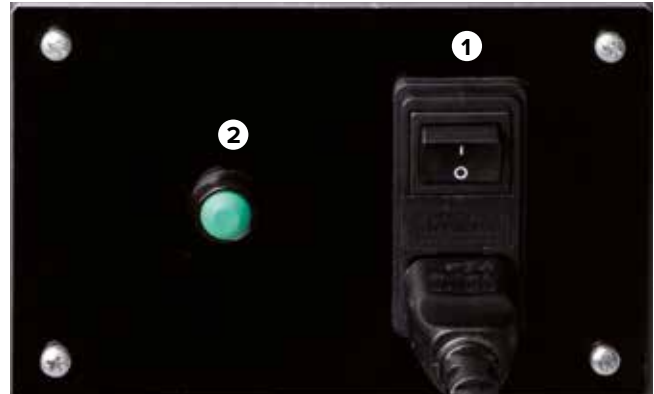
Figure 18: Main switch and acknowledge button

➔ **NOTE:**
When you switch on the main switch (1), the PC starts up and tries to establish communication with the birth mechanics. However, if the green acknowledge button is not pressed within the next 30 seconds, communication will not be established. The screen displays the message "Hardware Not Found".
The simulator goes into calibration mode. The user now has the option to calibrate the touchscreen. For calibration, see section "10.5 Restarting".

The PC is started.

➔ **NOTE:**
The very first time the application software is started, the text of the license agreement is displayed. When you click to confirm the contract, the contract enters into force and the system starts up the simulator application.
The text of the license agreement in printed from is included in delivery.

! **CAUTION!**
Risk of injury from moving components!
If the head of the fetus is not located in the zero position when the simulator is switched on, it is drawn into the middle of the device by the initialization process.
Therefore:
• There should be no body parts or foreign objects in the inside of the simulator.
• When switching on the simulator, do not reach into the area of the head.

➔ **Note on height adjustment**
Particular hazard of crushing. Failing to follow the safety instructions can result in serious injury.
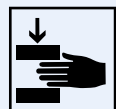
8.3.2 Selecting the language and starting up the simulator
When the PC starts, the selection dialog for the language of the application software is displayed on the touchscreen.
Select the on-screen language by tapping the flag of the country.

Figure 19: Language selection screen

> **CAUTION!**
> **Damage due to improper operation of the touchscreen!**
> Therefore:
> • Do not use sharp objects to operate the touchscreen.
>   We recommend using the stylus included in delivery.

The simulator's mechanical equipment is moved to the zero position. The application message opposite is displayed.
To minimize the friction between the silicone parts of the head and genitals as they move against each other, the inner and outer sides of the silicone labia must be lubricated.

1. Put on gloves.
2. Apply lubricant to the fingertips.
3. Apply and spread from inside and outside to create a film.
4. Monitor the lubricant film during use and repeat the procedure if necessary.
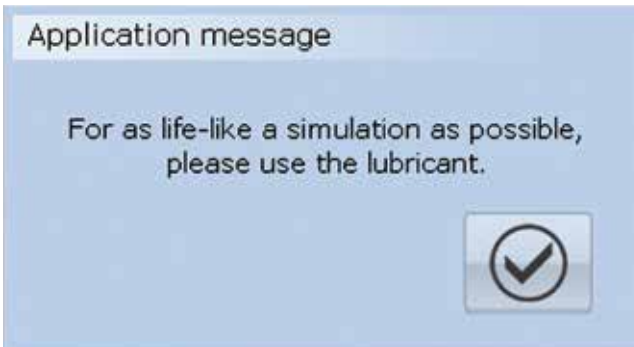
Figure 20: Applying lubricant

> **NOTE:**
> Insufficient lubrication of the silicone parts can trigger the front safety switch / housing circuit breaker. The simulator then switches off.

The following application message is displayed.
The force-torque sensor is adjusted. To enable this, the simulator moves the artificial child's head completely out of the birth canal and then back inside.
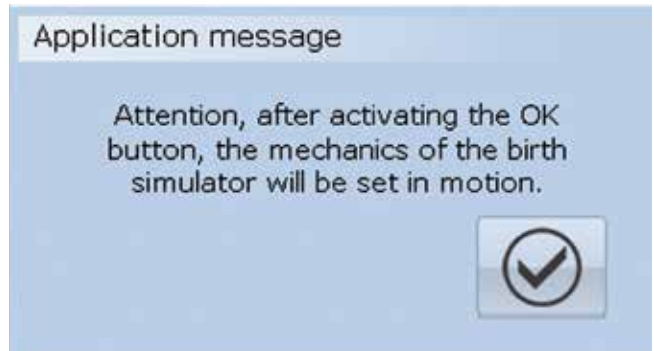
> **CAUTION!**
> **Risk of injury from moving parts!**
> The force-torque sensor is adjusted. The artificial child's head is moved completely out and then back inside.
> Therefore:
> • There should be no body parts or foreign objects in the inside of the simulator.
> • When confirming the application message, do not reach into the area of the head.

8.4 Simulation application

8.4.1 Selecting a scenario
A range of different birth scenarios are displayed on a virtual image drum that can be rotated with the stylus included in delivery.

Figure 21: Scenario selection screen

The photo in the middle position indicates the selection of a specific birth scenario. Below that is a brief description of the associated case history.
To select a different scenario, "grab" an image with the pen and pull it to the center of the screen.
Two scenarios types are distinguished:
■ Short scenarios (red square) for model-based teaching of instrumental delivery.
■ Scenarios for a complete birth process (blue square) with or without complications for problem-based teaching of birth management.

In each case, this icon represents the start of a process. Tapping this button on the selection screen starts the selected scenario.

In each case, this icon represents the end of a process. Tapping this button on the selection screen shuts down the PC and switches the device off.

You can find a detailed description of the different scenarios and the measures to be taken in section "9 Birth scenarios".

8.4.2 Display elements on the simulation screen
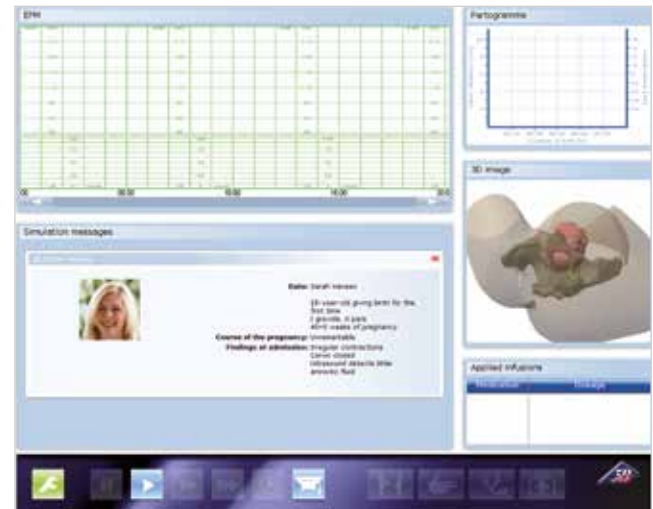
Figure 22: Simulation screen with selected scenario

1. EFM:
The EFM appears here when a CTG recording has been requested in the "Diagnosis" menu. This is done using the button:

2. Simulation messages:
At the beginning of the scenario, the case history is displayed. Other messages are displayed during the simulation, for example laboratory values after an FSBA request.

3. Partogram:
The chart created over the course of the birth shows the dilation of the cervix and the position of the presenting part over the preceding period.

4. 3D image:
• Displays the contour of the maternal abdomen, the pelvis and the fetal head.
• The illustration is in sync with the partogram and mechanics.
• The view can be rotated.
• The transparency can be changed under "Settings/Graphics". This is done using the button:

5. Applied infusion & pessaries:
Displays the medication administered using a drip during the simulation.

6. Controls / simulator buttons:
• Green: Device configuration
• Blue: Operation of the simulator as a device
• Red: Operation of the simulation application

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8.4.3 Simulator controls

The following section describes the controls on the simulation screen for a complete birth process.

Device configuration
This icon provides access to the options for setting the 3D graphics, the volume and for canceling the simulation. Tapping this button opens the menu shown below.

The following settings can be made:

Graphic:
Varies the transparency of the contour of the maternal abdomen and pelvis.

Audio:
Adjusts the speaker volume.

End simulation:
Ends the simulation.

Tapping the "Graphic" button opens the slider. You can move the slider to adjust the transparency of the contour of the maternal abdomen and pelvis in 3D view.

Tapping the "Audio" button opens the slider for volume adjustment.

Adjustment is also possible with the arrow buttons on the monitor.

Operation of the simulator as a device

Tapping this button stops the simulation temporarily (pause).

Tapping this button starts the simulation or resumes it after a temporary pause.

Tapping this button once runs the simulation at twice normal speed (slow forward). Tapping it again returns the simulation to normal speed.

Tapping this button once runs the simulation at four times normal speed (fast forward). Tapping it again returns the simulation to normal speed.

Tapping this button opens a submenu where you can select the size of a time leap in order to skip a period of the simulation.

Tapping this button switches the 3D view to dark, along with the position indicator in the partogram, so that students can assess the position impartially from the model (test mode).

Operation of the simulation application

Tapping this button displays the case history for the currently selected scenario in the message window.

Tapping this button performs a virtual diagnosis.

Tapping this button opens the Diagnosis menu (see below).

Tapping this button opens the Intervention menu (see below).

Diagnosis menu
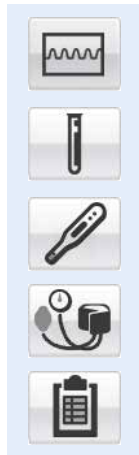
 Tapping the "EFM" button creates and activates the simulated EFM.

 Tapping the "FSBA" button performs a fetal scalp blood analysis. The result of the analysis is output in a text line.

 At the same time, result lines for body temperature and blood pressure can be displayed by selecting the respective buttons.

 Tapping the "Laboratory values" button opens a new selection window. You can tap to display a range of different laboratory test values.
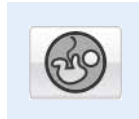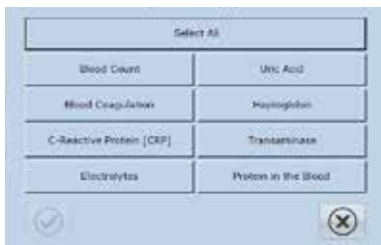
 Tapping the "Amniotic Fluid Quantity" button opens a new selection window, where you can tap the different quadrants to display the respective AF index. The entire AF index is also given.
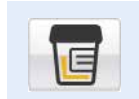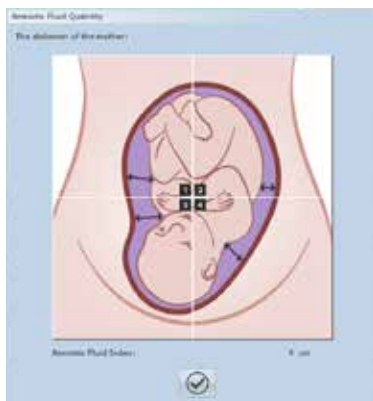
 Tapping the "Urine Screening Test" button opens a new window containing the test results for the urine screening test.

 Tapping the "Fetometry" button opens a new selection window.

 The performance of a manual fetometry is used for demonstration purposes only.

 If a fetometry using ultrasound is selected, a text line with the results is output.

 Tapping the "Placenta examination" button outputs a text line with the result.

You perform a placenta examination using ultrasound.
The maturity of the placenta is **3**.
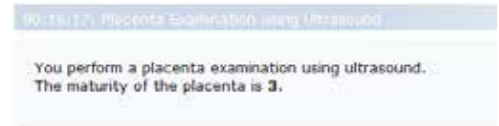
 Tapping the question button opens a new window in which a range of selected questions can be addressed to the simulated mother.

Ask the Mother Questions
Select a question to ask:
1. Would you like us to induce labor?

 You can tap the relevant button to send the simulated mother home. This does not end the simulation. The simulated mother is automatically presented again for observation.

Patient Sent Home
Patient Sent Home

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INTERVENTION MENU

All user interventions during the course of the virtual birth process are noted on the CTG and are available for a debriefing at the end of the process.
You can find a more detailed explanation of the effects of the drugs in section "2.7 Definition of terms".
The Intervention menu contains the submenus Medicinal; Operative; Other.

Medicinal submenu

This submenu can be used to administer medication to the simulated mother. This influences the behavior of the simulation.

Oxytocin:
Opens a new selection menu.

Medicinal/oxytocin submenu
The simulated mother is administered the hormone oxytocin as an infusion. You can change the dosage by moving the slider or tapping the control arrows.
Tapping the "Apply" button administers the selected dose to the simulated mother.
Tapping the "Remove" button cancels the administration of oxytocin.

Misoprostol:
Administers misoprostol (50 μg).

Prostaglandin:
Opens a new selection menu.

Medicinal/prostaglandin submenu
The simulated mother is administered a prostaglandin pessary (10 mg) or prostaglandin gel (1 mg).

Tocolysis:
Performs an emergency tocolysis.

Analgesia:
Opens a new selection menu.

Medicinal/analgesia submenu
You can use this submenu to provide pain relief to the simulated mother. This influences the behavior of the simulation.
Epidural anesthesia: The simulated mother is administered an epidural anesthesia for pain relief.
Pudendal block: The simulated mother is given a pudendal block for pain relief.
Opiates: The simulated mother is administered an opiate for pain relief.
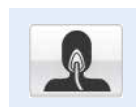
General anesthetic:
A general anesthetic is administered.

Paracetamol:
Opens a new selection menu.
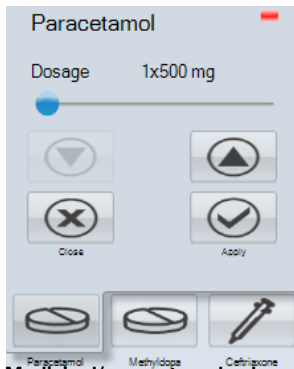
Medicinal/paracetamol submenu:
The simulated mother is administered paracetamol.
You can change the dosage by moving the slider or
tapping the control arrows. Tapping the "Apply" but-
ton administers the selected dose to the simulated
mother. Tapping the "Close" button cancels the ad-
ministration of paracetamol.

Methyldopa:
Administers methyldopa (250 mg).

Ceftriaxone:
Administers ceftriaxone (1000 mg).

Ringer solution:
The simulated mother is administered Ringer's
solution as an infusion.

NaCl:
The simulated mother is administered a sodium
chloride solution as an infusion.

Operative submenu

This submenu contains all interventions of an oper-
ative or surgical nature. To ensure that they are in-
cluded in the debriefing, selecting this button
leaves a note on the EFM trace. Possible operative
or surgical deliveries on which the student can decide are:

Forceps:
Delivery by forceps.

Vacuum extraction:
Birth acceleration using the suction cup.

Caesarean section:
Delivery by C-section, using either general or local
anesthesia.

Other submenu

You can use this submenu to carry out further
actions. These have no influence on the simulation,
but are stored for the debriefing.

Positional change:
The simulated mother is instructed to turn or
change her position.
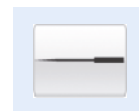
Acupuncture:
Acupuncture is performed on the simulated mother
for pain relief.

Amniotomy:
Can be used to initiate an amniotomy (opening of
the amniotic sac).
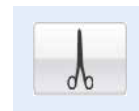
Episiotomy:
Performs a virtual episiotomy.

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8.4.4 Status messages during the simulation

Waiting for connection to hardware
This dialog is displayed when the hardware has not reached its target position When the target position is reached, the dialog disappears.

Figure 23: Waiting for hardware

Time lapse
This dialog box appears when the time lapse option is selected. The PC performs the necessary calculations. When the simulation has been adjusted to the selected time, the dialog disappears. You can use the X button to cancel the time lapse function.

Figure 24: Time lapse

Canceled by user
This dialog appears when the user taps "Cancel simulation". This safety prompt is designed to prevent accidental cancellation of the simulation. The X button means "No, do not cancel" and returns the user to the simulation.
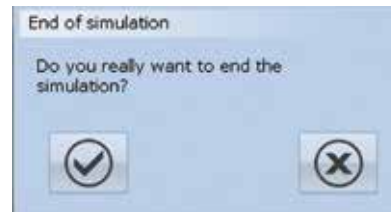
Figure 25: Canceled by user

Simulation terminated
This dialog appears when the simulation has been terminated. Termination of the simulation may have been forced by the user or by the simulation.

Tapping this button takes you to the debriefing.

Tapping this button restarts the simulation.

Tapping this button ends the simulation and takes you to the main menu.

Figure 26: Simulation terminated

8.4.5 Output of the simulation result / debriefing

1 EFM:
Outputs the cardiotocogram recorded during the simulation with all interventions. "Clicking" any point in the cardiotocogram selects a situation directly. All other displays on the screen change in sync.

2 Simulation messages:
The simulation messages are stored virtually one behind the other. Tapping the header brings the respective event window to the foreground.

3 Partogram:
Displays the dilation of the cervix against time.

4 3D image:
Displays the contour of the maternal abdomen, the pelvis and the position of the fetal head for the point in time selected in the CTG.

5 Applied infusions & pessaries:
Displays the medication administered using a drip during the simulation.

6 Controls on the debriefing screen

Figure 27: Simulation screen during the debriefing

8.4.6 Controls on the debriefing screen

The following section describes the controls on the debriefing screen.

This icon provides access to the options for setting the 3D graphics, the volume and for canceling the simulation.

Tapping this button opens the menu shown below.

The following settings can be made:

Graphic:
Varies the transparency of the contour of the maternal abdomen and pelvis.

Audio:
Adjusts the speaker volume.

End simulation:
Ends the simulation.
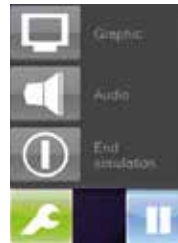
Tapping the "Chart" button opens the slider. You can move the slider to adjust the transparency of the contour of the maternal abdomen and pelvis in 3D view.

Tapping the "Audio" button opens the slider for volume adjustment. Adjustment is also possible with the arrow buttons on the monitor.

Tapping this button takes the output of the results of the simulation to the start of the recorded simulation protocol.

Tapping this button once slowly rewinds the recorded simulation protocol.

Tapping this button pauses the playback of the recorded simulation protocol.

Tapping this button starts or continues the playback of the recorded simulation protocol.

Tapping this button once slowly forwards the recorded simulation protocol.

Tapping this button takes the output of the results of the simulation to the end of the recorded simulation protocol.

You can move the slider to jump to any position in the recorded simulation protocol.

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8.5 Switching off

To switch the simulator off during the simulation or debriefing, proceed as follows:

1. Tap this button to open the Settings menu and select "End simulation".
2. Confirm the dialog that follows. The process is ended.

When canceling a simulation:

3. In the dialog box "End simulation", tap this button. The scenario selection screen is displayed.

4. Tap this button on the scenario selection screen to shut down the PC and switch the device off.
5. Switch off the simulator at the main switch (1) on the back of the device.

1 Main switch
2 Green acknowledge button
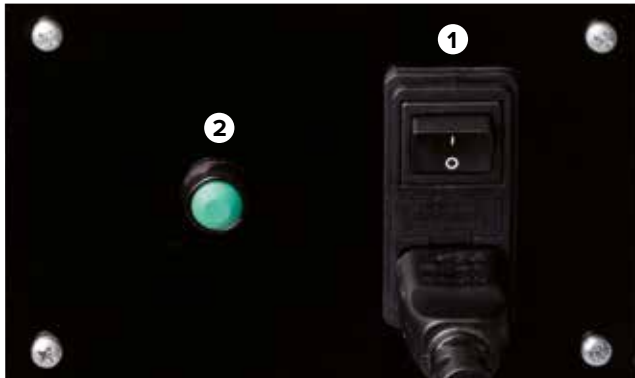
Figure 28: Main power switch on back

8.6 Activities after use

After use of the simulator, clean the lubricant from the head and artificial genitals with glass cleaner.

NOTE:

To prevent soiling of the simulator and objects getting into it accidentally, we recommend covering it with a protective cover (see section "13 Accessories and replacement parts"). These can be purchased from your authorized distributor or directly from the manufacturer (address → back of this guide).

8.7 Stopping in an emergency

In dangerous situations, stop the simulator as quickly as possible and switch off the power supply.

Stopping in an emergency. In case of danger, proceed as follows:

1. Initiate an emergency stop immediately at the nearest emergency stop button.
2. Inform those responsible on site.
3. Alert doctor and fire department if necessary.
4. Rescue people from the danger zone, initiate first aid measures.
5. Switch off the main switch and unplug at the mains.

After the rescue measures

6. Have specialist deal with the error.
7. Before restarting, check the simulator and ensure that all safety equipment is installed and working properly.

› 9. BIRTH SCENARIOS

9.1 Multipara (normal birth)

GÜLÇAN

29 years old
VIII-Gravida, V-Para
39th week of pregnancy

Course of pregnancy	Unremarkable
Gynaecological history	2 curettages 1 vacuum extraction (1st child) 4 spontaneous births
Findings on admission	regular contractions os uteri 3 cm

During this scenario, the student can watch the course of the birth and follow the mechanics of the birth as the foetal head passes through the birth canal.

In order for this scenario to begin, you must press the button ▶. The history will then appear in the window.

Above the buttons 🔴 and ▭ the CTG recording will start.

At this point in the scenario it is possible to determine, by a vaginal examination, which body part of the foetus is leading and at what level this is positioned, or what the relationship is between the lead position of the foetus and the interspinal plateau.

The width of the os uteri can also be called up using the button ⬅. Parallel to this, the partogram documents the width of the os uteri and the level of the foetus.

When the waters have broken is also shown when you push the button ⬅. You can use the buttons 🔴 and ▮ to carry out a foetal scalp blood analysis (FSBA), following which the laboratory values will appear in the window.

Although the student can operate the buttons 🔲 on the intervention menu and choose one of the possible interventions, this will not have any effect because in this situation it is not possible for the student to intervene in the simulation scenario.

In addition, when the foetal head exits, the student can perform the perineal protection manoeuvre.

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9.2 Nullipara (normal birth)

MAIKE

38 years old
IV-Gravida, 0-Para
40+2 weeks of pregnancy

Course of pregnancy	Unremarkable
Gynaecological history	2 abortions 1 extra-uterine pregnancy
Findings on admission	regular contractions os uteri 1 cm

During this scenario, the student watches the course of the birth and follows the birth mechanism during the passage of the head through the birth canal.
Pressing the button ▶ starts the scenario and the history appears in the window.

Above the buttons 🔲 and 🔲 the CTG recording starts.

At this point in the scenario it is possible to determine, by a vaginal examination, which body part of the foetus is leading and at what level this is positioned, or what the relationship is between the lead position of the foetus and the interspinal plateau.

The width of os uteri can also be called up using the button 🔲. Parallel to this, the partogram documents the width of the os uteri and the level of the foetus.

When the waters have broken is also shown when you push the button 🔲. You can use the buttons 🔲 and 🔲 to carry out a foetal scalp blood analysis (FSBA), following which the laboratory values will appear in the window.

Although the student can operate the buttons 🔲 on the intervention menu and choose one of the possible interventions, this will not have any effect because in this situation it is not possible for the student to intervene in the simulation scenario.

In addition, when the foetal head exits, the student can perform the perineal protection manoeuvre.

9.3 Uterine tetany (Polysystole)

VERONIKA

41 years old
IV-Gravida, III-Para
39th week of pregnancy

Course of pregnancy	Unremarkable
Gynaecological history	Status post-caesarean section 7 years ago (posterior pelvic position) 2 spontaneous births
Findings on admission	Regular contractions os uteri 3 cm

In this scenario the student will recognise that on the basis of lively contractions the infant is in a foetal crisis and an emergency tocolysis is required.

First the CTG recording must be started using the buttons 🫀 and ▱. After approximately 30 minutes there will be evidence of increased contractions: 4 – 5 consecutive contractions will take place without a pause between them. The foetus will respond by an absence of acceleration or late deceleration. At this point the student will not intervene actively in the course of the birth. This is because after 10 minutes the contractions will normalise and the child will once again demonstrate an unremarkable foetal heart frequency with accelerations.

After an hour (since the beginning of simulation), there will then be an approximate 10-minute uterine tetany (polysystole with 5 contractions per 10 minutes), with a subsequent prolonged contraction. The foetus first reacts with late decelerations. After the commencement of the prolonged contraction, the child will develop bradycardia. Now the student must carry out an emergency tocolysis within the next 15 minutes after commencement of the uterine tetany, which he/she can choose via the buttons 📋 and 🔲 and ✏. After the successful emergency tocolysis the foetus will slowly recover. The subsequent continuation of the birth process proceeds without event. The fetal cardiac frequency demonstrates late decelerations. But the student need not take any action.

If one passes the time frame of 15 minutes, the emergency tocolysis indeed has an effect upon the activity of the contractions, but the foetus continues to be in crisis: the foetal condition continues to worsen. The foetus can only be saved by an emergency caesarean section, to be chosen via the buttons 📋 and 🔪 and ⬤. If the emergency caesarean section is not carried out, the simulation will stop after, at most, another half an hour.

9.4 Contractile dystocia
(inefficient contraction activity)

SARAH

25 years of age
I-Gravida, 0-Para
40+5 weeks of pregnancy

Course of pregnancy	Unremarkable
Gynaecological history	No findings
Findings on admission	Irregular contractions os uteri closed sonography minimal amniotic fluid

In this scenario the student will recognise the strikingly slow course of the birth based on the weakness of the contractions without any evidence of an obstruction to the birth, and act accordingly. In addition, during this scenario the student can utilise the vaginal-operative delivery method.

First a CTG recording will be started that will last approximately 30 minutes, using buttons 🖐 and ▤ : the student will recognise the inefficient contracture activity and the indications for a medical stimulation of contractions using oxytocin[1]. Following an oxytocin[2] dose of 1 – 2 mU/minute the medical stimulation of contractions will begin. Every 15 – 20 minutes, the dose will be increased by a further 1 mU/minute. Starting at 5 – 6 mU/minute sufficient contraction activity will commence: the space between contractions is now clearly shorter and the relative contractile intensity will increase. The effect of the correctly set contractile activity will be demonstrated by the increasing opening of the os uteri.

Sufficient contractile activity should be set during the first 3 – 5 hours of the simulation; if this is not done, the uterus may reach full dilatation too late. In order to ensure that the simulation does not stop with this message: "the chosen measures did not lead to the desired consequences," the os uteri should have dilated fully during the first 15 hours.

If the IV for inducing labour is properly set, a larger part of the simulation can be skipped in terms of time with the aid of the blue 🕐 button. When the lead position of the foetal head exceeds the level +2, the next point that is relevant to successful scenario management has been reached. At this point a "birth stop" occurs. Despite the unremarkable foetal position (the CTG and FSBA are unremarkable), after a brief waiting period (2 – 3 hours) the student should decide on a vaginal-operative delivery (button combination 🔳 and ⤬ and ⤬ or 🔳 and ⤬ and ◤ and carry this out manually. Without the birth of the infant the simulation will also cease after 4 hours – after the occurrence of the "birth stop".

[1] Some students may have a tendency to first send the mother away (key word: take a walk) until the contractions commence on their own. Based on the scenario history, in particular the fact that the mother-to-be has already received prostaglandin, the continuation of the birth should be furthered here through the use of medication.

[2] It should be pointed out that before the use of oxytocin labor stimulation, administration should take place according to the recommended dosages of the relevant country, and manufacturers' instructions must be followed.

9.5 Intra-uterine asphyxia

LIN

30 years of age
IV-Gravida, III-Para
40+3 weeks of pregnancy

Course of pregnancy	Unremarkable
Gynaecological history	No findings
Findings on admission	Regular contractions full dilatation of the os uteri

This scenario is only for the implementation of a vaginal-operative delivery.

With the aid of model-oriented learning, the following steps can be carried out:
• Examination of level, position and direction
• Placement of the instrument
• Pulling and arranging the foetal head

First of all the student must be certain that the implementation of the procedure is not contraindicated. A (palpation) touch of the model to check the precise level, position and direction of the foetal head will answer this question.

The correct use and application of operative tools (forceps or vacuum extractor) are primary points: the position of the forceps and the hands, the sequence and the protection of the imaginary maternal soft tissue are of great significance when it comes to the implementation of a forceps delivery. If the vacuum extractor is used, the entrance procedure is of particular significance, as is the protection of the imaginary soft tissue and the speed of the increase in vacuum force.

The techniques for vaginal-operative delivery methods can be found in Chapter 4 of the Instructions for Use "Obstetrical medicine background".

If the vacuum extractor pulls off repeatedly, it is possible to change over to the use of the forceps within the learning scenario and practice this.

**9.6 Fever complication
(maternal cold signs of fetal distress)**

SOPHIA

**28 years old
II-Gravida 0-Para
39 weeks of pregnancy**

Course of pregnancy	Unremarkable
Gynaecological history	1 abortion
Findings on admission	Signs of having a cold, sniffing, coughing, headache, pain in the limbs Irregular contractions Amniotic sac intact

In this case the student will learn how to manage fetal tachycardia that was caused by the mother's cold symptoms. The increased fetal heat rate is a consequence of the mothers fever and should be treated using fluids and an antipyretic drug, if the proper treatment is administered it will lead to the birth of a child with normal laboratory and Apgar values.

First an EFM recording will be started by tapping on 🩺 and ▭ . The student will see a fetal tachycardia of 190 bpm with a variability of 7, the labor is aperiodic (2 contractions over 30 minutes). The student must request the mother's body temperature by tapping on 🩺 and 🌡 the value will be 39,5°C. The student can continue the investigation by performing all the rest of available tests from the diagnostic menu 🩺, all the other tests will display normal values suggesting that the fever and the rest of the symptoms on admission are caused by a viral infection.

The *correct action* the student should take is to control the mother's fever, which lead to the fetal distress. This is why the user should administer fluids by tapping on 💊 and 🔧 , after that he/she can choose between Ringer Solution or NaCl 💉 . The fluids alone have little effect on the fever and the user should administer Paracetamol by tapping on 💊 and 🔧 and 🍬. One tablet will decrease the body temperature to 37°C after 3 hours, two tablets administered at the same time will lead to a decrease to 36.6°C. The effect on the mother temperature of both fluids and Paracetamol follow their natural absorption. Because of the decrease in the mother's body temperature to around 36.6 – 37°C, the FHR will decrease and reach a normal baseline of 155 bpm and a variability of 15.

After stabilizing the mother's and fetus condition, a normal birth will occur at around 17 hours after admission.

The user has the possibility to speed up the birth by using labor inducing drugs which can be accessed by pressing 💊 and 🔧 , where he/she can choose between prostaglandin 🅟🅖 gel 🔧 or pessary 🔧, misoprostol 🍬 and oxytocin 💉 .

If the student takes *no action* during the simulation the mother's body temperature will increase to 40.2°C and the blood pressure will decrease to 70/50 mmHg. The fetus heart rate will remain at around 190 bpm, but the variability will decrease to 5. The simulation is stopped after 5:30 hours due to the mother and fetus worsening condition.

The remaining of the medicaments will have a general effect described in the General Medicament Effects section.

**9.7 Infection complication
      (maternal infection and signs of fetal distress)**

EMMA

**32 years old
III-Gravida I-Para
40+2 weeks of pregnancy**

Course of pregnancy	Unremarkable
Gynaecological history	Post spontaneous childbirth 1 extra-uterine pregnancy
Findings on admission	Ruptured membranes 3 hours ago Lime-green amniotic fluid is draining Cervix dilation 4 cm Signs of fever

In this case the student will learn how to treat a pregnant woman at term in labor with an infection. The trainee will contain the infection symptoms using antibiotics, fluids and an antipyretic drug and to reduce the fetal exposure to the infection the labor must be speed up using Oxytocin, resulting a healthy neonate. On the other hand if the user does not take any action the child will be born with low pH and Apgar score.

First a EFM recording will be started by tapping on 🟣 and ▭ . The student will see an infantile tachycardia of 170 bpm and the variability of 13. On admission the student can see that the laboratory values of the mother show an infection by tapping on 🟣 and 📋 (white blood cells are 16, C reactive protein is 4.5 and the haptoglobin is 250). The student must request the mother's body temperature by tapping on 🟥 and 🖊 , the value will be 38°C.

The *correct action* is to treat the infection symptoms by administering antibiotics (Ceftriaxone) pressing the button 🟥 and 🔫 and 🖊 . In this case the body temperature will decrease and the mother infection parameters (white blood cells, C Reactive Protein, haptoglobin) will remain stable, otherwise the parameters will worsen.

The student has to administer paracetamol by pressing the button 🟥 and 🔫 and ⬭ , this will lead to a decrease in the mother's temperature and thus also decreasing the FHR and increasing the variability, the improvement of the fetal state will also be denoted by an increase in the fetal pH (the pH can be determined by performing a FSBA pressing the 🟣 and ❘).

The student can administer fluids (Ringer Solution or NaCl) by pressing the button 🟥 and 🔫 and 💉 , this will lead to a slight decrease in the mother's temperature and slightly improve the fetus condition by decreasing the baseline and increasing the variability. The best effect on the child and mother can be attained if antibiotics, fluids and paracetamol are administered, then the neonate will be born with a normal FHR baseline of 150 bpm and with all his laboratory values in normal ranges (pH 7.34 and Apgar score of 9).

In order to speed up the labor and to limit the fetus exposure to the infection a value of maximum 13 U/min of oxytocin must be administered by pressing the button 🟥 and 🔫 and 🏃 (the adverse effects of exceeding the maximum recommended dosage of Oxytocin are described in the General Medicament Effects section).

If the student takes *no action* during the simulation the mother's infection and the fetal state will worsen. The fetal heart rate baseline will climb to 180, variability will decrease and slightly late decelerations will occur and finally the child will be born with a low PH and Apgar score.

The remaining of the medicaments will have a general effect described in the General Medicament Effects section.

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9.8 Heavy infection complication
   (maternal infection and signs of fetal distress)

OLIVIA

21 years old
I-Gravida, 0-Para
40+3 weeks of pregnancy

Course of pregnancy	Unremarkable
Gynaecological history	No findings
Findings on admission	Signs of fever The cervix is closed Amniotic sac intact

In this case the student will learn how to deal with a pregnant woman at term without labor and laboratory values describing a heavy infection. Despite all his/hers efforts to treat the mother and improve fetal state by administering antibiotics, fluids and antipyretic drugs the mother and fetal state will not improve and in the end the only solution for delivering the baby is to perform a caesarean section.

First a EFM recording will be started by tapping on 🫀 and ▬. The student will see an infantile tachycardia of 190 bpm and the variability of 7, the mother will have no labor activity.

Because of the admission findings the student should examine the laboratory values of the mother using buttons 🫀 and 🗋 which show a heavy infection (white blood cells are 17, C reactive protein is 6.5 and the haptoglobin is 400). The student must request the mother's body temperature by tapping on 🫀 and 🌡, the value will be 39.8°C.

The *correct action* for the user is to try to contain the infection and improve the fetal state by administering antibiotics, fluids and antipyretic drugs, and after they are absorbed he/she will notice that the fetal state has not improved. Given the critical state of the fetus a caesarean section (the gestational age is suitable) has to be performed in order to deliver the baby.

All attempts to start the mother's labor using labor inducing drugs will put additional strain on the fetus and the simulation will end with undesired results.

If the user takes *no action* after a simulation time of 2:30 the fetus will enter a sever hypoxia state and the heart rate will decrease to 60 bpm, after that the heart rate will display a sinusoidal pattern. If the user does not perform a caesarean section at this point the simulation will end with an undesired result.

The remaining of the medicaments will have a general effect described in the General Medicament Effects section.

9.9 Mild preeclampsia (labor induction needed)

MIA

19 years old
I-Gravida, 0-Para
37+5 weeks of pregnancy

Course of pregnancy	Unremarkable
Gynaecological history	No findings
Findings on admission	Increasing formation of edema (water retention in the feet) Cervix dilation 2 cm Cervix shortened but not effaced Amniotic sac intact

In this case the student will learn how to diagnose a young pregnant woman at early term with a mild preeclampsia. In this context the student will also learn how to induce the labor, not before obtaining the patient consent, leading to the birth of a healthy child.

First a EFM recording will be started by tapping on 🔲 and 🔲 , it will display normal FHR and no contractions. When requesting the blood pressure using buttons 🔲 followed by 🔲 , the value displayed will be 160/110 mmHg. Blood tests and urine screening test results show an increased transaminase level, a reduced thrombocyte level and proteins in the urine (the tests can be accessed via 🔲 and tapping on 🔲 and 🔲). The blood pressure and laboratory test results must be monitored carefully.

The *correct action* for the user is to firstly ask the mother if she would like the labor to be induced by pressing 🔲 and 🔲 , if she will accept. From the medicinal menu (can be accessed via 🔲 and 🔲) the labor can be induced with misoprostol 🔲 , prostaglandin 🔲 gel 🔲 or oxytocin 🔲 (maximum 13U/min, if this quantity is exceeded it will have the effect described in the General Medicament Effects section). In the same time the user should administer methyldopa, by tapping on 🔲 and 🔲 followed by 🔲 , the blood pressure will decrease. The actions above will lead to a normal birth with no further complications.

If the user takes *no action* after a simulation time of 3:00, the simulation will end with undesired results. If the user administers fluids like Ringer or NaCl (from the medicinal menu) the blood pressure will increase and the simulation will end, due to the already high blood pressure.

Administration of any labor inducing drugs without the mother's consent will lead to simulation end with undesired results. Also administration of prostaglandin pessary 🔲 will lead cause the mother to have long contractions leading to the deterioration of the fetal state and finally to the simulation end with undesired results. The rest of the labor inducing drugs, if administered incorrectly, have the same effect as described in the General Medicament Effects section.

The remaining of the medicaments will have a general effect described in the General Medicament Effects section.

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9.10 Severe preeclampsia (stage 2 event)

LILY

21 years old
I-Gravida, 0-Para
40+1 weeks of pregnancy

Course of pregnancy	Patient has not had a sufficiently thorough check-up
Gynaecological history	No findings
Findings on admission	Complaining of severe headache Cervix dilation 3 cm Amniotic sac intact

In this case the student will learn how to treat a high blood pressure of a young pregnant woman at term, with labor activity, by using antihypertensive drugs. The blood pressure has to be monitored carefully because in the beginning of stage 2 the blood pressure crisis will reoccur, and an emergency operative vaginal delivery should be performed in order to stabilize the mother's condition and deliver a healthy baby.

First a EFM recording will be started by tapping on 💗 and ⬛ , it will display a FHR of 140 bpm and irregular labor contractions (frequency at first 2 per 30 min). When requesting the blood pressure using buttons 💗 followed by 🔧, the user will see that the values are significantly increased (240/120 mmHg). Using buttons 💗 and 📋 the student can perform blood tests and notice that the results are in the normal ranges. When performing an Urine Screening Test (💗 and 🥤) the student should notice increased proteins in the urine. The blood pressure and laboratory test results must be monitored carefully throughout the labor.

The *correct action* for the user is to firstly administer methyldopa by tapping on 🎴 and 🔨 followed by 🥄 (at correct intervals, one every 6 hours), this will cause the blood pressure to decrease. At a cervix dilation of 10 and a station of +2, the blood pressure crisis reoccurs (240/120 mmHg), despite the antihypertensive treatment. At this time the simulator will warn the user by showing him, on the EFM and Simulation messages list, that the mother presents new symptoms "signs of exhaustion, visual disturbances, epigastric pain, nausea, vomiting and headache". The student has to perform an operative vaginal delivery (using buttons 🎴 and 🔪 and there he/she can choose between ventouse 🔦 or forceps ✂ aided delivery) that has to last less than 25 minutes, because of the critical condition, leading to the birth of a healthy child.

If the user takes *no action* after 1 hour the simulation will end with undesired results. When the new symptoms appear if the user is not able to perform the vaginal delivery in less than 25 minutes the simulation will end with undesired results (the vitals of the child will worsen).

Ringer or NaCl solution administration will also lead to the simulation end, because of the already increased blood pressure.
The remaining of the medicaments will have a general effect described in the General Medicament Effects section.

9.11 HELLP syndrome

EMILY

18 years old
I-Gravida, 0-Para
38+2 weeks of pregnancy

Course of pregnancy	Unremarkable
Gynaecological history	No findings
Findings on admission	Acute, serious, upper abdominal pain Nausea and vomiting Increased reflexes No edema Cervix is closed Amniotic sac intact

In this case the student will learn how to diagnose HELLP Syndrome in a young pregnant woman with no labor activity. After a general evaluation of the patient and fetal state it is essential for the student to perform an emergency caesarean section only under general anesthesia (this should be specifically chosen, being critical for the birth of a healthy neonate).

First a EFM recording will be started by tapping on [icon] and [icon] , it will display a FHR baseline of 115 and a small variability of 4, the mother has no labor activity. When the user requests the blood pressure by tapping on [icon] followed by [icon] the values are normal. Using buttons [icon] and [icon] the student will examine the mother blood tests and results will show a massively increased transaminase level, a Grade 3 thrombocythemia, hemolysis and a fall in the haptoglobin level. The student can perform all the other tests and notice that the results are in the normal ranges.

The *correct action* for the user is to diagnose the mother with HELLP syndrome despite the lack of hypertension and edema. Because of the mother's critical condition the student has to perform a caesarean section under general anesthesia (gestational age is suitable) within the first hour (pressing the buttons [icon] and [icon] and [icon]).

If the user takes *no action* during the simulation after 1h it will end with undesired results. Due to the critical situation performing a caesarean section under local anesthesia will lead to simulation end, because the local anesthesia would take longer to perform than the general one.

The remaining of the medicaments will have a general effect described in the General Medicament Effects section.

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9.12 Overdue
(mother refuses the labor induction procedure)

CHLOE

33 years old
IV-Gravida, I-Para
40 weeks of pregnancy

Course of pregnancy	Unremarkable
Gynaecological history	Post spontaneous childbirth 1 extra-uterine pregnancy 1 abortion
Findings on admission	The cervix is closed Amniotic sac intact

In this case the student will learn how to manage with a pregnant woman at term who came to a regular checkup with no signs of labor. The student has to ask the mother if she would like the labor to be induced the patient's decision is to wait for labor to start spontaneously. After several visits the labor will start spontaneously and a normal birth will be simulated.

First a EFM recording will be started by tapping on 💗 and ⌨️ , it will display a normal FHR and no labor. The results of the amniotic fluid quantity, fetometry, placenta examination tests are normal (the examinations can be performed by pressing the buttons 💗 and ⚙️ 🖌️ and ⚙️ and ⚙️). The student can perform all the other tests and notice that the results are in the normal ranges.

The *correct action* for the user is to ask the mother each time, by pressing the buttons 💗 and 🔊, if she would like the labor to be induced, but she will refuse each time. The user sends the patient home (by pressing the buttons 💗 and 📅) and the patient returns after two days and an updated history message appears in the Simulation messages list. When the patient returns for the sixth time (after 11 days), the birth starts spontaneously. This will lead to the birth of a child with normal laboratory values. After the birth process starts spontaneously, it can be sped up using labor inducing drugs.

If the user takes *no action* during the simulation after 3h it will end with undesired results. Simulation will also end with undesired results if the user administers oxytocin, misoprostol, prostaglandin gel or pessary before the labor started spontaneously, this happens because the mother did not give her consent.

The remaining of the medicaments will have a general effect described in the General Medicament Effects section.

9.13 Overdue
   **(mother accepts the labor induction procedure)**

CHARLOTTE

23 years old
I-Gravida, 0-Para
40 weeks of pregnancy

Course of pregnancy	Insulin-dependent gestational Diabetes (diagnosed in the beginning of the 3rd trimester)
Gynaecological history	No findings
Findings on admission	The cervix is closed Amniotic sac intact

In this case the student will learn how to use labor induction drugs with a pregnant woman at term, who came to a regular checkup with no signs of labor and agrees to the labor induction procedure. Labor starts after 1 day of induction and after that a normal birth will follow.

First a EFM recording will be started by tapping on 🩷 and ▭ , it will display a normal FHR and no labor. The results of the amniotic fluid quantity, fetometry, placenta examination tests are normal (the examinations can be performed by pressing the buttons 🩷 and ⚙1 🧹 and ⚪ and ⚙1). The student can perform all the other tests and notice that the results are in the normal ranges this denotes that the gestational diabetes is controlled and had no effect on the pregnancy.

The *correct action* for the user is to obtain the mother's consent (by pressing the buttons 🩷 and 📢 and asking her the appropriate question) before inducing the labor and to teach the trainee the proper way to induce the labor. The student can choose between all the available labor induction drugs (by tapping on 🔲 and 🔲):
• Misoprostol 50µg ⬭ or Prostaglandin Gel 1mg PG 🔑 once every 6h for 24h
• Prostaglandin Pessary PG 🔖 should be active more than 20 hours
• Oxytocin 10-15U/min 💉 should be active more than 20 hours

Before the contractions start the fetus will have several phases of decreased variability lasting less than 40 min, the student should identify this occurrences as fetal sleep and not a sign of distress.

If the user does not respect the administration times (too frequent, infrequent or administering 2 or more labor inducing drugs in the same time) and amounts specified above he/she will fail to induce the labor and the simulation will end with undesired results. Before augmenting the labor with Oxytocin the user has to make sure that the last Misoprostol was administered at least 3h ago and the last Prostaglandin gel was administered 6h ago.

If any of the above drugs are administered correctly, after 17 – 24 hours contractions will start to appear. Misoprostol is the fastest to induce labor, followed by oxytocin and lastly prostaglandin pessary and gel. After the contractions start, a child with normal laboratory values will be born within 12 hours. Labor augmentation can be used in this interval and will follow the effects described in the General Medicaments Effects section.

If the user does not ask the mother if she would like the labor to be induced the simulation will stop after 1h and if he/she does not administer a labor inducing drug within 1 hour after obtaining the mother's consent the simulation will end with undesired results.
The remaining of the medicaments will have a general effect described in the General Medicament Effects section.

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**9.14 Overdue (post caesarean section, mother refuses a
new caesarean section and the labor is induced)**

NORA

38 years old
III-Gravida, I-Para
40+3 weeks of pregnancy

Course of pregnancy	Unremarkable
Gynaecological history	Post caesarean section 1 extra-uterine pregnancy
Findings on admission	Cervix is closed Amniotic sac intact

In this case the student will learn how to deal with a pregnant woman at term post caesarean section, who refuses a second operative delivery and agrees that her labor should be induced. The cervix opens slowly (over 10 hours), until it is fully dilated but the child's head does not enter the pelvis. The birth process stops and a secondary caesarean section is now the only option.

First a EFM recording will be started by tapping on ⬚ and ⬚ , it will display a normal FHR and no labor. After the ultrasound fetometry is performed, the student will notice that the fetus is approximate weight is 4400g, this poses additional risks to the delivery and should be monitored carefully (the examinations can be performed by pressing the buttons ⬚ and ⬚ ⬚). The student can perform all the other tests the results will be in the normal ranges.

The *correct action* for the user is to firstly ask the patient if she wants a primary C-section should be performed using the buttons ⬚ and ⬚ , but she refuses and an appointment is booked up for the next day by pressing the buttons ⬚ and ⬚ . On the next day the user should ask the mother if labor should be induced using the buttons ⬚ and ⬚ and if she accepts.

First the student should try to administer Oxytocin but he/she will notice it is not effective due to the mother's receptors not being active. After that the user should try the labor inducing with Prostaglandin gel (1 mg) once every 6h using the buttons ⬚ and ⬚ and ⬚ and ⬚ . Two hours later from the first administration the mother starts to have contractions and after another 10 hours the cervix will be fully dilated but the fetal head/presentation will not advance more than station -2, the FHR will start to decrease (denoting a fetal distress). Given the previous caesarean section, the only solution is a new caesarean section, so the user has to perform it using the buttons ⬚ and ⬚ and ⬚ (local or general anesthesia can be used when performing the operative delivery).

If the user takes *no action* during the simulation after 2h this will end with undesired results. The same effect will occur if the user administers any other labor inducing drugs except Prostaglandin gel or if the user does not respect the administration times and the quantity of the Prostaglandin gel.

The remaining of the medicaments will have a general effect described in the General Medicament Effects section.

› 10. MAINTENANCE

10.1 Safety

Core requirements

(!) **WARNING!**

Risk of injury from improperly performed maintenance work!
Improper maintenance can lead to serious injury or damage to property.
Therefore:
- Maintenance work may only be carried out by qualified personnel who have been authorized and trained by the operator.
- Before starting work, ensure that there is sufficient space for assembly.
- Ensure that the assembly location is clean and tidy. Loosely stacked or scattered components and tools are sources of accidents.
- If components have been replaced: Ensure that replacement parts have been installed correctly. Replace all fastening elements correctly.
- Before switching back on, ensure that all covers and protective devices are correctly installed and working properly.

Electrical equipment

(⚡) **WARNING!**

Risk of death due to electrical current!
Contact with live components poses a danger to life. Switched on electrically operated components can start moving uncontrollably and cause very severe injury.
Therefore:
- Before starting work, switch off the device at the main switch and secure it against being switched back on by pressing EMERGENCY STOP and unplugging the power plug.
- All work on the electrical system, on individual electrical components and on the connections may only be carried out by qualified electricians.

Securing against restart

(!) **WARNING!**

Risk of death due to unauthorized restart!
When working on individual assemblies or components, there is a risk of the power supply being switched on by an unauthorized person, causing injury to those in the danger zone.
Therefore:
- Before all work, use the following procedure to secure the device against a restart:
  1. Switch off the device at the main switch.
  2. Press EMERGENCY STOP to lock.
  3. Secure the device against being switched back on by unplugging the power plug. (The device is not properly disconnected from the power supply until the power plug is disconnected).

10.2 Maintenance schedule
The following sections describe the maintenance work required for optimum and trouble-free operation. The maintenance work must be carried out as described below by the person responsible for the device.
In the event that you find an increased level of wear on the components during regular inspections, shorten the maintenance intervals on the basis of the actual wear and tear.
For questions concerning maintenance work and intervals:
Contact the manufacturer.

Interval	Maintenance work
After use	Clean the lubricant from the head and artificial genitals with glass cleaner.
Monthly	Clean simulator (see section "10.3.2 Cleaning the simulator").
Half-yearly/ as required	Check simulator mechanics for play. Check stability of the simulator. Check attachment of the touchscreen. Check silicone genitals for damage. Check foam core for dirt and damage. Check inside of simulator for foreign objects. If present, remove them. Check legibility of labels and signs.

10.3 Cleaning the touchscreen

10.3.1 Cleaning the touchscreen
To clean the TFT monitor, use a soft cloth and a commercially available cleaning agent recommended for TFT monitors. Glass cleaners and solutions containing alcohol are not suitable.

10.3.2 Cleaning the simulator
Check the simulator daily for dirt or soiling.

Cleaning the outer surfaces
1. Switch off the simulator and secure against restart.
2. Carefully remove all dirt. Please note:
   - Do not use aggressive cleaning agents or scouring additives. Rinse the simulator with clean water only.
   - Do not use hard sponges, floor cloths or brushes. Treat the simulator with a soft cloth only.
   - Dispose of cleaning cloths in an environmentally friendly manner and in compliance with the applicable local regulations.
3. After finishing cleaning work, check to ensure that all opened covers and safety devices have been properly closed and are working correctly.

Cleaning the inside of the simulator
- Before carrying out any work on the simulator, disconnect from the mains.
- Remove the three outer screws on the genitals.

- Carefully remove the genitals.

- Carefully remove the birth canal.
- Clean the birth canal and the female genitals under running water, then dry thoroughly.

- Check the birth canal and vulva for damage. Always replace in the event of damage.
- Insert the birth channel carefully back into the lower torso section.
- To avoid damage, ensure that the holes for fastening are exactly aligned with the screws.

- Replace the female genitals.

• Tighten the three outer screws back into place.

• Loosen the two screws in the leg attachments on the torso.

• Remove the lower torso section.

• Loosen the four screws in the upper torso section.

• Remove the upper torso section.

• Remove the foam core.
• Clean the foam core with soapy water and a slightly damp lint-free cloth. Take the opportunity to check the foam core for damage and always replace if damaged.
• Check the simulator's mechanics by hand for play. If you find that there is play, measure it with a gage and contact 3B Scientific Customer Service (contact ➞ back of this guide).
• Dry clean the inside of the simulator if necessary. Remove any foreign bodies by hand.

• Check that the fetal head is properly in place.
• If necessary, tighten the 4 hexagon socket screws with the Allen wrench.

• Insert the foam core back into place.

• Clean the upper and lower torso sections with a cloth and soapy water and allow to dry completely. Take the opportunity to check both torso sections for damage. Always replace damaged sections.

• Fit the lower torso section back in place.
• Tighten the two screws in the leg stumps.

10.3.3 Replacing the fuses

There are two fuses between the main switch and the mains connector. To replace them, proceed as follows:
1. Switch the simulator off.
2. Unplug at the mains.
3. Pull out the fuse holder with a screwdriver.
4. Remove fuses and fuse holder.
5. Replace defective fuses with fuses of the same type.
6. Push the fuse holder back into place.
7. Plug the mains plug back in.

10.4 Measures after completing maintenance

After completing maintenance and before switching back on, perform the following steps:
1. Check to ensure that all loosened screw connections are firmly back in place.
2. Check to ensure that all removed safety equipment and covers have been properly replaced.
3. Ensure that all tools, materials and other equipment used have been removed from the work area.
4. Clean the work area and remove any spilled materials.
5. Ensure that all safety equipment on the simulator is working properly.

10.5 Restarting

After maintenance, the simulator should be started for testing and calibration of the monitor.
To switch on, proceed as follows:
1. Insert the mains plug into the power outlet.
2. Check the position of the emergency stop button. If necessary, unlock it by turning to the right.
3. Press the main switch (1) but do not press the green acknowledge button (2) yet.

NOTE:
When you switch on the main switch (1), the PC starts up and tries to establish communication with the birth mechanics. However, if the green acknowledge button is not pressed within the next 30 seconds, communication will not be established. The screen displays the message "Hardware Not Found". The simulator goes into calibration mode.

4. You now have the option to calibrate the touchscreen. To do this, use the plastic stylus included in delivery to tap the points that appear on the screen one after the other. Because the screen is a touchscreen, do not touch its surface with any part of your body while tapping. The calibration data is saved.
The PC then shuts down and restarts.

5. Now press the green acknowledge button (2) on the back of the device to supply power to the simulator's mechanics. For the next steps, see sections "8.3 Starting the simulator" and "8.4 Simulation application".

Figure 29: Main switch (1) on the back of the simulator
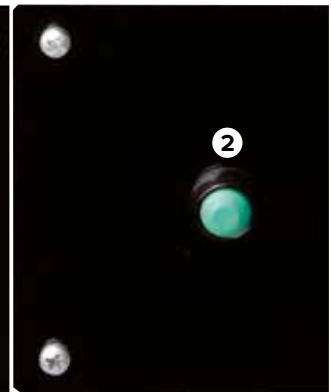
Figure 30: Acknowledge switch (2) on the back of the simulator

› 11. ERRORS

This section describes ways to eliminate possible causes of error. The maintenance intervals should be shortened to reflect the actual workload, inasmuch as similar errors occur more frequently as a result of above-average intensive use.

NOTE:
In the event of an error that cannot be corrected using the table above, you will find more up-to-date information in the "FAQs" section of the website www.birthsimulation.com.

Procedure in the event of errors

In general, the following applies:
1. For errors that pose an immediate danger to people or property, trigger an emergency stop immediately.
2. Switch off all power supplies and secure against restart.
3. Inform those responsible on site.
4. Depending on the type of error, have those responsible and authorized personnel identify and remedy the cause.

Error	Possible cause	Fehlerbehebung	Remedied by
Simulator not starting	The simulator's mains plug is not plugged in.	Plug the mains plug into a live power outlet.	Operator of the simulator
	Main switch not pressed.	Press main switch (see section "8.3.1 Switching on").	Operator of the simulator
	Acknowledge button not pressed.	Press acknowledge button (see section "8.3.1 Switching on").	Operator of the simulator
	Connection cable cover / simulator housing not assembled	Switch off device at main switch on back of simulator, pull power cord pull, carefully remove cover (two people) and connect cable ends	Operator of the simulator
	Emergency stop button is pressed.	Remedy cause of emergency stop. Unlock emergency stop (see section "3.6 Safety equipment").	Operator of the simulator
	Unknown error message on screen on system start-up.	Note error message and contact 3B Scientific Customer Service.	Customer Service 3B Scientific
	Failure of power supply.	Check power supply.	Electrician
	Defective simulator fuse	Check fuses (see section "10.3.4 Replacing the fuses").	Electrician
	None of the above causes.	Contact 3B Scientific Customer Service.	Customer Service 3B Scientific
No display on the screen	The simulator is not started.	See solutions under "Simulator not starting".	Operator of the simulator
	Monitor is not switched on / power indicator is not lit.	Switch on monitor with power button.	Operator of the simulator
	Monitor's mains plug is not plugged in.	Check monitor's mains plug.	Operator of the simulator
	Monitor plug is not plugged in.	Check monitor plug.	Operator of the simulator
	None of the above causes.	Contact 3B Scientific Customer Service.	Customer Service 3B Scientific
Touchscreen operation not possible	Simulator and monitor are not started.	See solutions under "Simulator not starting" and "No display on the screen."	Operator of the simulator
	USB cable not plugged in.	Check to ensure USB cable is in place.	Operator of the simulator
	None of the above causes.	Contact 3B Scientific Customer Service.	Customer Service 3B Scientific
Simulator mechanics not moving or not moving properly	The simulator is not started.	See solutions under "Simulator not starting".	Operator of the simulator
	Acknowledge button not pressed.	Press acknowledge button (see section "8.3 Starting the simulator").	Operator of the simulator
	The mechanics are blocked.	Check mechanics and remedy cause (see section "9.3.2 Cleaning the simulator").	Operator of the simulator
	Lubrication is not sufficient.	Apply lubricant (see section "8.3.2 Selecting the language and starting up the simulator").	Operator of the simulator
	The housing covers are not closed properly	Check to ensure that the cover is properly in place (see section "10.3.2 Cleaning the simulator").	Operator of the simulator
	The foam birth canal is not inserted correctly.	Check to ensure that the birth canal is properly in place (see section "10.3.2 Cleaning the simulator").	Operator of the simulator
	Emergency stop button is pressed.	Remedy cause of emergency stop. Unlock emergency stop (see section "3.6 Safety equipment").	Operator of the simulator
	None of the above causes.	Contact 3B Scientific Customer Service.	Customer Service 3B Scientific

Mechanics are making squeaking sounds	Lubrication of the drive shaft for the main arm not sufficient.	Grease drive shaft with allround high-performance type OKS 470 grease (see section "13 Accessories and Replacement Parts")	Operator of the simulator
Incorrect display of forces and torques	Faulty calibration (e.g. through touching the head).	Restart the simulator.	Operator of the simulator
	Faulty mechanics.	Shut down simulator and contact 3B Scientific Customer Service.	Customer Service 3B Scientific
	None of the above causes.	Contact 3B Scientific Customer Service.	Customer Service 3B Scientific
Frequent software crashes	Humidity or temperature to high.	Adjust climatic conditions or change installation site.	Operator of the simulator
	Defective PC.	Contact 3B Scientific Customer Service.	Customer Service 3B Scientific
	None of the above causes.	Contact 3B Scientific Customer Service.	Customer Service 3B Scientific

› 12. DISPOSAL

Where no return or disposal agreement has been reached, send disassembled components for recycling:

Electronic components
Electronic components (PC, motors, electronics box, switching power supply, sensors) must be treated as hazardous waste. They must be disposed of by a specialist waste management company.

Remaining components
In the design, every effort has been made to ensure that the majority of machine parts can be recycled. Send the electronic components removed from the mechanical equipment to a metal recycling company.
All other components of the simulator can be disposed of as normal household waste.

CAUTION!
Environmental damage due to incorrect disposal!
Electronic waste, electronic components, lubricants and other auxiliary materials must be treated as hazardous waste and may only be disposed of by authorized specialist companies.

Local municipal authorities and waste management companies can provide information on environmentally responsible disposal

› 13. ACCESSORIES AND REPLACEMENT PARTS

Item number	Replacement part
XP801A	1 day installation, start-up and training on the birth simulator SIM*one*™ P80/1
XP802	Replacement fetal head with metal rail
XP803-x	Suction cup (x is a placeholder for the model)
XP804-x	Vacuum pump (x is a placeholder for the type: manual or electronic)
XP805-x	Forceps (x is a placeholder for the model)
XP806	Lubricating gel, 2 x 200 ml
XP807-x	Latex-free disposable gloves, 100 pairs (x is a placeholder for the size S [7], M [8], L [9] or XL [10])
XP811	Replacement insert for the genitals, 2 pieces
XP812	White foam core for limiting the birth canal
XP813	Stylus touchscreen pen (a stylus is supplied with the touchscreen)
XP814	Protective cover for covering the device
XP815	Adapter for connector types B, D, E, F, G/BS1363, I, J, L and M (150 countries).
XP816	Assembly toolset (1 x Allen wrench 4, 1 x Allen wrench 8, 1 x Phillips screwdriver PH2, 2 x combination wrench 13)
XP817	Lubricant for drive shaft: OKS 470 allround grease, 100 g tube
XP818xx	Folder with operating instructions (xx is a placeholder for the language by ISO 3166 country code)
XP819-x	External speaker pair, 2 x 2.5 W sinus, x is a placeholder for 115 V or 230 V
XP820	Birth canal with spinae

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