SMART

GM INSTRUMENTS

SMART

STANDARDISED MEASUREMENT OF AIRWAY RESUSCITATION TRAINING

NEWBORN resuscitation training system

USER MANUAL

V3

TRADEMARKS

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WARNINGS AND CAUTIONS

WARNING

The SMART system is not intended to be used in a patient environment and must only be used with the modified manikins supplied with the system.

CAUTION

The use of the SMART system near to sources of electromagnetic radiation, such as mobile phones, radio transmitters, x-ray equipment etc., may prevent it from functioning correctly.

CAUTION

Servicing is only to be carried out by GM Instruments approved and authorised personnel.

CAUTION

No modification of this equipment is permitted.

CAUTION

The SMART manikins are not to be used for any other purpose other than as part of the SMART system. Under no circumstances should they be used for simulated mouth to mouth resuscitation or chest compressions.

STORAGE

The SMART system and its accessories should be stored within the following temperature and humidity range: Temperature -40°C to +60°C; Humidity 20% to 80% relative humidity non-condensing.

ACKNOWLEDGEMENTS

The SMART system has been developed in conjunction with Dr Charlotte Kemp and Dr Fiona Wood of the Medical Physics Department and the Department of Neonatal Medicine at the James Cook University Hospital, Middlesbrough; part of South Tees Hospitals NHS Foundation Trust.

Contents

1 INTRODUCTION

Face mask ventilation is a key life-saving technique taught on many resuscitation courses, and providing effective ventilation is vital in newborn resuscitation. This technique can be difficult to master and has therefore been the subject of numerous research studies. These have evaluated masks, ventilation devices, resuscitator techniques, and the effectiveness of training; and work continues to identify and fill knowledge gaps.

Studies have shown that resuscitators commonly demonstrate significant leak at the mask/face interface (mask leak) when performing face mask ventilation. This can vary on an almost breath by breath basis, consequently ventilation is inconsistent with a potential for harmful extremes in tidal volume delivery. Research has identified that face mask ventilation technique is key to resolving such issues.

This manual describes the features and use of the SMART newborn resuscitation training system.
Other manuals accompanying this system include:

- Service Manual and Software Manual

1.1 DEVICE DESCRIPTION

- The acronym SMART stands for **S**tandardised **M**easurement of **A**irway **R**esuscitation **T**raining
- The SMART processing unit is used with a specially modified manikin and the data acquired are displayed using SMART software
- To augment face mask ventilation training the SMART software displays typical respiratory function waveforms (pressure, flow and volume) and the measured percentage mask leak
- Airway pressure and gas flow are measured directly. Gas flow is measured both as it is supplied, passing through the mask towards the manikin lung system, and on its return when expelled by the recoil response of the manikin
- Tidal volume is derived from the measured gas flow; and this is used to calculate mask leak
- If mask leak occurs, the volume of gas collected and returned back through the flowhead (the recoil volume) will measure less than that supplied
- The SMART software measures the difference between supplied volume and recoil volume and expresses that as a percentage. Acceptability is shown visibly by a colour coded emoticon

1.2 INTENDED USE

The SMART system is intended to provide objective feedback on the efficacy of newborn resuscitation in the simulated environment. The SMART system permits effective demonstration of techniques and enables individuals and groups to practise differing techniques with real-time feedback. This feedback allows individuals to find their most effective mask hold and can be used to highlight any areas for continued development that may be pertinent to clinical practice. It can also be used to explore a range of aspects that may impact on the efficiency of face mask ventilation, from devices to team factors. The SMART system can subsequently be used in self-directed practise.

Simple presentation of respiratory waveforms with easy to read scales, including a time stamp, enable the user to examine delivered positive pressure ventilation (PPV) and its variation on a breath by breath basis. The system does not require the user to be familiar with respiratory waveforms as mask leak is simultaneously presented numerically with accompanying colour coded graphics in a clear and unambiguous way.

By means of the user-friendly visual feedback, the effectiveness of the resuscitation devices and/or techniques can be assessed, altered and improved.

1.3 INDICATIONS FOR USE

This system is best used to facilitate training and development; continued practise is encouraged to reinforce and maintain skills learned. Individuals or resuscitation teams can also use the specially modified term and preterm (25 week) manikins to assess their performance with both new and existing equipment. It permits risk free practise, enabling adjustment of an individual's technique in real-time to: achieve important outcomes; establish a stable, comfortable and reproducible technique; reduce mask leak; and so provide more consistent ventilation delivery.

1.4 APPLICATIONS

Examples of situations in which the SMART system may be used include:

- On accredited national training courses, such as the Advanced Resuscitation of the Newborn Infant (ARNI) course, run by the Resuscitation Council (UK)
- During facilitated resuscitation training and group work
- During self-directed practise to maintain and enhance performance after resuscitation training

1.5 TECHNICAL NOTE

This manual assumes that you are familiar with your computer's hardware and basic Windows™ commands. If you are not familiar with these items you may wish to keep a Microsoft® manual and your computer's users guide close at hand when installing your SMART software.

2 PACKAGE CONTENTS, COMPONENTS AND CONSUMABLES

PRODUCT NAME	SMART newborn resuscitation training system
NAME OF MANUFACTURER	GM INSTRUMENTS LTD
MANUFACTURED IN	IRVINE, UK

The following components and software programmes are available with the SMART system

2.1 INSTRUMENT AND ASSOCIATED PARTS

□	SMART processing unit	SMART
□	USB Cable	S-USB cable
□	Flowhead	S-FL
□	Twin tube set	S-2T
□	Installation Manual	S-IM
□	User Manual	S-UM
□	Service Manual	S-SM
□	SMART + MCC Software	S-USB soft
□	Term Manikin	S-TM
□	Preterm Manikin	S-PTM
□	Carry Case	S-C/C

2.2 MASK PACK (Optional)

2.2.1 Term resuscitation masks

□	LM_0/1	□	AR_1
□	FP_60	□	IN_1

2.2.2 Preterm resuscitation masks

□	LM_0/0	□	FP_35
□	FP_42	□	IN_0

2.3 COMPUTER (Optional)

□ Laptop PC pre-configured with the SMART software

3 SAFETY CONSIDERATIONS

3.1 WARNINGS AND CAUTION MESSAGES

WARNING MESSAGES: A warning message describes a condition or situation that may present danger to an individual if the guidance in the manual and/or an operating procedure is not followed. Warning messages are highlighted with the  symbol.

CAUTION MESSAGES: A caution message is used to inform of a condition or situation that may result in damage to the SMART system components or cause data loss. Caution messages are highlighted with the  symbol.

4 ENVIRONMENTAL REQUIREMENTS

4.1 TEMPERATURE

The normal operating temperature range is from 15°C to 35°C. The transducers are temperature compensated between these limits, but the flowhead calibration will be affected at a rate of 5% per 20°C change outside of this range. The calibration is initially set at 18°C.

4.2 HUMIDITY

The operating relative humidity range is from 20% to 80% non-condensing.

4.3 COMPUTERS SUPPORTED

The software and hardware can be provided in a format suitable for IBM or compatible PCs with a free USB port. Computers built to BS EN 60950-1 are recommended.

4.4 PRODUCT SPECIFICATION

4.4.1 SMART

Size	27 x 8 x 30cm
Mass	2kg
Flow Range	±100ml/s (±6l/min)
Pressure Range	±50cmH_2O

Accuracy	±2%
Supply	Derived from computer USB port
Standards	Electrical Safety and EMC BS EN 60601-1 series
Warm up time	5 minutes
Operating Temperature	+15°C to +35°C
Operating Humidity	20% to 80% relative humidity non condensing
Duty Cycle	Continuous

4.4.2 MANIKINS

4.4.2.1 Term manikin

Size	59 x 26 x 13.5cm
Mass	1.85kg
Rate of air leakage when pressurised to 50cmH_2O	Less than 0.1cmH_2O/min
Static compliance (approx. 2 x dynamic compliance)	Within the range 0.8-1 ml/cmH_2O

4.4.2.2 Preterm manikin

Size	30 x 20 x 8cm
Mass	0.9kg
Rate of air leakage when pressurised to 50cmH_2O	Less than 0.1cmH_2O/min
Static compliance (approx. 2 x dynamic compliance)	Within the range 0.5-0.6 ml/cmH_2O

5 PRODUCT SUPPORT

If you have any questions about your SMART system, user or service manuals, contact GM Instruments using the details given in 5.1. When contacting GM Instruments for product support, please have the following available:

- This user manual
- Details of the operating system of your computer (e.g., Windows XP, Vista, 7, 8, 10 etc.)

It may also be helpful if you are in front of your computer when you call in order to help our personnel to quickly and accurately answer your questions.

5.1 CONTACT INFORMATION

Address: GM INSTRUMENTS LTD.
Greig House
Block 1, Annickdale Innovation Park
Annick Road
IRVINE
KA11 4LF
UK
Telephone: 01294 554664
Email: enquiries@gm-instruments.com
Website: www.gm-instruments.com

6 COMPONENTS DESCRIPTION

6.1 OVERVIEW

The main components of the SMART system are the SMART processing unit, flowhead, term/preterm manikins and laptop.

6.1.1 SMART processing unit

The SMART processing unit provides processing of the flow and pressure signals. It is connected to and powered by the laptop via the USB interface. The USB-B plug on the SMART/laptop cable connects to the USB-B socket on the rear panel of the SMART processing unit and the USB-A plug on the SMART/laptop cable connects to a spare USB-A port on the laptop. When connected and powered by the laptop, and when the USB interface driver has recognised the USB module present (by running the program Instacal on the first installation), the green power light on the front panel of the SMART processing unit will illuminate continuously.

The pressure sensor is located within the SMART processing unit enclosure; connection is made to the pressure sensor via the red port on the front panel of the SMART processing unit.

6.1.2 Flowhead

The flowhead is used to measure air flow and is connected to the front panel of the SMART processing unit via the green and red ports. The dimensions of the flowhead ports are as follows:

- Male connector (green label), external diameter = 15.47mm, compatible with most standard ventilation devices/circuits
- Female connector (red label), internal diameter = 15.36mm, compatible with most standard patient interface connectors, e.g. masks / endotracheal tubes

6.1.3 Laptop

The laptop computer provides user interface and data display functions and is supplied with all necessary software applications pre-loaded.

6.1.4 Manikins

The term and preterm manikins supplied have been modified for use as part of the SMART system. Manikin qualities include a fully sealed tubing system from the mouth of the manikin to a standard ‘lung’; which, when connected to the SMART processing unit, form a closed circuit. The complete system has a

fixed airway resistance and compliance with no inherent leak or airway obstruction. Therefore, the only source of leak measured would be due to an ineffective mask seal during PPV.

The SMART manikins differ from unmodified manikins; subtle chest rise may be observed when there is substantial mask leak present during PPV, particularly when using positive end expiratory pressure.

CAUTION

The SMART manikins are not to be used for any other purpose other than as part of the SMART system. Under no circumstances should they be used for simulated mouth to mouth resuscitation or chest compressions.

6.1.4.1

Term manikin

When used as part of the SMART system, air pressure within the term manikin is measured from the red ringed tube on the front of the SMART unit.

Preterm manikin

When used as part of the SMART system, air pressure within the term manikin is measured from the red ringed tube on the front of the SMART unit.

7 USING THE SMART SYSTEM

The SMART system can be used to measure the gas flow and pressure as it moves in to and out of a manikin during simulated PPV. The SMART system can be used with any commonly used ventilation devices, such as:

- A self-inflating bag
- A flow-inflating bag
- A t-piece resuscitator (supplied with a regulated, continuous flow gas source)

⚠ **CAUTION**

If the SMART system is to be used with a t-piece resuscitator and regulated gas source, the flow rate of the gas supply must not exceed 6l/min

7.1 SYSTEM ASSEMBLY

7.1.1 Connecting the flowhead to the SMART processing unit

- Connect the green/red tubing pair to the green and red ports on the SMART processing unit and connect the flowhead to the other ends of this tubing (red tubing attaches nearest to mask, green tubing attaches nearest to ventilation device), as shown in Figure 1.

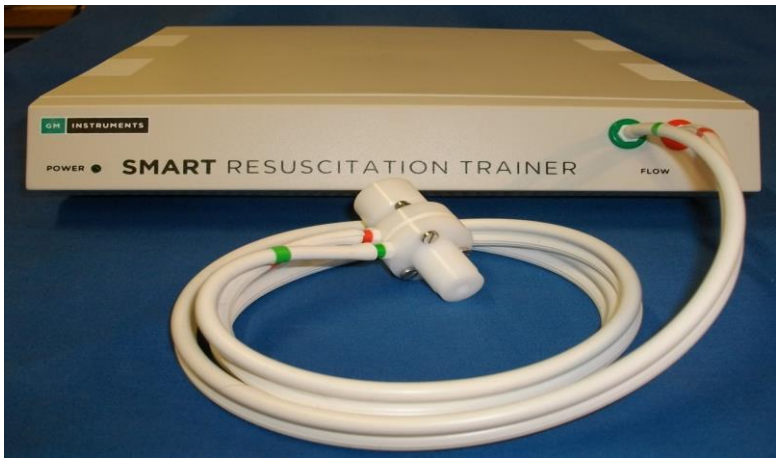


Figure 1: SMART processing unit, flowhead, ventilation device, mask and associated tubing

7.1.2 Connecting the mask and ventilation device to the flowhead

- Gently push the mask into the female connector of the flow sensor until it is secure
- Holding the flowhead firmly, gently push the ventilation device over the male connector until it is secure

7.1.3 Connecting the manikin pressure line to the SMART

7.1.3.1 Term manikin

- The pressure signal is tapped off of the flow red ringed tube within SMART

7.1.3.2 Preterm manikin

- The pressure signal is tapped off of the flow red ringed tube within SMART

7.1.4 Connecting the SMART processing unit to the laptop computer

- Plug the matching end of the black SMART processing unit cable into the socket at the back of the SMART processing unit and plug the other end into a spare USB port on the laptop
- Place the SMART and laptop on a suitable stable, hard, flat surface near to the manikin, ensuring that all cables and tubing can comfortably reach the manikin (i.e. are not stretched or kinked) during use

7.2 SYSTEM USE

- Using the charger cable, plug the laptop in to a mains supply socket and switch it on
- Switch the laptop on and wait for it to fully boot up
- Allow 5 minutes warm-up time before opening the SMART software

- Double click on the SMART software icon and the welcome page will load (Figure 2)

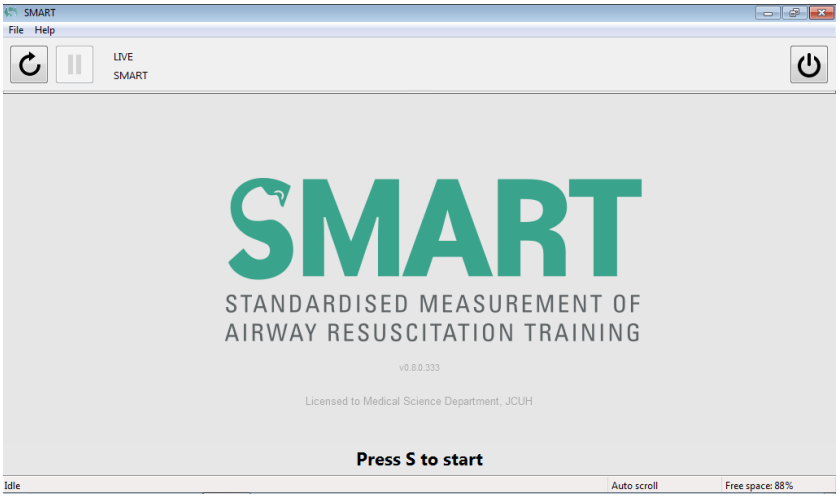


Figure 2: SMART welcome page

- Click on **S** to start
- The software will automatically zero all of the traces; this will take about 5 seconds to do and a warning will appear in red font at the bottom of the screen whilst this is in progress

CAUTION

Keep the sensors and tubing absolutely still and disconnected from any gas flow sources during the zero or the traces will display incorrectly

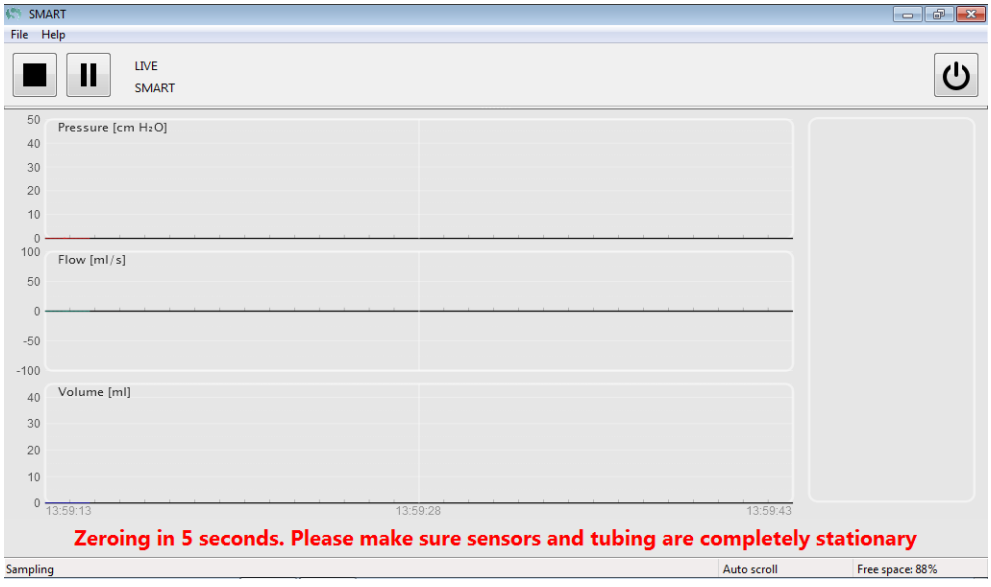


Figure 3: Warning displayed whilst sensors are being zeroed

- Once the zeroing process is complete, the system is ready to use

7.2.1 Sensor checks

Once the traces have been zeroed, it is good practice to check that they are displaying correctly before using the system for training. Check the pressure and flow/volume traces by following sections 7.2.1.1 and 7.2.1.2. If the traces are out of tolerance, re-zero them and if they remain out of tolerance, contact your Medical Engineering Department or any other appropriately qualified personnel who will recalibrate the sensors (see Service Manual).

7.2.1.1 Pressure trace

Using a "T" piece link the red and green front panel nozzles together, with the 3rd leg taken to a 50ml syringe and a calibrated digital manometer (with accuracy greater than 1% over the measurement range) or a water manometer as described in the service manual. Using the syringe, pressurise the system to 10, 20, 30, 40 and 50cmH_2O and check that the pressure trace matches with the reading on the manometer to within ±2%.

7.2.1.2 Flow/Volume traces

As the volume trace is calculated from the measured flow, the easiest check for these traces is to input a known volume of air and see if the volume trace measures correctly. Using a suitable connector (not supplied), connect a 25ml syringe to the female connector of the flowhead (where the mask usually connects) with the plunger pushed completely in and then draw 20ml of air slowly through the flowhead. Check that the volume displayed is 20ml ±2%.

7.2.2 Stop, pause, restart and zero

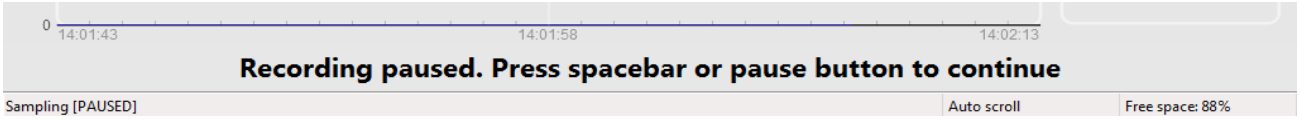
The software can be controlled using either function icons or keyboard shortcuts.

7.2.2.1 Function icons

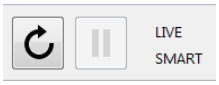
Function icons can be found in the top left hand corner of the screen and are as follows:

STOP (above left) and PAUSE (above second left) icons are displayed whilst the software is sampling.

When the PAUSE icon is clicked, the following text is displayed at the bottom of the screen and **[PAUSED]** will appear alongside the **Sampling** statement on the left hand side of the screen footer, as shown below:



When the STOP icon is clicked, it is replaced by a RESTART icon and the PAUSE icon becomes deactivated (greyed out), as shown below. In addition, the **Sampling** statement changes to **Idle**.



Clicking on the RESTART icon triggers a re-zeroing of all traces. As on initiation of the software, a warning message will be displayed whilst the sensors are being zeroed; see Figure 3.

7.2.2.2 Keyboard shortcuts

Keyboard shortcuts are as follows:

Spacebar Pauses / resumes trace (same as clicking on the PAUSE function icon)

0 (zero) Whilst the traces are running (**Sampling**), pressing the 0 (zero) key on the keyboard at any time will zero the flow and pressure traces. As before when you do this **the sensors and tubing must be entirely still and disconnected from any gas flow sources**

CAUTION

Keep the sensors and tubing absolutely still and disconnected from any gas flow sources during the zero or the traces will display incorrectly

It is good practice to zero the traces intermittently whilst the traces are running, for example, before a new user or after a period of inactivity. Traces should also be re-zeroed if the user observes an unexpected offset on any of the traces.

7.3 Screen interpretation

The SMART software displays typical respiratory function waveforms (pressure, flow and volume) and the measured percentage mask leak alongside an associated emoticon, see Figure 4.

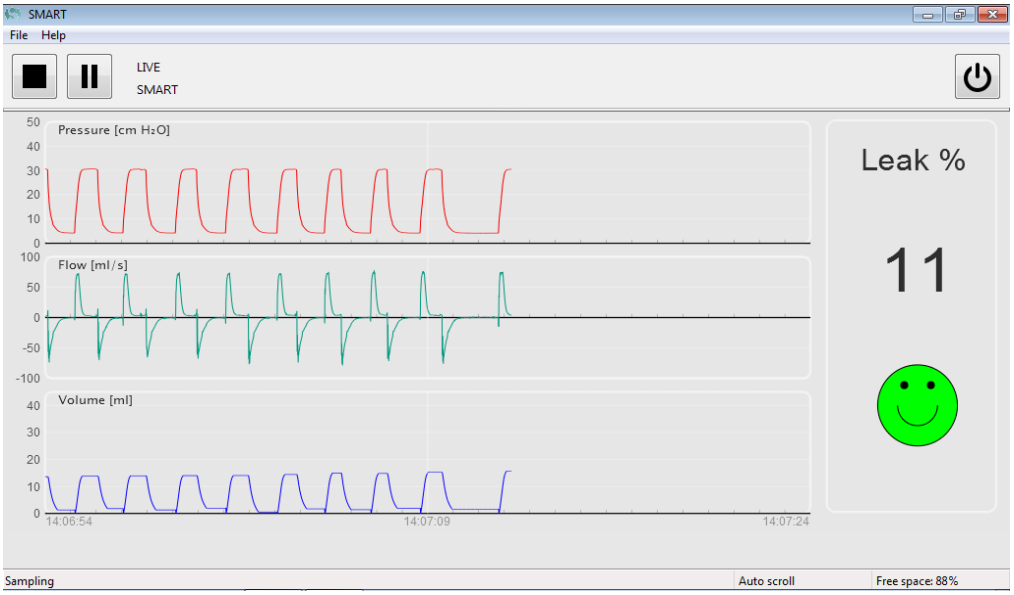


Figure 4: Pressure (top), flow (middle) and volume (bottom) traces, measured percentage mask leak (right)

The numeric display and emoticon are updated on a breath by breath basis. The number and emoticon displayed are representative of the last complete breath and will not update until the next complete breath has occurred. Ensure that a complete breath has been delivered before interpreting results.

In manikin studies, the average leak seen prior to technique training exceeded 50%; with training, leak is significantly reduced. Currently, there is no evidence to support the need to provide PPV with a leak below a specific value. Therefore, the values and colour coding used have been chosen pragmatically, as shown in Figure 5, and will be subject to change in line with emerging evidence.

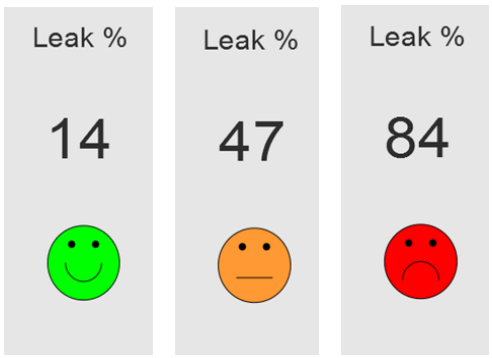
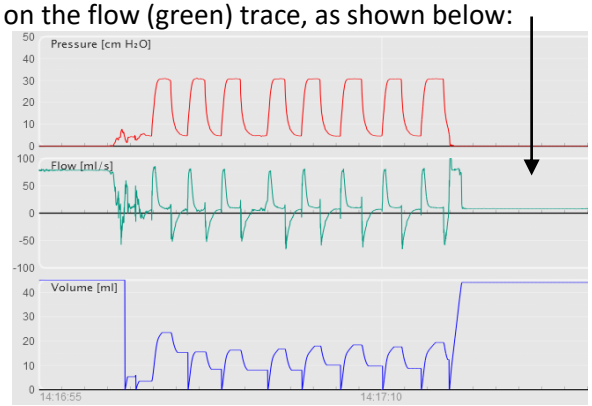
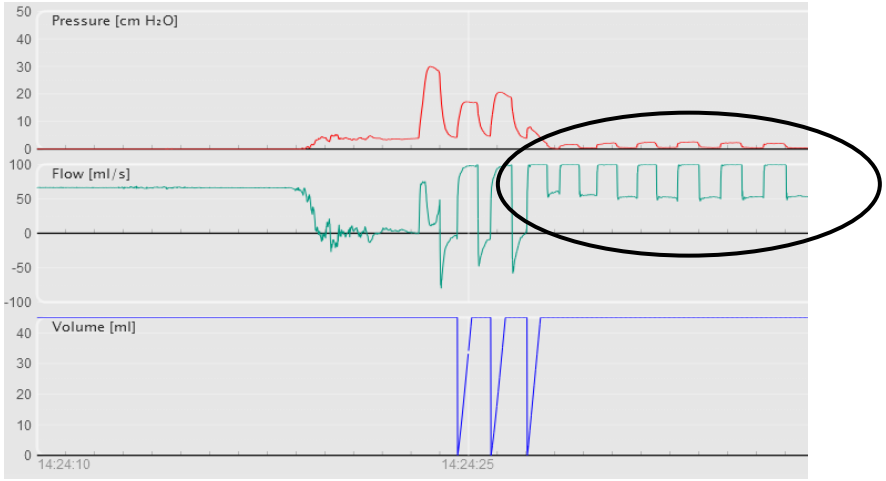


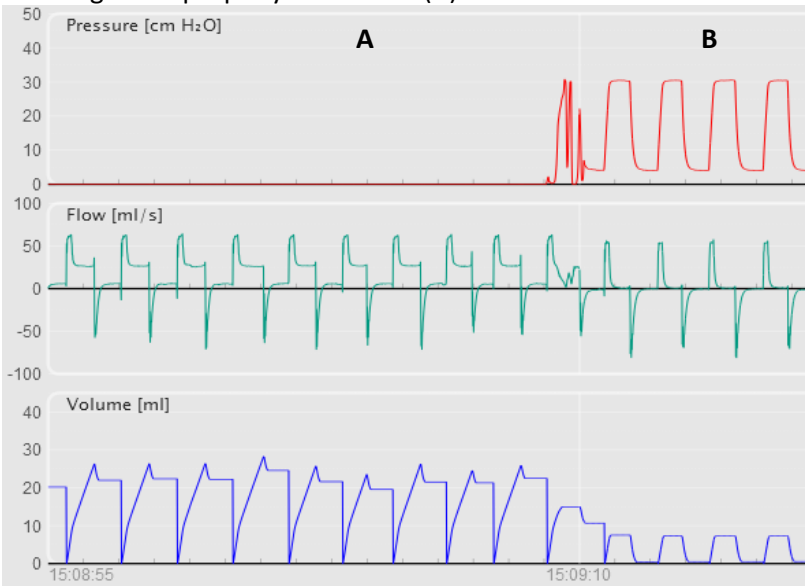
Figure 5: Green face = 0-29% leak (left), orange face = 30-50% leak (centre), red face >50% leak (right)

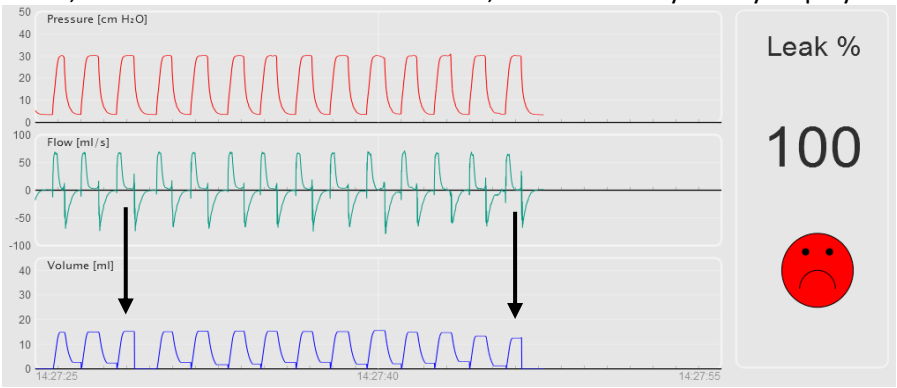
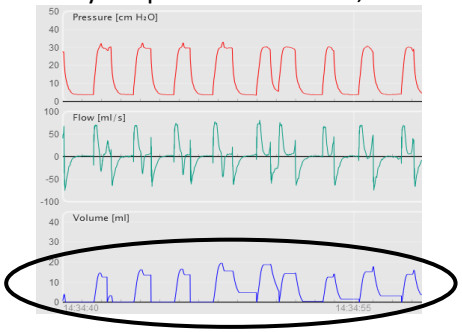
8 SYSTEM TROUBLESHOOTING

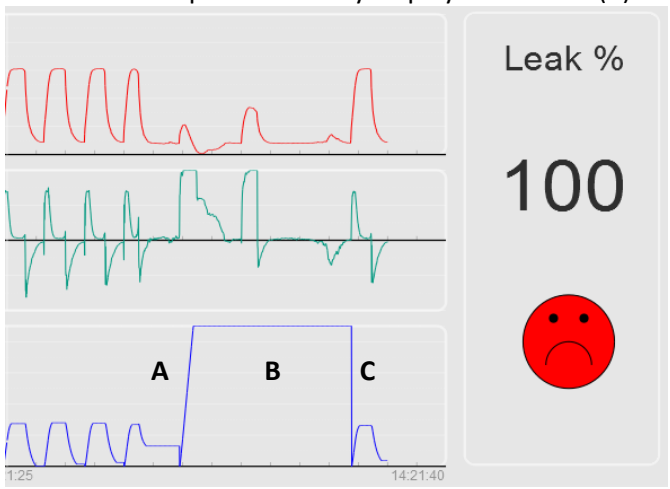
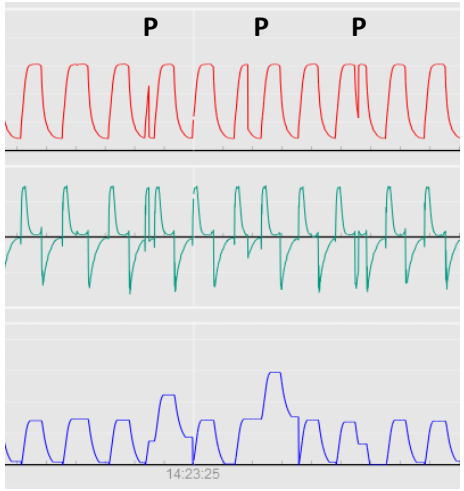
If the SMART system does not function as expected, check all components thoroughly (see section 9) and then set up the system by carefully following the steps outlined in section 7. See below for details of some common problems and their solution/s:

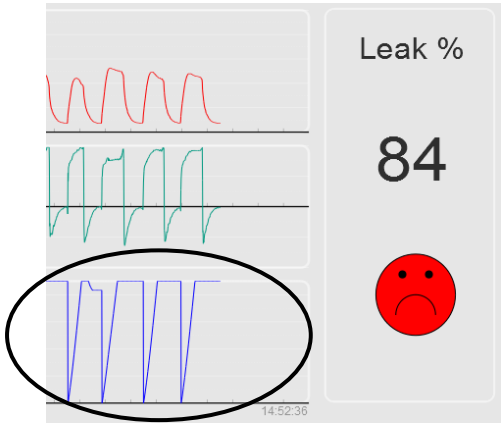
SYMPTOM	CAUSE/S	SOLUTION/S
When the software is opened, there is an error message (device not recognised) and the software won't work	1. USB connector not fully inserted 2. Wrong SMART/software pair	1. Re-insert USB connector carefully and check that the green light is illuminated on the SMART processing unit 2. Check that the code displayed by the software matches that on the back of the SMART processing unit. If it doesn't match, and you only have one SMART system, contact GM Instruments. If you have multiple SMART systems, connect the laptop to the matching SMART processing unit
The leak % number / emoticon are not updating	1. There is an offset on the flow (green) trace, as shown below:  	1. Re-zero the traces after removing all signals applied to the flowhead and pressure transducer.

	2. There is 100% leak: no gas flow returning from the manikin back through the flowhead (i.e., a complete breath is not being achieved). In this instance, the flow (green) trace remains positive, as shown below: 	2. This is a mask ventilation technique issue; the problem will resolve once the % leak at the facemask reduces below 100%

The pressure trace is not reading zero	The pressure tubing is not properly connected (A) 	Screen shot shows no pressure being generated (A) and then connected (B), but with CPAP switched on.
Despite perceived good mask ventilation technique, the leak displayed remains very high	1. The SMART system has not been properly assembled 2. The flow tubing is damaged/slack 3. Faulty or poorly connected ventilation device (e.g., self inflating bag, t-piece) 4. Poor mask ventilation technique	1. Refer to section 7.1 of this manual 2. Refer to section 9 of this manual 3. Check ventilation device and replace, if required 4. The problem will resolve once mask ventilation technique is improved

Some waves on the volume trace appear distorted	This issue may be seen because of the high sensitivity of the flowhead and can be caused by: 1. Unstable hold/user technique 2. Variable/unstable flowrate delivered by ventilation device (e.g., vigorous squeezing of SI bag or instability in the flowrate delivered by the t-piece device) When 0% or near 0% leak is being achieved, 1. and 2. can cause clipping of some of the volume wave, as shown below. For these waves, the leak % may falsely display 100%  3. Additional pressure applied to the mask and or through the ventilation device during ventilation can cause an unusually shaped volume wave, as shown below: 	1, 2 and 3. Eliminate sources of instability in mask ventilation technique and ventilation device

First breath delivered after a pause in the delivery of breaths shows 100% leak but looks as though it should be less	Breath preceeding the pause is incomplete (A), there is a pause in the delivery of breaths (B) and the first breath after the pause is falsely displayed as 100% (C) 	Disregard the first breath delivered on commencing a period of PPV
Traces look unusual when the pause function is used during a period of ventilation	The software will pause/resume display of the traces immediately on activation of this function, irrespective of the time that has elapsed. Paused sections of the trace below are shown by the letter P 	This is a feature of the software and does not require any remedial action

The volume wave exceeds the maximum value on the axis (i.e., the top of the wave is off the scale) and so looks clipped	This will occur when the leak is in excess of 80% and is a result of the set scale of the volume trace 	This is a deliberate feature of the software; the scale of the volume axis has been chosen to enable use of the SMART system with both the term and preterm manikins (the preterm manikin produces much smaller volumes than the term manikin and so would be difficult to view if the scale was increased to encompass volume waves for leaks >80% on the term manikin)

9 Routine Maintenance

The following routine maintenance checks should be carried out on a regular basis:

- The condition of both the flowhead and the plastic tubing that connect it to the SMART processing unit should be regularly checked. The flowhead should be kept clean, as dust build-up on the gauze will lead to inaccurate results. The gauze can be washed in soapy water, but must be thoroughly air dried prior to making any measurements. The tubing should be replaced if it has kinks in it or becomes slack either on the flowhead or the SMART processing unit connector ports

- The condition of the SMART processing unit to PC interconnecting cable should be inspected regularly for damage to the insulation and replaced if damaged

- The enclosure of the SMART processing unit should be inspected regularly for signs of contamination or damage. If the enclosure requires cleaning, unplug it from the PC and wipe it with a damp cloth, a cloth soaked in a mild alcohol based solution or cleaning wipes. Do not allow liquid to run into the enclosure. After visual inspection, if the enclosure is found to be damaged, discontinue use and contact GM Instruments.