SMART

GM INSTRUMENTS

SMART

STANDARDISED MEASUREMENT OF AIRWAY RESUSCITATION TRAINING

NEWBORN resuscitation training system

SERVICE 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

South Tees Hospitals NHS
NHS Foundation Trust

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

This manual describes how to carry out routine maintenance on the SMART newborn resuscitation training system. It also details how to carry out calibration checks and make adjustments to the SMART processing unit. Full circuit diagrams are available on request.

Other manuals accompanying this system include:

- User Manual
- Installation Manual

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

Please refer to the User Manual for details of the manikins supplied with the SMART system.

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, Annickbank 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 driver set up program Instacal has been set on first connection to SMART, 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 to the pressure sensor is shared 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 ring), external diameter = 15.47mm, compatible with most standard ventilation devices/circuits
- Female connector (red ring), internal diameter = 15.36mm, compatible with most standard patient interface connectors, e.g. masks / endotracheal tubes

6.1.3 Laptop

Please refer to the User Manual for details of the Laptop supplied with the SMART system.

6.1.4 Manikins

Please refer to the User Manual for details of the manikins supplied with the SMART system.

7 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

8 Calibration Checks

The SMART processing unit contains two transducers with associated instrumentation amplifiers, balance and gain controls and an isolated +5V to ±12V DC converter.

A calibration check should be made, and if required, the instrument adjusted, in the following circumstances:

- If the pressure or flow transducers are changed
- If the flowhead is contaminated with dust or other particles or has been washed or disinfected
- If some time has elapsed since the last calibration
- If there is any uncertainty about the results achieved

Two transducers are employed; one to measure pressure and one to measure flow. The pressure transducer may be set using a liquid column as a pressure gauge and the flow transducer may be set using a rotameter to accurately measure flow.

8.1 Pressure transducer check

In addition to the SMART system, a liquid column covering the range 0-50cmH_2O, a hand pump and a reservoir are required. The calibration check of the pressure transducer is carried out using the set up shown in Figure 1 and by following the steps shown below:

NB as the connection to the pressure transducer is now internal, and to avoid overloading the flow transducer, use a "T" piece to connect both flow ports together, with the 3rd leg going to your source of pressure, marked "To SMART Pressure Port (black) below.

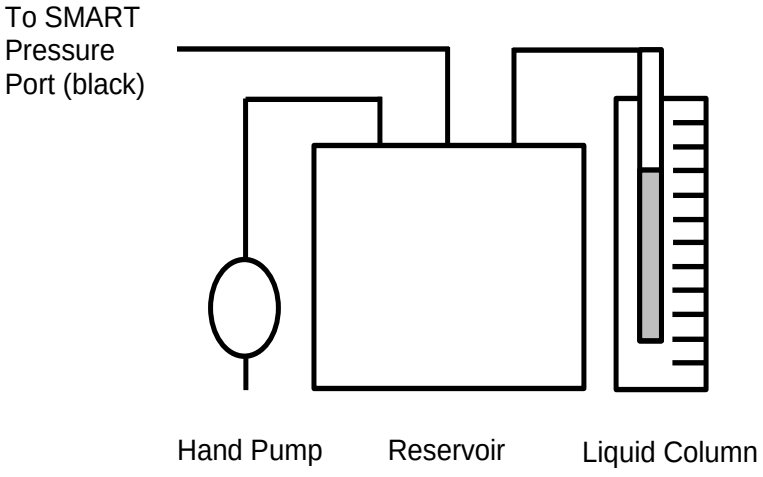

Figure 1:Equipment set up required for the pressure transducer check

- 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)

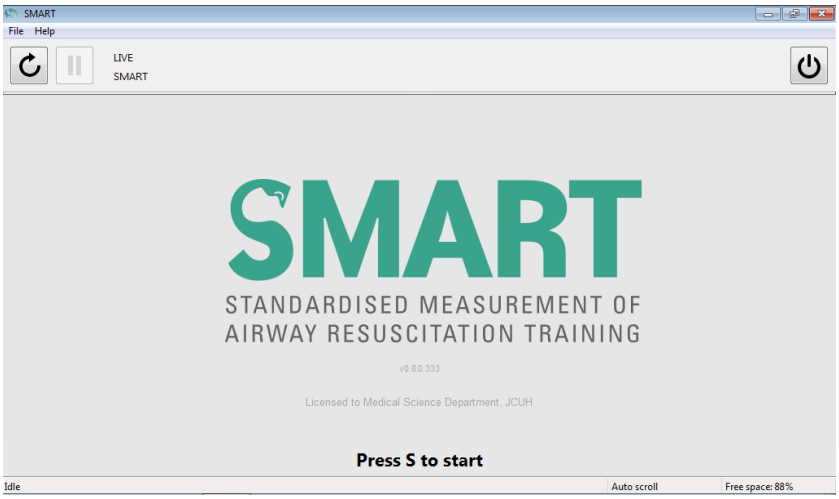

Figure 2: SMART welcome page

- 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

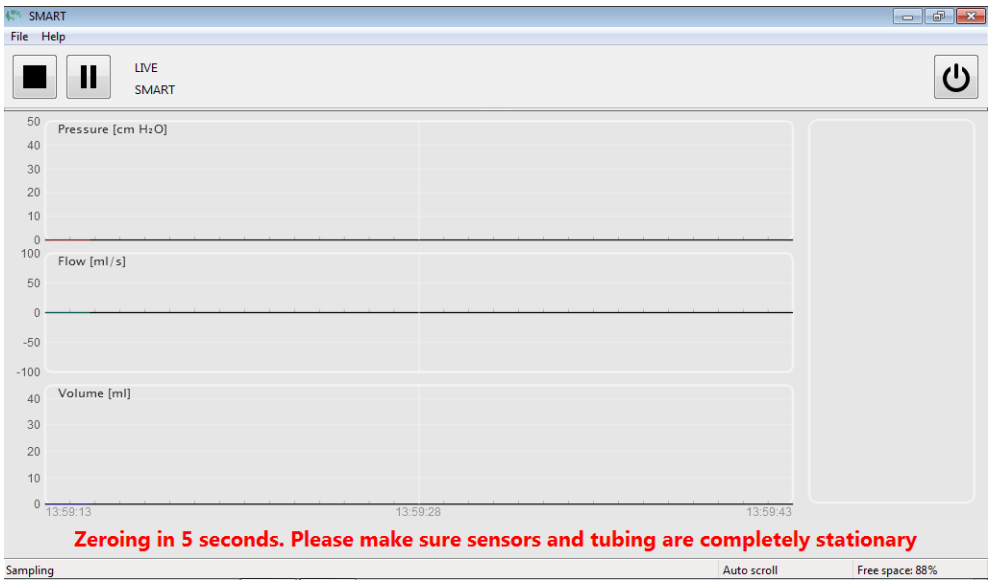

Figure 3: Warning displayed whilst sensors are being zeroed

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

- Using the hand pump and the liquid column, increase the pressure from zero to 50cmH_2O. Check that the pressure reading on the SMART is in agreement with the liquid column ±2% (i.e., reading between 49 and 51cmH_2O)
- Remove the pressure by disconnecting the tubing at the "T" piece and check that the value on the pressure trace returns to zero.

If either of the above readings on the pressure trace is out of tolerance, it is necessary to adjust the amplifier offset and gain for that transducer. Details on how to do this can be found in the Calibration Adjustment section of this manual.

8.2 Flow transducer checks

In addition to the pressure system, a rotameter covering the range 0-167ml/s (0-10l/min), a vacuum motor (available from vacuum cleaner manufacturers) and a variable transformer (to produce an adjustable source of flow with a variable voltage supply) are required. The calibration check of the flow transducer is carried out using the set up shown in Figure 4 and by following the steps shown below:

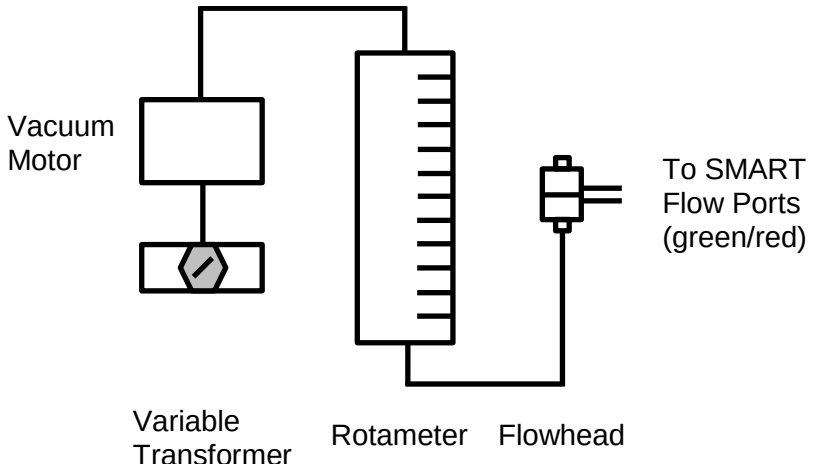

Figure 4:Equipment set up required for the flow transducer check

- 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
- Following the SMART software instructions in section 8.1, start the software and allow the zero function to complete its cycle

CAUTION

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

- Once the zeroing process is complete, the system is ready to use
- Using the variable transformer and rotameter, increase the flow from the vacuum motor to 100ml/s (6l/min). Check that the flow reading on the SMART is in agreement with the rotameter ±2% (i.e., reading between 98 and 102ml/s)
- Remove the flow by disconnecting the tubing at the flow ports (green/red) on the SMART and check that the value on the flow trace returns to zero.

If either of the above readings on the flow trace is out of tolerance, it is necessary to adjust the amplifier offset and gain for that transducer. Details on how to do this can be found in the Calibration Adjustment section of this manual.

9 Calibration Adjustment

If the calibration checks show either of the transducers (pressure, flow) to be out of tolerance, the amplifier offset and gain can be adjusted as follows:

- 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
- Following the SMART software instructions in section 8.1, start the software and allow the zero function to complete its cycle

CAUTION

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

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

9.1 Adjusting the offset

It is good practice to adjust and correct the offset before modifying the gain; how this is done for each amplifier is explained in sections 9.1.1 and 9.1.2.

9.1.1 Pressure

- With the pressure transducer exposed to zero pressure (i.e., disconnected from the test equipment described in Figure 1), measure the voltage between test point 5 (ground) and test point 4 using a sensitive DC voltmeter
- Adjust the pressure offset pot (VR4) to give a reading of 0V

9.1.2 Flow

- With the pressure transducer exposed to zero pressure (i.e., disconnected from the test equipment described in Figure 4), measure the voltage between test point 5 (ground) and test point 6 using a sensitive DC voltmeter
- Adjust the flow offset pot (VR1) to give a reading of 0V

9.2 Adjusting the gain

Once the offset has been corrected, the gain can be adjusted as described in sections 9.2.1 and 9.2.2.

9.2.1 Pressure

- With the pressure transducer exposed to 50cmH2O pressure, using the test set up described in Figure 1, measure the voltage between test point 5 (ground) and test point 4 using a sensitive DC voltmeter
- Adjust the pressure gain pot (VR5) to give a reading of 5V

9.2.2 Flow

- With the pressure transducer exposed to 100ml/s (6l/min) flow using the test set up described in Figure 4, measure the voltage between test point 5 (ground) and test point 4 using a sensitive DC voltmeter
- Adjust the flow gain pot (VR2) to give a reading of 5V