FERRARIS MEDICAL LTD
A FERRARIS GROUP PLC COMPANY
4 BLOORS LANE
RAINHAM, KENT, ME8 7ED, ENGLAND
TEL +44 (0) 1634 373 865
FAX +44 (0) 1634 371 681
email: info@ferrarismedical.com
website: www.ferrarismedical.com

DEVELOPMENT DEPARTMENT

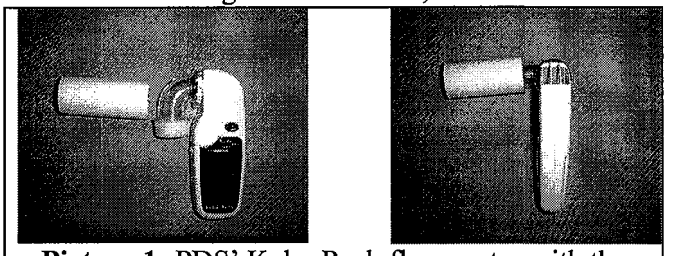
SAFETY VALVE TESTING. MOUTHPIECES FOR PDS "PEAK FLOW" DEVICES

22/04/2003

INTRODUCTION

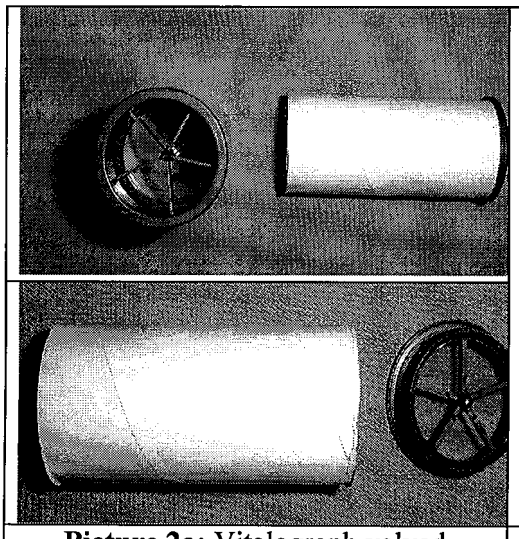
PDS produces an electronic Peak Flow Meter (KOKO PEAK) which is a single patient use device. In an attempt to make the device safe to use with multiple patients consideration of cross contamination between users was necessary.

PDS proposed initially a disposable mouthpiece (see Picture 1), which reduces the risk of contamination by contact. From discussions with a microbiological consultant[1], this method was thought to be inadequate in providing effective cross contamination prevention. The prospect of inspiration occurring with a standard mouthpiece is low but possible, despite the non-return nature of the KOKO device.

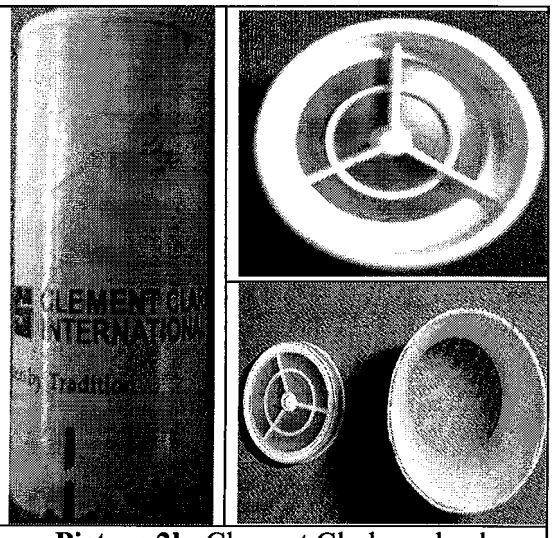


Picture 1: PDS' Koko Peak flow meter with the initial mouthpiece (non valved)

An enhanced mouthpiece employing a "one way valve" was proposed (see examples illustrated on **Pictures 2a** and **2b)**, and the validation for its effectiveness would be based on the inability of inspirate to be drawn from the device by the user.



Picture 2a: Vitalograph valved mouthpiece.



Picture 2b: Clement Clarke valved mouthpiece

FERRARIS MEDICAL LTD
A FERRARIS GROUP PLC COMPANY
4 BLOORS LANE
RAINHAM, KENT, ME8 7ED, ENGLAND
TEL +44 (0) 1634 373 865
FAX +44 (0) 1634 371 681
email: info@ferrarismedical.com
website: www.ferrarismedical.com

SCOPE

The scope of this investigation is to study the effectiveness of the proposed "one way valves", in preventing a subject from inhaling through them and to verify that the introduction of this kind of valve on the Koko Peak flow meter will not compromise its accuracy.

METHOD

a) Valve Effectiveness

The method used to evaluate the one-way valve's effectiveness as an "inhalation prevention" device is to subject the one-way valve to incrementing levels of reverse pressure until it fails.

These levels of reverse pressure can then be compared against the possible levels of inhalation pressure that a patient can unconsciously and accidentally achieve. The purpose of this valve is to prevent accidental inhalation through the tube and *NOT* to withstand pressure that can be produced by the conscious effort of a patient.

According to data collected from respiratory data for resting inhalation and from sources like the specification of the diving breathing regulators, the valve can be characterised as adequate for its intended use if it is able to withstand 100mBar (≈ 75 mm Hg) reverse pressure.

b) Effect of Valves on KOKO PEAK accuracy.

To investigate the effect the added valve has on the Koko Peak flow meter performance and accuracy a full functional and accuracy test of the two types of valved mouthpieces was required, as described accordingly by the American Thoracic Society in "Standardisation of Spirometry (1994)".

A computer controlled pump ('ATS pump') will be used to provide the required 26 test waveforms.

The procedure will be applied to a KOKO PEAK FLOW meter using the plain (non-valved) mouthpiece, the Vitalograph and then the Clement Clarke valved mouthpieces.

The obtained results will be recorded and then used to compare the three available KOKO PEAK configurations. (non valved, Vitalograph, Clement Clarke)

APPARATUS

a) Valve Effectiveness

To simulate a subject's breathing pattern a sinusoidal pump was used. The pump was set to be able to produce a flow rate of 30 l/min (2 l/cycle) and a breathing rate of 15 breaths/min.

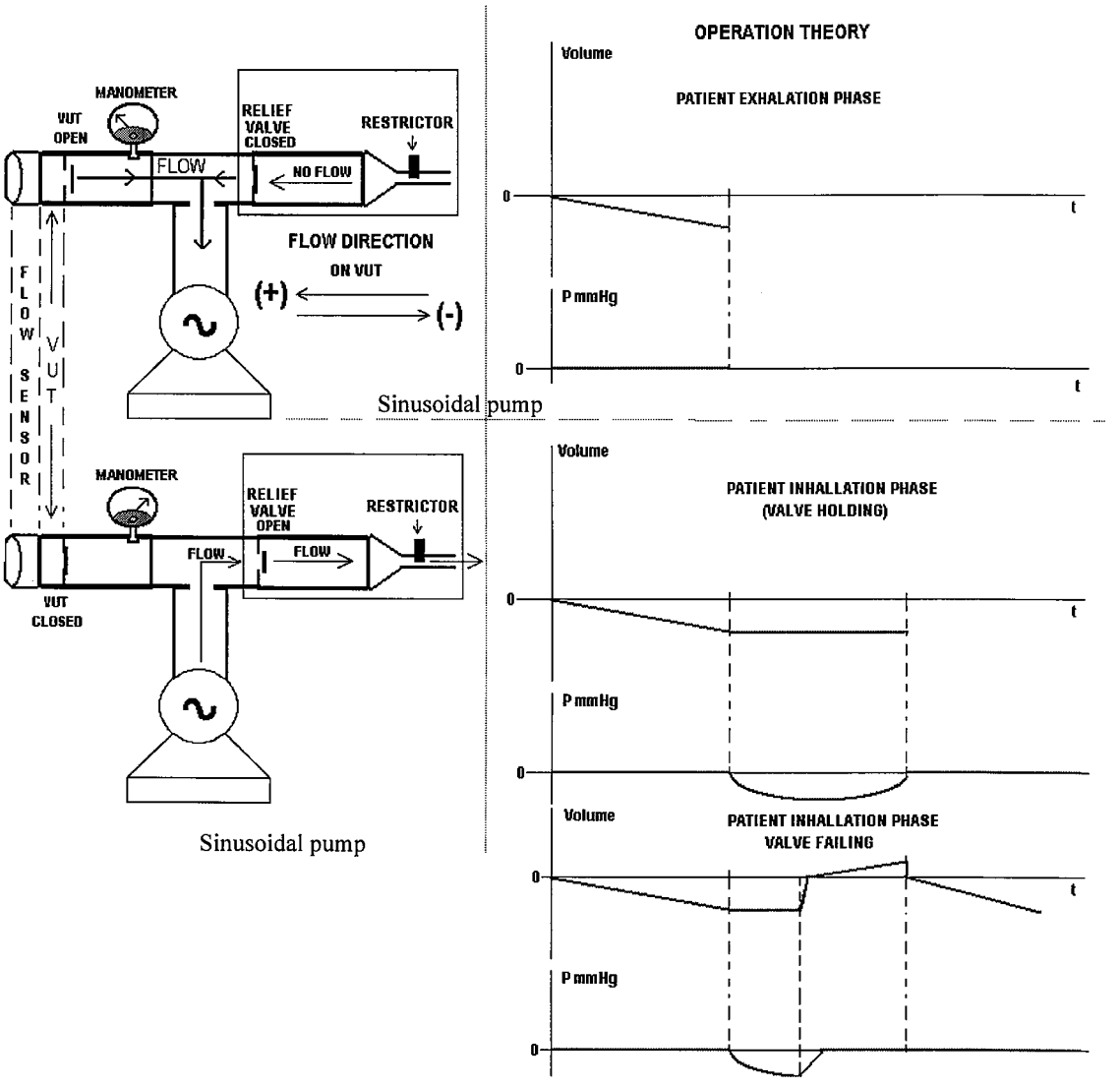
The pump was connected using a T connector to provide air flow/pressure to the "valve under test" (VUT). A second valved mouthpiece was used to provide the relief or pressure control circuitry during the "inhalation" period of the sinusoidal pump, in combination with a variable restrictor. Varying the relief exhaust during the "inhalation phase", using the restrictor, different levels of pressure could be maintained allowing the testing of the valve.

The pressure was measured using an in-house built pressure sensor calibrated to produce

FERRARIS MEDICAL LTD
A FERRARIS GROUP PLC COMPANY
4 BLOORS LANE
RAINHAM, KENT, ME8 7ED, ENGLAND
TEL +44 (0) 1634 373 865
FAX +44 (0) 1634 371 681
email: info@ferrarismedical.com
website: www.ferrarismedical.com

1 volt output for 100 mm Hg. The calibration was carried out using a Hg column (see Appendix Section1 for calibration chart).

The following diagram (Picture 3) illustrates the theoretical set up of the experiment as well as the expected response of the components used



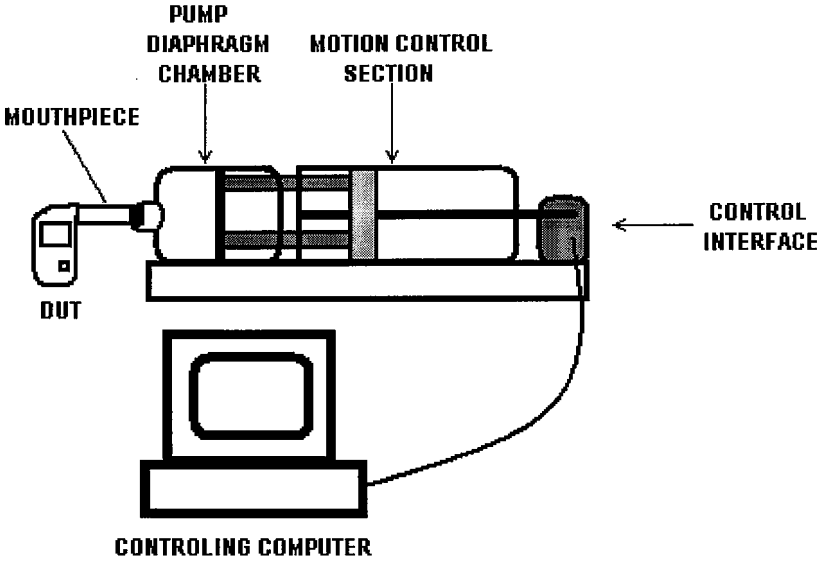
Picture 3

The last two graphs on Picture3 represent the expected response of the flow sensor and the pressure sensor on the event of valve seal failure. The flow sensor will detect the opposite air flow and attempt to reset itself instantly, while the pressure in the mouthpiece will reduce rapidly before the patient inhaling stage is complete. The pressure indicated before the valve fails is the amount of the reverse pressure the valve can withstand, which according to our research will be adequate if it is on the level of 100 mBar or 75 mmHg

FERRARIS MEDICAL LTD
A FERRARIS GROUP PLC COMPANY
4 BLOORS LANE
RAINHAM, KENT, ME8 7ED, ENGLAND
TEL +44 (0) 1634 373 865
FAX +44 (0) 1634 371 681
email: info@ferrarismedical.com
website: www.ferrarismedical.com

b) Effect of Valves on KOKO PEAK accuracy.

Following the procedures recommended by the ATS in "Standardisation of Spirometry (1994)" the apparatus used to carry out this investigation is illustrated on Picture 4



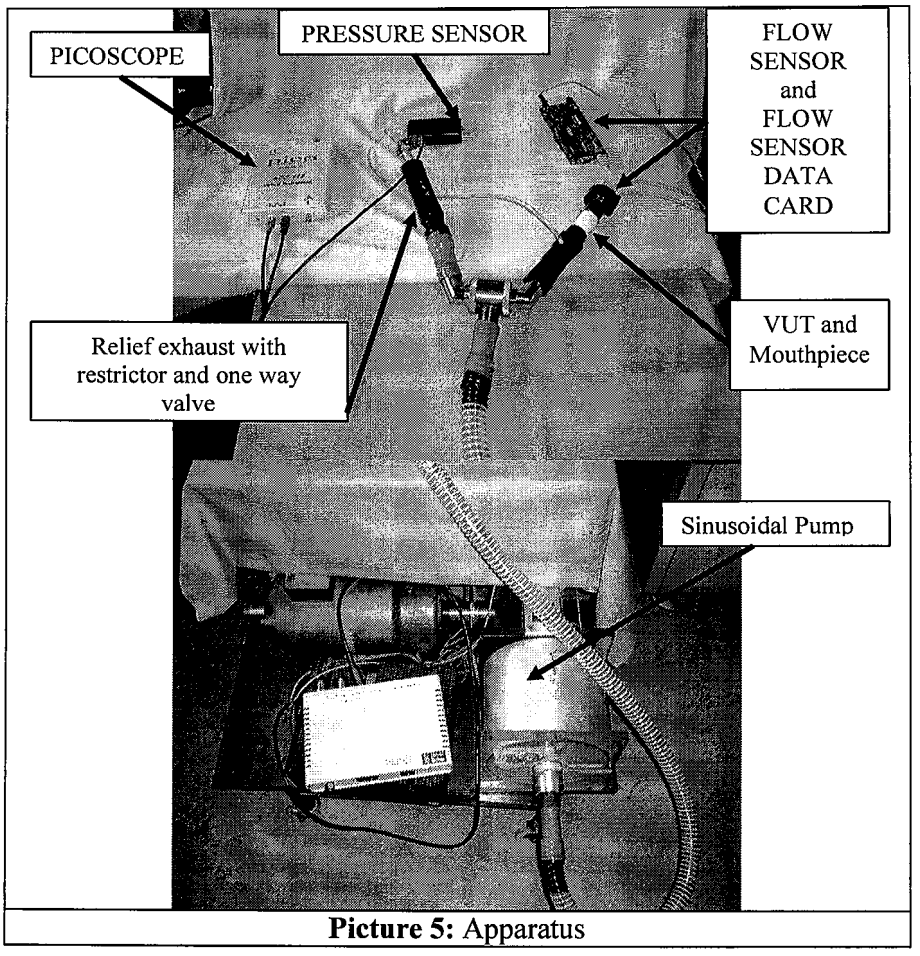
PICTURE 4: The effect of valved mouthpieces on KOKO PEAK investigation apparatus

FERRARIS MEDICAL LTD
A FERRARIS GROUP PLC COMPANY
4 BLOORS LANE
RAINHAM, KENT, ME8 7ED, ENGLAND
TEL +44 (0) 1634 373 865
FAX +44 (0) 1634 371 681
email: info@ferrarismedical.com
website: www.ferrarismedical.com

RESULTS

a) Valve Effectiveness

The following picture (Picture 5) illustrates the circuitry used for the experiment.



Picture 5: Apparatus

The above apparatus was kept exactly the same for both valved mouthpieces. A computer-based oscilloscope was used as a means to collect the data, which were electronically stored on the computer (Picoscope AD212 – TE 1147).

The graphs produced from the data obtained during the experiment are illustrated on the following pages on this report.

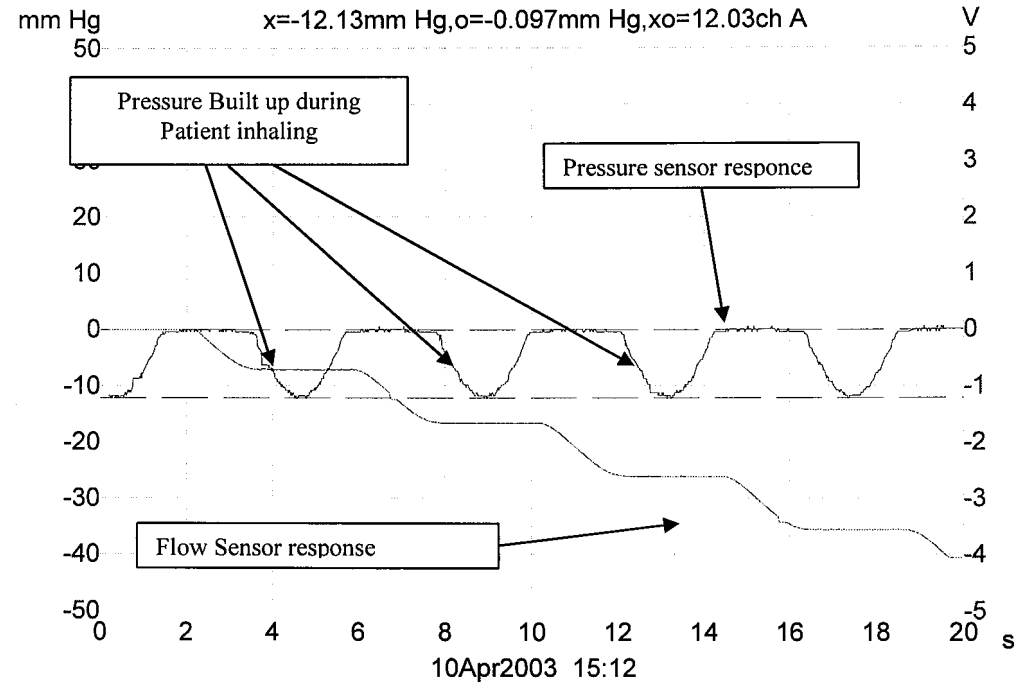
The Pressure axis (blue) has been normalised so mm Hg is indicated instead of volts (which is the generic output of the pressure sensor).

Since we are interested only in the "reset" event of the sensor and not in the levels of flow. The flow axis (red) is in volts (which is the generic output of the pressure sensor).

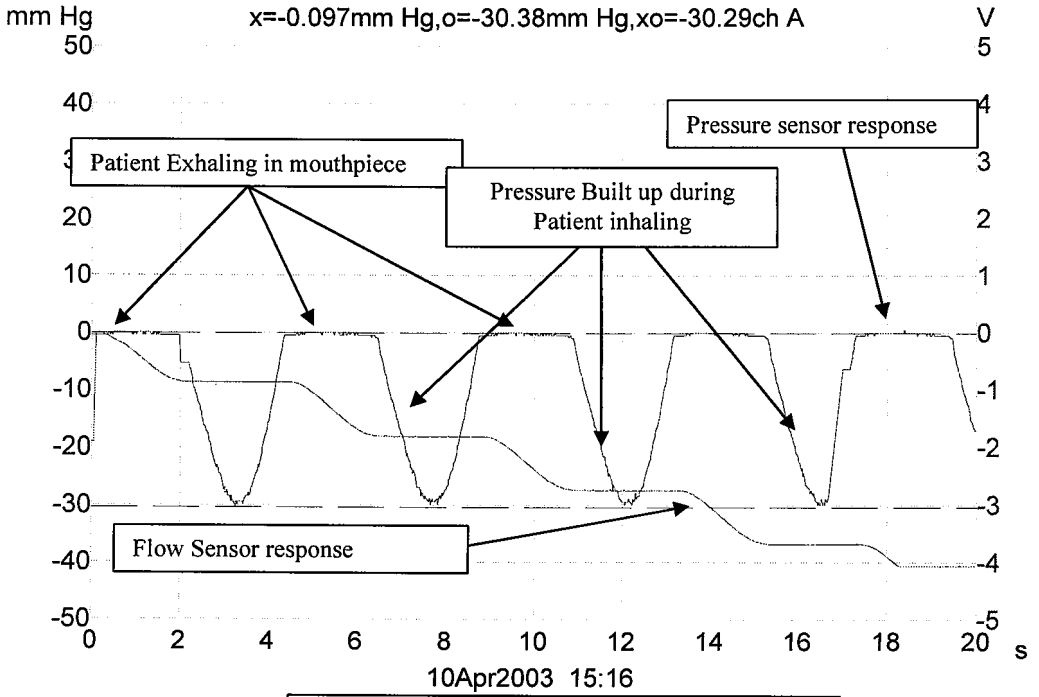
The graphs that follow illustrate the durability of the valves incorporated in the mouthpieces, against reverse pressure levels (approximate levels: -10, -20, -50) while the last graph represents the brake point of the valve (ideally >75mm Hg or 100 mBar).

FERRARIS MEDICAL LTD
A FERRARIS GROUP PLC COMPANY
4 BLOORS LANE
RAINHAM, KENT, ME8 7ED, ENGLAND
TEL +44 (0) 1634 373 865
FAX +44 (0) 1634 371 681
email: info@ferrarismedical.com
website: www.ferrarismedical.com

1) *VITALOGRAPH MOUTHPIECE*

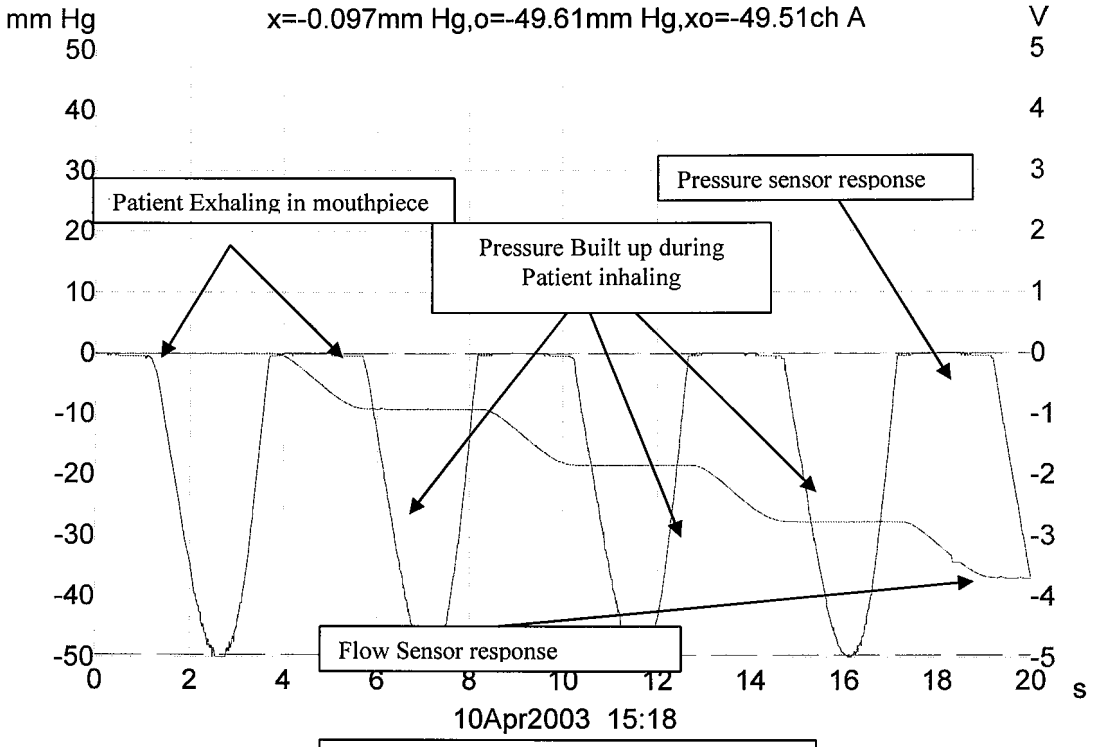


P≈ 10 mmHg
Graph 1: Vitalograph mouthpiece

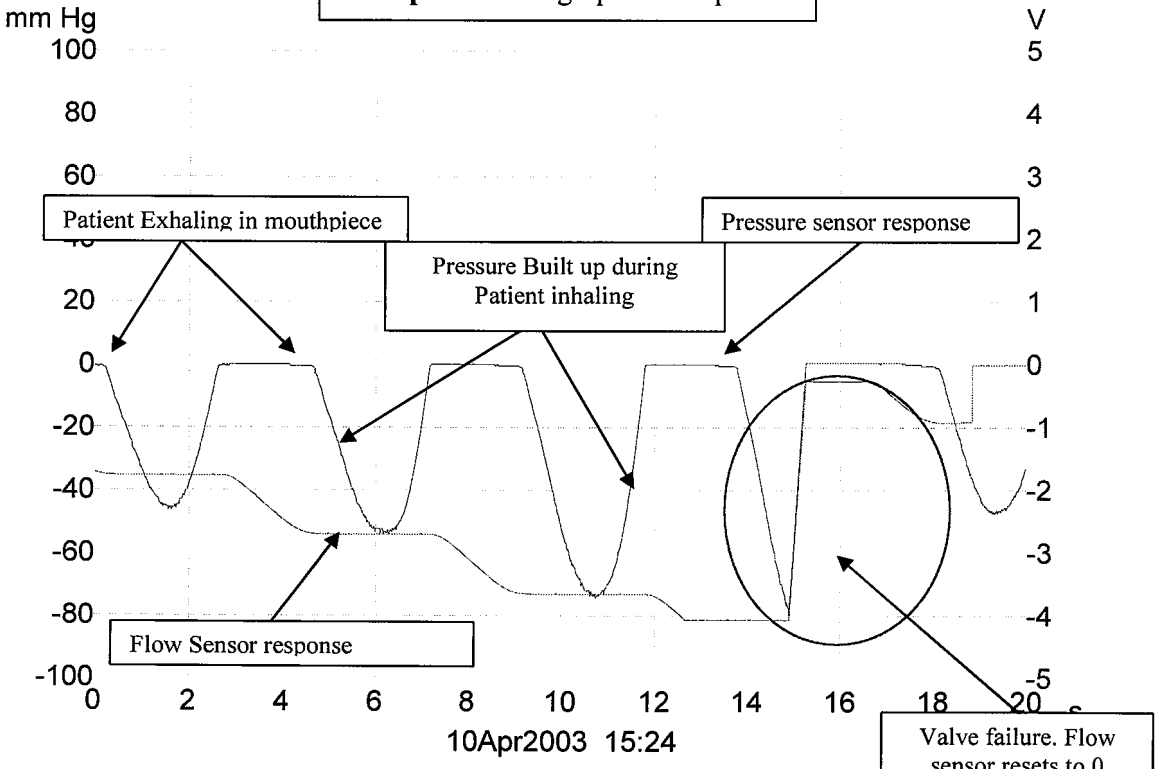


P≈ 30 mmHg
Graph 2: Vitalograph Mouthpiece

FERRARIS MEDICAL LTD
A FERRARIS GROUP PLC COMPANY
4 BLOORS LANE
RAINHAM, KENT, ME8 7ED, ENGLAND
TEL +44 (0) 1634 373 865
FAX +44 (0) 1634 371 681
email: info@ferrarismedical.com
website: www.ferrarismedical.com



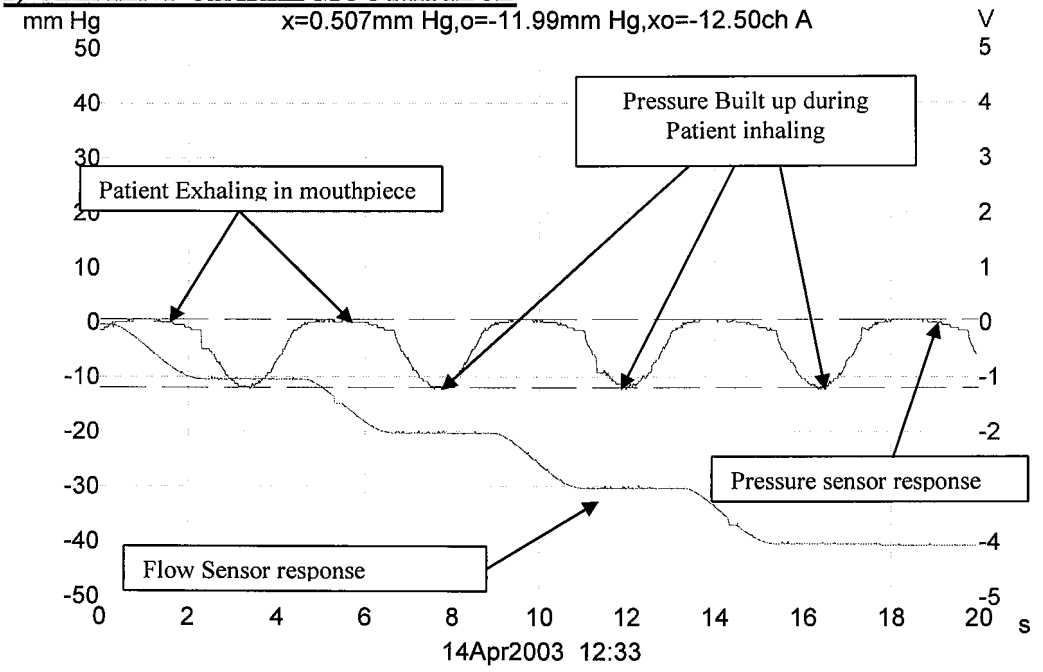
P≈ 50 mmHg
Graph 3: Vitalograph Mouthpiece



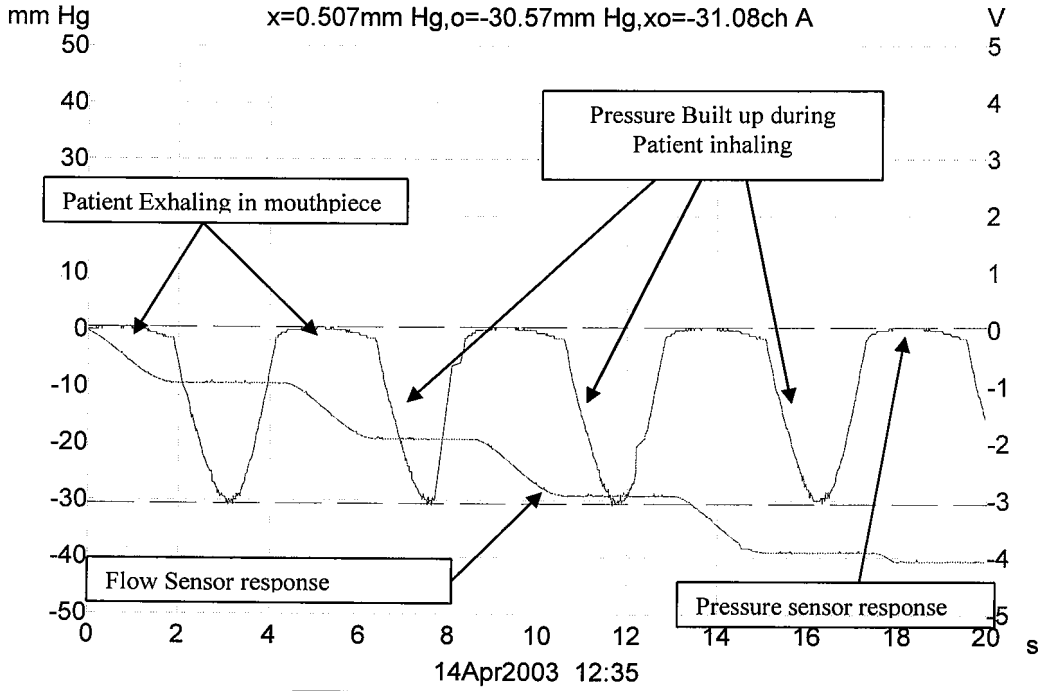
P≈ 75 mmHg
Graph 4: Vitalograph Mouthpiece

FERRARIS MEDICAL LTD
A FERRARIS GROUP PLC COMPANY
4 BLOORS LANE
RAINHAM, KENT, ME8 7ED, ENGLAND
TEL +44 (0) 1634 373 865
FAX +44 (0) 1634 371 681
email: info@ferrarismedical.com
website: www.ferrarismedical.com

2) CLEMENT CLARKE MOUTHPIECE

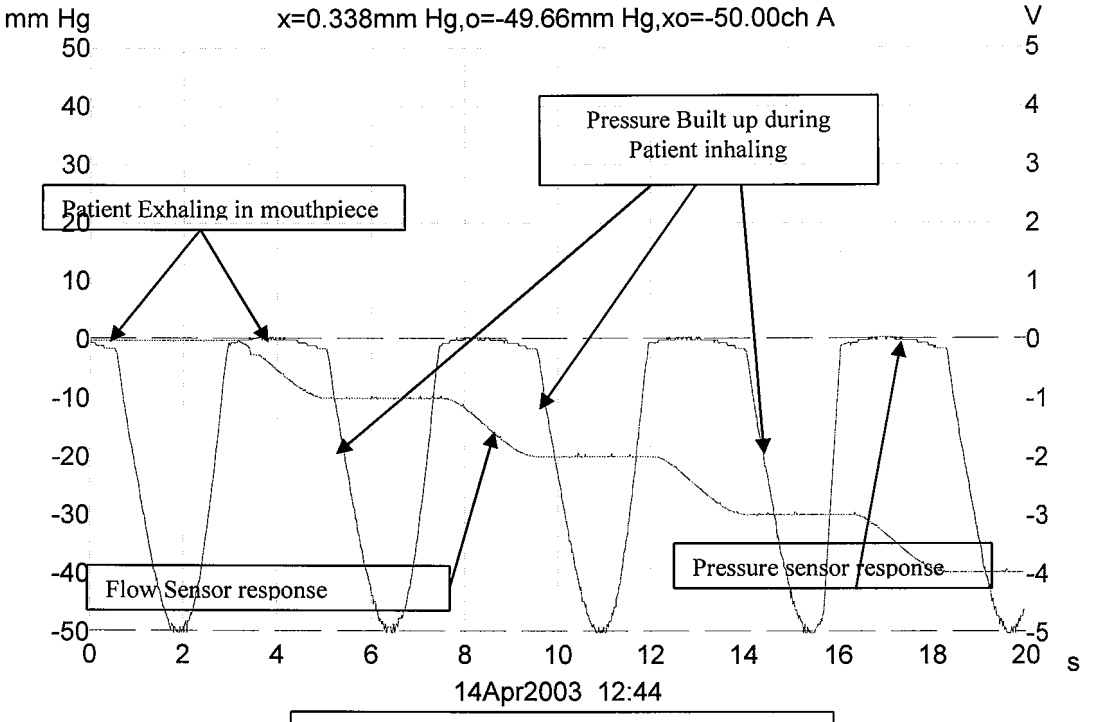


P≈ 12 mmHg
Graph 5: Clement Clarke Mouthpiece



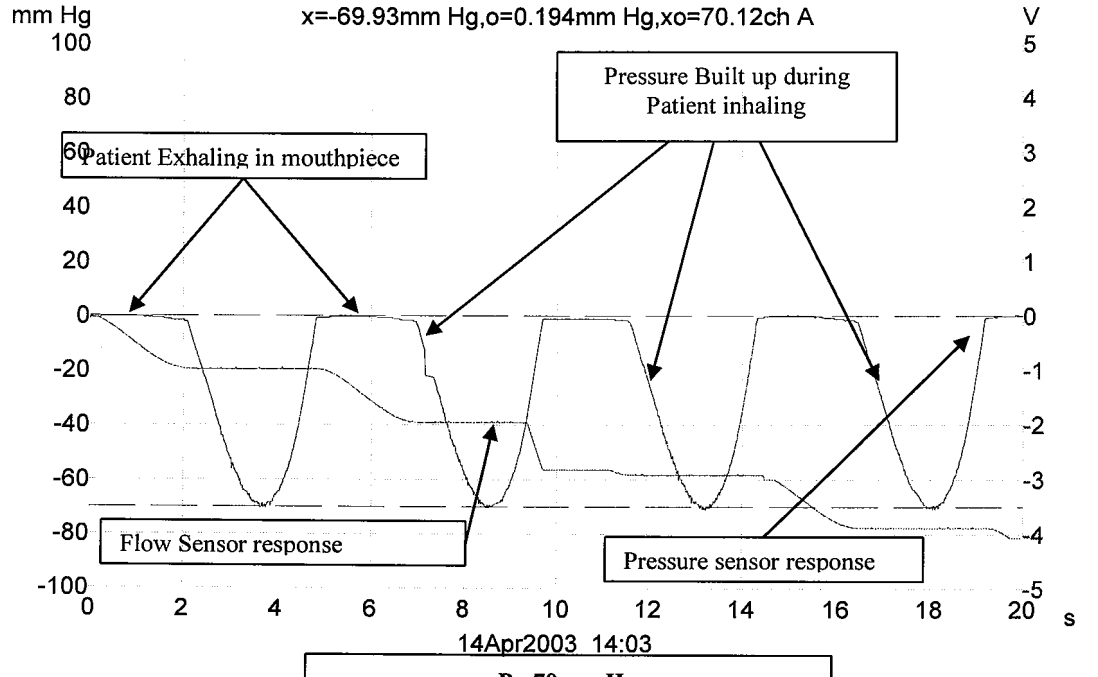
P≈ 30 mmHg
Graph 6: Clement Clarke Mouthpiece

FERRARIS MEDICAL LTD
A FERRARIS GROUP PLC COMPANY
4 BLOORS LANE
RAINHAM, KENT, ME8 7ED, ENGLAND
TEL +44 (0) 1634 373 865
FAX +44 (0) 1634 371 681
email: info@ferrarismedical.com
website: www.ferrarismedical.com



P≈ 50 mmHg

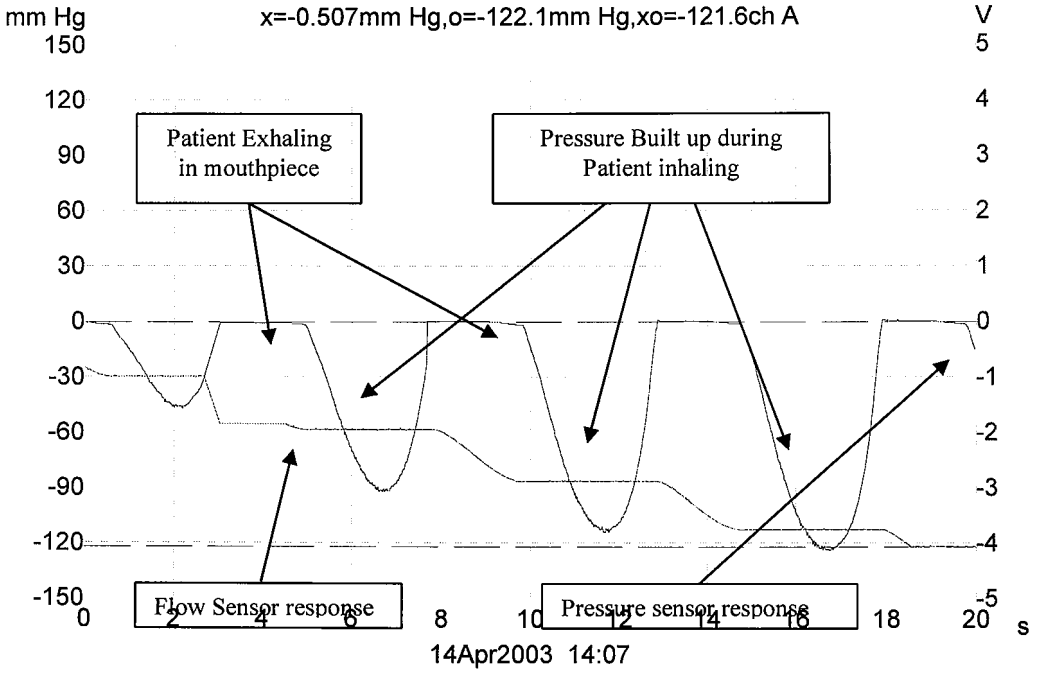
Graph 7: Clement Clarke Mouthpiece



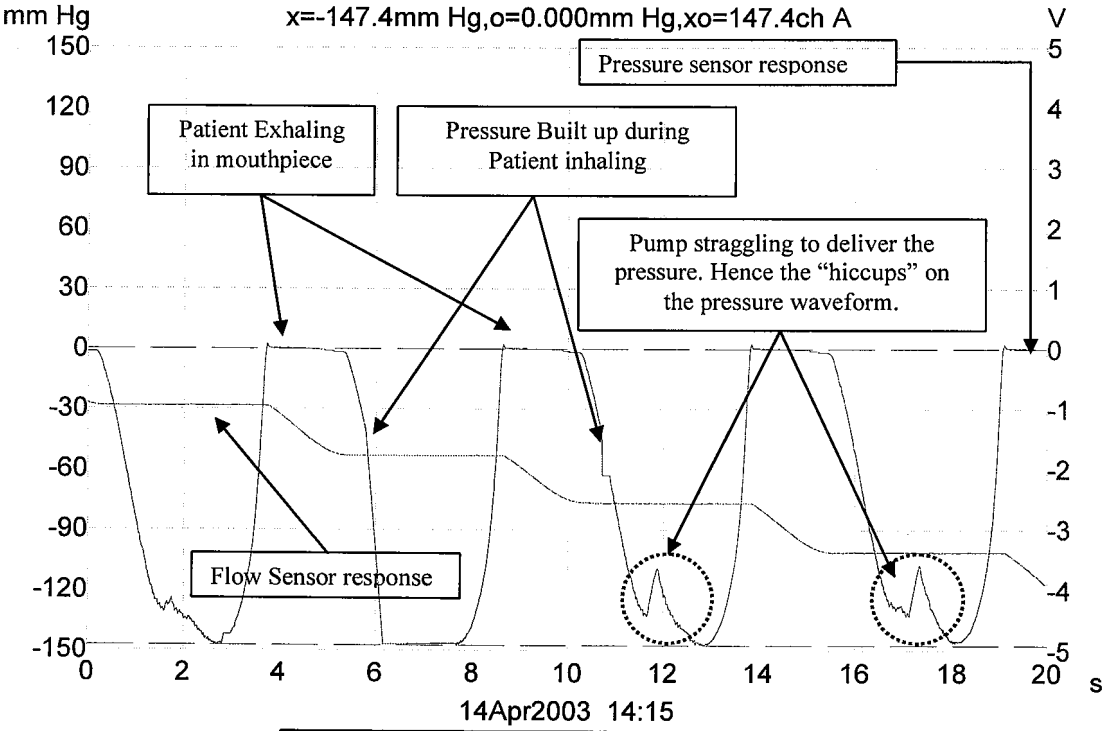
P≈ 70 mmHg

Graph 8: Clement Clarke Mouthpiece

FERRARIS MEDICAL LTD
A FERRARIS GROUP PLC COMPANY
4 BLOORS LANE
RAINHAM, KENT, ME8 7ED, ENGLAND
TEL +44 (0) 1634 373 865
FAX +44 (0) 1634 371 681
email: info@ferrarismedical.com
website: www.ferrarismedical.com

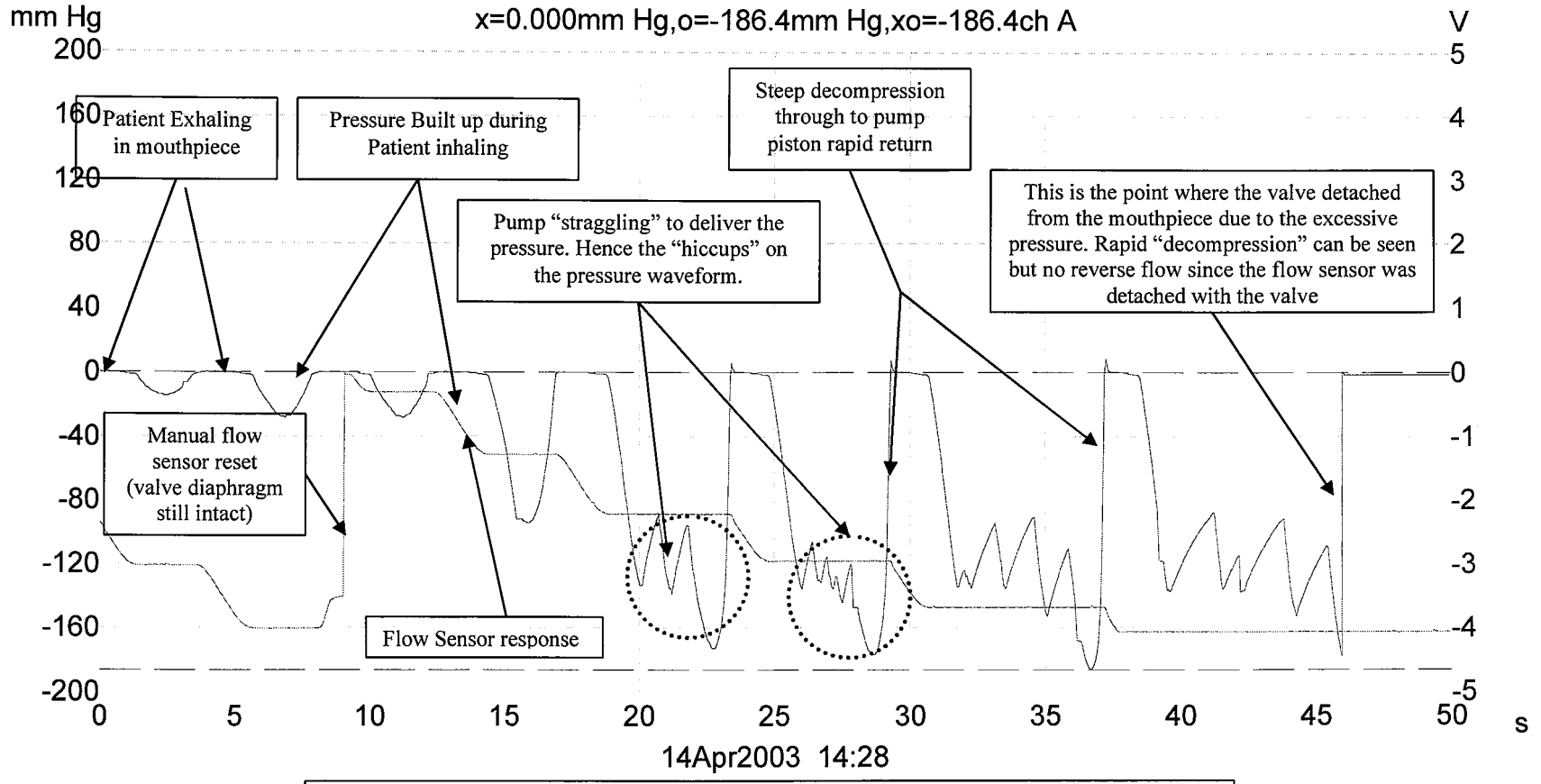


P≈ 120 mmHg
Graph 9: Clement Clarke Mouthpiece



P≈ 150 mmHg
Graph 10: Clement Clarke Mouthpiece

FERRARIS MEDICAL LTD
A FERRARIS GROUP PLC COMPANY
4 BLOORS LANE
RAINHAM, KENT, ME8 7ED, ENGLAND
TEL +44 (0) 1634 373 865
FAX +44 (0) 1634 371 681
email: info@ferrarismedical.com
website: www.ferrarismedical.com



P≈ 186 mmHg

Graph 11: Clement Clarke Mouthpiece – pressure built up resulted in the detachment of the valve component from the mouthpiece. After inspection the valve found intact and could withstand the same levels of pressure successfully.

FERRARIS MEDICAL LTD
A FERRARIS GROUP PLC COMPANY
4 BLOORS LANE
RAINHAM, KENT, ME8 7ED, ENGLAND
TEL +44 (0) 1634 373 865
FAX +44 (0) 1634 371 681
email: info@ferrarismedical.com
website: www.ferrarismedical.com

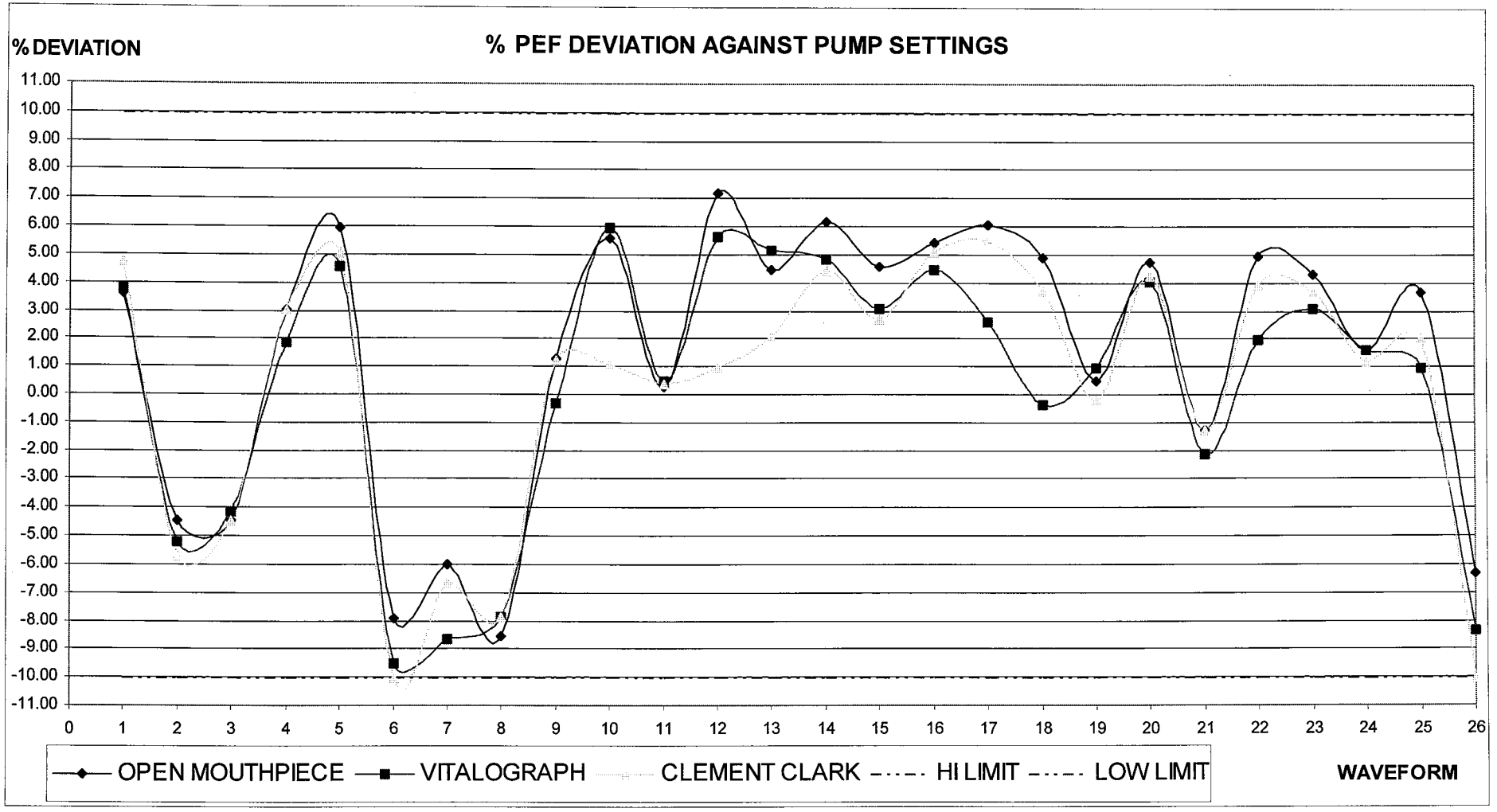
b) Effect of Valves on KOKO PEAK accuracy.

The data collected during the investigation for any changes on the KOKO PEAK behaviour due to the added valves on the mouthpiece can be seen on Appendix A of this report. The data illustrate the mean value after five strokes for each waveform for each mouthpiece (Open (non-valved), Vitalograph, Clement Clarke) as well as the calculated output of the ATS compliant Pump (PEF and FEV1).

The graphs that follow are the plotted data obtained and they compare the performance of KOKO PEAK using the three types of mouthpiece against the pump and against each other.

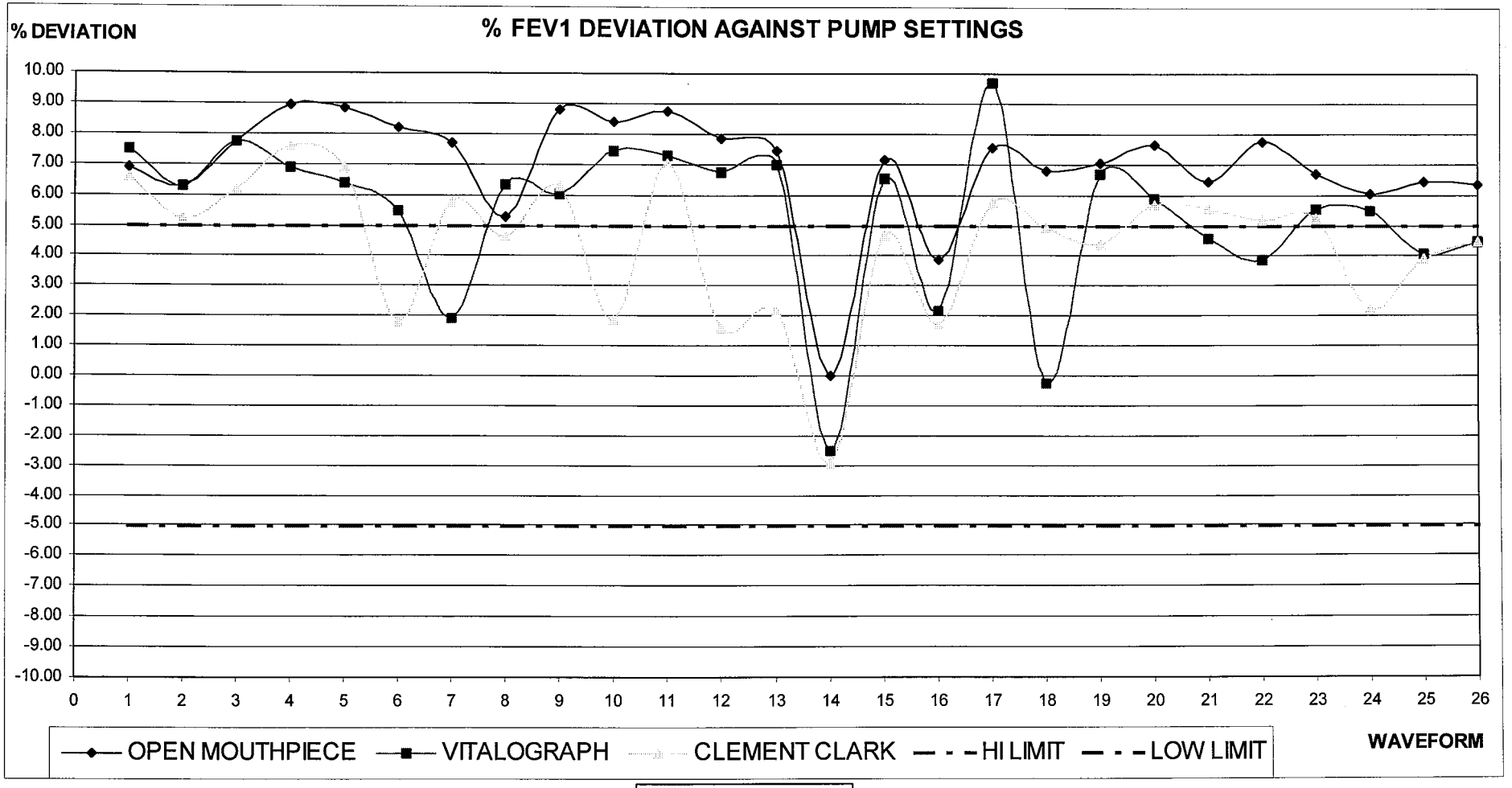
According to the ATS standard the accuracy of peak flow device should be within ±10% for PEF and ±5% for FEV against the test values. These test values are calculated and provided by the computerised pump on the completion of every pump stroke.

FERRARIS MEDICAL LTD
A FERRARIS GROUP PLC COMPANY
4 BLOORS LANE
RAINHAM, KENT, ME8 7ED, ENGLAND
TEL +44 (0) 1634 373 865
FAX +44 (0) 1634 371 681
email: info@ferrarismedical.com
website: www.ferrarismedical.com



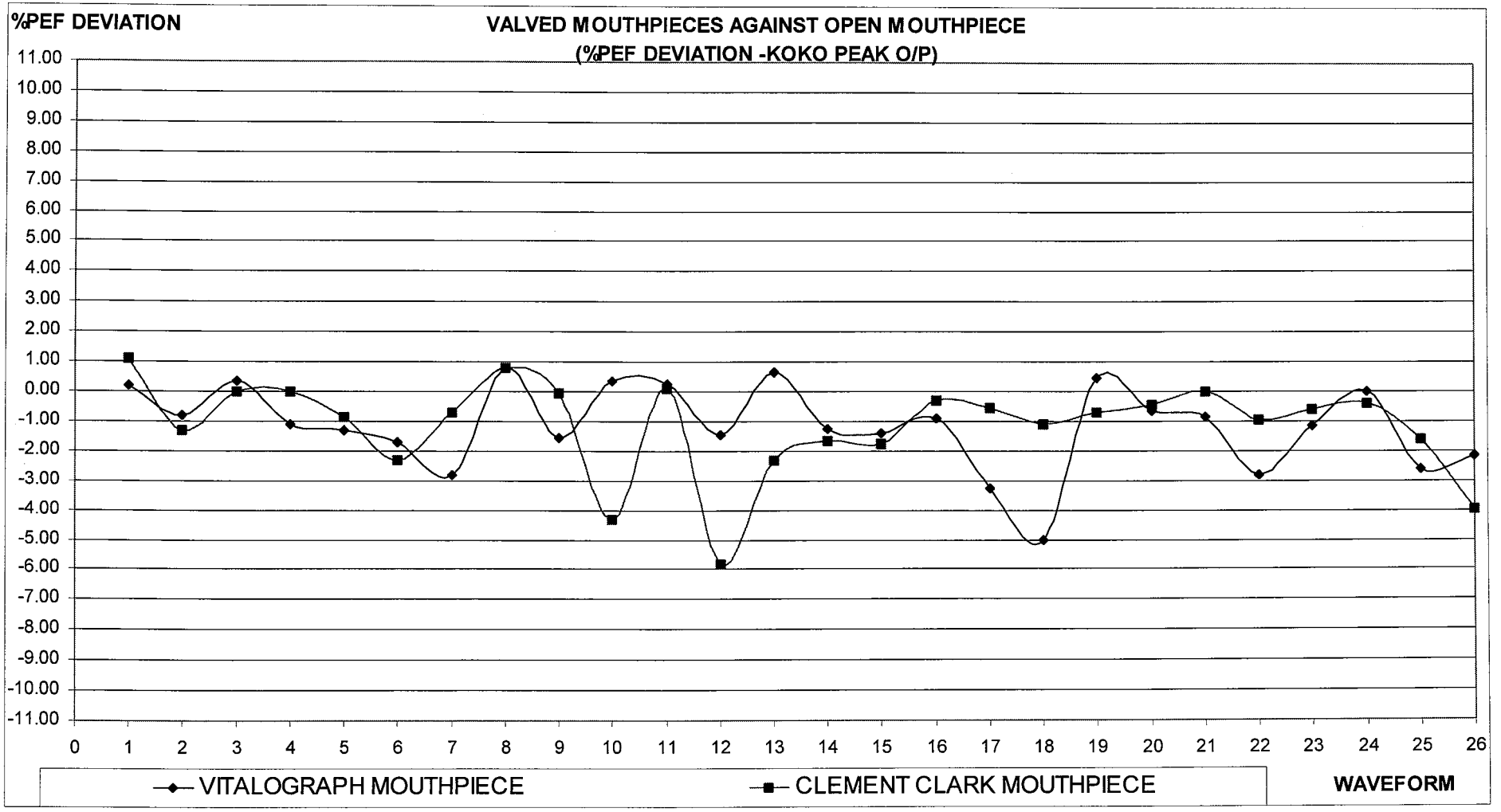
Graph 12

FERRARIS MEDICAL LTD
A FERRARIS GROUP PLC COMPANY
4 BLOORS LANE
RAINHAM, KENT, ME8 7ED, ENGLAND
TEL +44 (0) 1634 373 865
FAX +44 (0) 1634 371 681
email: info@ferrarismedical.com
website: www.ferrarismedical.com



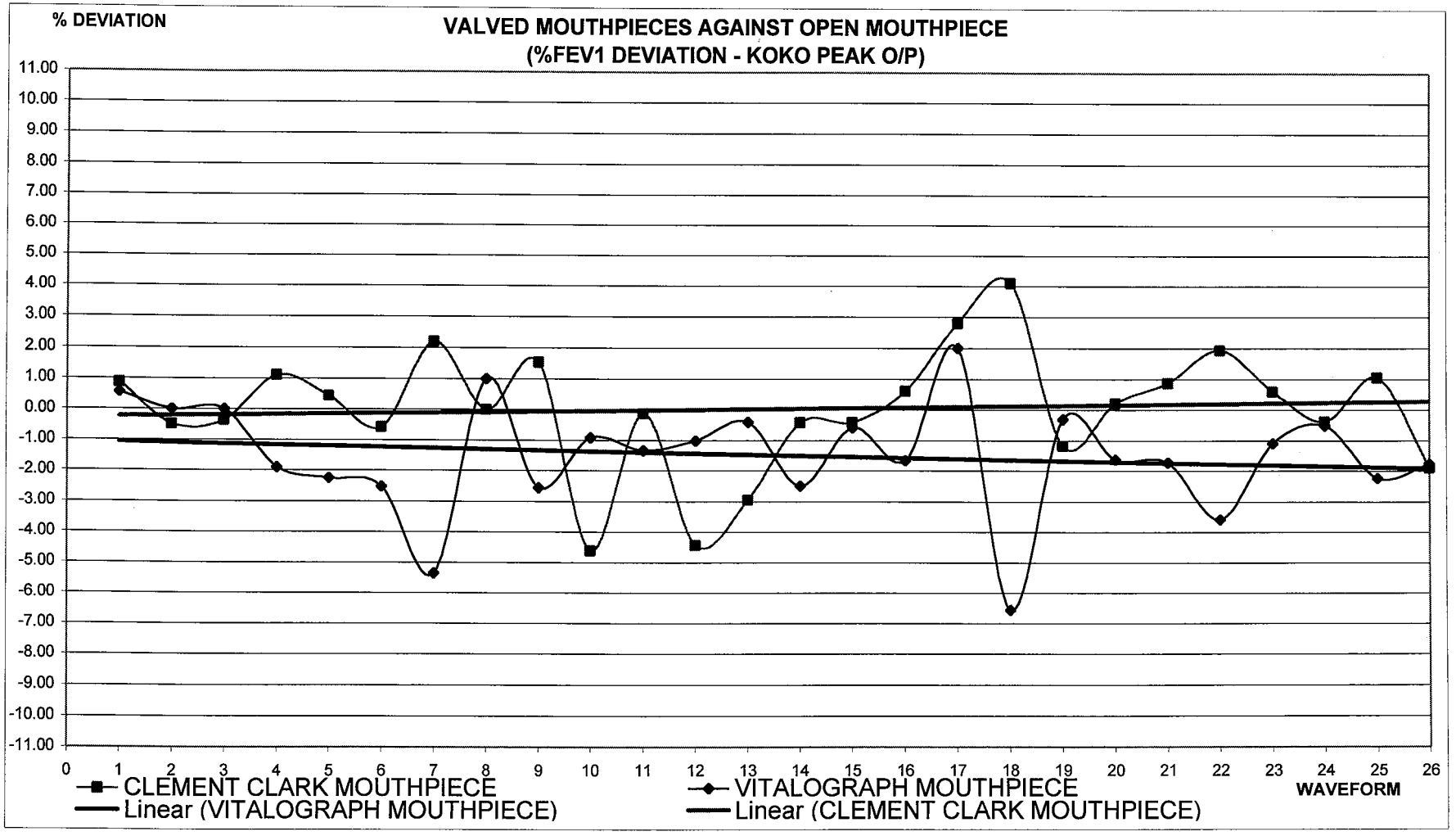
Graph 13

FERRARIS MEDICAL LTD
A FERRARIS GROUP PLC COMPANY
4 BLOORS LANE
RAINHAM, KENT, ME8 7ED, ENGLAND
TEL +44 (0) 1634 373 865
FAX +44 (0) 1634 371 681
email: info@ferrarismedical.com
website: www.ferrarismedical.com



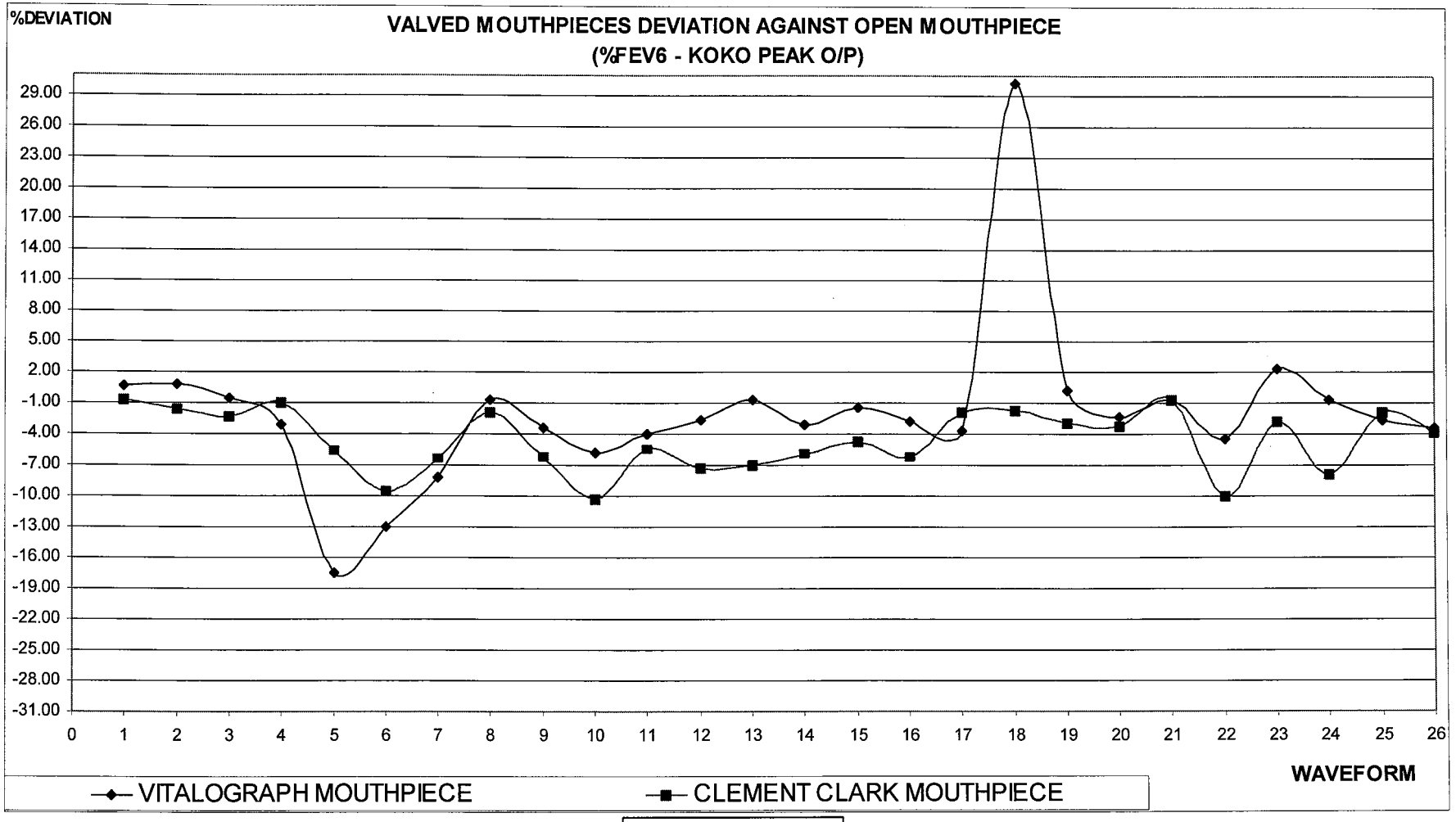
Graph 14

FERRARIS MEDICAL LTD
A FERRARIS GROUP PLC COMPANY
4 BLOORS LANE
RAINHAM, KENT, ME8 7ED, ENGLAND
TEL +44 (0) 1634 373 865
FAX +44 (0) 1634 371 681
email: info@ferrarismedical.com
website: www.ferrarismedical.com



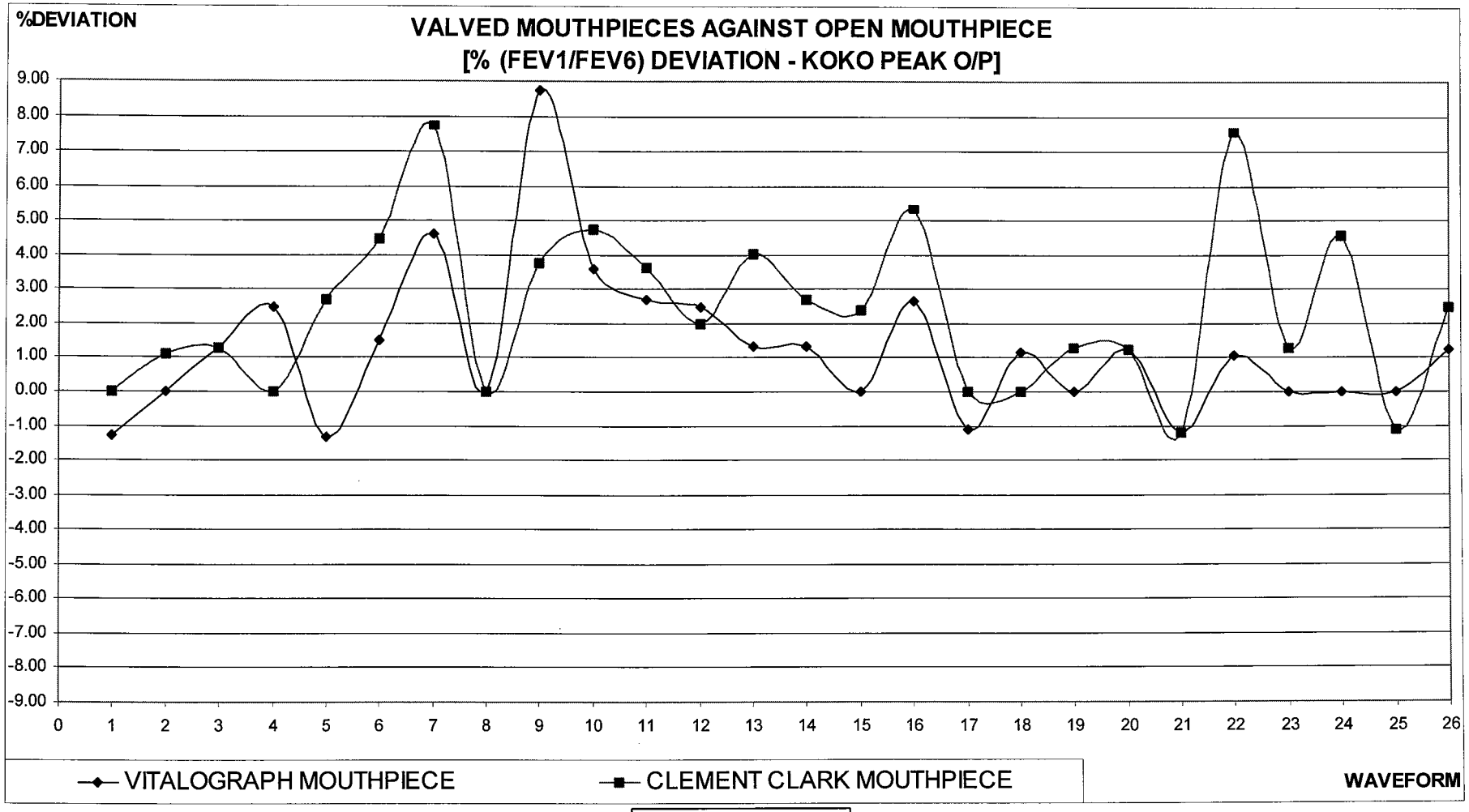
Graph 15

FERRARIS MEDICAL LTD
A FERRARIS GROUP PLC COMPANY
4 BLOORS LANE
RAINHAM, KENT, ME8 7ED, ENGLAND
TEL +44 (0) 1634 373 865
FAX +44 (0) 1634 371 681
email: info@ferrarismedical.com
website: www.ferrarismedical.com



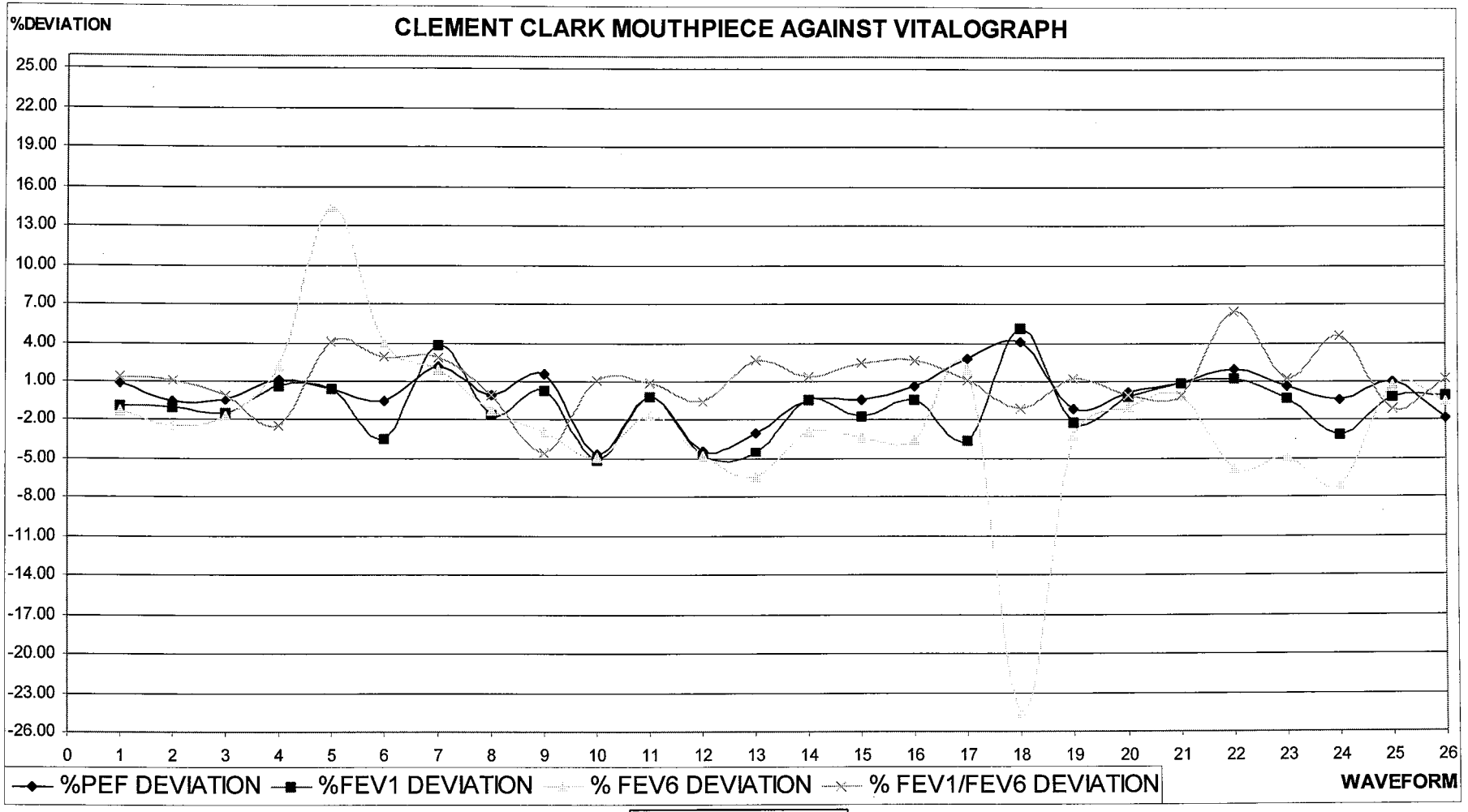
Graph 16

FERRARIS MEDICAL LTD
A FERRARIS GROUP PLC COMPANY
4 BLOORS LANE
RAINHAM, KENT, ME8 7ED, ENGLAND
TEL +44 (0) 1634 373 865
FAX +44 (0) 1634 371 681
email: info@ferrarismedical.com
website: www.ferrarismedical.com



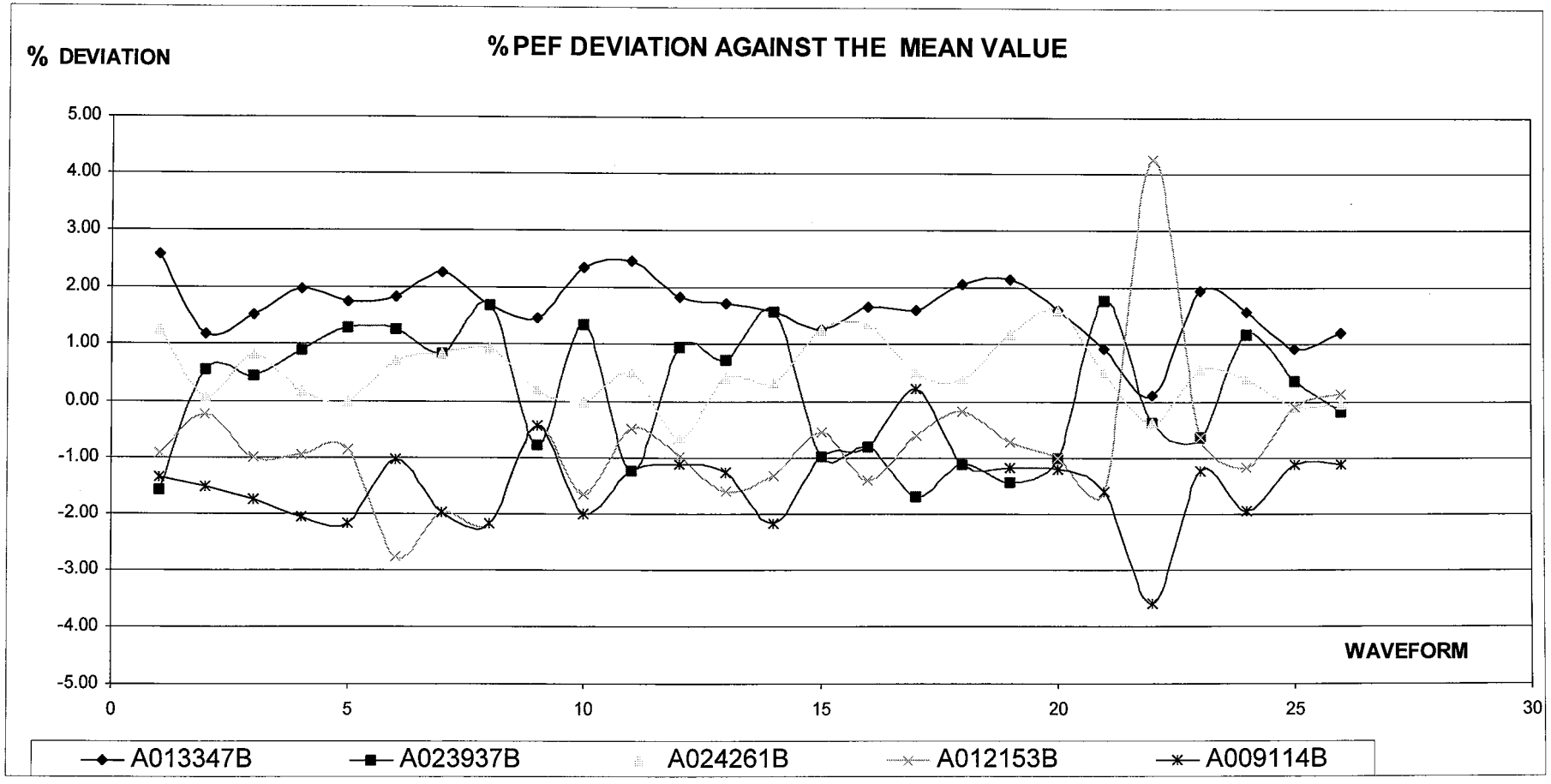
Graph 17

FERRARIS MEDICAL LTD
A FERRARIS GROUP PLC COMPANY
4 BLOORS LANE
RAINHAM, KENT, ME8 7ED, ENGLAND
TEL +44 (0) 1634 373 865
FAX +44 (0) 1634 371 681
email: info@ferrarismedical.com
website: www.ferrarismedical.com



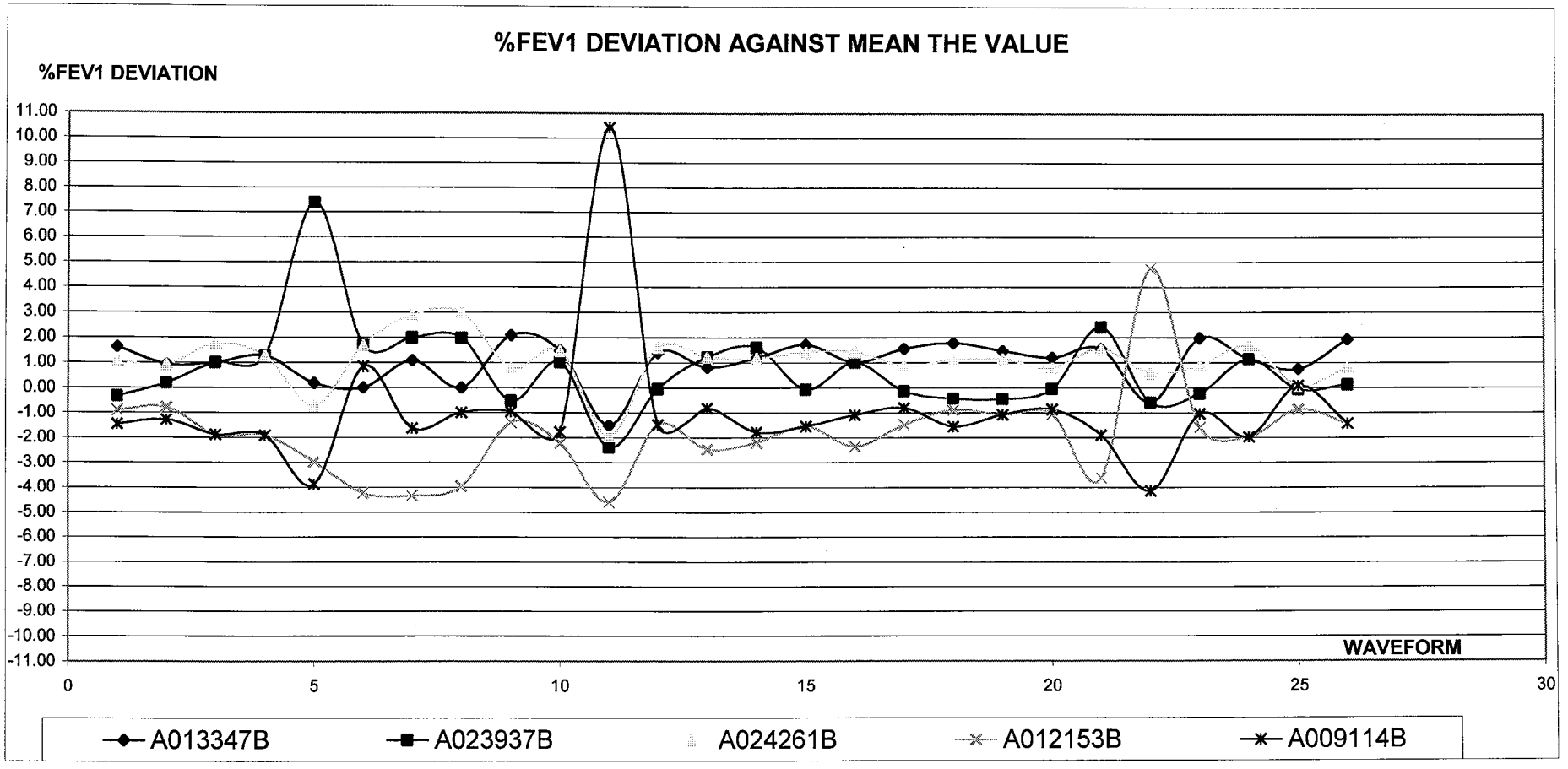
Graph 18

FERRARIS MEDICAL LTD
A FERRARIS GROUP PLC COMPANY
4 BLOORS LANE
RAINHAM, KENT, ME8 7ED, ENGLAND
TEL +44 (0) 1634 373 865
FAX +44 (0) 1634 371 681
email: info@ferrarismedical.com
website: www.ferrarismedical.com



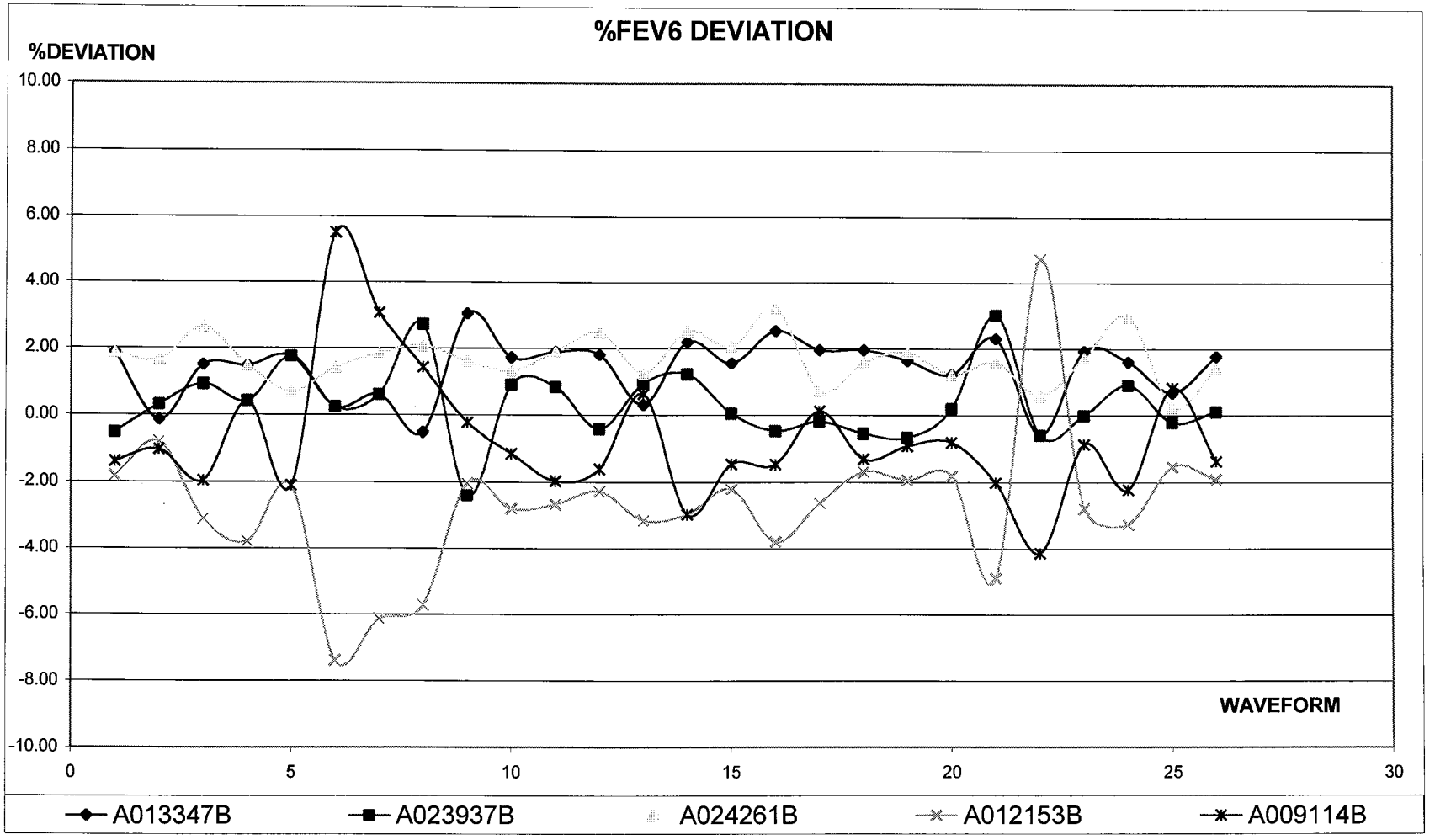
GRAPH 19 – Performance of 5 production Koko Peak flow meters over PEF

FERRARIS MEDICAL LTD
A FERRARIS GROUP PLC COMPANY
4 BLOORS LANE
RAINHAM, KENT, ME8 7ED, ENGLAND
TEL +44 (0) 1634 373 865
FAX +44 (0) 1634 371 681
email: info@ferrarismedical.com
website: www.ferrarismedical.com



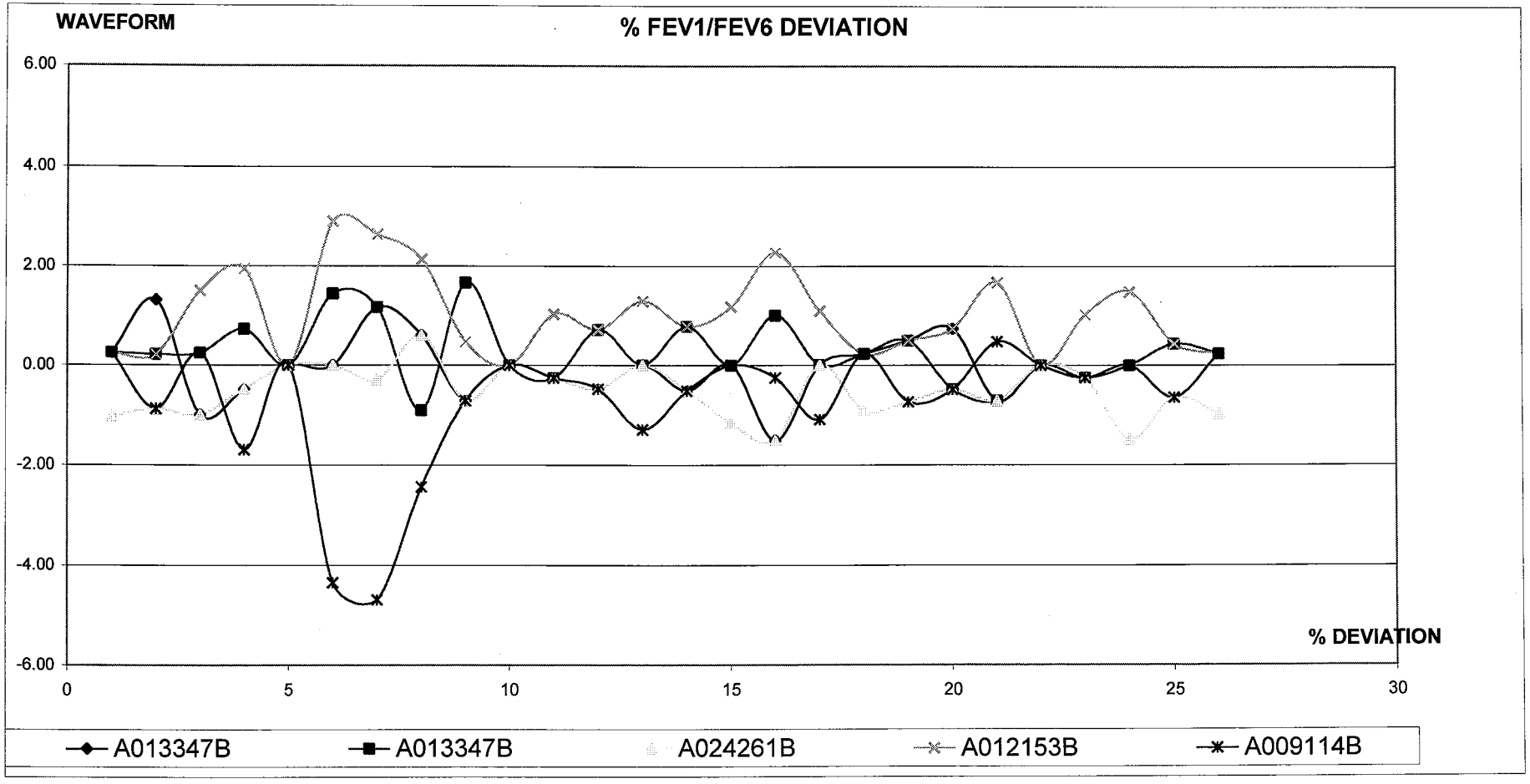
GRAPH 20 – Performance of 5 production Koko Peak flow meters over FEV1

FERRARIS MEDICAL LTD
A FERRARIS GROUP PLC COMPANY
4 BLOORS LANE
RAINHAM, KENT, ME8 7ED, ENGLAND
TEL +44 (0) 1634 373 865
FAX +44 (0) 1634 371 681
email: info@ferrarismedical.com
website: www.ferrarismedical.com



GRAPH 21 – Performance of 5 production Koko Peak flow meters over FEV6

FERRARIS MEDICAL LTD
A FERRARIS GROUP PLC COMPANY
4 BLOORS LANE
RAINHAM, KENT, ME8 7ED, ENGLAND
TEL +44 (0) 1634 373 865
FAX +44 (0) 1634 371 681
email: info@ferrarismedical.com
website: www.ferrarismedical.com



GRAPH 22 – Performance of 5 production Koko Peak flow meters over FEV1/FEV6

FERRARIS MEDICAL LTD
A FERRARIS GROUP PLC COMPANY
4 BLOORS LANE
RAINHAM, KENT, ME8 7ED, ENGLAND
TEL +44 (0) 1634 373 865
FAX +44 (0) 1634 371 681
email: info@ferrarismedical.com
website: www.ferrarismedical.com

CONCLUSIONS

On the basis that a patient will not inspire at a pressure less than -100mB below ambient, the two valved mouthpieces tested were shown to be fit for purpose, in that they both prevented accidental inspiration causing any flow from the peak flow meter.
The valved mouthpiece was therefore effective as a cross contamination prevention device.

Comparing the variations in accuracy between the non valved and valved mouthpiece tests, the differences are within the acceptable limits for the measurements taken.

- All valved and non valved mouthpiece PEF measurements gave readings within ± 10% of the administered value.
- Differences between FEV1 for non valved and valved measurements were of the order of 1.5% mean worst case, and given that the FEV1 spread (graph 20) was ± 2%, this was regarded as acceptable

The valved mouthpieces were therefore effective in purpose without the imposition of any unacceptable accuracy errors.

The following notes result from observations of the graphs.

1. In graph 13, an unaccountable 7% positive offset was seen in the mean FEV1 for devices, measured with and without valved mouthpieces. This is an absolute effect not an incremental change due to the valved mouthpiece over the non valved.
2. The effect of valved compared to non valved can be seen in graph 15, where mean measured FEV1 is reduced by 1.5% for Vitalograph, and 0.1% for Clement Clarke.
3. FEV6 measurements are not meaningful, since the waveforms do not last for 6 seconds.