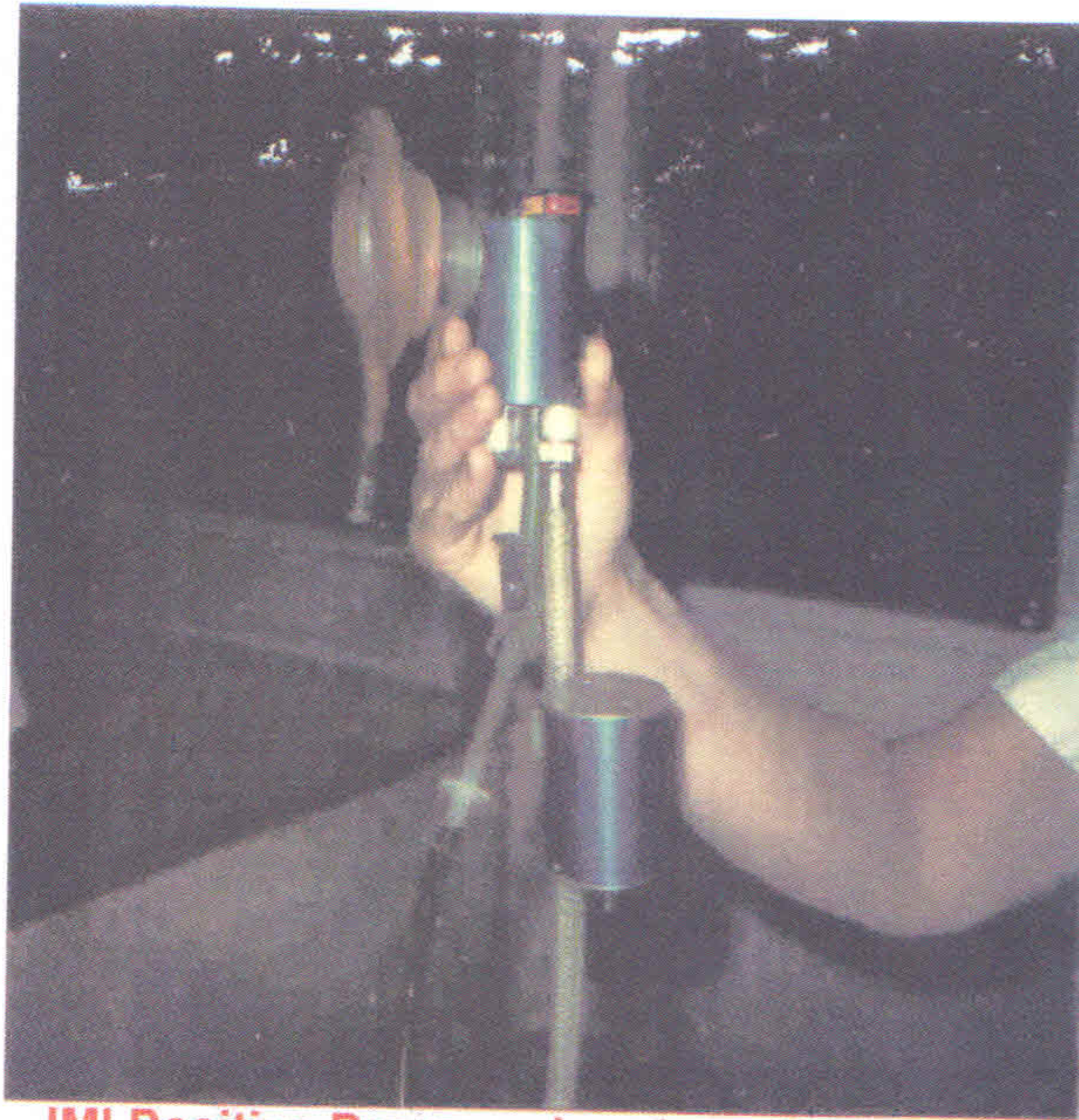


Clinical Trials Tom Thumb

The Tom Thumb was designed and introduced into the market many years (1993) prior to the introduction of the CE mark and the formalisation of clinical trials.

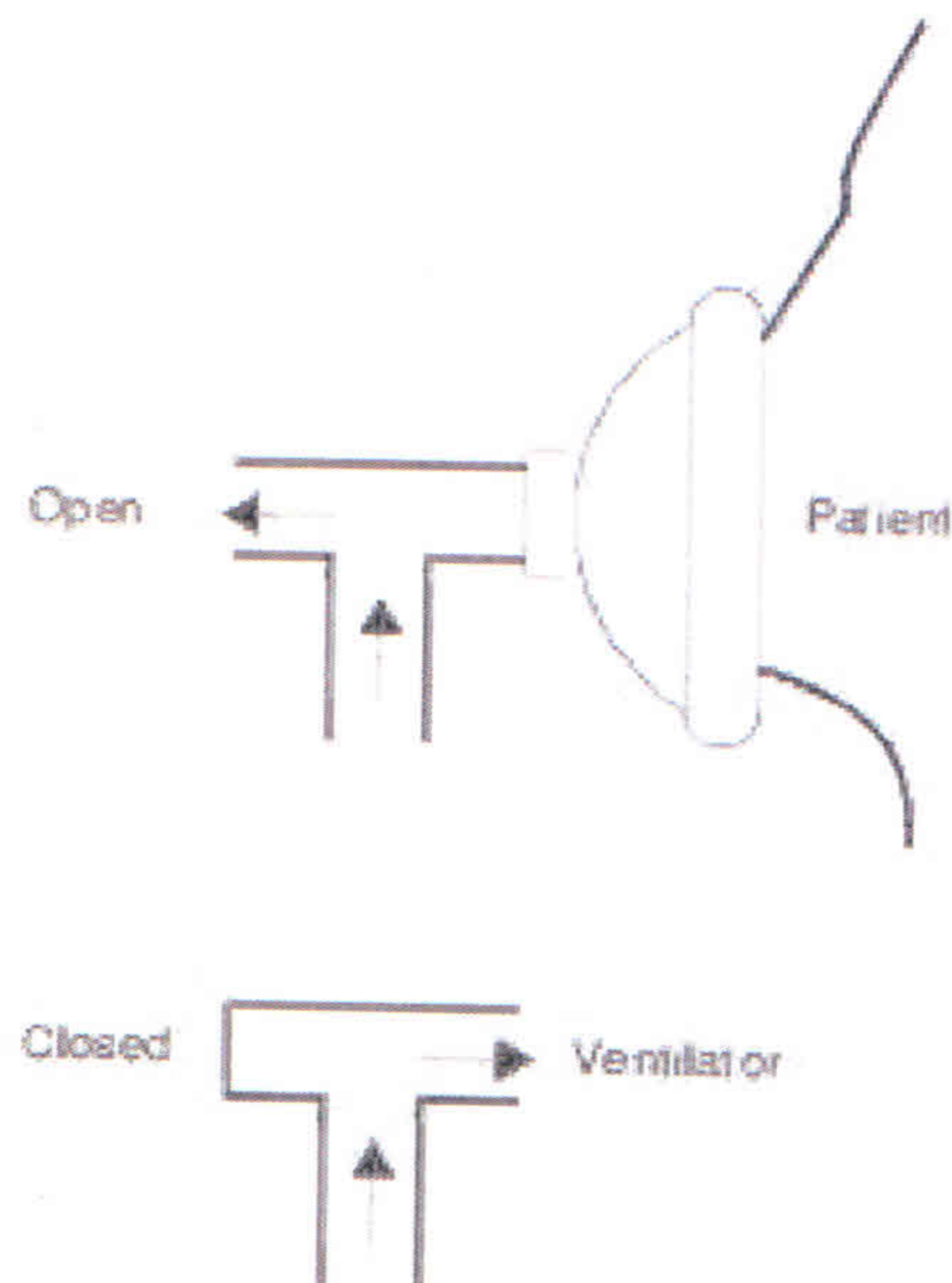
In that era many products started as an idea and were developed in the field in conjunction with clinicians.

The principle of the T occluder or positive pressure hand ventilation was first encountered by Viamed in 1983 when several were purchased from IM! (a Beckton & Dickinson company).



IMI Positive Pressure hand ventilator 1983

**SCBU Fairfield Hospital, Bury.
Supplied with EME Neotherm**



Tom Thumb Theory

Gas is fed into a Tee and allowed to escape into room air. When the leg of the Tee is occluded the

Clinical Trials Tom Thumb

gas is diverted into the patient.

It is important that

The Flow rate can be varied,

The pressure can be measured.

The maximum pressure can be set

If the system fails a valve can limit the absolute maximum pressure to the patient.

The Tom Thumb was designed to full fill these requirements.

The prototypes were developed by hospital engineers in the Princess Mary Hospital Newcastle in the early 1980's

The late Dr S Richmond of Sunderland Royal infirmary carried out extensive tests and published a paper and book on positive pressure ventilation using the Tom Thumb as against resuscitation bags.

Dr S. Oddie Consultant Neonatologist published the paper Use of self-inflating bags for neonatal resuscitation in 2004 which discusses the use of the Tom Thumb.

The very early Tom Thumbs were used extensively by Dr Millagan consultant neonatologist at the Royal Victoria Infirmary Newcastle who helped finalise the design by incorporating additional safety features to reduce some user problems. These relate to changing the input and output tube sizes to prevent the Tom Thumb from being omitted from the circuit.

There are 5 customer complaints in the CE Technical file some of which resulted in "incidents" however all have been traced to operator error and subsequently cleared by the UK MHRA.

J.S.Lamb

4 June 2014