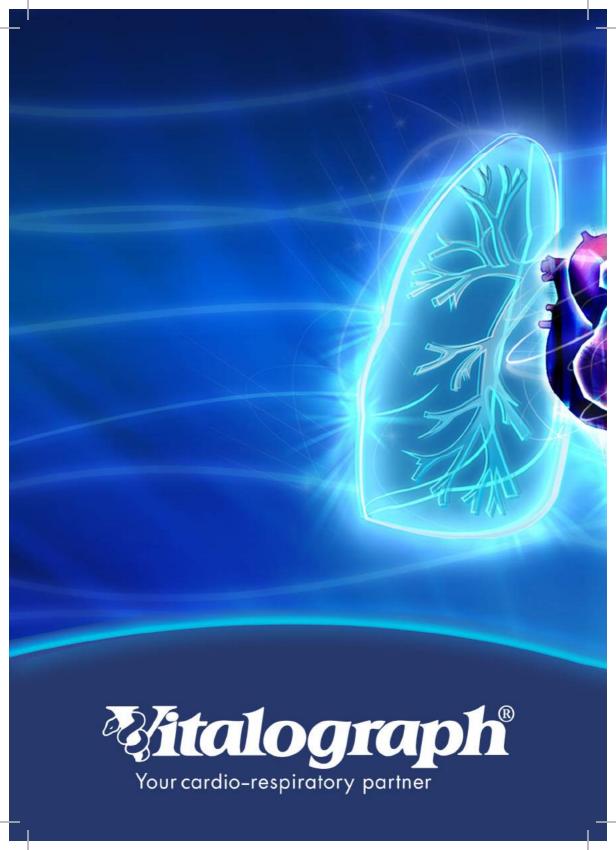
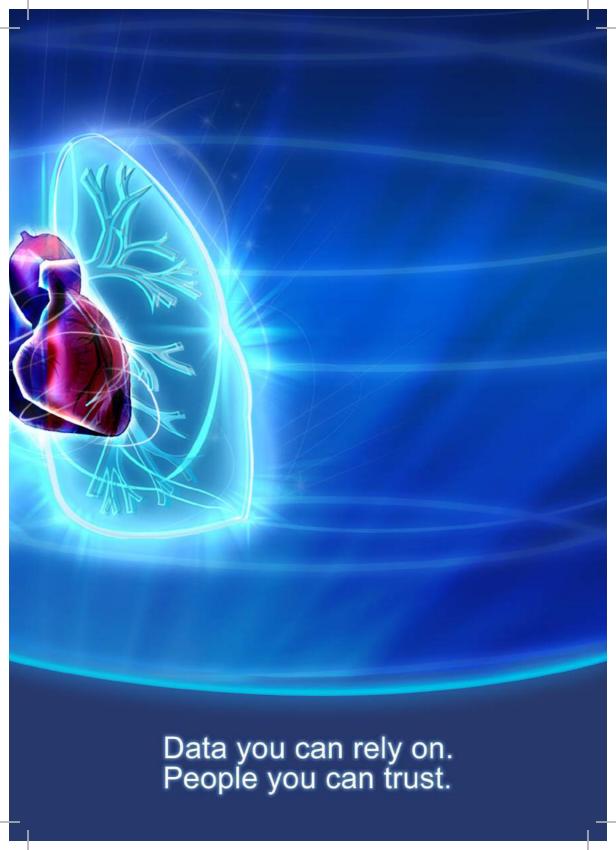
THE Witalograph STORY

Blazing the trail of excellence in cardio-respiratory solutions for over half a century





Foreword

The ability to measure lung function using a portable spirometer is now something often taken for granted by today's clinicians. This booklet outlines the fascinating story of Vitalograph spanning the last 50 years. It summarises the innovation, creativity and ingenuity that has led to the production of reliable lung function testing equipment which has kept abreast of ever changing technological developments.

Margaret and Dietmar Garbe, through their expertise, originality and problem solving abilities, invented lung function testing devices and brought them to market. They created an original and independent company responsible for the ongoing development of medical equipment which has proved essential for the effective management of people suffering from respiratory disease. Margaret and Dietmar's sons Bernard and Marcus have continued to develop and expand their good work to give us the Vitalograph of today. Over recent years Bernard and Marcus have worked diligently in collaboration with clinical scientists to ensure their equipment is the best. They have also personally contributed enormously with expertise towards setting the standards that lung function equipment must now meet to be sure that the needs of patients and clinicians are best served.

We have been greatly honoured to write this foreword to the 'Vitalograph Story' and know that Margaret and Dietmar Garbe would be immensely proud of what Vitalograph has subsequently achieved. Their story and the Vitalograph story endures in the form of this booklet.

Dr Mark L Levy General Practitioner, London www.consultmarklevy.com Professor Martin R Miller Institute of Occupational and Environmental Medicine University of Birmingham, B15 2TT

Dedication

This book is dedicated to my parents, Dietmar and Margaret Garbe, who never wavered in their determination to create a successful business. When one venture did not grow fast enough they tried another, again and again. Their entrepreneurial vision, grit and determination gave Vitalograph its enduring legacy of innovation and integrity, which I like to think that we retain to this day.

A company is the sum of its people and I would also like to thank our employees, past and present, who over the many decades helped create this wonderful company.

Vitalograph Managing Director

The birth of spirometry

Forms of spirometers were used as early as around 150 A.D. when Greek philosopher Claudius Galen, a physician, was recorded as experimenting on human ventilation by getting a child to breathe in and out of a bladder. Understanding of respiratory function and disease increased in 1679 when Swiss physician Theophile Bonet used the phrase 'voluminous lungs', to report findings of emphysema during autopsy.

In 1816, in France, René Laënnec invented the stethoscope. Known as the 'father of auscultation' he correlated sounds, diseases and autopsy findings. He wrote the first description of bronchiectasis and identified emphysema.

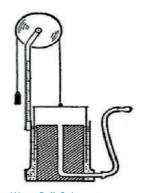
In the year 1846 physician John Hutchinson built a spirometer, a device for measuring lung capacity, using an inverted bell floating on water. He used this to

Sir John Hutchinson capture the volume of air expelled by thousands of people,

a measurement for which he coined the phrase 'vital capacity'. This early spirometer which was capable of giving fairly accurate static lung volumes was developed as a calibrated device and commercialised for use in laboratories.

The inverted bell spirometer developed into many models of water seal spirometer which could measure dynamic as well as static lung volume.

Water seals
were eventually
superseded
by bellows and
rolling seal
spirometers,
both of
which could
be oriented
horizontally



Water Bell Spirometer

or vertically. Accurate volume displacement spirometers are still available today and regarded as the 'gold standard' for spirometry measurements.

The Vitalograph story begins

Modern advances in spirometry over the last 50 years can be explored through the history of Vitalograph®, a world leading provider of respiratory



Margaret and Dietmar Garbe

devices founded over half a century ago. The Vitalograph story begins with the meeting of Dietmar Garbe and Margaret Gardiner among the devastation of a Europe ravaged by war. From a sheltered upbringing in a town near Oxford, Margaret left Manchester University in 1947 with a degree in Administration and took a job as a probation officer in the bomb scarred city of Liverpool, the first ever female in that role. It was a tough job and she was a tough lady! In 1948 she used her summer holiday to volunteer to help people in Germany who were still struggling in those post-war years. She travelled to Düsseldorf where she met Dietmar, a gymnastics coach, who was trying to find work there following years in hospital recovering from war injuries sustained in Russia.

From translations to medical devices

Margaret returned home and the following year Dietmar travelled to England to find her. The young couple married in 1950 and went on to have four children. They originally settled in Farnborough, Kent, where they started their first business 'Gardiner's Translation & Direct Mail Services'. Gardiner's Translation Service specialised in German to English translation and soon established a reputation for excellent translation of medical device technical manuals.



Gardiner's Translation Service

Garthur (London) Ltd

Dietmar and Margaret quickly discovered that several German medical device companies were seeking distributors in the UK and, with a partner called Thurston, decided to form Garthur (London) Ltd in 1951 (Garbe/Thurston) to distribute. commission these and service

devices. In the 1950s, with rationing still in force and money tight, sales of new equipment were rare, so most of the Garthur business was the repair and adaption of existing equipment. The polio epidemic in the early 1950s led to Garthur distributing iron lungs and ventilators used to assist polio victims with their breathing, the start of an increasing specialisation in cardiorespiratory diagnostics and therapy.



Garthur Exhibition Display

A move to Buckingham in the heart of England

In 1956 Garthur moved from Kent to the site of its current head office, Maids Moreton House in Buckinghamshire, with funding from a very generous gift from Margaret's mother, Joyce. The village of Maids Moreton was chosen for

its central location and the po-

tential of the large, and at that time, nearly derelict Victorian

property with many outbuildings, some built during the war for a machine tool company.

Within a short period of time Garthur started to also represent UK manufacturers, notably the revolutionary portable positive pressure Barnet Ventilator. This



was the world's first portable ventilator, freeing the patient from the dreaded iron lung. Garthur earned some welcome publicity when, in 1961, a Barnet ventilator device was rushed from Buckingham to the London Hospital under police escort in a successful attempt to save the life of Elizabeth Taylor who had developed double

Taylor who had developed double pneumonia whilst filming Cleopatra.

Ground breaking invention of the first Vitalograph spirometer

Elizabeth Taylor & Barnet ventilator

Dietmar and Margaret's young son, Bernard, suffered from asthma and often struggled to breathe. The worried parents put their medical business contacts to good use and were able learn from pulmonary experts about asthma and the medical devices used in the diagnosis and treatment of respiratory diseases.

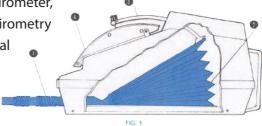
This knowledge was soon put to good use when, in 1962, Dietmar was asked by the Medical Research Council Pneumoconiosis Panel to develop a simple, mobile spirometer to screen coal miners for what was then called 'Black Lung'. Up until this point spirometry could only be performed in lung function laboratories and took hours to complete. Dietmar responded by designing and

developing a revolutionary portable spirometer, which made it possible to undertake spirometry

wherever required in occupational

health and primary care settings.

Dietmar and Margaret had a strong belief in the value of their new invention. Having failed to find a medical device company to manufacture the Vitalograph



AIR ENTERS THE BELLOWS (2) VIA THE BREATHING TUBE (1) THE CURVED STYLUS ARM (3) FOLLOWS AN ARC WHICH CONFORMS EXACTLY TO THAT OF THE VITALOGRAM PLACED ONTO THE CHART CARRIER (4) ON DYNAMIC TESTS (FVC) THE CHART CARRIER MOVES ACROSS THE STYLUS, THUS GIVING A TRACING OF VOLUME AGAINST TIME

Workings of the Vital-o-graph Spirometer

spirometer under licence, they decided to go it alone. The first Vitalograph was built in 1962 by a team working from the converted stables at Dietmar and Margaret's family home at Maids Moreton.

This innovative spirometer, named the 'Vitalograph' (derived from 'Vital Capacity' and 'Graph') was designed

t o m e a s u r e static and, most importantly for obstructive airways disease, dynamic lung volumes in the physician's office. The low cost Vitalograph fast, made accurate assessment and early detection of respiratory disease possible. Updated versions of this volume displacement spirometer with wedge bellows continued to be developed and produced until 2015 when the wedge bellows was replaced by a horizontal/vertical rolling seal Vitalograph.



Vitalograph Wedge Bellows Spirometer

The challenge of accurate calibration

The design of the portable spirometer had to overcome a considerable technical challenge, one that is challenging even today – accurate calibration. Vitalograph met this challenge in the early 1960s with the robust and accurate wedge bellows spirometer, which was calibrated in manufacture using water displacement. During the 1960s Vitalograph devices were brought into laboratories for their annual accuracy check. Today of course the daily accuracy check for an office spirometer is achieved very simply with a few strokes of a precision syringe (the term 'calibration' is confusing because calibration can mean many different things). Certification of accuracy traceable to international standards is required for all calibrated measuring equipment.

Vitalograph becomes the office spirometer

Acceptance of the new Vitalograph spirometer was fast and widespread in the UK. It was reliable, accurate, robust and highly portable compared to laboratory spirometers, most of which were water seal designs which were delicate, could not be moved without emptying out the water first, and on replacement the water needed to be left for 24 hours at a constant temperature. Best of all, the



Vitalograph becomes Synonymous with Spirometry

single breath 'Vitalogram' pattern was recognisable to healthcare professionals, even those with limited spirometry experience. The instant Vitalograph volume/ time tracing enabled the technician to ensure the subject produced high quality repeatable, tracings and allowed the physician to interpret the results in the clinic or at the patient's bedside. The key indices, Slow Vital Capacity (VC), Forced Expiratory Volume in the first second (FEV1) and Forced Vital Capacity (FVC) could be read directly from the tracing. Furthermore, overlaying multiple efforts enabled instant assessment of repeatability of the test manoeuvre, a vital quality element. Within a very short time such testing became a routine part of patient care and for many people the Vitalograph name remains synonymous with spirometry.

Vitalograph takes the lead

With the success of the Vitalograph spirometer the distribution and service activities of Garthur Ltd gradually became secondary and Vitalograph Ltd became the primary business. Garthur, however, continued trading into the 1970s and is still a registered company today. The present day Vitalograph logo still retains the snake image, inherited from the original Garthur logo, associated with Asclepios the ancient Greek God of Medicine.



Within Vitalograph thoughts now turned to expansion by export. This was not an easy thing to do in the 1960s with currency controls and low economic growth, as well as import barriers in many countries. The finding and training of international distributors was led by Margaret Garbe who continued in this role until her death in 1974 aged only 47. Today Vitalograph exports to over 113 countries around the world through a network of trained distributors.

Vitalograph GmbH

An early success in exporting was, perhaps unsurprisingly, to Germany. Here there was a great demand for the Vitalograph and they found a good agent called Hans-Heinz von Allwörden. Some years later Vitalograph set up a branch office which became Vitalograph GmbH in Hamburg and remain based in that great city today.



Hamburg Office

Vitalograph Inc.

In the early 1970s a Vitalograph facility was opened in Kansas City to support US sales and distribution, building on the initial dealerships previously supported directly from the UK.

In 1972 Dietmar developed the concept of a low-cost peak flow meter after being inspired by an inventor of a ski anemometer strapped to a skier's shoulder in the Rocky Mountains. The

'Peak Flow Monitor' was brought to production and is now regarded by many experts as an essential tool in the home management of asthma. This remains a top selling Vitalograph product, with millions of units sold.

While Dietmar was in Kansas City he formed a collaboration with Hans Rudolph Inc. to sub-contract the manufacturer of the Vitalograph wedge bellows spirometers as demand was exceeding supply.

In recent years Vitalograph Inc. has grown very rapidly, acquiring more office and warehouse space, but still based in Kansas City.



Kansas City Office





Resuscitation and intubation

Even after Vitalograph became the main operating company, the successful Garthur range of resuscitation equipment continued to be developed and manufactured by Vitalograph.

1973 saw the launch of the 'The Royal Free Hospital Intubation Trainer'. This successful training model was the brainchild of consultant anaesthetist Hilary Howells - who had a long association with Vitalograph starting with ventilators and the Vapour Condenser. The RFH Trainer was used in teaching anaesthetists, paramedics and other specialists how to insert (endo)tracheal tubes into the airways of anaesthetised or unconscious patients.



RFH Intubation Trainer



ResusBag

Vitalograph (Ireland) Ltd.

In 1974 Vitalograph set about increasing its manufacturing output to meet demand by building a manufacturing facility in Ennis, Co Clare, Ireland. In 1976 the company moved to its new, purpose-built manufacturing facility in the town where it remains to this day, albeit with several expansion phases. The manufacturing processes inside the factory have changed markedly over the decades, with automated printed circuit board assembly, paint shop, moulding shop, fabrication, machine shop and other processes gradually being outsourced due to advances in manufacturing technology leaving the specialist assembly, final test and calibration capabilities in house. From 2014-2016 the factory underwent a complete refurbishment programme to bring it totally up-to-date.

Vitalograph Factory in Ennis



The advent of electronic spirometers

In the early 1970s, well before the widespread use of computers, Vitalograph began using electronics in their spirometers including the 'Digital Meter', a very successful product which displayed FEV1, FVC and the ratio on a neon tube array display.

The 1970s saw Vitalograph launch several innovative respiratory devices including the 'Opening Interrupter' – a device for measuring airways resistance during tidal breathing.



Vitalograph Digital Meter

The next generation of Garbe's join Vitalograph

The late 1970s saw the two sons of Margaret and Dietmar join the family company. Marcus joined in 1977, having trained at the distinguished London accountancy firm Brebner, Allen and Trapp (now Brebners).

He was followed in 1979 by his elder brother Bernard, a chartered engineer who had formerly worked with British Aerospace and Lucas group. In 1980 Dietmar passed away aged 55. In the same year the Vitalograph spirometer was awarded a GS (tested safety) award from the internationally renowned TÜV which provides certification for various international standards.

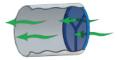


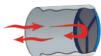
Marcus Garbe



Bernard Garbe







Getting this GS involved several safety-related developments in the spirometer, including a 'safety mouthpiece', which became the patented and very successful 'SafeTway®' mouthpiece.

1980 also saw the birth of PC spirometry

SafeTway Mouthpiece and the very first

version of the Vitalograph Spirotrac® software using the Commodore PET®, followed very successfully by the Apple® II computer connected to the Vitalograph-

S model bellows spirometer.



Apple II Computer

Evolution of electronic flow sensing spirometers

Until the early 1980s most spirometers measured volume directly, using water bells, rolling seal or bellows technology, and were very accurate.

Flow sensing spirometers measure flow and integrate this signal with respect to time to obtain lung volumes. This change in technology opened the door to measurement errors from multiple sources, primarily the technology used for flow sensing but also the electronics and programming associated with the complex calculations required. Japanese companies were early innovators in flow measuring spirometers but their initial flow-measuring devices were liable

to inaccuracies. However customers liked the small size and low cost of these 'electronic spirometers'.

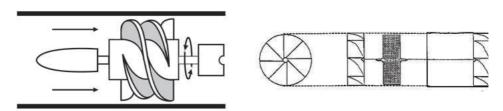
The recognition that a full electronic spirometer was required to compete with Japanese competition led Vitalograph to develop an electronic flow measuring spirometer. After extensive research to



discover the best flow-measuring technology, having rejected many different types including venturi, moving vanes, platinum wires, ultrasonic, pitot tubes and others, the Lilly and Fleisch pneumotachograph technologies were chosen as the most suitable technologies, with the Fleisch later becoming preferred for its superior linearity, accuracy and robustness.



With the increasing availability of early microprocessors in the 1980s over 200 manufacturers started to manufacture flow-sensing spirometers using low cost sensors for their spirometers. Many used sensors such as vortex shedders, polystyrene rotating impellers, turbines and the ubiquitous stator rotor devices (misnamed 'turbines') which still proliferate today. Very few of these alternative flow sensors have been shown to be sufficiently accurate for spirometry.



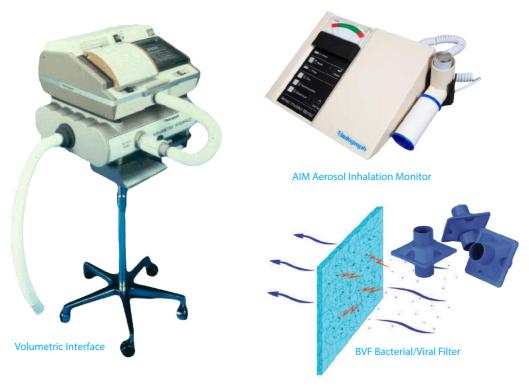
Turbine Spirometer

Stator-Rotor Spirometer

No flow sensing spirometer can match the accuracy in measuring lung volumes of volume displacement spirometers, especially at the very low flow rates found in subjects with lung disease. Indeed, very few commercially available spirometers today have been demonstrated to pass the testing required in the current international spirometry standard, ISO26782:2009 which applies to all diagnostic spirometers. This standard has been officially adopted by nearly every national standards body. It replaces and supersedes the technical components of guidelines evolved by the ATS and ERS in their 2005 joint statement.

Vitalograph extends its product range

During the 1980s Vitalograph was collaborating with clinical experts to bring innovations and new products to market. One particularly successful innovation was the Aerosol Inhalation Monitor (AIM™). This device and its successors gave objective assessment of inhaler use for the first time outside the laboratory. Another pioneering product was the Volumetric Interface which addressed



concerns over cross-infection. This device provided a solution to spirometry testing subjects with transmissible diseases by using a fully disposable breathing circuit in a volume spirometer.

In later years high efficiency particle filters were introduced which made this type of system obsolete. Vitalograph have evolved their pioneering work with filter specialist Pall in the late 1980s from a simple barrier filter into the highly efficient electrostatically charged Bacterial/Viral Filter BVF™.

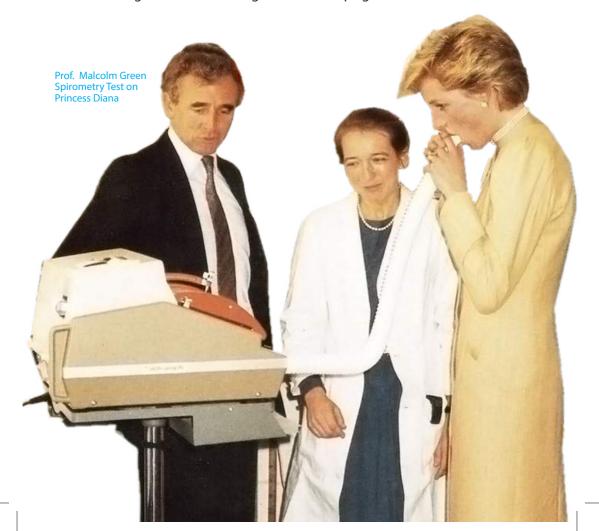
Design awards

1985 was a champagne year for Vitalograph, starting with a Design Council Award presented by Prince Philip for the Emergency Aspirator. In that same year the company opened its newly extended and refurbished factory in Ennis, more than doubling its size. More awards



Vitalograph COMPACT 1985

followed in 1986, this time for the COMPACT which won both a Design Council Award and a gold medal for design from the Leipzig Messe.



The nineties

The early 1990s brought Vitalograph further success with the launch of several new products including the ALPHA™, Peak Flow Whistle, the Escort, the 2120, the TUT (a new bespoke inhaler trainer device for the Turbuhaler), the Vitalograph micro and PEF/FEV Diary.

Personal computers were in their infancy still and although local area networking was starting to be used, the explosion of the internet was still to come with the 'Spirotrac' spirometry software making the transition to the PC platform to take advantage of the PCs increasing availability and capabilities.



Vitalograph micro & Vitalograph ALPHA with Lilly Pneumotachograph



Vitalograph 'S' with PC and Spirotrac Software

Vitalograph raises funds for the BLF

Vitalograph supported the British Lung Foundation in the millennium year to launch a new style mouthpiece with the Foundation's striking 'red balloon' logo displayed on millions of mouthpieces. Vitalograph donated £1 for every box sold – raising thousands of pounds every year for 5 years.



BLF Balloons Celebration

The launch of the Vitalograph Pneumotrac

2002 saw the launch of the first generation Pneumotrac™, the first pure PC spirometer and one of the company's most successful products, now in its third generation due to its exceptional accuracy, low cost, robustness and high reliability.



Pneumotrac Spirometer

Vitalograph & clinical trials

In 2003 the first multi-centre global centralized data clinical trial run by Vitalograph began. The data management was outsourced to Lubeck-based Varigon, having the best technology and most experienced service provider in this emerging sector of secure medical data in Europe. Sending the signed and encrypted data almost instantly, automatically and securely to a central server offered enormous benefits and cost savings for the sponsor. All the data from a study has a full audit trail and can be fully reviewed in hours, rather than weeks.

When Varigon went into receivership Vitalograph acquired rights to the company and moved data management operations to

England. Vitalograph decided to specialize only in studies with electronic data capture, although at this time most studies were still mainly paper based. Today the Buckingham servers are mirrored (real-time backup) in Milton Keynes, London and Ennis to ensure data security and business continuity in the case of a disaster on any site.

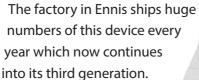


Clinical Trials Model

Prestigious design award

In 2007 Vitalograph expanded into a new purpose designed facility on their Buckingham site designed to accommodate the growing business. The 4000 series of respiratory monitors and screeners, including asma-1™ and copd-6™, was launched in that year and won a prestigious Design Business Association 'Design Effectiveness Award' in 2008 with the designers Kinnear Dufort. The range expanded to include the first Bluetooth® versions in 2010 and updated again in 2015 to BT4 low energy 'Smart'.

In 2009 Vitalograph launched the innovative In2itive[™] handheld spirometer and e-Diary. Automatic synchronisation with a SQL database, customised questionnaires, ePRO, remote data transmission by Bluetooth[®], cellular or landline made this the most advanced medical device of its type.



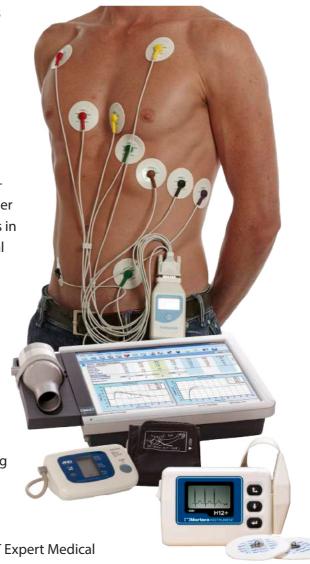
DBA Design Award





Beyond office spirometry

Since 2013 Vitalograph has collaborated with other companies in the cardiorespiratory diagnostics field to expand into areas such as lung function analysers, lung diffusion, body plethysmographs, electrocardiographs, cardiopulmonary exercise and other testing apparatus. Advances in technology, including digital gas sensors and solid state single chip solutions, make it possible for smaller, more accurate and reliable devices to be developed. Vitalograph is committed to being at the forefront of these advances and to maintain its compliance with increasingly demanding new regulations on medical devices.



The launch of the COMPACT Expert Medical
Workstation in 2015 and the evolution of Spirotrac
software has seen Vitalograph branch out from spirometry to
offer a host of new functionality including ECG, audiometry, pulse oximetry,
COPD assessment, blood pressure measurement and challenge testing.

Vitalograph strategy

The Vitalograph Group has been growing rapidly since 2010. The current Vitalograph strategy is to continue to invest heavily in research and development, to maintain a high degree of market specialisation, conform to all applicable regulations and standards and to continue to deliver innovative, high performing products and services that push back the boundaries of possibility in respiratory care.



Vitalograph Marketing

Being a privately held company means the experienced Vitalograph management team is able to respond rapidly to market needs and make significant commitments and investments without the need for lengthy consultations with outside investors.

The success enjoyed by the company is also due in no small part to its employees, 40% of whom have been with the company for over 10 years. The large number of long-serving employees helps support the strong relationships with customers and suppliers that characterise Vitalograph.



Excellent Standards

Another key advantage that
Vitalograph has over its' competitors
is a deep understanding of the everchanging regulatory framework in the
medical device, software, technical
and clinical arenas in which it operates.
Vitalograph quality systems and
ongoing adoption of new standards,
guidelines and regulations has played
a large part in the development of
the company's reputation for quality
products and services.

"As we look back on over 50 years of service in the field of respiratory care we are proud of our long heritage of innovation, engineering integrity and personal customer care. We remain committed to continuing to support our customers, developing our team and improving the quality of life for patients with respiratory conditions. I am sure that my parents, who founded our company in 1963, would be amazed to see how far we've come from our small beginnings in our family home to a multi-national organisation with facilities in England, Ireland, Germany, Hong Kong, the United States and Japan, and a distributor network spanning 113 countries'.

BUG

Vitalograph Managing Director,



Witalograph

Locations and Distributors



- Vitalograph Locations
- Vitalograph Distributors

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