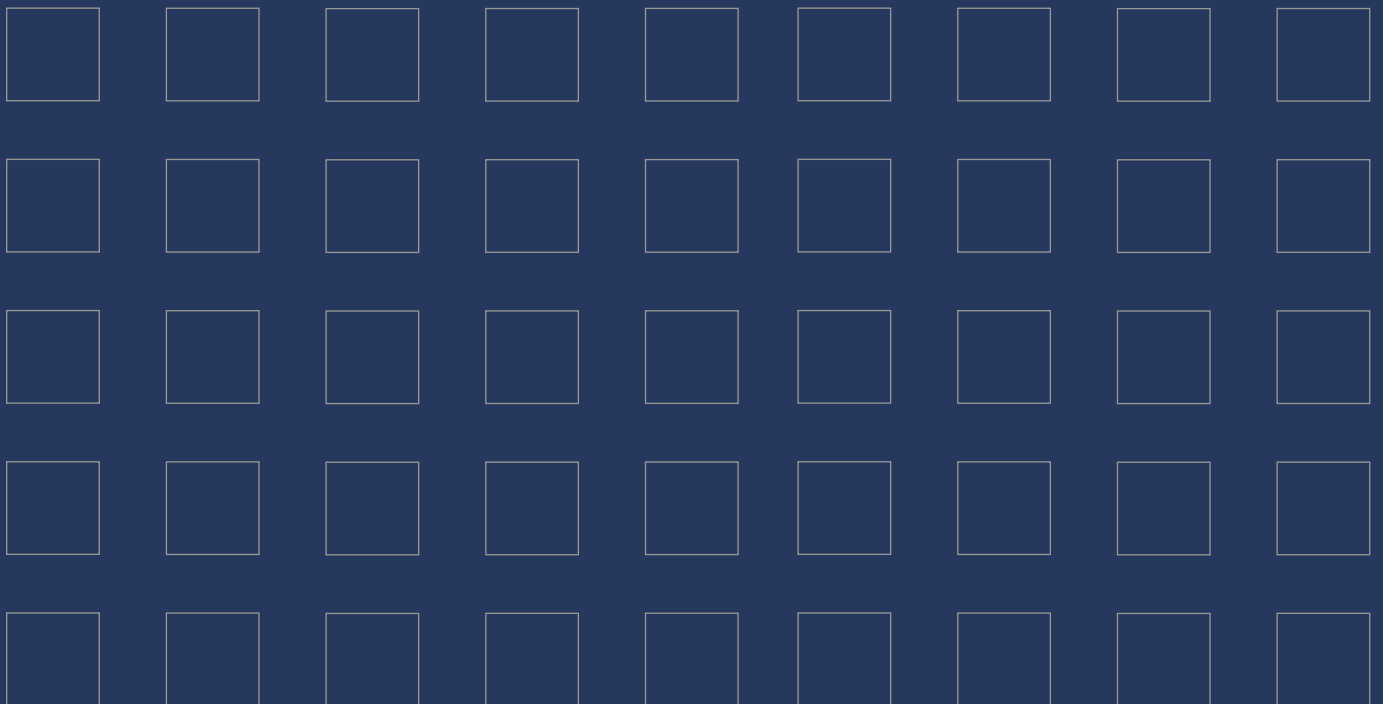


45

YEARS

HELPING TO
PRESERVE
PROTECT
AND
NURTURE
CELLS



At Planer we specialise in the control of temperature and other parameters to help our customers maintain sample viability - in the fields of reproductive medicine, cell biology and biological research.

We help their processes by managing the micro environment, storage, safety, records and data of biological samples.



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the safe preservation
of biological specimens
– embryos, blood
products, tissue and
biological samples

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For over 45 years we have been supplying laboratories, hospitals, pharmaceutical companies and the assisted reproduction fields with hardware, software and systems for the safe preservation, storage and monitoring of biological specimens such as embryos, blood products, tissue and biologicals.

We design and build equipment: specialist freezers, incubators, sensors and systems. These involve measuring, monitoring and controlling parameters like temperature, pH, VOC, humidity, oxygen - all in strictly regulated and compliant ways.

Our equipments can be found in most countries around the world and our watchwords are robust design, compliant operation, Just-in-Time manufacture and long-standing relationships with our sales and service distributors. There are users of our products in over 80 countries – from Azerbaijan through to Zambia.



PLANER



Geoffrey Planer
Chairman



Adrian Fuller
Managing Director

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Building on our 45 years of experience, our close links with scientists around the world and our global network, we are in a strong position to significantly grow the business

Geoffrey Planer
Chairman

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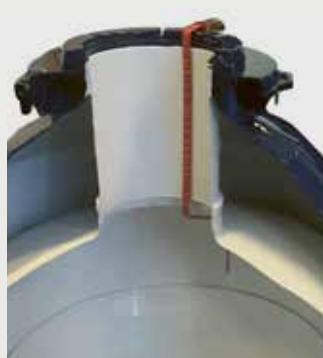
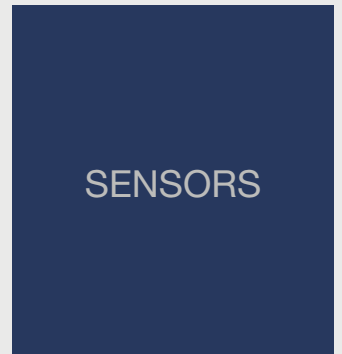
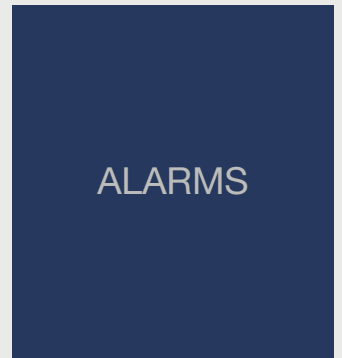
Since we started in 1973, our company has evolved from pioneering one off machines for cryogenic researchers to becoming the gold-standard supplier of equipment for cell preservation.

Over the years our products have helped scientists around the world achieve many breakthroughs, including the first baby born from a frozen embryo in 1984 and the first successful frozen ovary transplant 2014.

But in our customers' world, a routine successful outcome every day is quite as important as a breakthrough and they depend on us for the viability of their samples, day in and day out.

From our factories near London's Heathrow airport, we now export 90% of our products with the help of our 80 or so sales and service distributors around the world. Over our 45 years, we estimate that together we have sold more than 20,000 items of sophisticated equipment.

It is important to recognise everyone along the line: our designers, the people who supply us and all our staff who make, service and ship our products to end customers in so many countries.





Our range of products

Cryopreservation

To freeze one straw or 8,000 vials we have a programmable freezer to help increase post thaw viability with repeatable, consistent results plus a compliant record. This improved viability comes from freezing down, with user defined freezing profiles, past the glass transition point, to below -180 °C.

Incubation

Our convenient and precise benchtop incubators are increasingly used in human and veterinary assisted reproduction applications. They offer the best possible in-vitro environment, with rapid gas and temperature recovery times, chamber temperature uniformity of +/- 0.2 °C across a petri dish and uniquely, with battery back-up.

Monitoring

Temperature, humidity, carbon dioxide, liquid nitrogen level, oxygen, door status etc., all need monitoring to keep laboratories safe, both for samples and for operators. Our range is sophisticated but economic and flexible with wired, or wireless, sensors monitoring a variety of parameters via up to 120 sensors. Alerts are sent to named staff on the device of choice, with full audit trails and granular reporting.

Cryostorage

Ultra low cryo storage offers security for biological samples at -190 °C with long holding times. These vessels are used in areas such as assisted reproduction, immunology, gene therapy, tissue banking, stem cells, cord blood, algae, fungi and viruses. The range extends from small 'dewars' through to large capacity electronically controlled vessels with automatic filling.

Cryopreservation

By the 1970s new forms of cryobiology were emerging around the world. We were at the forefront of this field, working with Professor David Pegg, a founding father of the science. The early controlled rate freezers allowed samples, until then difficult or impossible to deep freeze successfully, to be slowly frozen down in controlled stages, or 'ramps', within a cryo-protective solution, for storage in liquid nitrogen before later use. An early success was the first birth from a frozen bovine embryo.

In 1984 in Melbourne, Australia the first human baby from a frozen embryo was born, helped on her way by Drs Alan Trounson and Carl Wood using a Planer freezer. As the bio-banking industry expanded, controlled rate freezing became a more mainstream technology - routinely employed around the world. In the 1980s and 90s the first successful freezing of a human oocyte and then arterial graft material were reported, using Planer controlled rate freezers.

Since then our users have increased worldwide with some 10,000 machines having been manufactured. Investigations continue into new areas of preservation such as controlled vitrification and equipment for the monitoring of freezing rates. The Planer equipment range expands and continues to help in key developments, new treatments and scientific breakthroughs around the world.

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Optimum post
thaw sample
viability
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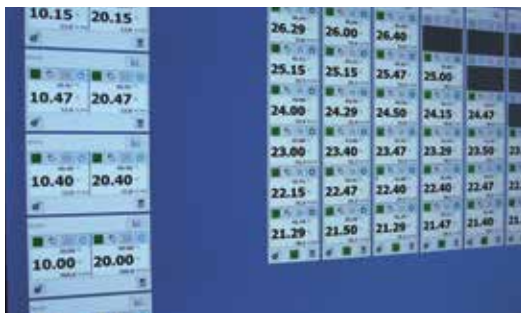


Many different types of cells, including cord blood, bone marrow, semen, skin, ovarian tissue, heart valves and blood vessels are controlled rate frozen and then carefully stored in the cryogenic vessels we also supply. As their sample and batch numbers increase many users take advantage of our DeltaT software which allows them to deploy one profile to several freezers, with those profiles being displayed on the same graph, each run having a time stamped compliant summary.

Incubation

Well known for our freezing expertise, we piloted our first incubator in 1976, as a novel form of anaerobic chamber. We continued in the area of controlled warm environments and in 2008 we developed a prototype high precision benchtop incubator. The distribution of this, the BT37, by Cooper Surgical Inc., Origio AB and IMV Technologies SA put that unit at the forefront of many of the world's human and animal IVF laboratories and helped establish us as more than just experts in 'cold'.

The success of the BT37 benchtop incubator was due to its reliability, rugged construction and its worldwide regulatory compliance. Later, we felt that space-limited laboratories might need the same precision but in a more compact form, and so designs for a high capacity incubator – to complement the BT37 – were started in 2014. Our CT37stax™ benchtop incubator uses the best of our existing technology within a unique modular, patented, 'stack' to produce accurate environments for optimal clinical conditions inside each independently humidified incubation chamber.



◀ All our incubators use our proprietary software management system PIMS, a 21 CFR Part 11 compliant, password protected, logger that alerts users of any out of range alarms and provides placement information to easily locate samples as well as giving full audit reports of function.

▶ The space saving design of the CT37stax, provides high dish capacity. Additional chambers can be added enabling a laboratory's capacity to grow in modular fashion.





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Relied on
by clinicians
around the
world
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Cryostorage and Monitoring

Early in our corporate life we were asked to supply other key parts in the cell environment process to complement our freezers. For a long time we have offered a wide range of liquid nitrogen supply and storage vessels, and have added level and temperature alarms and relating compliant software.

Our next step was the introduction, in the 1990s, of our own temperature logging system for frozen samples in transit. A large number of these original 'ShipsLog' systems are still in use today and we recently launched the latest version, ShipsLog3™.

To watch over the many types of freezing vessel as well as other key laboratory equipment, we introduced our wireless systems. First was DATAcentre - and now DATAssure™ - to monitor whilst complying with FDA and MRHA legislative requirements. These systems are stand-alone and connect directly to an IT network without the need for dedicated PCs, servers or specialist software. Hundreds of our monitoring systems have been installed throughout the world.





“ Keeping
equipment,
samples and
labs safe and
compliant ”

Our milestones

1974

Company commences business

1974

First controlled rate freezers sold

1984

First successful human frozen embryo birth



1984

Queen's Award for Technology received



1986

First pregnancy from frozen human oocyte

1996

Kryo 750 range launched



1987

R206 veterinary freezer



1990

Kryo 10.1.7 with MR1 controller

1974 1975 1976 1977 1978 1979 1980 1981 1982 1983 1984 1985 1986 1987 1988 1989 1990 1991 1992 1993 1994 1995 1996



1976

First incubator, anaerobic, launched



1975

R204 freezer for research use

1985

Kryo10/16 with MR1 controller



1985

Auto seeding device for freezers developed



1989

Cryo microscope launched at London Zoo



1994

First PC software control suite developed

2001

Monitoring
and alarm
systems

**2014**

First animal
ovary frozen /
transplanted

**2016**

New range
of sensors
launched

**1998**

MR2 controller
launched

**2003**

Medical Device
status approved

**2007**

UK 'SEEDA'
award on
Liquidus Tracking

**2010**

USA birth from
frozen embryo
stored 20 years

**2018**

CT37
precision
incubator



1997 1998 1999 2000 2001 2002 2003 2004 2005 2006 2007 2008 2009 2010 2011 2012 2013 2014 2015 2016 2017 2018

**2000**

Kryo 360 and
560 launched

**2002**

Large vaccine
freezer, Kryo 1060

**2005**

First embryonic-
like stem cells
from umbilical
cord blood

**2004**

First successful
birth from frozen
ovarian tissue

**2009**

BT37
benchtop
incubator

**2017**

LN2 transport
monitor -
ShipsLog3™

2015

UK 'SMART'
award for
incubator research



Our operations

From our 2000 sq. metre factory – near London's Heathrow – we undertake the full process of design, manufacture, sales and service. Many of our products are used in critical medical applications so Medical Device regulations figure early in the design process – detailed regulatory compliance is needed in North and South America, China, Europe and increasingly other areas.

We hold a number of patents and received the Queen's Award for Technology and awards from the DTI for Innovation and Good Practice in Microelectronics, and are approved and assessed to the demanding standards of medical device manufacture: ISO13485: 2016 & Medical Devices Directive, Annex 11 93/42/EEC: LRQA. ISO 9001:2008.



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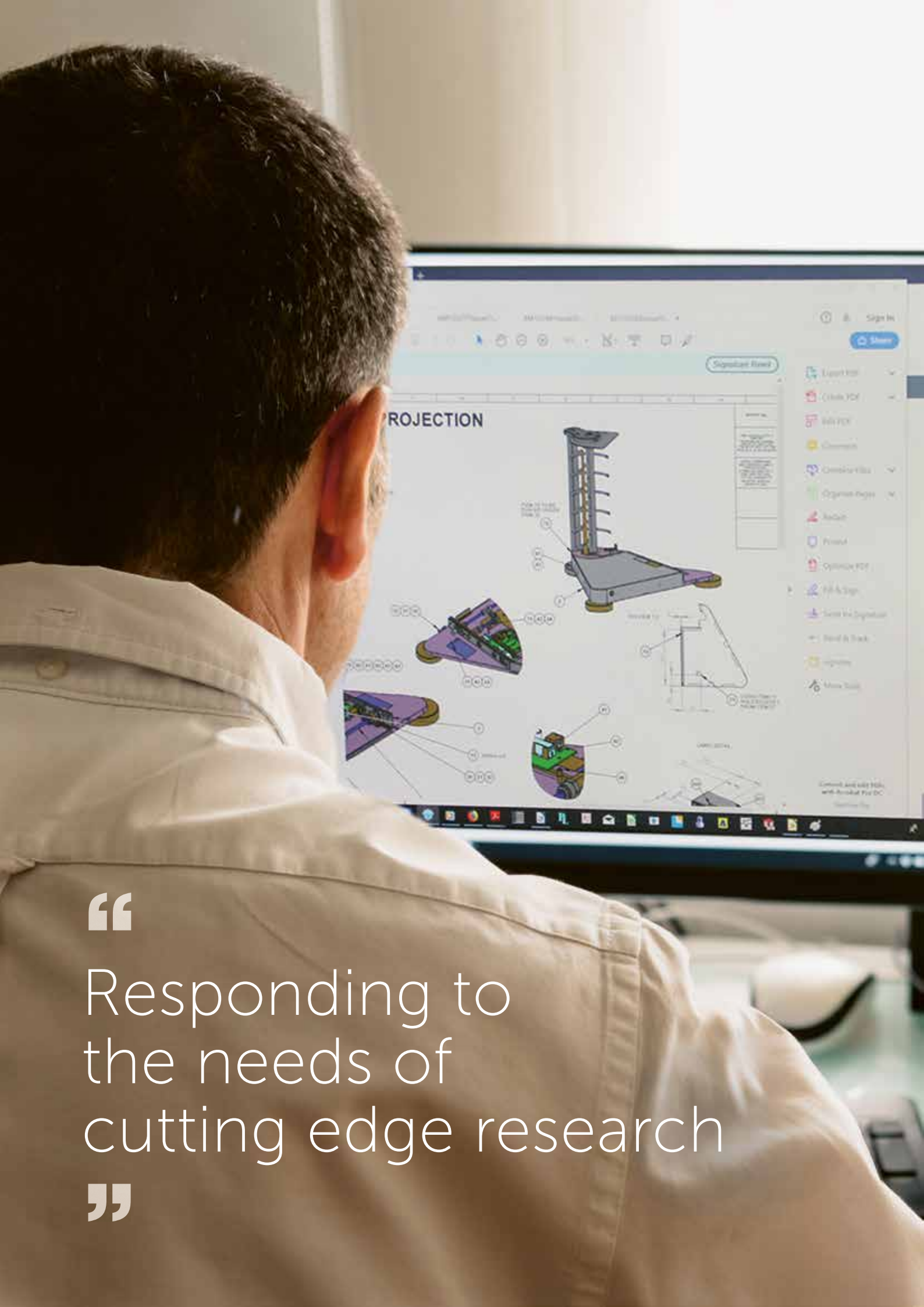
Traceability on the implementation, verification and validation stages of the design process

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Development and engineering

Our development and engineering team are responsible for the design of new products and for supporting products through their entire lifecycle. Following a formal design process, all requirements are tracked through a highly customised ticketing system to ensure full traceability between the initial requirements and the implementation, verification and validation stages of the design process.

The core internal team covers all of the key disciplines of mechanical, electronic and software design with support from specialists as required. Our intellectual property is maintained within the company. Projects are managed through a gated development process by use of online project management software and a ‘key-deliverable’ tracking dashboard. All documentation is held electronically via a number of bespoke databases that facilitate communication of engineering knowledge throughout the company. A variety of software tools are used in the design and support of the products including Solidworks 3D mechanical CAD with thermal and fluid modelling, Altium electronics CAD, and Java, C and C# IDEs.



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Responding to
the needs of
cutting edge research

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Close ties with academia and research

Over the past 45 years, we have worked closely with leading scientists across a broad range of fields including IVF, cryobiology and stem cell research to understand their requirements and to develop a range of freezers, incubators and laboratory monitoring systems that help them achieve many notable scientific breakthroughs.

This type of collaboration has also led us to support PhD students in their research and to contributing to various books such as with Professor David Pegg in “Current Frontiers in Cryobiology” and to “Reproductive Aquaculture, Transfusion and Transplantation Science” and recently to publish “Operating a successful cryopreservation facility”, a book by James Bennet and Professor Brian Grout.

We aim to continue working closely with research institutions such as Université Catholique de Louvain (Belgium), University of Minnesota BioCor (USA) and University College London (UK) so that we continue to learn from and support the diverse needs of the scientific community worldwide.



Our production process

We produce hundreds of items a month and so we started using Lean Manufacturing techniques as early as 2008, leading to significant benefits in efficiency, quality, and profitability. A Just-in-Time management system helps to optimise product build, arranging for suppliers to deliver components as predicted by forecast, with a 'Kanban' system topping up stock.

Our continuous work-in-progress auditing eliminates the need for annual shut-downs. The IT system is updated frequently to reflect real inventory levels and changes in parts costs. Calibration dates for each piece of measurement equipment are scheduled in advance to avoid interruptions.

Purchase orders are entered onto the production software's MTMS material control system, and an inventory forecast system and purchase order system are monitored by the MRP software which generates material schedules of products to be built. The team handle order processing, purchasing, sub-assembly, final assembly, test, packing and dispatch.





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Since 2008 we've used
the Kanban scheduling
system for lean and just-
in-time manufacturing

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The demanding standards
of ISO 13485:2016 & the
Medical Devices Directive

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The commitment to quality

The Quality and Regulatory Affairs department is responsible for gaining, maintaining and improving the Quality Management System to ensure compliance with ISO13485.

This management system covers many areas including Product Performance, CAPA, Post Market Surveillance, Vigilance, Supplier Performance and Documentation Control.

The system is subjected to regular internal audits in addition to external audits by our Notified Body. The department is also responsible for obtaining the CE Mark for all devices, both medical and non-medical which is achieved by ensuring that the products comply with all the relevant Directives such as, 93/42/EEC Medical Devices Directive as amended by 2007/47/EC; 2014/30/EU EMC Directive; 2011/65/EU RoHS Directive; 2006/42/EC Machinery Directive; 2006/95/EC Low Voltage Equipment Directive.

The ever-evolving area of Regulatory Affairs present an ongoing challenge: most countries require medical devices to be registered before they can be placed on the market. This involves complying with the relevant directives of each Competent Authority such as the US FDA, Chinese FDA and Singapore HSA and the implementation of the 2017/745 Medical Device Regulations.



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Expert
technicians
around the
world

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Customer care starts from the point of supply

We strive to make the quality of our post sales maintenance as good as the quality of our original products. A laboratory is a busy place so ensuring equipment is fully functional is essential to prevent downtime.

Customer care starts from the point of supply and customers are offered installation, training sessions and IQ/OQ options with maintenance contracts to cover the 'post warranty' period - distributors, after their training with us, undertake this locally. Technicians who successfully attend the course are presented with a qualification certificate.

Back office

Finance

The Directors meet formally each month and the Finance department furnishes full monthly management accounts and reports as a basis for the meeting. Progress against previous year and budget, contractual and commercial arrangements, quality, production forecasts and development progress are reviewed against our yearly plan. Exchange rates are carefully watched too, as we sell in three currencies - GBP, USD and Euros.



Systems

Planer uses 'MTMS', an enterprise resource planning system, which operates the MRP - manufacturing resource planning - and the accounts system. We also run IBM Lotus Domino for routine business operations (such as e-mail and CRM applications) and raising quotations for customers. The basic function of the MRP system includes inventory control, bill of material processing and purchase and build scheduling and it applies both to items purchased from outside suppliers and to sub-assemblies produced internally.

IT

ESET endpoint protection is installed on all PCs and servers to protect against malware and viruses, plus anti-virus software on the company firewall.

Disc to disc data archiving is managed by Commvault Simpana for the IBM UNIX and Dell servers. Copies of backed up data are stored in near-real time mode, and a snapshot tape is generated each month and stored off-site. The company has a Business Continuity plan audited to ISO 22301 standard.



Our distributor family around the world

We have users from Azerbaijan right through to Zambia and each of these is serviced by a local distributor – some of whom have been with us from nearly the ‘word Go’.

Over the years our team have tried to be as supportive as possible. Help with complying with local standards, hedging currency, monitoring credit, facilitating letters of credit, shipping, handling duties and freight all to the four corners of the world.

We support our Distributors with newsletters, fact sheets and scientific updates through a password protected sub web site – and they in turn have supported us. They visit with us regularly for training sessions, we meet with them locally and we jointly attend seminars, exhibitions and symposia. Our exceptional network of distributors provide us with access to thousands of customers around the world. Their teams have been key in putting and keeping us on the map.





Working with scientists for a better future

Planer continues to support scientists around the world to advance knowledge across many exciting areas including regenerative medicine and ART.

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Our strategic business partnerships and our close links with research and academia help us to successfully deliver a pipeline of products that lead to scientific breakthroughs that change people's lives

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