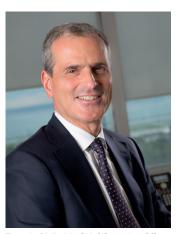
THE BUSINESS INTERVIEW

A medical imaging company that's on the move

The onset of the COVID-19 pandemic nearly two years ago forced many healthcare companies — including many of those supplying medical imaging equipment — to urgently change their established production plans to focus on the top priority of supplying equipment necessary for the diagnosis and treatment of sometimes very ill COVID-19 patients. The Italian company Esaote was no exception to this, having being called on to deliver at very short notice literally hundreds of ultrasound systems to national health services in early 2020.



Eugenio Biglieri is Chief Operating Officer, Esaote

However, this in no way meant that Esaote had to stop its already-planned new product development and production plans. On the contrary, these continued at full pace, with

the result that Esaote has this year announced the launch of several significant new products, including an innovative open-design MRI.

With all these developments, Esaote is clearly on the move. We wanted to find out more, so we spoke to Eugenio Biglieri, Chief Operating Officer.

Q Before we get on to the new products can you briefly summarize how Esaote performed as a whole over the period of the COVID-19 Pandemic till now?

Sure. As you mentioned in your introduction, in 2020 the medical industry as a whole was strongly affected by a demand for technology that was directly useful in the diagnosis and treatment of COVID-19 patients. However, in this new and complex context, we at Esaote were able to anticipate the market needs so we weren't caught short by the trend. In fact, we closed 2020 with an extremely positive result. In particular, our ultrasound business grew by about 7%, thus clearly outperforming the overall global market trend. Our portable ultrasound systems, which are agile, versatile, and well suited for the needs of intensive care units and hospital emergency rooms did especially well, as did the medium-high segment. As for the future, the substantial order backlog with which we opened 2021 and the gradual resumption of hopefully more "normal" activities in the healthcare sector means that we look forward to the future with optimism.

However, and as you allude to in the introduction, during all this sales activity, we never stopped development or our R&D programs. In fact, we actually increased our investment, including increasing our R&D headcount, with the result that we launched not just our very innovative MRI system but also two new ultrasound systems.

Q Ok let's get on to the new product, the Magnifico Open. Given your strong position in ultrasound, many people may not realize that you also have a long and extensive expertise in magnetic resonance.

Yes. In fact the recently launched —and appropriately named — Magnifico Open MRI system is the latest outcome of our long experience in MRI which began 30 years ago when we were the first to introduce dedicated magnetic resonance systems for musculoskeletal applications onto the market. These systems were really innovative at the time and had great success in the market. This was the origin of our MR experience which has now led us to our new wholebody MR technology, the result of many years development. The technological evolution of MRI over recent years has seen major developments not just in terms of data processing, image quality and meeting clinical needs, as well as healthcare sustainability. We incorporated these factors in our development process, but, of course, it was not just technological development for its own sake. A significant incentive for the development came from our clinical customers who, already extremely satisfied with our dedicated MSK systems, could also see the clinical importance of whole body MRI systems. Anyway, we were sure of our technological ability and so decided to accept the challenge of producing an open whole body MRI system, with the aim of not just entering this market segment but of playing an important role in it. I believe that the end-result — the Magnifico Open — fully justifies the confidence we had in undertaking the development.

Regarding the development itself, the basic philosophy behind its development process was to bring MRI to the patient rather than the patient to MRI as in dedicated systems. We aimed to incorporate the same technological competencies in a whole body system that we showed with our dedicated MRI systems.

Magnifico Open is equipped with the most recent Esaote technologies such as: Speed Up, which assures optimal image quality with reduced examination times; True-Motion real-time imaging, offering a complementary approach to standard MRI for a more comprehensive clinical and diagnostic picture, particularly in high-level sports medicine; and MAR (Metal Artifact Reduction) allowing excellent image quality of particular use in post-surgical imaging. Our objective for the Magnifico Open is nothing less than to become the gold standard in the field of open Magnetic Resonance Imaging.

Q Technologically the Magnifico Open is advanced, but from the point of view of the patient, or the healthcare system as a whole, what is the added value of the machine?

Let me first make one general comment, namely that the advantage of being in the healthcare market is that the justification of our presence in the market is clear — it depends ultimately on what good the patient receives, so we have a concrete objective. In this context, Esaote has always paid close attention to aspects such as ensuring that the patient is at the center of all technological development, as well as responding of course to the clinician's needs, and also dealing with



Magnifico Open from Esaote is an open MRI system with advanced technology, developed from the company's experience in MRI dating for more than 30 years. The system incorporates the latest MRI technology for uncompromised diagnostic quality, combined with a permanent magnet that guarantees low operating costs. A broad choice of receiving coils and state-of-the-art MRI technology provides excellent image quality and the permanent magnet makes for simple installation and low operating costs. The open magnet and easy-to-access patient table facilitate fast and comfortable patient positioning, ideal for claustrophobic patients and children alike. Magnifico Open has just received the CE MDR certification, under the new regulations which came into force

on Magnifico Open has just received the CE MDR certification, under the new regulations which came into force on May 26, 2021. The Magnifico Open is one of the first MRI systems to have been approved under this new European regulation.

https://www.esaote.com/dedicated-mri/mri-systems/p/magnifico/

factors such as sustainability and patient protection.

These objectives are achieved in the Magnifico Open, not only through providing clinically reliable images but also by responding to the patient's need for comfort and reducing patient stress and anxiety during the exam. In addition, overall, the system has very low power consumption, and so, apart from having reduced running costs it can be considered as a "green machine".

But, to get back to your question regarding the added value, I believe in general that the healthcare sector must simply respond much better to the needs of patients. With the COVID-19 pandemic, we unfortunately saw what happens when the sector cannot meet the needs of the patients.

This may sound simple, but inevitably to achieve such aims usually means increased costs. The obvious counterargument in the medical imaging sector is that any machine that can combine high image quality and respond to patient/ clinicians needs but do so at low costs has certainly a great market advantage.

In the case of the Magnifico Open, it has been shown that permanent magnet MRI systems can be equivalent with most large MRI systems when it comes to delivering value-based solutions without compromising quality. This is exactly what this technology is about.

As in many other imaging sectors, in MRI there has also been a growing trend away from hardware-related solutions towards software implementations. For example, the many improvements we have seen lately regarding image quality, scan-times and workflow are largely due to software developments. MRI in general evolves gradually year by year, so it often needs several years in retrospect to really appreciate significant performance improvements. However, you don't need to wait for years to appreciate the importance of two recent quantum leaps in the improvement of MRI performance. The first of these was the introduction a few years ago of Compressed Sensing which

gave a significant boost in image quality and scan times. The second major development is Spin Echo Dixon (SPED) which enables the possibility to achieve Fat/Water separation T1 contrast as well as a PD weighted image by changing the repetition time. An added advantage is that it is very efficient in the presence of metal for example in post-operative imaging.

These software-based innovations show that sheer magnetic field strength is no longer the main driving force behind MRI image quality.

For a long time now you at Esaote have embraced the potential of relatively low magnetic field systems in MRI, which seem nowadays to increasingly being rediscovered. What is the value of such systems?

As world leaders and pioneers in the field of dedicated MRI, we introduced the concept of dedicated low-field magnetic resonance imaging, simply because it provided a series of considerable advantages compared to traditional standard MRI. First of all, the images are of a diagnostic quality which is adequate for clinical needs. However the low-field machines that produce such images have low operating costs, ease of installation and therefore a better overall service for the patient. This is already of value in the hospital environment but is even more so in "in-office MRI systems" such as in medical practice facilities. Instead of the patient having to go to a hospital for diagnosis and then back to a clinician for treatment, the whole process can be speeded up through use of in-office MRI systems. The fact Low-field MRI systems offer these possibilities and, thanks to the remarkable technological progress that has taken place in recent years, can provide improved and clinically acceptable image quality and shorter scan times, so that overall the performance is becoming closer and closer to traditional high-field machines. So we believe that today such systems can increasingly play an important role in diagnostic imaging, alongside conventional high-field systems.

You have described the in-house technological expertise and experience in imaging at Esaote, but behind every development project there surely must also be an active collaboration with the world of clinicians. How do you handle this?

In our 30 years' history we have always cooperated closely with clinicians in many countries, a process that is really fundamental for us simply because clinicians are the ones who actually tell us what they need and what are the priorities we should set for technological development, all with the objective of optimizing clinicians' activity in the diagnosis and management of their patients.

So what are they telling you? How do you see the evolution of the needs of clinicians and patients in terms of diagnosis? In addition to precision diagnostics and very high quality images, what other diagnostic needs do you foresee in the next few years?

Diagnostic imaging has evolved dramatically over time thanks to technological progress and the improvements in software and hardware of the various equipment. There is an increasing need on the part of clinicians and radiologists to have access to high definition images with high resolution, and especially in MRI, with adequate contrast for the optimal diagnosis of pathologies. However nothing is static - new frontiers are opening up all the time, in particular thanks to the application of artificial intelligence(AI). Not only will AI facilitate the identification and characterisation of pathological lesions be improved, thus facilitating the radiologist's determination of the diagnosis, but there is another need that I am convinced will become increasingly important, namely the ability to determine the risk profile that a patient has of developing future disease. Thanks to validated algorithms and AI software it will become possible not only to read the image, but also to identify prodromal signs that can indicate what is the likely evolution and the onset of the disease. Simply put, this means that the greatest need is so-called "early detection", so that a pathological condition can be identified before the disease has actually evolved in order to be able to intervene sooner with the appropriate pharmacological or surgical treatment.

So far we have been talking mostly about the clinician's or radiologist's point of view. What about the patient in all this?

Of course the patient's position in all this is absolutely fundamental. The aim must always be to have tangible benefits in terms of quality and better care for the patient. There is no point in developing technologies which improve the clinician's or radiologist's diagnostic capabilities if the process involved in doing so is so uncomfortable — or even unacceptable— for the patient that in practice the technology is not used to its full potential.

MRI is a good case in point. The technology itself has high performance capability but in practice we mustn't forget that many patients actually decline an MRI scan because of misconceptions about the procedure, discomfort during the scan and for other reasons such as claustrophobia, long waiting times, costs....

Since the patient factor has always influenced — and directed our strategic choices, we can confidently say that all our machines are patient-centered, none more so than the Magnifico Open. The entire design was always concentrated and focused on all aspects and ergonomics factors from the patient's point of view. A weak point of MRI has always been the long time that the examination takes, during which the patient is generally not at ease. Nowadays, thanks to technological development, examination times have been considerably reduced. We have always tried to put the patient at the center of the examination process to minimize discomfort which otherwise could result in patient movement and artefacts and even the need to repeat the whole process. For this reason in our development process, from the table right through to the coil — which is one of the key components of the overall system- we have always tried to take into account the ergonomic aspects from the patient's point of view. Our Research and Development department continually focusses on meeting these patient ergonomic criteria and standards, which are also becoming more and more referred to in international directives.

They remain a key guideline in the design of our magnetic resonance machines.