

Integrity^{TM*}

Digital Linear Accelerator Control System

Kevin Brown, Global Vice President Scientific Research
Elekta, UK

The Foundation of Advanced Radiation Treatment

Elekta installed the first digital linac control system at the Royal Marsden Hospital, UK back in 1985 and, for 25 years, there was nothing else like it on the market. In that time, the digital control system has been transformed as we have developed and improved it over the years. We have learned from experience, listened to customers and grown in expertise - building, enhancing and refining our digital control system along the way to achieve the industry leading product that we offer today.

As with any pioneering journey, we have overcome many difficulties, stretching the boundaries of science and technology to provide intelligent and resource-efficient solutions that offer confidence to both healthcare providers and patients alike.

*Integrity is works in progress and not available for sale or distribution in all regions.



ELEKTA

INTRODUCTION

Delivering peace of mind for decades

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Designed by the experts

Our digital linac control system has been thoroughly researched, designed, tested and analyzed throughout its development by Elekta engineers, carefully selected outside experts and valued clinical partners. At every stage we have considered the usability of the system and we have tried to anticipate and deal with potential “use” errors and possible hazards long before the release of each new version. We actively seek and consider reports and observations from the field, which have informed the development process to ensure that the system achieves the highest levels of safety and reliability.

Not only that, but collaboration with clinical and service users has allowed us to be at the very forefront of developing new and advanced treatment techniques, such as Intensity-Modulated Radiation Therapy (IMRT) and Volumetric Modulated Arc Therapy (VMAT), ensuring that such advanced treatment techniques, developed using the Elekta Digital Control System, are brought to market quickly and seamlessly.

“When we introduced the world’s first digital linear accelerator it caused quite a stir. The inherent capabilities of such a system were years ahead of clinical practice - and the promise of what such a sophisticated device could do was extremely exciting. University hospitals who wanted cutting edge technology that could support future clinical advances formed strong partnerships with Elekta in order to leverage the power of full digital control. There are many examples of this, most notably our Intensity Modulated Radiation Therapy (IMRT) consortium; a very eminent group of key opinion leaders and experts from across the globe whose innovations in clinical practice were fully supported by our cutting edge digital technology. We are the only linear accelerator vendor to have so many years experience with digital control systems - a true and sustainable first for Elekta.”

Dee Mathieson, Senior Vice President, Oncology, Elekta

Development of the linac hardware and critical real-time hardware control software has involved close interaction with physicists, electrical, mechanical engineers and software engineers.

For the development of all software and hardware in the digital control system our engineers review and approve designs according to precise requirements, based on clinical needs, customer feedback and hardware developments. They used standard FMEA (failure modes and effects analysis) tools to identify where and how things might fail so that they could be addressed in the design process to ensure that the system is inherently safe and reliable from the start.

“We have all got into the habit of continuously asking the question, would I be happy for this system to be used on a member of my family? This helps us to ensure that safety to the patient is always at the forefront of our minds.”

Paul Boxall, Software Systems Engineer, Elekta

Flexible treatment delivery

Our digital linac control solution provides customers with the flexibility to program changes to many parameters during delivery to obtain an optimized dose distribution for each individual patient. For example, they can change the gantry angle, collimator angle and MLC leaf positions. They can deliver virtual arcs⁽¹⁾ and vary the dose rate to achieve the required intensity variation. They can also deliver the dose in a single arc or in multiple arcs. Not only do they have all this flexibility, but they also can have confidence that they are delivering exactly what is expected because the integrated digital control system automatically checks all delivery parameters against the prescribed parameters. If a problem is detected, the radiation beam is paused without delay.

Elekta is the only company to offer a fully integrated, single digital linac control system for both the multi-leaf collimator (MLC) and the linear accelerator. This permits real-time communication of information, allowing Elekta linacs to be faster and more accurate than other non-digital systems.

The product of experience and expertise

Integrity is the latest product of our history and expertise in the development of our digital linac control system – the 6th generation, which builds on our wealth of experience and expertise.

Integrity has been developed at three clinical sites, with physicists on site to test the system using real treatment plans. This has been an important part of the development process, allowing us to make sure that the system delivers what we say it will deliver, with practical and clinical benefits.

"Integrity maintains our leadership in digital control systems for linear accelerators. In 25 years we have come a long way, learning and refining all the time, to bring this latest generation, with unparalleled monitoring and control capabilities, to the radiation treatment community."

Adrian Smith
Principal Engineer, Hardware Engineering, Elekta

Case Study: Royal Marsden Hospital Sutton Branch, UK

The Royal Marsden Hospital, UK, was the first hospital in the world dedicated to cancer treatment and research into the causes of cancer. Today the hospital with its academic partner, The Institute of Cancer Research, forms the largest comprehensive cancer centre in Europe with over 40,000 patients from the UK and abroad seen each year.

The first digital Linac in the world was installed at the Sutton site of The Royal Marsden Hospital in 1985. Since then, the hospital has been a valued and important clinical partner for Elekta, working closely with us on the development of new systems and techniques. The Royal Marsden at Sutton partnered with Elekta in the development of VMAT and was the first centre in the world to use this advanced technique.

Jim Warrington, Head of Radiotherapy Physics, comments,

"My recollection of the Elekta '5001' SL25 installation at The Royal Marsden, Sutton in 1985/6 was that it was the first major project involving our newly established Radiotherapy Research Team, under Professor Bill Swindell's visionary leadership. Exciting research projects, led by Phil Evans and Steve Webb, involved ground breaking radiotherapy imaging and inverse planned, intensity modulated radiotherapy (IMRT) developments. For this work, the SL25 proved a remarkably adaptable platform, successfully delivering, in 2001, the first inverse planned, dynamic MLC based IMRT treatments (prostate and pelvic nodes) in the UK. All this on a fifteen year old linac! For these treatments we used an MLC leaf interpreter developed here by David Convery, a physicist sponsored by Elekta."

"The Elekta 5001 remained clinical for 20 years until 2006, after safely treating thousands of patients. Although this first digital linac suffered from reliability problems during its early years, Elekta and our technical team learned from the experience. The latest Elekta linacs, of which we have seven, reliably perform with a mean clinical uptime of 98%, no doubt helped by our two engineers, Nick Brigden and Paul Mayhew, who have logged a total of 44 years on Elekta systems."

"In the latest Synergy machines, the digital control has allowed the reliable execution of VMAT treatments here since January 2008. It does this by continuously monitoring gantry angle, MLC leaf positions and delivered dose, adjusting these to faithfully deliver clinical treatments according to prescriptions from James Bedford's 'AutoBeam' VMAT planning system. Our repetition tests show that these dynamic treatments have a repeatability of

delivery that is better than we can measure, even with treatment interruptions and deliberate terminations during the arcs. Elekta's latest Integrity developments look promising, with an improved speed and smoothness of delivery to further enhance radiotherapy treatments of our patients."

INTEGRITY DIGITAL LINAC CONTROL SYSTEM

Continuous monitoring and control

In radiation dose delivery, it is essential to have high speed monitoring and precise control systems in place in order to have confidence in the performance of the linac – how it moves and how the radiation dose is delivered. Integrity provides this confidence, with additional features to permit the faster, smoother delivery of all treatment techniques, from simple static deliveries to more advanced, complex treatments. The result is enhanced patient safety, a smoother patient flow and improved patient throughput.

Integrity is the new monitoring and control foundation of Elekta treatment delivery systems. Acting both as guardian of treatment quality and interface to digital efficiency, it is the foundation on which our groundbreaking innovations can be built. In supporting a wide variety of different techniques, from conformal, through IMRT to VMAT for conventional and stereotactic applications, it enables clinicians to prescribe treatment techniques that match each individual patient.

Integrity was designed to offer radiation treatment centers:

- Smooth, safe delivery of all techniques
- Flexible delivery systems offering speed and control
- Systems optimized for improved accuracy and performance
- Smoother workflows
- Flexibility to integrate into any clinic, offering compatibility with both Elekta and non-Elekta equipment.

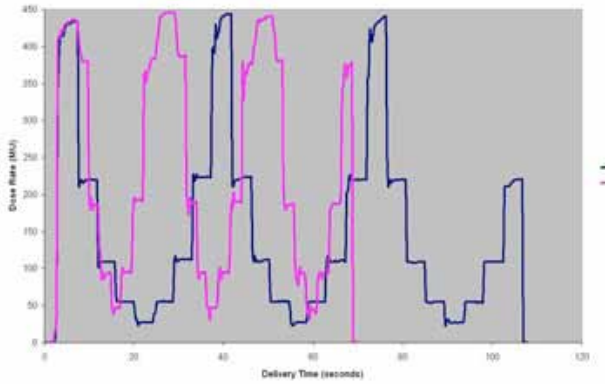
These requirements have been met with the introduction of a number of new features, including:

LynxOS operating system

Integrity is built on the robust medical and aerospace operating system, LynxOS SE, the gold-standard in mission critical industry sectors

Continuously variable dose rate

Integrity supports Continuously Variable Dose Rate (CVDR), which allows the dose rate to be adjusted to its ideal value during delivery of both dynamic and VMAT prescriptions. This option makes the delivery of the prescription smoother and faster when compared to previous discrete dose rates.



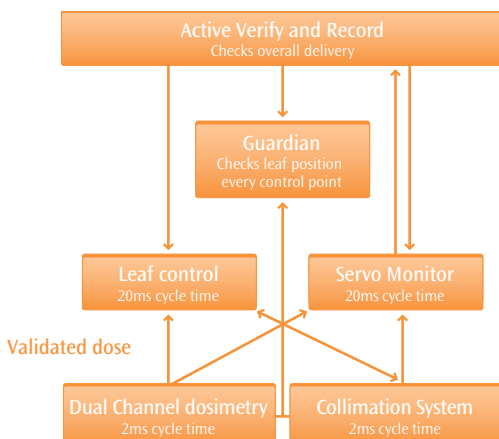
The graph (above) compares discrete dose rates (blue) and CVDR (pink), highlighting the improvement in delivery time achieved using CVDR.

Interdigitation on MLCi2

Integrity also supports interdigitation using the new Elekta MLCi2, for accurate planning and beam shaping of multiple target islands during all treatment techniques, including static, arc, IMRT, Omniwedge, dynamic, dynamic arc and VMAT. This precise, beam-shaping capability ensures maximum conformance to target volumes, for improved efficiency of dose delivery, and reduced radiation to both normal tissue and critical structures.

Three tiers of safety

Integrity is the only digital linac control system to employ three tiers of safety to ensure confidence in the delivery of radiation dose (see below). The first tier records and verifies the prescription when it is received from MOSAIQ[®] and checks that all the linac parameters are set up correctly according to the prescription. The second tier checks and controls the MLC leaves, gantry, collimator and the dose delivery every 40 milliseconds to ensure that all parameters are in the correct position and the correct dose is being delivered. Overseeing all of this is the third tier, Guardian, which supervises and checks that all the systems are operating correctly.



Guardian

Advanced treatment techniques, such as VMAT, place additional demands on the control system. Guardian verifies that the field currently being delivered by the digital accelerator matches the prescribed treatment parameters to within a set of permissible tolerances. It does this by constantly monitoring and verifying control points throughout treatment, including MLC and gantry parameters. If a discrepancy occurs, Guardian will stop the treatment. Guardian technology provides confidence to perform advanced delivery techniques.

Intelligent behavior

Interruptions to treatment are upsetting to patients and upsetting to workflows. To minimise this, Elekta engineers have developed a control system that allows the linac to behave intelligently. Whatever the demands of the prescription, the control system determines and selects the optimal operating conditions, dose rates, speed etc. The control system also determines what level of performance can be achieved in this particular situation and then the actual performance is checked against that level. This ensures that, the treatment will only be terminated in the event of a genuine fault minimizing interruptions whilst maintaining reliability and safety. This feature gives complete reassurance that the plan proposed for the patient is delivered correctly in every situation. This feature has been extensively assessed at clinical research sites.

Leaf control algorithm

Integrity's new leaf control algorithm enables the digital linac control system to improve the accuracy and reliability of all Elekta's integrated MLCs. It combines re-engineered control of leaf positioning to maintain tight tolerances for all delivery techniques. This feature also improves the serviceability of Elekta MLCs.

Service diagnostic improvements

Integrity offers a variety of service diagnostics improvements, which enable service engineers to diagnose issues more quickly in the field to improve clinical uptime.

INTEGRITY

LynxOS operating system	The Gold Standard in mission critical industries
Fully integrated control system	Faster, more accurate dose delivery
Three discrete photon options	Flexibility of choice
Full field delivery	Greater precision
360 degrees of freedom for collimator	Flexibility and accuracy, and improved plan quality
Leaf control algorithm	Improved accuracy and reliability
Market leading patient clearance	Full support for non-coplanar techniques
Continuously variable dose rate	Smoother, faster deliveries
Interdigitation on MLCi2	Improved conformation and speed of delivery
Optimized for Elekta VMAT	Full suite of VMAT planning options and one-button delivery
Patented, multi-arc delivery	Full flexibility for treatment delivery
Hybrid plan capability	Allows different treatments (static, dynamic, IMRT and VMAT) to be incorporated in a single delivery
Fully upgradable	From static, through dynamic, to VMAT deliveries
Virus Microsoft® Service Pack with hotfixes and updates	Safe and reliable connectivity
Supported through MOSAIQ®	Complete, independent, real-time verification and integrated patient management system
Complete suite of service tools	Maximizes clinical uptime
Multilingual	Flexibility to choose language of choice

SAFETY BY DESIGN

Safety is integral in our design philosophy. While manufacturing processes have to comply with industry standards, at Elekta we aim to do even more to ensure that our leading edge products are among the safest on the market. Hazard analyses and other safety methods are used throughout the design process to achieve this goal.

Our extensive, continuous monitoring and control capabilities, with built-in safety checks, would not have been possible without our digital linac control system. Some of safety features that have been incorporated over the years and are now inherent in Integrity include:

- **User entry confirmation**

This ensures that only trained and qualified personnel are able to access and use the linear accelerator.

- **Range checking**

'Out-of-range' or illegal values will be rejected, minimizing the possibility of manual data entry errors.

- **Self test**

Many components within the system utilise 'self test' features. These components, in addition to a higher level system, monitor themselves and if an error is detected then the system returns to a safe state.

- **End-to-end checking and data integrity**

This ensures that the prescription data received from treatment planning or an OIS (oncology information system) like MOSAIQ is unchanged during delivery. The flow of data is checked from the software systems to the hardware that executes the prescription. This involves 'handshaking' between systems, delivery receipts and checking for data integrity.

- **Redundancy**

The system has been designed so that all critical data is monitored or measured by two or more systems. This allows the measurements to be cross checked so that a single fault may be detected in either system. For example, in the dosimetry system, multiple ion chamber plates are monitored by two separate dose measurement cards powered by independent power supplies.

- **Diversity**

Safety can overly rely on redundancy. (It would be like asking the same question of three different people. Is the answer trustworthy if they all got the answer from a single source?) Because of this, wherever possible, diversity is used in addition to redundancy. This is commonly referred to as a "common mode" failure. Diversity may use two different sensor types to measure one parameter or it may involve measuring a parameter from two different monitoring points. It may also use two different systems to detect a

particular fault type, rather than relying on two instances from the same system.

- **Tolerance checking**

The system continues to check all geometric parameters during set-up and delivery to ensure that they are always in the correct position, according to the prescription in the treatment plan.

- **Hardware interlocks and watchdogs**

In addition to software monitoring and interlocks, the digital linac is protected by many hardware interlocks that supplement the software safety. These interlocks are based on simple intrinsic rules that rarely change, giving the system an inherent safety baseline. The hardware expects continuous communication with the software. In the event that the software fails to respond, or gives an unexpected response, then the hardware will conservatively take control and return to its defined safe state.

- **Defined workflow**

User work flows and interfaces that allow efficient and safe use of the equipment have been defined in conjunction with our experienced clinical staff and research partners. A strict usability process is followed to ensure that possible “use” errors are considered and mitigated. The work flow guides the user to correct use and prohibits activities that may result in a hazard.

‘Design-out’ strategy

At Elekta we have a dedicated team of analysts who ensure that processes are in place within our research and development department to anticipate, preempt and forestall potential failures or malfunctions of our systems. Challenging our systems to improve their inherent safety is their primary responsibility.

Working closely with our software and hardware engineers, as well as with customers, they ensure that all feedback is constantly reviewed. In this way, we revise and improve the safety features of our equipment and digital control system on an on-going basis. By ‘designing-out’ potential issues, we ‘design-in’ safety features that will stop such problems from occurring, whether they are in equipment performance or operator usage. Furthermore, we ensure that the necessary system alerts and inter-locks are in place so that, in the unlikely event that a malfunction does occur, our equipment stops safely.

Treatment control

Once the patient treatment plan has been produced, accurate delivery of that treatment is of major importance. The engineers at Elekta constantly review the design of our control software, making

improvements and analyzing the effects of any modifications made. Our overall aim is to ensure that the control software delivers inherent safety.

Complementing the expertise of our in-house team, we also work with leading software consultants, experienced in safety critical systems, to challenge our thinking and to contribute new ideas for improvements and modifications.

Hardware control

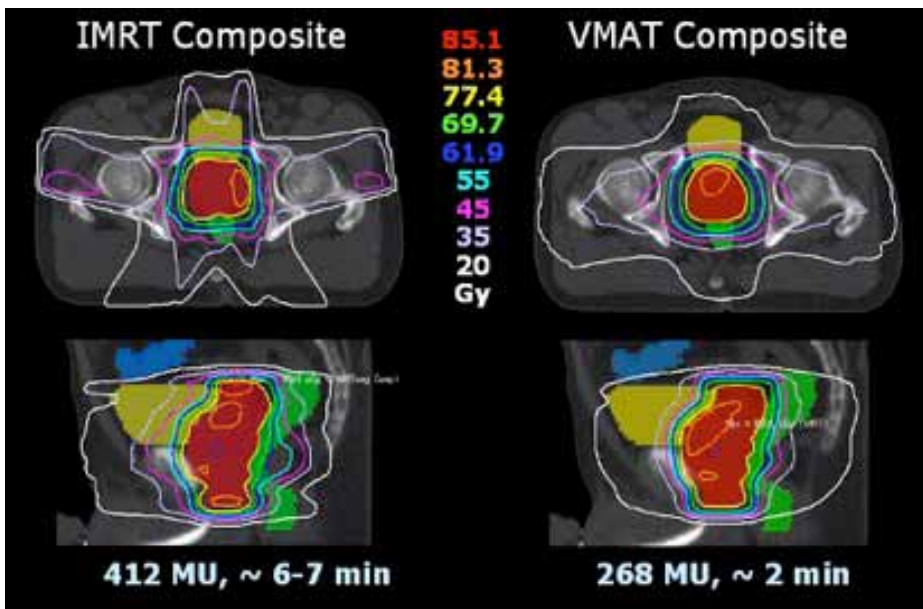
We have a separate team dedicated to hardware-centric control software – the real-time software that is used to operate our equipment. This team works closely with customer service teams and our own dedicated service engineers, to ensure that our equipment works in the safest possible manner, protecting both the patient and the operator.

CONFIDENCE FOR ADVANCED DELIVERY TECHNIQUES

Building on Elekta’s heritage in fully integrated, digital control for radiation treatment delivery, Integrity offers options for CVDR and interdigitation to enhance current treatment techniques and to provide opportunities and confidence to perform more aggressive, advanced treatment delivery techniques, such as VMAT.

Elekta pioneered the development of VMAT through a number of significant innovations.

- In 1990, Elekta introduced the first MLC to the market – an essential component in the pursuit of more conformal deliveries.
- In 1992, we founded the IMRT consortium to specifically investigate and discuss the requirements, in both hardware and software, for modulated techniques. From that group the concept of rotational IMRT (IMAT) was formed and trialled and we were the first company to clinically release IMRT as a step and shoot delivery.
- In 1995, Elekta patented intensity modulated arc therapy (IMAT) - the use of multiple arcs in intensity modulated treatment and the precursor to VMAT
- In 2005, we brought 3D volume imaging to the market with Elekta Synergy®. This was the key development that would ensure that highly conformal dose distributions could be delivered precisely to the right place in the patient.
- Then, in 2008, we delivered a VMAT delivery solution to the market, offering efficient workflows as well as accurate and fast treatment deliveries.



Courtesy Martha Matuszak, William Beaumont Hospital Detroit

Fast and efficient treatment deliveries

Our research partners, IMRT consortium members and an ever growing number of clinical reference sites are proving that VMAT, delivered using the Elekta digital linac control system, provides fast and efficient treatment deliveries. The example from the William Beaumont Hospital, Detroit, USA, (above) demonstrates significant time savings when performing a VMAT delivery for improved dose distribution compared to other treatment techniques.

Case study: University Medical Center Mannheim, Germany

The Department for Radiotherapy and Radiation Oncology at the University Medical Center Mannheim is part of Heidelberg University's Faculty of Medicine. Since 1997, the department has been active in developing the use of multileaf collimators in advanced treatment techniques. Through the use of the most advanced radiation therapy technology available, the Mannheim center has become one of the most important treatment facilities for cancer patients in the Rhein-Neckar area.

The clinical team at Mannheim center has worked closely with Elekta on the development of Integrity. The department also conducts clinical training courses on VMAT for Elekta.

Prof. Frank Lohr, Vice Chairman of the Department of Radiation Oncology, says,

"We depend on the digital control system to ensure that the Linac does what it is supposed to do. It is essential. It's a bit like a pilot who depends on the electronics of the aeroplane to transfer the movements from the yoke to the rudders, thus giving him

confidence to successfully land the plane. If they don't, you crash – it's as simple as that."

"Our preliminary data, using Integrity on a variety of treatment plans, shows that (as can be expected from the features of Integrity such as continuous dose rate modulation and several more) VMAT plans are significantly accelerated and the treatment delivery is a lot smoother than with the current control system. On average, it has reduced treatment times by 20-30% (for example, head and neck treatment times are reduced from 6.5 to 4.5-5.0 min and prostate treatment times from 4.0 to 2.5 min)."

"We currently perform 50% of all our treatments as modulated treatments with around 50% of those already being VMATs. This will soon approach 70%. Integrity is further improving our capability to perform these treatments by improving treatment speed."

"I look forward to a new feature of Integrity that will assist Linac-specific quality assurance (QA). This would enable QA to be performed on the Linacs reliably and easily."

Enhanced Quality Assurance

A suite of QA delivery tools will be provided as part of the integrity service software. This will enable efficient and flexible implementation of VMAT protocols. The University Medical Center Mannheim has played a key role in testing these options

REASSURANCE

Elekta linear accelerators are fully digitally controlled, providing rich, unbiased operational data. Elekta IntelliMax™ translates this data into straightforward information for proactive service and management actions. Unlike any other system, the combination of

the Elekta digital control system and Elekta IntelliMax™ facilitates unprecedented remote support capabilities to ensure optimized equipment availability and fine-tuned clinical performance.

Quicker response, minimal interruptions

Elekta IntelliMax™ radically improves clinical availability and minimizes the need for service interruptions. Reports are available to notify of impending issues, enabling preemptive action before problems occur. Real-time alerts are available to allow quicker response in corrective actions. Furthermore, comprehensive online support ensures speedy, accurate problem resolution.

CONCLUSION

Integrity has been specifically designed to offer smooth upgradeability and, with ongoing support from Elekta, you can build on a solid foundation to extend your treatments capabilities. With Integrity installed, you will enjoy the flexibility to choose the most accurate and advanced delivery technique required to meet each individual patient's needs.

Safety is paramount in everything we do at Elekta. The processes and procedures we have in place enable us to deliver products with control systems that make them inherently safe for users and their patients. Our commitment to safety is your quality reassurance.

References

- [1] Virtual arcs describes a non irradiating segment of a VMAT treatment delivery.

Summary of systems

Summary of enabling technologies
(http://www.elekta.com/healthcare_international_elekta_oncology.php)

Learning from our customers

Customer involvement and feedback is all important. We work in close collaboration with many of the world's leading university hospitals to test the systems in research sites, to challenge the system. Our development teams and engineers also go to sites to shadow radiographers to see our equipment in use. They see for themselves the implications of downtime. This affects the way in which the software is developed – always with the patient in mind.

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Human Care Makes the Future Possible

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