

STERNMED[®]

we make it possible

SternMed GmbH

COMPANY PROFILE

Designed &
Produced
in Germany

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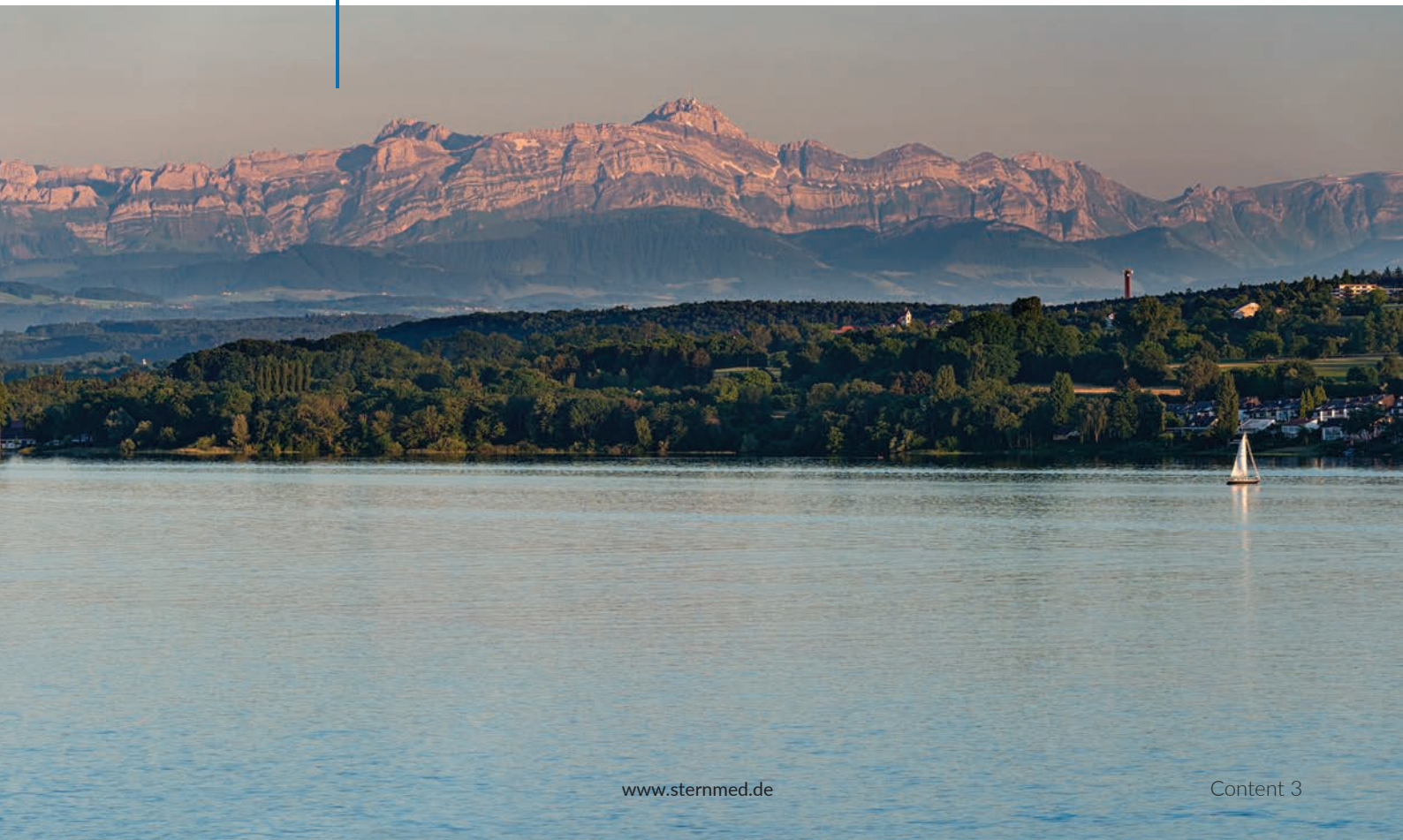
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BADEN-WÜRTTEMBERG

Baden-Württemberg, which is in the southwest of Germany, is the home of many global technology leaders across numerous industries. Well-known examples are Daimler, Porsche, ZF, SAP and Bosch.

SternMed is located in Ravensburg, Baden-Württemberg, close to Austria and Switzerland.





ABOUT STERNMED

SternMed GmbH is a medical device manufacturer and solution provider for healthcare turnkey projects, with head office in Baden-Württemberg. The company was established in 2011, with the idea of manufacturing affordable and durable medical devices with German quality standards to enhance healthcare globally.



Make quality healthcare accessible worldwide

Vision statement



TOGETHER, WE MAKE IT POSSIBLE

At SternMed, we prioritize assessing the needs of your healthcare project beyond offering our medical devices. We aim to provide a comprehensive solution that serves your budget, timeline, and technical requirements to enhance your patients' well-being.

Together, we make quality healthcare accessible in your community

We understand that executing a healthcare project and selecting appropriate medical devices is a complicated procedure; it requires a transparent process based on available resources and recognition of your infrastructure to accommodate current projects and future developments without compromising patient care.

Poor choices may lead to inappropriate use of the devices, a vulnerable system, or faulty medical devices which, as a result, will waste valuable resources and put the safety of patients and care providers significantly at risk. At SternMed, we adhere to all relevant healthcare regulations and standards to ensure excellent, ethical, and legal practices by providing medical devices for your community.

We at SternMed believe that "having access to a proper healthcare is the right of every human all over the world and – **we make it possible.**"

A crucial decision: Buying a medical device

When buying a medical device, several important considerations are crucial to ensuring the right purchase and optimal utilization. Knowing what you need and proposing the most suitable solution is the commitment of SternMed to your project.

Our focus lies on meeting your project requirements by following the SternMed "3A's": **Appropriate**, **Accessible**, and **Affordable** solutions for you:

Appropriate. Ensuring that our medical device meets the specific needs, resources, and requirements of your healthcare facility or your project.

Accessible. Verifying that the device is compatible with current healthcare systems for seamless integration.

Affordable. We balance the initial cost of our device with its long-term benefits to propose a cost-effective purchase for you. Evaluating the device's lifetime cost helps estimate its reliability and durability.



By manufacturing our products in Germany, we strive for ongoing excellence and conforming to the highest applicable norms and standards.

Dr. Stefan Fiedler
CEO

We will ensure that your medical devices are:

Safe. Verifying that our device complies with local standards and regulations to ensure patients' safety and reliable performance.

Reliable. A more durable device may result in fewer breakdowns, reduced downtime, and increased efficiency in healthcare operations.

SternMed also commits to providing:

Training and Support. Putting forward the availability of training and technical support from SternMed to ensure proper device implementation and maintenance.

Regulatory Compliance. Ensuring that the device meets all necessary regulatory approvals and certifications.

By taking these factors into account, we support our customers in making informed decisions and acquiring medical devices that align with their requirements, enhance patient care, and offer value for investment.

Healthcare projects: Planning and executing

Managing a healthcare project is a complex procedure in comparison to buying only one medical device. For a healthcare project owner, several crucial aspects are essential to ensuring successful project execution such as clearly defined objectives, project planning, stakeholder engagement, resource allocation, quality control, risk and change management. SternMed's strength is offering recommendations for all these aspects.

Developing with our customers a comprehensive project plan that outlines medical devices, timelines, financial resources, and regulations is part of our effective healthcare project management.

Identifying potential risks and developing strategies to mitigate them is vital to minimize project disruptions. Making well-informed and timely decisions is crucial to keeping the project moving forward and avoiding delays. We support you to make wise decisions during your project.



STERNMED

Vento 62



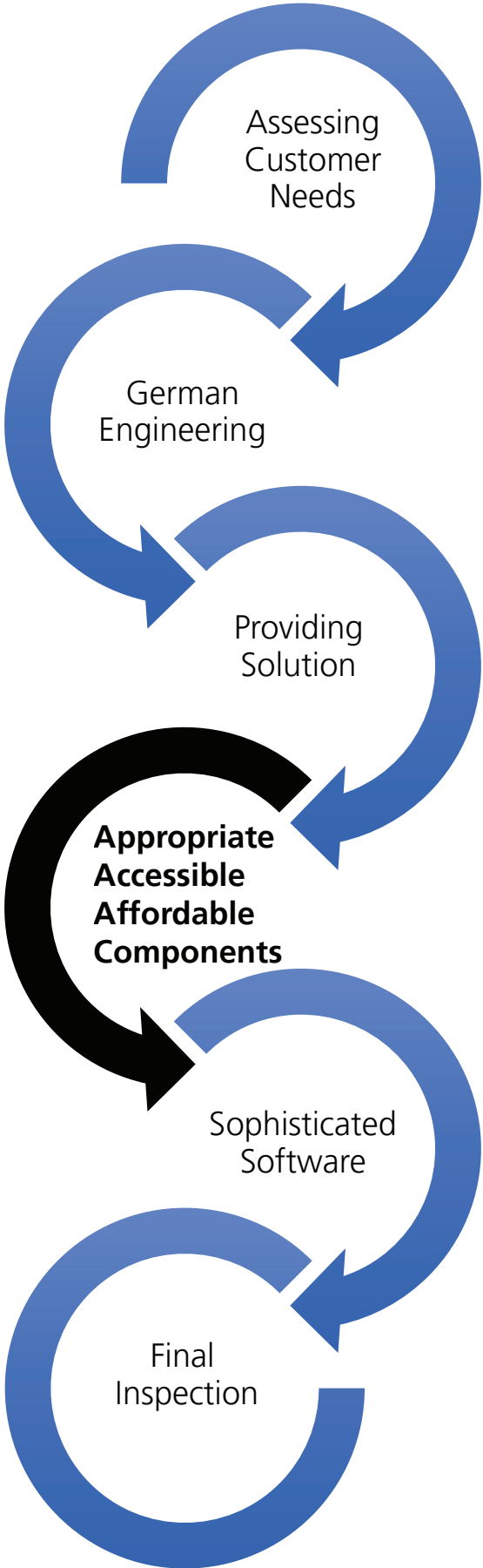
**OUR
VISION & MISSION**

OUR VISION

Make quality healthcare accessible worldwide.

OUR MISSION

Manufacture a wide range of affordable, German-quality healthcare products and solutions, while offering long-term commitment and local support.



Quality

Reliable. By engineering our products in Germany, we strive for ongoing excellence and to conform to the highest applicable norms and standards.

Diverse. Being multi-disciplinary – in terms of our people, expertise and approach – helps to consistently optimise the quality of how we work and what we deliver to our customers.

User-friendly. We design our robust solutions around a solid, core functionality that makes them easy to understand, use and maintain.

Knowledge

Supportive. We provide any training, expertise and other resources necessary to ensure our solutions work seamlessly and optimally.

Locally relevant. We strive to be fully aware of local conditions, customer needs and market developments, so we can take the right decisions and adapt our solutions when required.

Cost-awareness

Durable. We design our products for minimum downtime and long-lasting performance, so they generate a significant return on customer investment over a sustained period.

Affordable. We make cost-conscious decisions so we can offer our customers a wide range of solutions that matches budgets of all sizes.

Integrity

Trustworthy. We are a dependable business partner; a company that keeps its promises and which places great value on building and maintaining sustainable relationships.

Ethical. We believe in taking responsible choices, being fully accountable for our actions, and in working to a strict set of business ethics that we will not compromise on.

Passionate. We commit to improving access to healthcare in every corner of the world and encourage our employees – as well as customers and other partners – to contribute.

OUR CORE VALUES

- Quality
- Knowledge
- Cost-awareness
- Integrity

TUV NORD

ZERTIFIKAT / Certificate

DIN EN ISO / EN ISO 13485 : 2016

Hiermit wird bescheinigt, dass die Firma / This certifies that the company:

SternMed GmbH
Schubertstraße 31
88214 Ravensburg
Deutschland

ein Qualitätsmanagementsystem nach der Norm DIN EN ISO 13485 : 2016 / EN ISO 13485 : 2016 - Medizinprodukte - Qualitätsmanagementsysteme - Anforderungen für regulatorische Zwecke - eingeführt hat und aufrechterhält. Dieses Zertifikat stellt nicht den erforderlichen Nachweis zur Anbringung der CE-Kennzeichnung dar.

has established and maintains a quality management system that meets the requirements of DIN EN ISO 13485 : 2016 / EN ISO 13485 : 2016 - Medical devices - Quality management systems - Requirements for regulatory purposes. This certificate is not an authorisation to affix the CE mark.

Geltungsbereich / Scope

Entwicklung, Design, Produktion, Vertrieb und Service von bildgebenden Systemen, Magnet Resonanz Tomographen (MRT), Computer Tomographen (CT), Injektoren, Ultraschallgeräten, Ultraschallsonden, Mammographiegeräten, Röntgengeräten, Anästhesiegeräten, Hochfrequenzchirurgiegeräten, Operationstischen, Operationsleuchten, Beatmungsgeräten, Patientenmonitoren, Vitalzeichenmonitoren, Infusionsgeräten, Spritzenpumpen, Defibrillatoren und Zubehör

Development, design, production, sales and service of imaging devices, magnetic resonance imaging (MRI) scanners, computer tomography (CT) scanners, injectors, ultrasound scanners, ultrasound probes, mammography units, x-ray machines, anesthesia machines, high frequency electro-surgical units, operating tables, operating lights, ventilators, patient monitors, vital signs monitors, infusion pumps, syringe pumps, defibrillators and accessories

Reg.-Nr. / Reg.-No. 94 221 151260	Qualität / Quality von / from 2022-05-21 bis / until 2025-05-20
Bereich Nr. / Report No. 3531 4006	Edition 4

Zertifizierungsstelle für Medizinprodukte
Certification body for medical devices

Die Gültigkeit kann unter <https://www.tuv-nord.de/interne/medizintechnik/zertifizierung/zen99a.kissdatenbank> verteidigt werden.
Validity can be verified at <https://www.tuv-nord.de/interne/medizintechnik/zertifizierung/zen99a.kissdatenbank>

TUV NORD CERT GmbH Am TÜV 1 45397 Essen www.tuv-nord-cert.de medical@tuv-nord.de

Benannte Stelle Kenn-Nr. 0044 / Notified Body ID. No. 0044

 DAKKS
Strahlende
Zertifizierungsstelle
02438 13207 05-08

TUV NORD

EG-Zertifikat / EC-Certificate

gem. 93/42/EWG Anhang II ohne (4) / acc. 93/42/EEC Annex II without (4)

Hiermit wird bescheinigt, dass die Firma / This certifies that the company:

SternMed GmbH
Schubertstraße 31
88214 Ravensburg
Deutschland

für die Produkte / die Kategorie: Liste der Produkte siehe Anlage 1
for the products / product category: List of products see annex 1

Bildgebende Systeme, Magnet Resonanz Tomographen (MRT), Computer Tomographen (CT), Injektoren, Ultraschallgeräte, Ultraschallsonden, Mammographiegeräte, Röntgengeräte, Anästhesiegeräte, Hochfrequenzchirurgiegeräte, Operationstische, Operationsleuchten, Beatmungsgeräte, Patientenmonitore, Vitalzeichenmonitore, Infusionsgeräte, Spritzenpumpen, Defibrillatoren und Zubehör

Imaging devices, magnetic resonance imaging (MRI) scanners, computer tomography (CT) scanners, injectors, ultrasound scanners, ultrasound probes, mammography units, x-ray machines, anesthesia machines, high frequency electro-surgical units, operation tables, operation lights, ventilators, patient monitors, vital signs monitors, infusion pumps, syringe pumps, defibrillators and accessories

ein Qualitätssicherungssystem für die Auslegung, die Fertigung und die Endkontrolle der genannten Produkte nach Maßgabe des Anhang II (ohne Abschnitt 4) der Richtlinie 93/42/EWG einrichtet. Zusätzlich zur CE-Kennzeichnung muss die Kennnummer der Benannten Stelle angebracht werden. Die Gültigkeit dieses Zertifikats beruht auf der Aufrechterhaltung des Qualitätssicherungssystems in Übereinstimmung mit den Anforderungen der Richtlinie und seiner Überwachung durch die Benannte Stelle gem. Anhang II Abschnitt 5. Das Zertifikat ist unter keinen Umständen übertragbar.

has established a quality system for design, production and final testing acc. to the requirements of Annex II (without section 4) of the directive 93/42/EEC. Additional to the CE-marking the notification number of the Notified Body has to be affixed. The validity of this certificate is based on the maintenance of the quality system in accordance with the requirements of the directive and its surveillance by the Notified Body according Annex II section 5. The certificate may not be transferred under any circumstances.

Reg.-Nr. / Reg.-No. 44 232 151260	Gültigkeit / Validity von / from 2019-05-21 bis / until 2024-05-20
Bereich Nr. / Report No. 3521 7634	Edition 2

Zertifizierungsstelle für Medizinprodukte
Certification body for medical devices

Essen, 2019-05-20

TUV NORD CERT GmbH Langenarckstraße 20 45141 Essen www.tuv-nord-cert.de medical@tuv-nord.de

Benannte Stelle Kenn-Nr. 0044 / Notified Body ID. No. 0044

 UKCA
Zertifizierungsstelle
für Medizinprodukte
02438 13207 05-08



PRODUCT CATEGORIES

The product portfolio of SternMed is divided into three different Product Lines. The goal is to provide solutions for a broad range of healthcare turnkey projects.



Medical Imaging

Imaging Systems

SternMed's imaging devices provide a comprehensive portfolio of complete hardware and software solutions tailored for global imaging needs.

- MRI
- CT
- Fluoroscopy
- Radiography
- Mobile C-arm
- Mammography
- Ultrasound

Operation Room

OR Solutions

OR Solutions from SternMed are designed to support clinicians worldwide to provide healthcare for their patients.

- Surgical Lights
- Surgery Tables
- Anesthesia Unit
- ESU

ICU

Patient Care

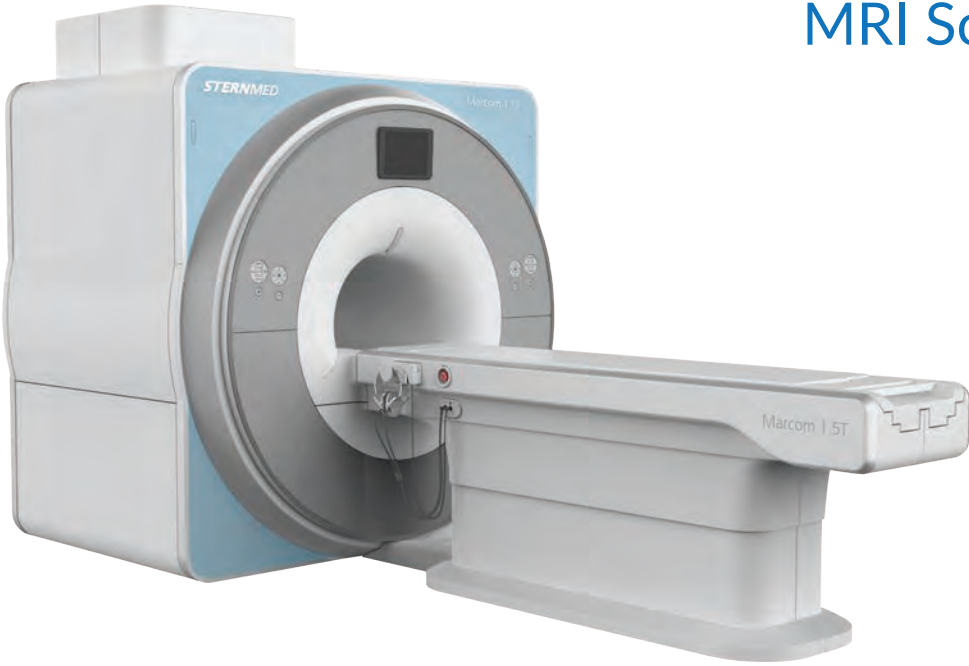
SternMed provides ICU equipment to support specialists in giving exceptional patient care.

- Patient Monitors
- Medical Pumps
- Ventilator

A photograph of three medical professionals in a clinical setting. In the center, a young woman with brown hair in a ponytail, wearing glasses and blue scrubs, is smiling and looking at a tablet. To her left, a woman with blonde hair is looking at the tablet. To her right, a man with glasses, wearing a white lab coat and blue scrubs, is also looking at the tablet. The background shows a blurred medical device, possibly an MRI or CT scanner.

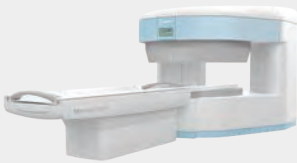
MEDICAL IMAGING

SternMed core products are the medical imaging devices including Magnetic Resonance Imaging (MRI), Computed Tomography (CT-scan) and other X-ray devices along with Ultrasound systems, these devices deliver hardware and software solutions which are customized for global medical imaging requirements.



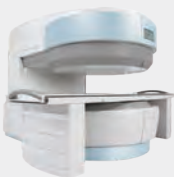
Marcom 1.5T

Marcom 1.5T is a new generation superconducting MRI scanner with 1.5 Tesla field strength with the ability to perform whole body scans, such as of the nervous system, spine, joints, soft tissue, pelvic and abdominal cavity.



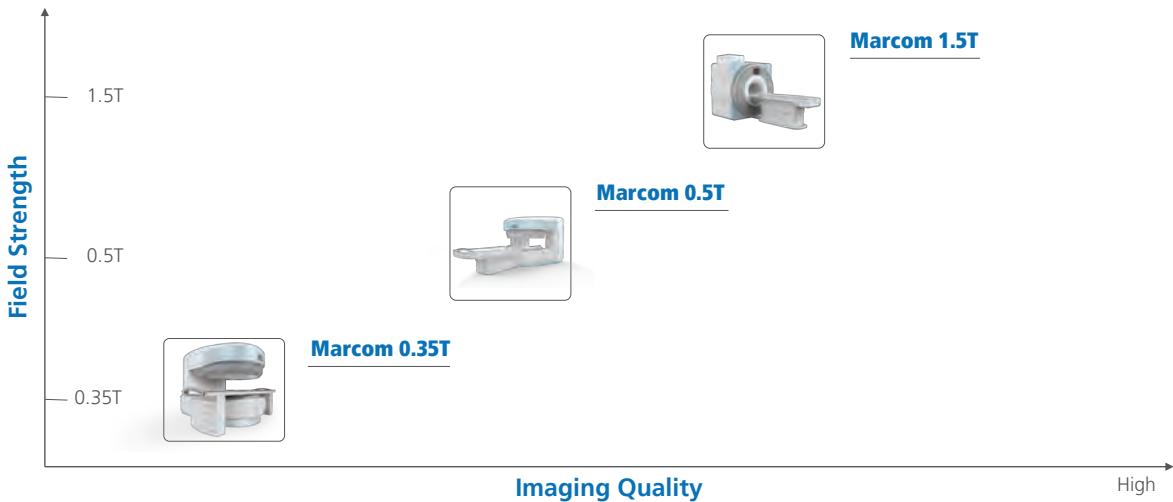
Marcom 0.5T

Marcom 0.5T is an open 0.5T permanent magnet MRI system equipped with a powerful RF and gradient system. In combination with the advanced imaging technology, making it a high-end system, it is comparable to high-field MRI systems.

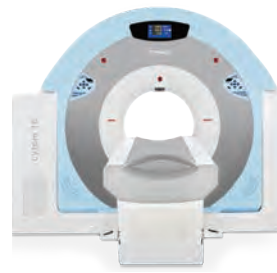


Marcom 0.35T

Marcom 0.35T is an open 0.35T permanent magnet MRI scanner which supplies fast imaging and high-quality images and provides rich preset scan protocols as well as advanced applications.

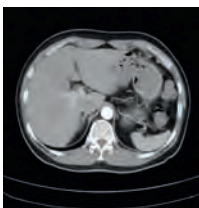


CT Scanner



Cytom 16

Cytom 16 is a multi-slice ultra-fast CT scanner with PowerLink Non-Contact Power Technology. PowerLink eliminates the limitations of today's rotating gantry systems providing the lowest cost, highest reliability CT power system, and non-contact slip ring design.





Xenox M100

The Xenox M100 is a fully digital, motor-driven mobile x-ray with an amorphous silicon flat panel. In the Xenox M100, the High-Frequency Stable Operating Technology provides the stability to generate quadrature waves to give better penetration for the tube. The tube and main unit are protected against overheating by a safety circuit that constantly monitors the tube's heat capacity.



Xenox M70

Light-weight and small analog mobile x-ray unit designed for radiological examinations at the patient's bed and in the emergency room.



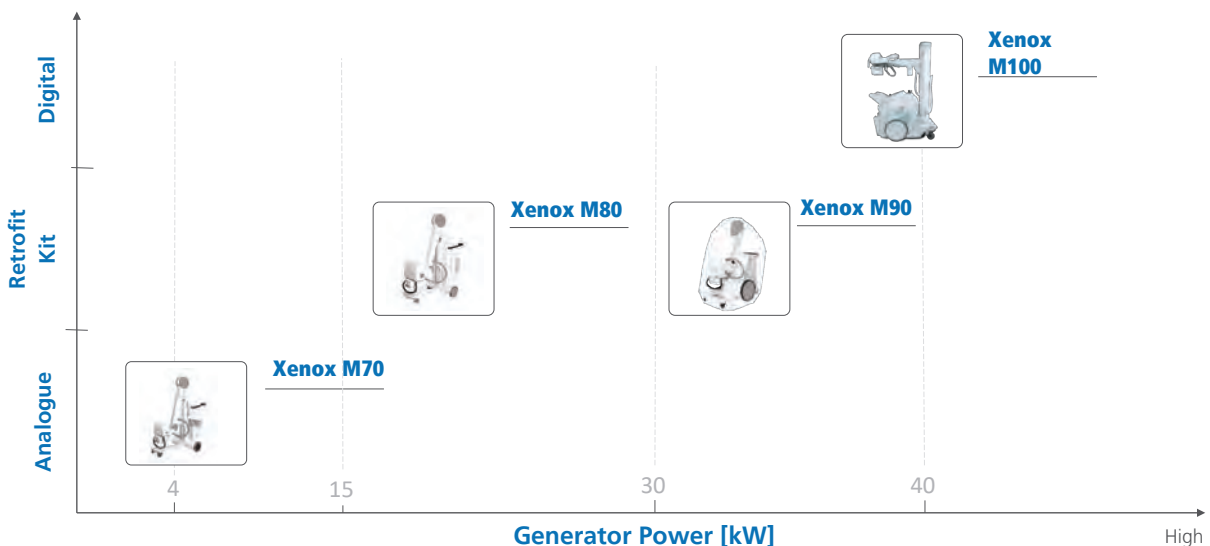
Xenox M80

Mobile x-ray unit designed for radiological examinations at the patient's bed and in the emergency room.



Xenox M90

Mobile x-ray unit designed for radiological examinations at the patient's bed and in the emergency room with a touch screen control panel to display and set the radiographic parameters.



X-Ray Systems



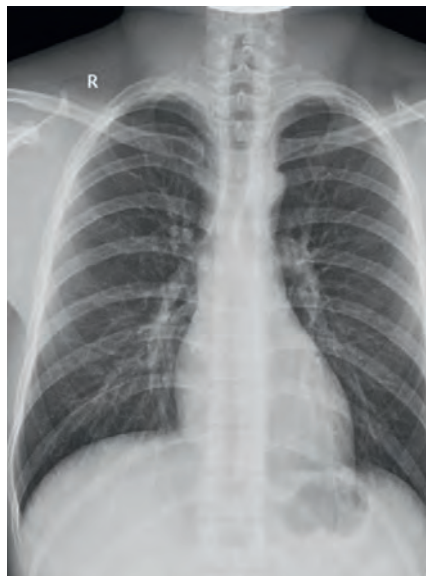
Xenox RAD400

Xenox RAD400 is designed to meet the highest quality standard and ensure the best radiographic performance. It is available in both conventional and fully digital configurations.



Xenox DR500

A versatile and fast ceiling suspension radiography system with an amorphous silicon flat panel providing higher quality images at a lower dose.





Xenox RF1000

Xenox RF1000 is a radiography system with a compact and versatile remote controlled tilting table for radiographic, angioseriographic and fluoroscopic examinations.



Mobile C-Arm Systems



Xenox C400

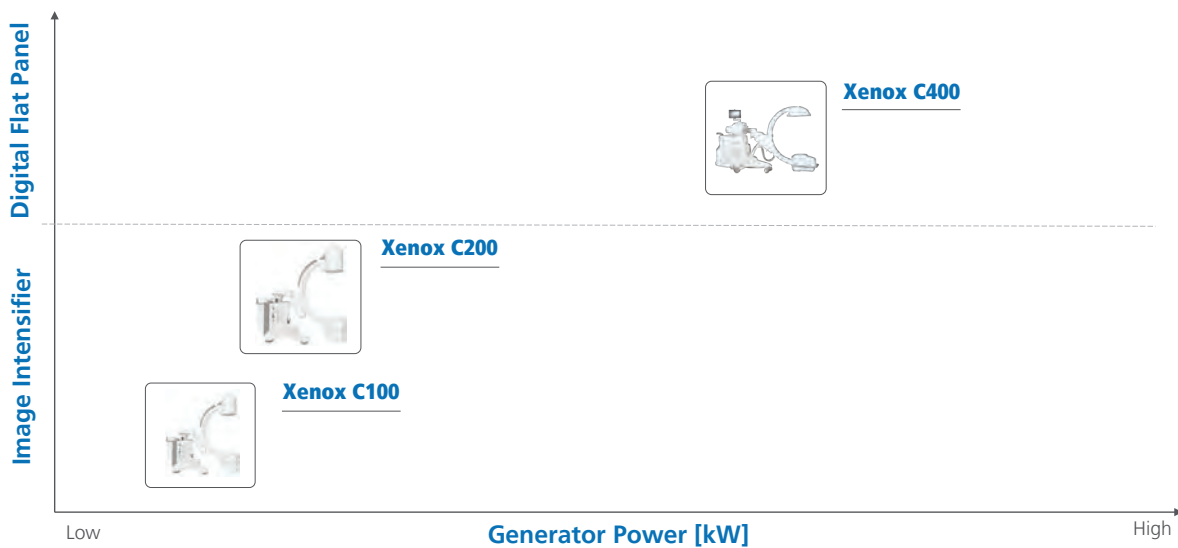
Xenox C400 is a highly reliable, durable, and enduring digital mobile system with a flat panel equipped with digital angiographic memory, which makes it suitable for all applications having high diagnostic content.



Xenox C100



Xenox C200



Mammography Systems



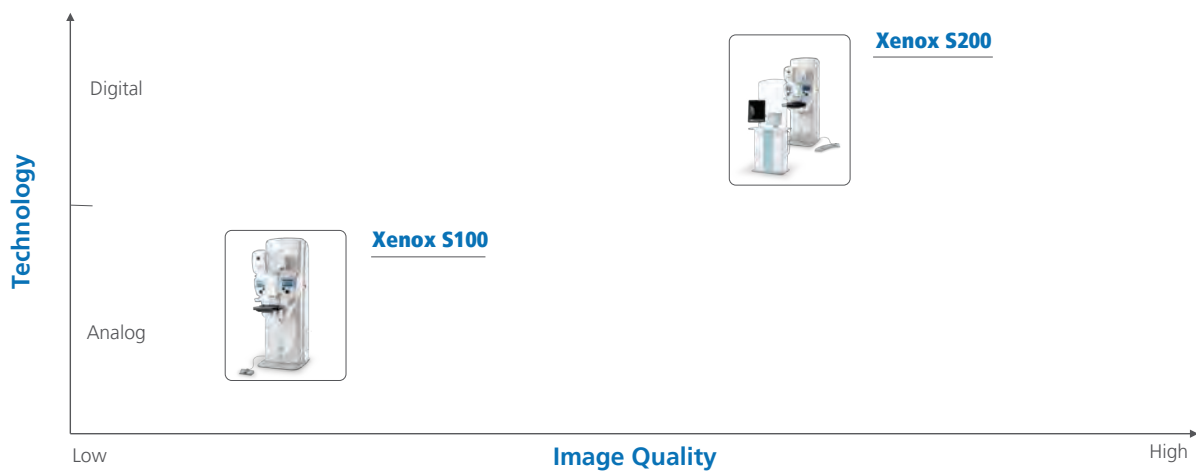
Xenox S100

A versatile analog mammography system with an iso-centric c-arm and magnificent image quality at the most efficient cost.



Xenox S200

A full-field digital mammography system (FFDM) complete with control and image acquisition station, which is equipped with a transparent protection screen for the operator. Can be configured for any type of digital mammography exam including Tomosynthesis.



Ultrasound Systems



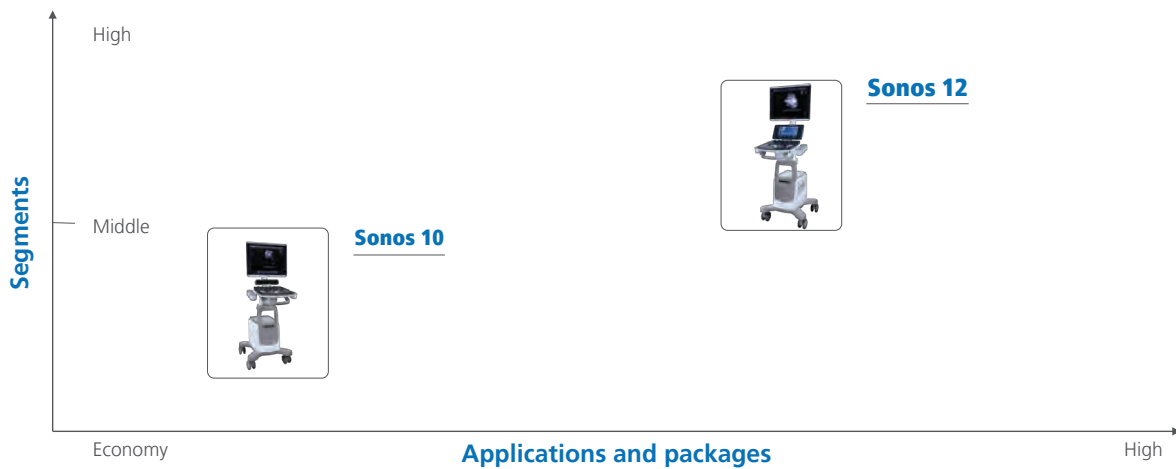
Sonos 10

Digital color ultrasound system that supports different applications and provides a wide range of solutions in the areas of general imaging, OB/GYN and cardiology in the healthcare facility.



Sonos 12

A state-of-the-art of volumetric 3D/4D ultrasound system with perfect image quality of 2D images. It is the best solution for general imaging, OB/GYN and cardiology in clinics and hospitals with a variety range of specialities.



“ *we make it possible* ”

Together, we make quality healthcare
accessible in your community.



OR SOLUTIONS

SternMed products in operation room category including Anesthesia Machine, OR Surgery Table and Surgical Light are designed to support healthcare facilities worldwide to provide safe and cost-effective health care to their patients.

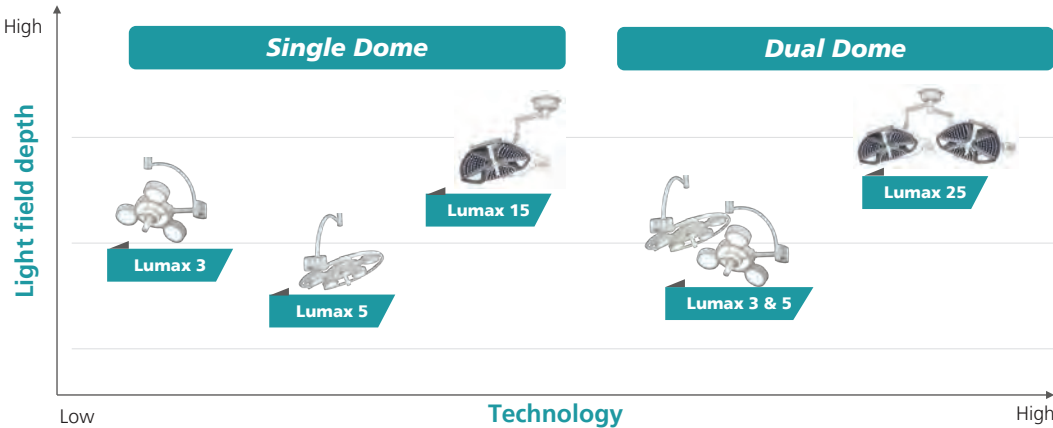


Lumax 3 & 5

Lumax 3 & 5 are surgical lamps with LED technology. Due to the constant attention to the evolution of technology and clinical needs, Lumax 3 & 5 are born to meet the user requirements, providing reliability, visual comfort and optimal performance.

Lumax 25

Lumax 25 is a dual dome surgical LED light system, which provides exceptional performance to satisfy the user needs in diverse surgical fields, including general surgery, microsurgery, E.N.T., OB/Gyn., orthopedic and cosmetic surgery. This is also available as the single dome version Lumax 15.



Manual Surgical Tables



Onex 101

Onex 101 is a manual surgical table with a stable hydraulic weight capacity of 200 kg. It can easily be set up and positioned to meet the requirement of a wide range of surgeries.



Onex 201

The Onex 201 is a manual surgical table that has a weight capacity of 297 kg. The table can easily be set up and positioned to meet many kinds of surgical needs.



Electro-hydraulic Surgical Tables



Onex 102

Onex 102 is an electro-hydraulic surgical table that can be set up and positioned easily with remote control. The interchangeable top is made of shape memory material (SMM) to provide great comfort for the patient. With its highly stable hydraulic system, the system provides all kinds of surgical positions, precisely and quietly to perform a wide range of surgeries.



Onex 202

The Onex 202 is an electro-hydraulic operating surgical table that can be adjusted and positioned easily with remote control. The interchangeable top is made of antistatic, radiolucent material with latex-free cushions to provide great comfort for the patient. Engineered with a highly stable hydraulic system, this device can carry up to 297 kg patient weight.



Onex 203

The Onex 203 is a modern and multifunctional electro-hydraulic operating table that is engineered for the complex demands of modern surgical rooms and can be set up and positioned easily with a remote control or a membrane keyboard on the central column. The hydraulic system can carry up to 297 kg patient weight.



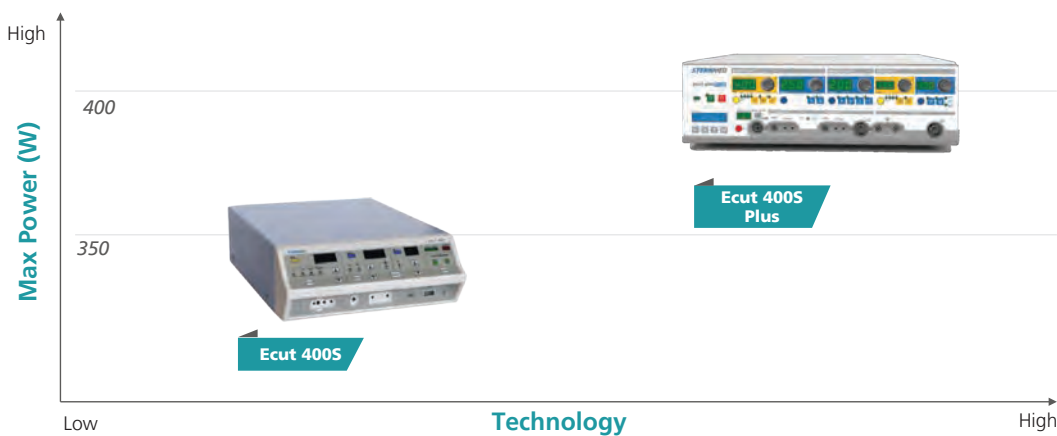
Ecut 400S Plus

Ecut 400S Plus is an advanced electrocautery unit enabling surgeons to perform mono and bipolar surgery simultaneously in a wide range of applications such as: ambulatory surgery, endoscopy, first aid, gastroenterology, general surgery, Gynecology, neurosurgery, otorhinolaryngology, orthopedics, pediatric surgery, plastic surgery, pneumology and vascular surgery in urology.



Ecut 400S

A versatile electrocautery unit for all surgical procedures through all types of tissue. It has an integrated seven power output, tissue responding and automatic solid or split return electrode recognition function, with which surgeons can perform safe and highly precise operations.





Avacs 50

Avacs 50 is a versatile and advanced anesthesia workstation for adult, pediatric, and infant applications equipped with a sophisticated built-in ventilator equipped with all common ventilation modes.



PATIENT CARE AND ICU

SternMed manufactures various patient care devices such as patient monitors, infusion pumps, syringe pumps, and medical ventilators to enable healthcare professionals to monitor their patient's vital status, administer targeted and finely dosed medication, and provide minimally invasive ventilation to patients postoperatively and in the ICU.

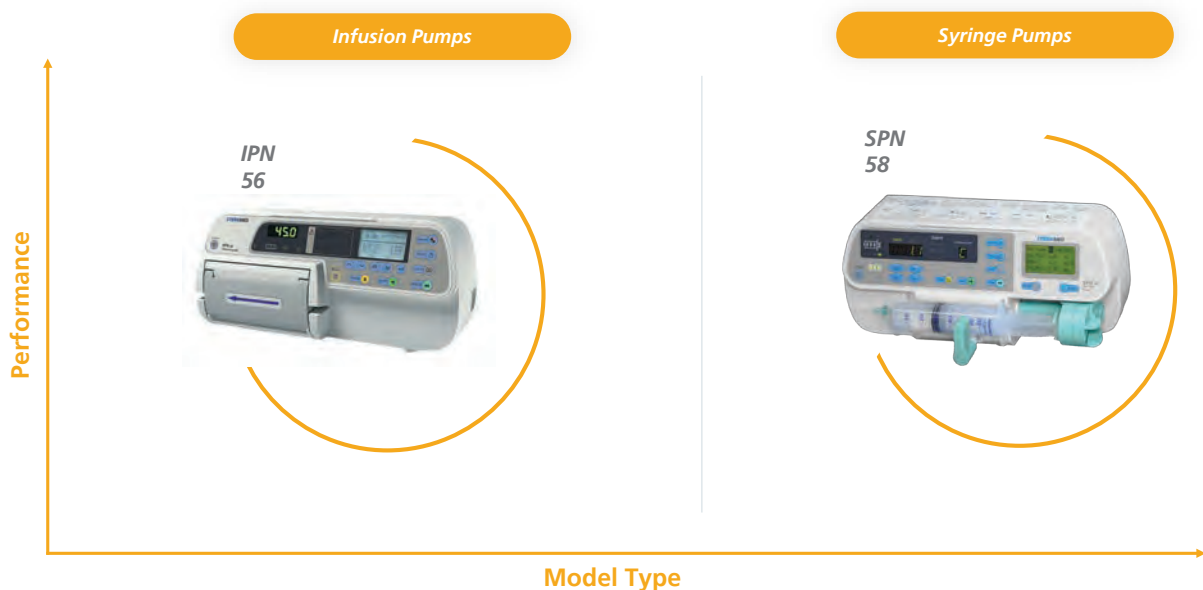


SPN 58

SPN 58 is a one channel drive syringe pump for the finely dosed application of medications with 2 LCD screens. This device can be handled and operated easily with its simple and clear user interface. Its stable and great quality makes it popular worldwide.

IPN 56

IPN 56 is an infusion pump for the finely dosed application of drugs with an integrated preheating module. Its horizontal design effectively prevents drug liquid leakage into the pump.



Pre-Configure Patient Monitors



Macs 30

Macs 30 is a multi parameter monitor offering a variety of applications. It can be used to measure and monitor parameters of SPO2, NIBP, Pulse, TEMP, ECG and RESP. Optional mainstream, sidestream EtCO2 and 1 or 2-Channel IBP monitoring functions are also available.



Macs 10

Macs 10 is an affordable and compact portable patient monitor, which shows essential basic parameters such as ECG, RESP, temperature, SPO2 and NIBP and benefits from 7" high-resolution color TFT screen.



Macs 20

Macs 20 delivers monitoring capacity and functionalities intuitively and it fulfills all unique needs of adult, pediatric, and neonatal during intensive care; anesthesia and peri-operative care as well as cardiac care condition.



PC Macs Series

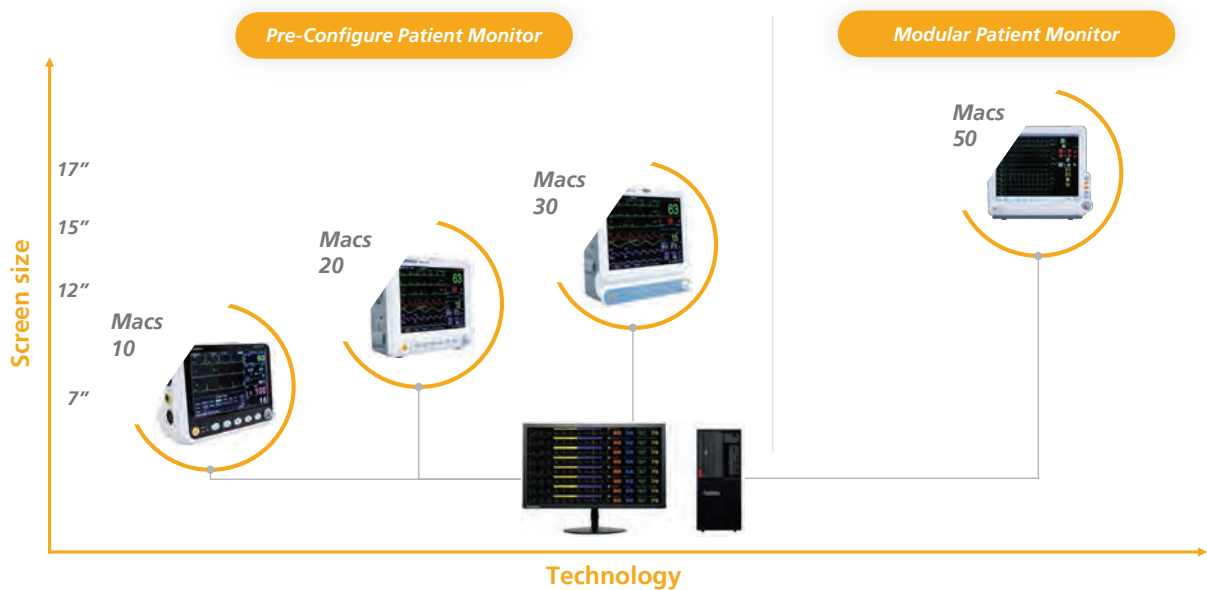
SternMed PC-Macs Series is an intelligent central multi-bed and multi-physiological parameter monitoring system, which can be connected by wire or wireless network with up to 64 bedside patient monitors and is suitable for performing continuous monitoring of several patients in CCU and ICU wards simultaneously.

Modular Patient Monitors



Macs 50

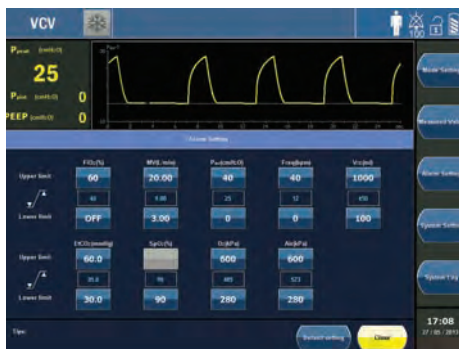
Macs 50 is an all-in-one modular patient monitor with a display & built-in battery. The large 17" touch screen color display makes viewing patient data easy. The Macs 50 offers a flexible solution for the varying needs of patients in ICU.



ICU Ventilator

Vento 62

Vento 62 is an advanced critical care ventilator with various ventilation modes to fulfill all requirements of intensive patient care units for adults and pediatric. The system is equipped with a 15" TFT touch screen monitor.



 *We make it possible* 
Wir machen es möglich



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v. 7.00

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