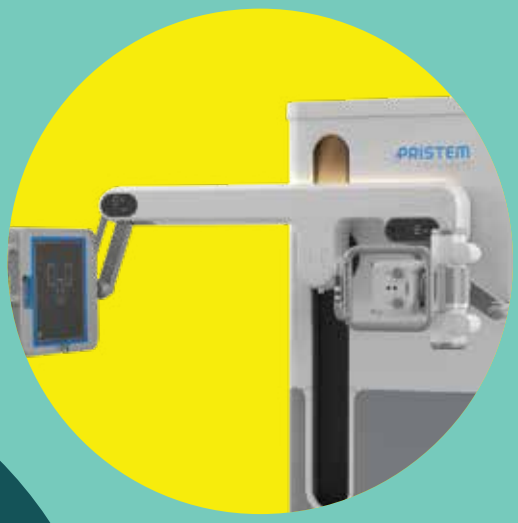
Quality Xray diagnostics

Opening doors to Xray diagnostics



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Uncompromising quality Xray diagnostics

Open Diagnostics is a group of diagnostic centers, offering quality diagnostic services to underserved communities.

Born out of Pristem as a humanitarian and socially responsible approach to healthcare, Open Diagnostics upholds the principle that every human being has the right to quality healthcare. This is the driving force behind our Open Diagnostics centers, which offer high-quality diagnostic imaging technology and positive patient experiences to underserved communities in the most challenging environments.

This technology is the result of a comprehensive project which involved the co-operation of EPFL (Swiss Federal Institute of Technology in Lausanne), Essential Tech, healthcare institutes and radiologists on the African continent, as well as technology experts and healthcare institutes in Switzerland.

This collaborative approach remains key to Open Diagnostics success as the technology remains supported and managed by Pristem to ensure the highest quality outcomes.

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A new Xray diagnostics alternative on the market

Pristem owns exclusive licenses for 3 international patents for technologies which are built into the Cristalix-T1 system. This Xray technology delivers high-quality images, as well as efficacy, reliability and durability even in challenging environments.

The development of the Cristalix-T1 digital Xray system started from scratch, taking all the parameters of such environments into consideration (e.g. high temperature and humidity level, power outages). Stakeholders from across the entire value chain – from Xray component manufacturers to medical experts, radiographers and maintenance technicians – collaborated with Pristem throughout the development process. So as to create a digital Xray system that could operate anywhere in the world.

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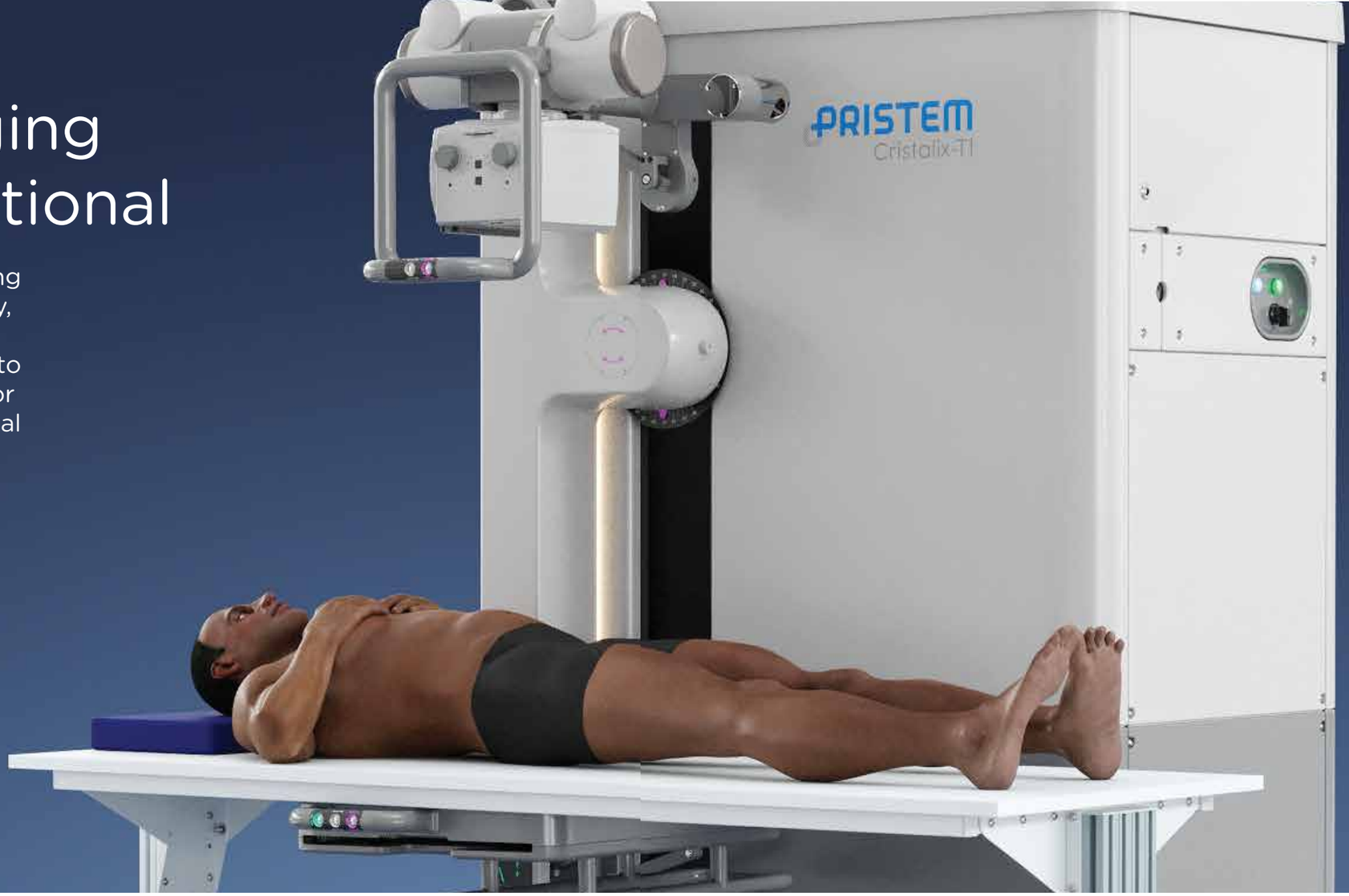
Challenging the traditional

In addition to achieving superior image quality, our solution has been specifically designed to respond to the 6 major issues facing traditional approaches.



Medical efficacy

Medical efficacy is increased by delivering high-quality images. The high-sensitivity digital detector and the smart software yield optimal resolution images, thus allowing accurate diagnosis of various medical conditions. Higher efficacy is further achieved by our simply designed and safe to use system. This, together with the 117 integrated multimedia tutorials with pre-set projections and guidelines, supports the user in achieving successful images.

Equipment ease of use

The Xray equipment ease of use has been at the very heart of the product development. Over 80 radiographers and health professionals have played an active role in helping to produce a highly intuitive digital Xray system. Color-coding, icons, and thorough guidance for the operator have been built into our device interface and allow the operator to successfully carry out exams with great ease and efficiency.

Robustness & durability

Robustness has been a primary goal of the design, inspired by industrial technologies (such as transportation industries, space and machine tools), which are intended to operate in harsh environments. The system patented robust mechanical elements can withstand high temperatures, humidity and dust – designed to be maintenance free (for instance, the movements are mostly mechanical, which make our device more reliable than fully automated Xray devices with electrical movements only).

Uptime

The uptime of our new Xray device is guaranteed by design: the device switches automatically to a 3hr battery backup when no more power supply is available from the mains, allowing the radiographer to continue the on-going Xray exam without interruption. A room light is integrated into the arm of the device which allows the operator to continue to operate in the event of power cut.

Pristem's preventive maintenance module allows the user to address any potential risk of error or malfunction. This is remotely managed by our technicians to reduce the likelihood of interruptions in the daily operation of the Xray system.

Intrinsic safety

The system is entirely compliant with the European norms high-quality standards and is CE-certified by TÜV-SÜD.

The system was also designed to reduce radiation doses for the patient and to protect the operator. By design, the source is always aligned with the detector, which makes the Xray machine very safe to use and further guarantees patient's safety.

Power supply

The specific power supply has been designed to operate the 50kW high power system within very weak and unstable power grids, together with solar panels in off-grid hospitals and medical centers.

The very low-consumption system (<200W in average and <1000W max) is protected against electrical surges that represent the main reason for the breakdown of existing equipment.

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High precision meets heavy-duty engineering

Cristalix-T1 digital Xray system

Ergonomic and simple interface

Intuitive user interface developed with users, makes training on this device extremely simple and everyday use highly efficient.

UX created for better outcomes

Built for variable environments

Shock-proof design able to withstand high levels of temperature, humidity and dust.

shock proof

45°C, 85% RH

Precision image quality at low dose

The superior quality of the images acquired by the Cristalix-T1 technology sets it apart from equivalent systems.

High power (50kW) for better image quality to dose ratio. Good images up to 45°C, 85% RH.

High reliability

Reliable and robust mechanics

The electronic design protects the system from destructive electrical perturbations, which are the most common cause of medical equipment failure (typically 30%).

3 hour power reserve

Energy use and efficiencies

The power generator design is adapted to accommodate very weak power supplies and to prevent the high-power Xray source from drawing high current peaks. This makes it compatible with weak electrical infrastructures (e.g. diesel generators which are often used in the case of power cuts).

An additional advantage is that in a short period, traditional Xray equipment may consume as much power as the entire hospital (20 to 50kW), while Pristem's product consumes less than 200W in average and less than 1000W max.

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Patient experience at the forefront

Proximity

Open Diagnostics network of world-class diagnostic centres for primary healthcare and diseases screening, are situated within communities where access is most needed. The optimized workflow minimizes waiting time for both the patient and the treating general practitioner or nurse.

Price

A pricing policy designed for all South Africans to access affordable Xray services in their communities. Intentionally intended to be simple, so as to take out the complexity and stress from Xray medical imaging.

Experience

Every person has the right to the same quality healthcare is the underlying principle that Open Diagnostics is founded on. All centers have trained staff, from local communities, that are skilled to engage, connect and support patients where necessary. Their primary role is to create an approachable patient-centric healthcare space, where all people are given the same treatment and access to Xray diagnosis.

Highest quality

Cristalix-T1 is an advanced, general-purpose radiographic Xray system suitable for use in a wide variety of medical imaging applications. This world-class system is engineered to create access to radiography of uncompromising quality. Our goal is to provide underserved communities with access to Swiss standards of efficiency and quality in healthcare. This principle drives the operation of our diagnostic centers and the technology that they are equipped with.

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World-class image quality at low dose

The superior quality of the images acquired by the Cristalix-T1 technology sets it apart from equivalent systems. Studies conducted in 2022 by Pristem and HESAV (Haute Ecole de Santé Vaud, a medical university based in Vaud, Switzerland) demonstrate that the quality and resolution of images acquired by the Cristalix–T1 digital Xray system were equal or superior to those acquired by equivalent, state-of-the art Xray equipment.

Details of the study are described below.

Pristem

System B

System C

Image quality and clinical safety evaluations

The study undertook a comprehensive evaluation of the Cristalix-T1 digital Xray system with 3 objectives:

1. To validate the high quality of the images acquired by the Cristalix-T1 digital Xray system.
2. To demonstrate that the quality of images acquired by the device was equal to or better than images acquired by equivalent, state-of-the-art Xray equipment available on Swiss and European markets.
3. To demonstrate that the radiation dose administered to patients was less or equal to equivalent, state-of-the-art Xray equipment available on Swiss or European markets.

The studies were performed through subjective user evaluation based on images acquired and simultaneous dose measurement techniques according to accepted protocols used by the university. A summary of the results and conclusion of the studies follows.

1. Image quality validation

The first phase of the study focused on evaluating the quality of images acquired by the Cristalix-T1 digital Xray system.

Methodology

To evaluate image quality of Cristalix-T1, 11 projections were selected (these projections are representative of the Xray exams performed in conventional radiology).

The images were evaluated using 2 distinct sets of quality assessment criteria – one for the chest and another for bones.

The criteria used for this evaluation were based on several anatomical criteria and image quality criteria including contrast, noise and spatial resolution.

The evaluation was carried out by 3 radiologists and 3 radiographers for 11 projections and the raw data were statistically analyzed by HESAV (Haute Ecole de Santé Vaud) and Pristem.

Results

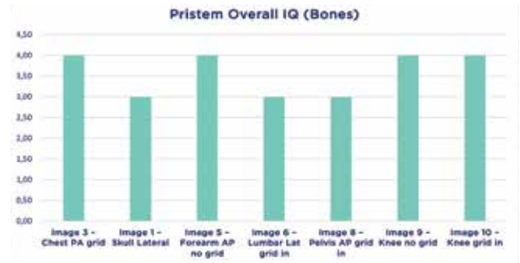
The results demonstrated that the images achieved a median score of “very good” across all criteria with 91% of the images achieving or exceeding the median.

The study concluded that the images acquired from the Pristem system visualized anatomical details required for the skull, chest, pelvis, knee, lumbar and forearm very well.

Overall, the subjective evaluation achieved a PASS, with the rating “very good”, especially on quality and resolution of the images.

	Chest images	Bone images
Image 1 Skull Lateral		x
Image 3 Chest PA grid	x	
Image 5 Forearm AP no grid		x
Image 6 Lumbar Lat grid in		x
Image 8 Pelvis AP grid in		x
Image 9 Knee grid out		x
Image 10 Knee grid in		x

Chest and bones images



Pristem overall image quality

2. Subjective comparison with equivalent equipment

The same 6 skilled observers also performed the subjective comparison of the image quality. The images were acquired from the Pristem digital Xray system (A) as well as similar images acquired from 2 equivalent systems (B and C).

To eliminate bias, evaluators were not able to identify which system was used to acquire the images being compared. The observers compared the images according to accepted protocols and criteria while the raw data was statistically analyzed by Pristem and HESAV.

To pass this subjective evaluation, the resulting score from images acquired by Cristalix-T1 equipment needed to be equal to or higher than 0 (which means that the quality of the reference image being the Cristalix-T1 image is equal or better than the other image).

Results
All Pristem's images passed the inter-equipment test compared with system B or C, the median of all scores from all observers (except one), is greater or equal to 0. Concerning the image quality of the forearm, since it was already rated "very good" by the observers panel (see analysis in the section 'Image quality validation'), we have decided to accept it even though the quality is slightly 'inferior' to the corresponding image from the system C.

The study concluded that the Cristalix-T1 equipment provides a similar or better image quality when compared to the 2 other state-of-the-art radiographic systems B and C.

Inter-equipment comparison validation results

		anatomical criteria bones				anatomical criteria chest						image quality criteria					
Image	Manufacturer	Cortical margins	Trabecular patterns	Joint spaces	Skin borders	Vascular pattern	Heart and aorta	Coronaries	second thoracic vertebrae (T2)	spine through the heart	Skin borders	Contrast	Noise	Overall IQ	Spatial Resolution	MEDIAN ALL OBSERVERS	PASS / FAIL
3 Chest PA_grid in	A	n.a.	n.a.	n.a.	n.a.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.00	OK
	B	n.a.	n.a.	n.a.	n.a.	0.0	1.0	0.0	-1.0	-1.0	-0.5	1.0	0.0	1.0	1.0	0.50	PASS
	C	n.a.	n.a.	n.a.	n.a.	1.0	1.0	1.0	-1.0	-1.0	0.0	1.0	0.0	1.0	1.0	1.00	PASS
1 Skull lat_grid in	A	0.0	0.0	0.0	0.0	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	0.0	0.0	0.0	0.0	0.00	OK
	B	0.0	0.5	-0.5	-1.0	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	0.5	-1.0	0.0	1.0	0.00	PASS
	C	1.0	1.0	0.5	1.0	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	1.0	0.0	1.0	1.0	1.00	PASS
5 Forearm no grid	A	0.0	0.0	0.0	0.0	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	0.0	0.0	0.0	0.0	0.00	OK
	B	0.5	-0.5	0.0	0.0	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	1.0	1.0	1.0	0.0	0.00	PASS
	C	-1.0	-1.0	0.0	-0.5	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	-1.0	0.0	-0.5	-1.0	-1.00	Accepted Deviation
6 Lumbar lat_grid in	A	0.0	0.0	0.0	0.0	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	0.0	0.0	0.0	0.0	0.00	OK
	B	0.0	-0.5	-0.5	0.0	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	1.0	-1.0	-0.5	0.0	0.00	PASS
	C	0.0	-1.0	-0.5	0.5	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	1.0	-0.5	1.0	-0.5	0.00	PASS
8 Pelvis AP_grid in	A	0.0	0.0	0.0	0.0	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	0.0	0.0	0.0	0.0	0.00	OK
	B	0.5	-0.5	0.0	-1.0	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	1.0	0.0	1.0	0.5	0.00	PASS
	C	0.0	-1.0	-0.5	1.0	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	0.5	0.0	0.0	0.0	0.00	PASS
9 Knee AP_no grid	A	0.0	0.0	0.0	0.0	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	0.0	0.0	0.0	0.0	0.00	OK
	B	0.0	0.0	0.0	-1.0	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	1.0	0.5	1.0	0.0	0.00	PASS
	C	-0.5	-0.5	0.0	1.0	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	0.0	0.0	-1.0	-0.5	0.00	PASS

Pass / Fail results for inter-equipment subjective evaluation.

3. Radiation dose comparison

Minimising radiation exposure is central to safeguarding both patient and health worker safety. This phase of the study therefore included an evaluation of radiation dose delivered during image acquisition for the comparative study previously described.

Methodology

The study was conducted using the same Xray equipment and images acquired in the previous comparative study. The Estimated Surface Dose (ESD) at skin entry was calculated based on the recorded exposure conditions with the accepted formula used by the industry and standards.

Results

The results are tabulated below:
The average Pristem ESD score is significantly lower than equivalent systems B and C.

The comparative study demonstrated that under identical exposure conditions, the Cristalix-T1 equipment generates lower or equal radiation doses when compared to equivalent low dose Xray benchmarked devices B and C without compromising image quality.

Incident #	Phantom	ESD Pristem [mGy]	ESD System B [mGy]	ESD System C [mGy]
1	Skull lateral	0,53	1,08	0,74
3	Chest PA grid	0,11	0,14	0,17
5	Forearm AP no grid	0,09	0,09	0,09
6	Lumbar Lat grid in	2,50	5,59	3,62
8	Pelvis AP grid in	1,25	1,75	1,35
9	Knee grid out	0,42	0,42	0,42
10	Knee grid in	0,65	0,65	0,65
	Average all	**1,46**	**2,94**	**2,29**

Chest and bones images

Sustainable impact

Pristem is dedicated to deliver true positive and sustainable solutions for both healthcare and social concerns.

Our Cristalix-T1, together with our Open Diagnostics centers directly improve the lives of underserved communities, by bringing medical imaging services closer to patients. This also contributes to the reduction of mortality and morbidity caused by chronic and communicable diseases.

From a social perspective, the deployment of the Pristem digital radiographic system and the Open Diagnostics centers, bring benefits in terms of inclusive and meaningful employment. By recruiting and training local people, Pristem will increase the number of trained healthcare professionals in the sphere of radiology.

As such the Pristem Cristalix-T1 is a perfect fit for the healthcare landscape in South Africa and beyond.

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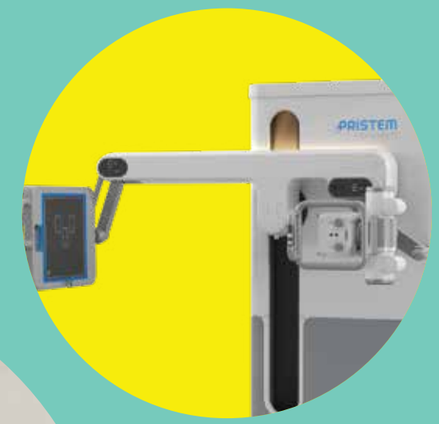

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