DELFT IMAGING

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EasyDR Whitepaper

The impact of multipurpose X-ray system for TB screening and beyond

Building a brighter future through innovation

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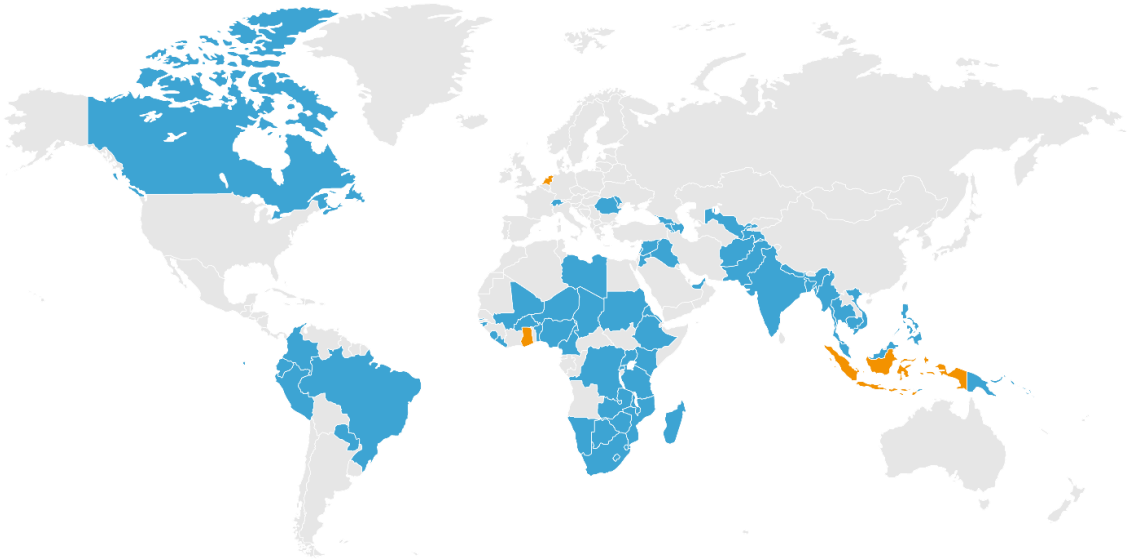
Contents

Preface

This whitepaper is to support the Ministries of Health (MoH) and National Tuberculosis Programs (NTP) in the selection, incorporation, and implementation of multipurpose stationary X-ray systems for TB screening and triage as well as general radiographic examinations, particularly in resource-constrained settings. The document outlines the technical information and case study of EasyDR, a digital X-ray system based on the World Health Imaging Systems (WHIS-RAD). This document aims to guide the selection of optimal digital X-ray systems based on the clinical needs, local infrastructure, operational environments, human resources, and budgets/total cost of ownership.

About us

Delft Imaging is a social enterprise headquartered in the Netherlands with regional offices in Africa and Asia. We are committed to eradicating tuberculosis by promoting health equity, providing reliable and sustainable diagnostic imaging solutions to emerging countries, and harnessing the power of AI in healthcare.

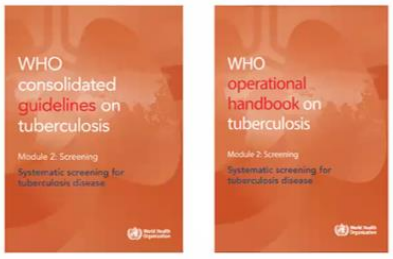


Delft Imaging has implemented TB projects in over 60 countries. With 1,200+ installations of radiology systems and CAD4TB, we are proud to say that we have facilitated the TB screening of over 14 million people globally.

1 Introduction

1.1 The Value of Digital X-rays and AI for TB and Health Systems Strengthening

Chest X-ray (CXR) plays a critical role in the early detection of TB. It is fundamental to achieving the targets outlined in the WHO End TB Strategy and consolidated guidelines on TB[i].



> *CXR was found to be a sensitive screening tool that has an important role in the early detection of TB in children and adults who are at higher risk of TB, as well as potential to reduce the population burden of TB diseases when combined with early treatment.*
>
> **WHO consolidated guidelines on tuberculosis Module 2: Screening**

Strategic documents by key stakeholders highlights the importance of CXR. The Global Fund Strategy (2023-2028)[ii] and the TB Information Note[iii] underline the role of digital X-rays in early and accurate TB diagnosis, with an emphasis on finding missing people with TB and prioritising screening interventions. The latest plan includes scaling up and improving systematic screening for TB with more sensitive CXRs and CAD software.

Additionally, the value of X-rays for integrated and multi-disease screening plus diagnosis within respiratory care and case management services is mentioned in the context of Resilient and Sustainable Systems for Health, Community System Strengthening and Pandemic Preparedness.[iv]

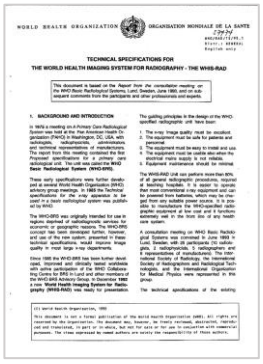
The Stop TB Partnership's Global Plan to End TB 2023-2030[v] highlights the importance of leveraging modern technologies. Solutions such as CXRs with CAD enhance the rapid detection of TB and expand early diagnosis, including at sub-clinical stages. The plan underlines the excellent value of digital CXRs for pulmonary TB screening in combination with confirmatory tests, especially in populations with high TB rates.

The USAID's Global TB Strategy 2023-2030[vi] aims to maximise TB detection in individuals of all ages by increasing access to new technologies, such as portable digital X-rays with AI.

Specifically, in low-resource settings where radiology and imaging services is limited, Artificial Intelligence (AI) enabled CAD software can significantly improve how we practice medical imaging and holds great promise. Despite some challenges to its successful deployment in clinical practice, Delft Imaging has gained considerable experience deploying cutting-edge yet simple-to-use technology in low-resource settings. We have successfully facilitated TB screening and triage of over 14 million people globally.

CAD4TB in Nigeria

1.2 WHO's World Health Imaging System for Radiology (WHIS-RAD)



In 1995, the World Health Organization (WHO) released the **Technical Specifications for the World Health Imaging System for Radiology** (WHIS-RAD) for a multifunctional X-ray. According to WHO, the WHIS-RAD is "intended for use in primary care and at first-level referral hospitals. It is especially suited for use in small rural hospitals and large health care centres but serves well also in X-ray departments of large hospitals, especially as a first-choice unit for examinations using a horizontal X-ray beam.[vii]"

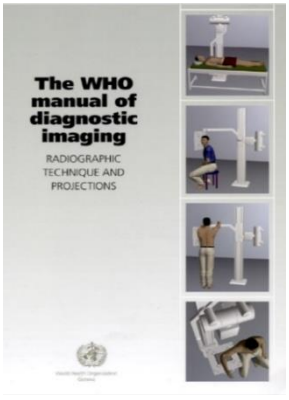
The guiding principles in the design of the WHO-specified radiographic unit have been:

1. The X-ray image quality must be excellent.
2. The equipment must be safe for patients and personnel.
3. The equipment must be easy to install and use.
4. The equipment must be usable even when the electrical mains supply is unreliable.
5. Equipment maintenance should be minimal.

Furthermore, WHO released the Consumer Guide for the Purchase of X-ray Equipment.[viii] It states that **the X-ray equipment of choice at the first referral level is the WHIS-RAD unit**. Such a WHIS-RAD system allows increased accuracy, reproducibility, and less radiation dose to patients and personnel than with any other X-ray unit.

> *The WHIS-RAD unit is the only X-ray unit needed at a primary health care centre or in a small hospital at the first referral level. Any other X-ray unit, which does not meet the WHIS-RAD specifications would be a questionable investment".*
>
> **WHO's Consumer guide for the purchase of X-ray equipment**

Additionally, **the WHO Manual of diagnostic imaging: radiographic technique and projections**[ix] is designed for the use of multipurpose X-rays systems that comply with WHIS-RAD. The manual also includes technical specifications for the WHIS-RAD equipment. The guidelines cover various important aspects such as maintenance, radiation protection and patient care.



2 EasyDR

EasyDR is a multipurpose stationary X-ray system that is designed in accordance with the WHIS-RAD. It is ideal for chest imaging and equally well-suited for general radiographic examinations. Compact, easy to install, and durable, it is a highly robust system that can be installed in small X-ray rooms, mobile vehicles or containers. These features make it highly beneficial for deployable field requirements.

The EasyDR can perform every form of X-ray examinations on all body parts at primary healthcare clinics as well as 95 % X-ray examinations at district hospitals. It eases radiographic imaging for the following patient positioning: erect, supine, prone, decubitus, oblique and lateral of all body parts.

Proving its reliability in various settings globally, the EasyDR can perform **over 300 exposures per day**.

The EasyDR is designed according to the WHIS-RAD. In fact, it exceeds the WHO technical requirements. For instance, EasyDR was designed with a fixed SID of 145 cm, a motorised up/down and rotation movement, and a fully integrated X-ray system (single console operation). These features mitigate potential points of failure, ultimately reducing the risk of system downtime and costly maintenance expenses.

(Top left) EasyDR in X-ray room in Bangladesh
(Top right) EasyDR in containerised clinic in Ghana
(Bottom) EasyDR in X-ray room in Sierra Leone

2.1 Advantages of the EasyDR

- **Meet the WHO WHIS-RAD specifications:**
  Provides high-quality images, is safe to use, reliable as well as easy & simple to learn and operate.
- **Multifunctional:**
  The U-arm can be positioned both vertically and horizontally, enabling all X-ray examinations at primary healthcare clinics and 95% at district hospitals.
- **Robust and easy to install:**
  Installation time is only one day, and can be installed in a small X-ray room. It can also be installed in a container, a truck or a van to deploy hard-to-reach areas.
- **Easy to operate:**
  Relatively little experience is needed for the output of high-quality images with the Automatic Exposure Control and automatically aligned detector as well as X-ray beam.
- **Powered by solar energy**:
  An integrated power pack enables continuous operation in case of grid power failures.

The EasyDR consists of Canon's proven reliable detector and imaging software. Canon Flat Panel Detector has a single-tile construction for ultimate convenience, quality, and reliability. It ensures high sensitivity for the lowest patient dose. Canon CXDI-NE Imaging Software is integrated with an X-ray generator and provides high-resolution images at the lowest possible dose.

Additionally, Delft Imaging was the first provider of solar-powered digital X-ray systems. The EasyDR power supply uses single-phase 220V to facilitate solar power packs and electricity spikes protection. The solar power packs support service availability, stability, and financial sustainability. No carbon fuels are required to operate our X-ray solutions, thus contributing to reducing operating costs and CO2 emissions.

(Left) Solar-powered EasyDR in a containerised clinic in Ghana
(Right) Solar-powered OneStopTB clinic (Wellness on Wheel) in Nigeria

2.2 Service & Maintenance

The EasyDR digital X-ray allows ease of use, high maintainability, and uptime. The system's basic designs fully benefit from the latest digital imaging technology and comprise a few moving parts. Maintainability of the EasyDR is high in case of system failure: built-in test equipment and software can identify the faulty component. In case of failure, these components can be swapped on-site. No "break and fix" maintenance services are required, allowing for rapid repair and higher uptime.

First-line

This is typically done by hospital engineers or technicians who are as close to the end user as possible to ensure the highest possible uptime. After basic training, they can restart or reset the system, do minor repairs, such as replacing fuses and light bulbs, and solve minor software problems. They can also perform preventive maintenance routines such as cleaning and calibration.

Second-line

This is typically done by trained (in-country) bio-medical engineers or IT personnel. After training, these engineers can do essential repairs such as replacing an X-ray tube and motors, calibrating the X-ray system and (re) installing software.

Third-line

This is the manufacturer's support. In some cases, a problem is not easily identified or cannot be solved timely. For those problems, Delft Imaging has over 20 highly qualified and certified engineers who can be on-site in a matter of days. Furthermore, our state-of-the-art global customer service centre is available for customer support. Most of the installed equipment and software can be monitored over the internet in real-time, making the remote diagnosis of upcoming problems or reported maintenance needs a real option.

2.3 Capacity Building

Healthcare technology is developing rapidly, with new models of medical equipment appearing almost every year. In order to warrant uptime and system usability, health professionals need to operate this new range of digital medical equipment effectively. Several on-site and remote training programs are available and integral to every 'digital X-ray project'. Furthermore, e-learning modules of several key system components are available free of charge.

3 Considerations to Select Optimal X-ray Systems

Chest X-ray (CXR) plays a critical role in the early detection of TB. It is fundamental to achieving the targets outlined in the WHO End TB Strategy. Moreover, it is a crucial component of resilient and sustainable systems for health and future pandemic preparedness.

A range of stationary digital X-ray systems is available for multipurpose screening. Each system has distinct strengths and benefits along with important considerations such as operational features, environments, human resources, maintenance, and total cost of ownership. Thus, it is crucial to consider the following points when selecting an X-ray system:

- Programmatic goal and facility's intended use

The use of X-ray technology can be an effective way to provide diagnostic imaging for a variety of medical conditions. Thus, it is vital to understand the programmatic goal and the health facility's needs to determine the optimal X-ray. When selecting an X-ray system, it is essential to carefully consider the target number of screens in a specific screening strategy. For instance, the expected daily throughput of the sites can be categorised based on the level of throughput: e.g. low (50 exposure per day), medium (200 exposures per day) or high (over 300 exposures per day). Additionally, there is a trade-off between portability, daily throughput, and the coverage of radiological exams.

The EasyDR is a multipurpose stationary X-ray system suitable for primary health clinics and district/regional hospitals. The robust system can perform high throughput (over 300 exams per day) and allow 95% of all radiological exams. The EasyDR is also a proven digital X-ray system to install in a mobile clinic or a van (OneStopTB clinic), enabling deployment in hard-to-reach areas.

- Space requirements

It is crucial to consider the physical space where the stationary X-ray system will be installed and comply with any relevant national regulatory requirements. In comparison to other stationary X-ray systems, EasyDR is compact and simple. It can be effortlessly assembled and installed within a compact area, such as a single block on the X-ray room floor. Its versatility allows for assembly even in limited spaces, making it suitable for installation in mobile vehicles or containers with a restricted room.

- Installation & Operation settings

Generally, robust X-ray systems require installation considerations. But the EasyDR system comes as a single component. Therefore, installation is simpler and only requires one day to complete. The EasyDR uses single-phase 230 VAC, and when external power sources are unstable, one can source the system with the help of a solar power pack.

- Environments

Even though the EasyDR is robust and durable, environmental factors such as temperature and humidity should be considered.

- Human Resources

Limitation of human resources can be a significant challenge in resource-constrained settings, as there may be a shortage of qualified radiographers, healthcare professionals, X-ray technicians and IT staff.

Operating an EasyDR is simple and easy for radiographers since relatively little experience is required to produce high-quality images. This is thanks to the Automatic Exposure Control with an automatically aligned detector and X-ray source. It helps to assure optimal imaging geometry and eliminates the negative influences of variable distance and angulation, contributing to fewer exposures for a sufficient X-ray image.

- Capacity Building & Training

Healthcare professionals must receive appropriate training on how to operate and maintain the system safely and effectively, as well as minimise radiation exposure. Therefore, training and capacity building are key for both theoretical and practical aspects of digital X-ray systems. The EasyDR requires a basic level of radiology knowledge.

Radiologists may not be required on-site when CAD software is used for TB screening and triage.

- Support and Maintenance

For optimal system uptime and seamless operation, a supplier should offer a high-standard maintenance contract or extended warranty service agreement, in collaboration with a trained local service partner in the country. It is critical that the maintenance strategy, including inspection, corrective and preventive maintenance, is in place.

- Budget and the Total Cost of Ownership

The costs of X-ray systems vary greatly depending on the modalities. Thus, selecting a system that meets the needs and is value for money is vital.

When selecting and budgeting X-ray systems (with/without CAD), the total cost of ownership (TCO) and economics per screen are critical considerations. The TCO means the total amount of all direct and indirect costs related to the procurement, distribution and operation of a diagnostic product. The implementers are advised to consider the TCO of the equipment, including capital expenditure of the equipment, training/installation costs, the useful life of the equipment, necessary consumables, and maintenance costs. This includes training, maintenance and service costs as part of the TCO is advised.

4 Case Study: Ghana

Various X-ray specialists recognise the EasyDR as well-designed for sustained operations in resource-constrained settings. Its rapidly growing installed base, new clients and repeat orders from TB programs prove it. The following case study demonstrates the reliability of the EasyDR for continuous operations and diagnostic impact, especially in resource-constrained settings.

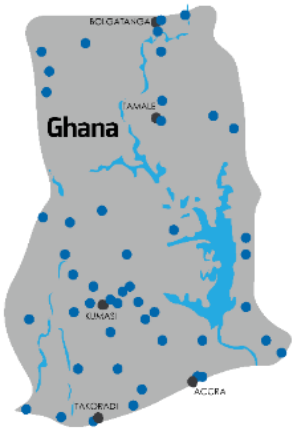
Ghana ORIO Project: Acceleration of TB Case Detection

In February 2016, the Ghanaian government approved one of the largest eHealth projects in Africa to date: "Acceleration of Tuberculosis Case Detection in Ghana". The project aimed to support the early detection of pulmonary TB, deliver diagnostic testing in an efficient and affordable manner, and strengthen the Ghanaian health systems.

With the support of a Dutch Government's ORIO facility, Delft Imaging executed the project, including system installation, project management, training and maintenance. We installed 52 EasyDR multipurpose X-ray systems across Ghana, equipped with CAD4TB and teleradiology interlinked to a central database and diagnostic viewing station.

Most of these systems were installed by the end of 2017, and others were installed in 2018 or later. Over 400 health professionals have since participated in the capacity-building program.

The project covers the initial warranty period of two years, followed by the Operations and Maintenance Period for an additional five years. Service and support include corrective maintenance and periodic planned preventive maintenance of all EasyDR X-ray systems (including other existing systems), CAD4TB and viewing stations.



Project Summary

- 52 X-ray systems across Ghana, all using CAD4TB software and teleradiology:
  - 30 EasyDR in containers
  - 20 EasyDR in X-ray rooms
  - 2 EasyDR in OneStopTB clinics
- Capacity building, including radiographer training.
- A total of seven-year service & maintenance support.
- Also used for the COVID-19 Pandemic.

The project was featured in BBC World News (2017)

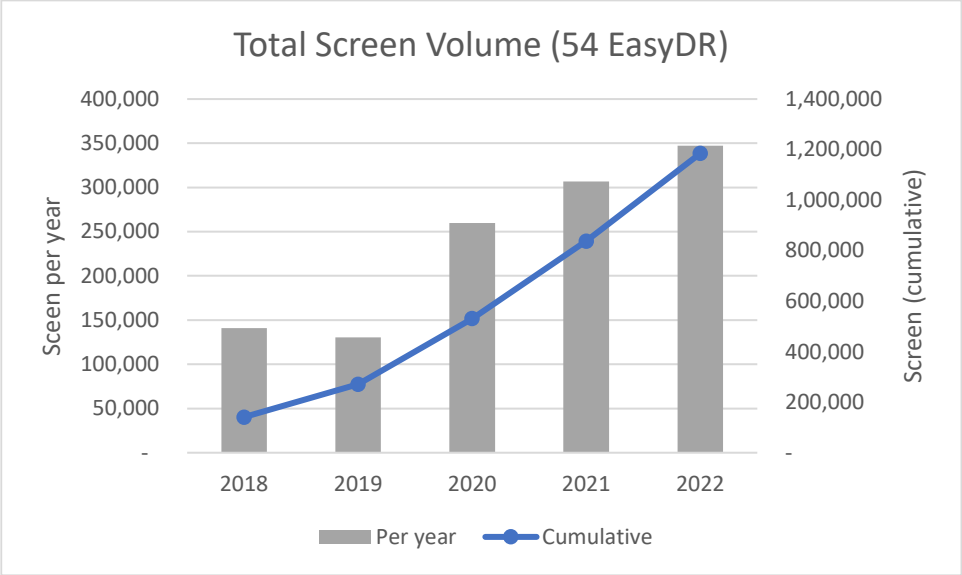
DIGITAL INNOVATION TO REDUCE THE SPREAD OF TB IN GHANA.


EasyDR and Containerised clinic


EasyDR in an X-ray room and CAD4TB

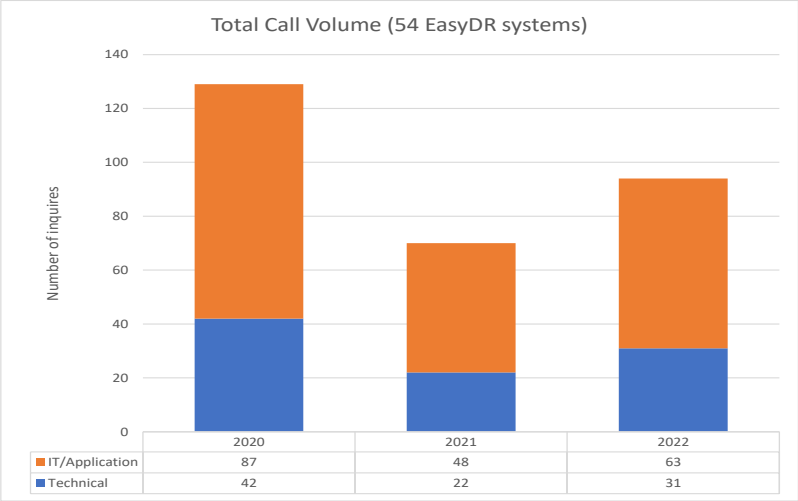
4.1 Performance Overview

Most of the EasyDR were installed in the end of 2017, and started operation in 2018. The annual total screen volume trends in the last five years show that the screen volume has been increased steadily. This trend strongly suggests that the EasyDR systems have been operating continuously, and clients have actively patronised using the X-ray systems.

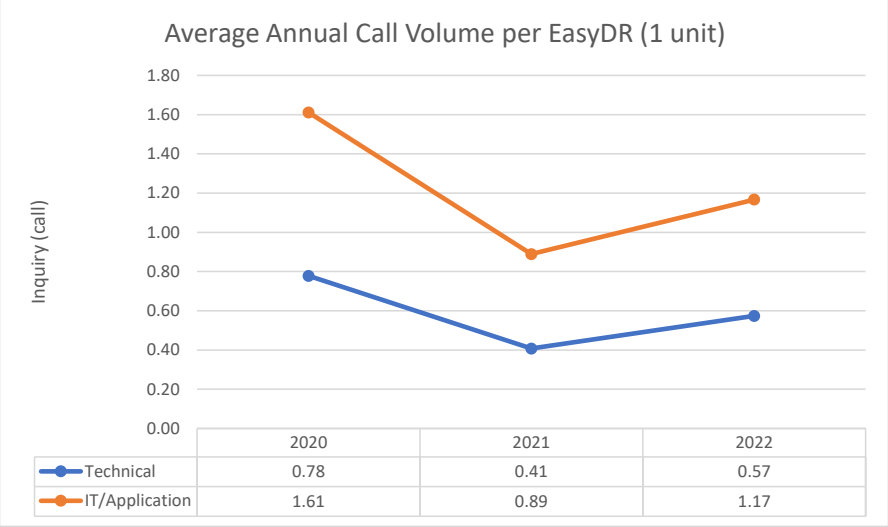


4.2 Corrective Maintenance

The corrective maintenance addresses technical and IT/Application issues. The technical maintenance includes any technical-related issues of the EasyDR, and the IT/Application includes network-related issues, software & licenses, Canon-related applications, and printer. The resolution type is remote resolutions, all done remotely or on-site resolutions, which Delft engineers do in-person. In the past three years, on average, there were more IT/Application-related inquiries (68%) than technical-related inquiries (32%).



Frequency of Inquiries



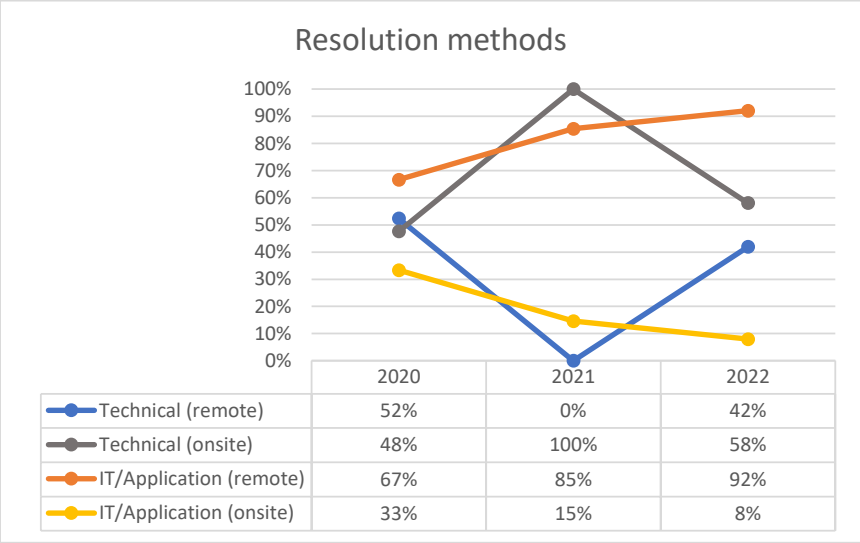
1.22 calls/year
For IT/Application issues (3yrs ave.)

0.59 calls/year
For technical issues (3yrs ave.)

From 2020 to 2022, there were an average of 66 inquiries for IT/Application yearly for the 54 units of EasyDR (2020: 87 calls, 2021: 48 calls, 2022: 63 calls). This indicates that, on average, 1.22 calls were for IT/Applications per EasyDR system annually. Meanwhile, on average, there were 31 technical inquiries per year for the 54 units of EasyDR (2020: 42 calls, 2021: 22 calls, 2022: 31 calls). This means that, on average, 0.59 calls were for technical issues per EasyDR system annually. **These meagre numbers confirm that the EasyDR is reliable for continuous operation with minimal technical issues.**

Resolution Methods

In the past three years, most IT/Application issues were resolved remotely (2020: 67%, 2021: 85%, 2022: 92%). Meanwhile, the technical-related inquiries were resolved by on-site support (2020: 48%, 2021: 100%, 2022: 58%).



	2020	2021	2022
Technical (remote)	52%	0%	42%
Technical (onsite)	48%	100%	58%
IT/Application (remote)	67%	85%	92%
IT/Application (onsite)	33%	15%	8%

Resolution Time

In 2022, the average resolution time for IT/Application issues was within a working day, and the average resolution period for technical issues was within two working days. When the resolution took longer, they were primarily due to spare parts (e.g. batteries) that needed shipping from outside Ghana. The issues were resolved immediately once the spare parts were available.

<1 day
To resolve IT/Application issues

<2 days
To resolve technical issues

4.3 Planned Preventive Maintenance

The Delft Imaging Ghana team and the Clinical Engineering Department of Ghana Health Service (GHS) conduct annual on-site visits for the maintenance work at all sites. The maintenance work is based on the maintenance protocol approved by GHS. This includes mechanical inspection, software version verification, electrical inspection, dose measurement, X-ray field alignment, system calibrations (tube and detector) and image quality tests. For the containerised systems, an additional maintenance protocol for the solar panels, battery pack and the container itself was adhered to.

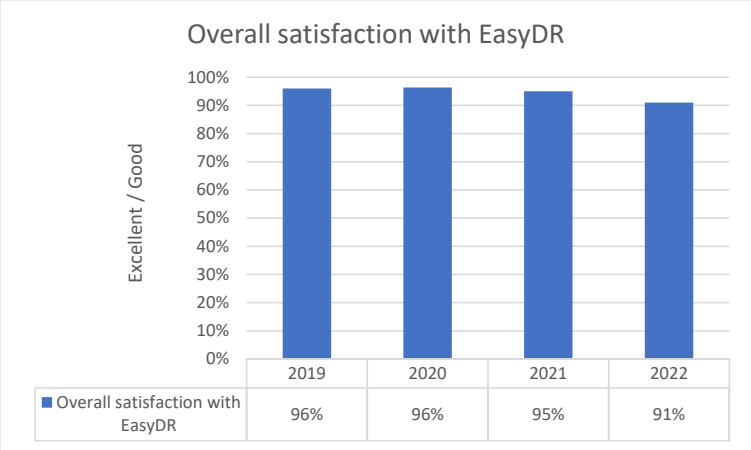
Additionally, an on-site capacity-building program is provided annually for engineers and IT staff of the Ministry of Health and GHS. Different key themes are applied each year to ensure that daily operations and maintenance of the EasyDR, as well as the use of communication systems, are

done effectively. The training sessions also invite local hospital engineers, radiographers, IT staff, and regional engineers to ensure that practical knowledge and new updates or features are well-informed. These on-site training facilitate knowledge and skill transfer among health professionals and contribute to the continued patronage of the EasyDR.

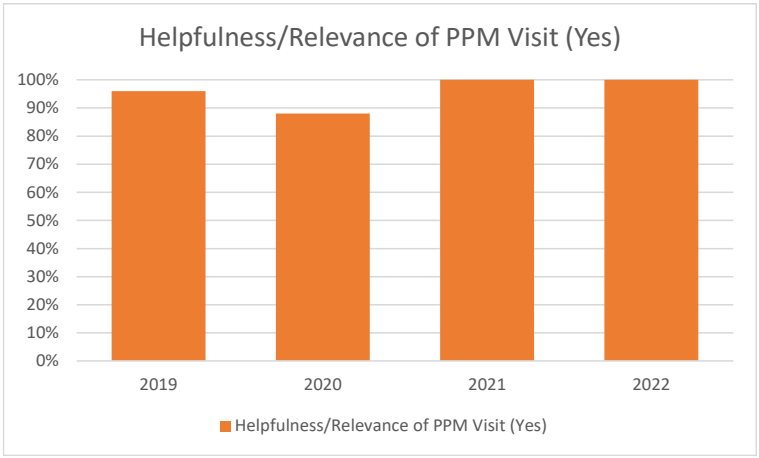
4.4 Client Survey

During the planned preventive maintenance visits between 2019 and 2022, the Delft Imaging team in Ghana conducted customer surveys. The average response rate was 48%. In most years, respondents were radiographers, engineers, medical superintendents, IT officers and administrators, among others.

The survey results show that clients remain satisfied with EasyDR's performance (95% of Excellent and Good on average). Additionally, most clients find the planned preventive maintenance at their facilities extremely relevant and helpful in carrying out their operations (96% positive on average).



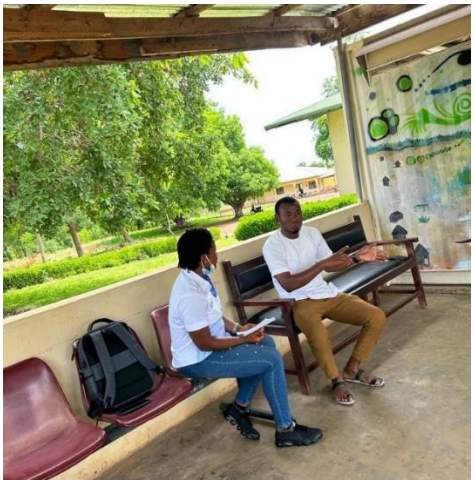
95%
Excellent/Good satisfaction with EasyDR



96%
Clients found helpfulness / relevance of PPM

Survey questions & findings (2019-2022 on average)

Question	Finding
How satisfied are you with the overall service?	98% Excellent and Good - satisfaction with the service.
How satisfied are you with the overall performance of the EasyDR?	95% of Excellent and Good - satisfaction with the EasyDR.
How relevant and helpful is our visit for your job/organisation?	96% found PPM as very important.
Were you adequately informed about our visit?	89% affirmed adequately being informed.
Did we inform you in time concerning our visit?	88% affirmed receiving timely communication.
Did our engineers report on the specified day as planned?	83% assented to good planning & communication.
Did you have problems with the machine before our visit?	24% affirmed having issues before PPM.
Did the engineers successfully answer all your questions?	99% confirmed satisfaction with how issues were addressed.
Did our engineers report what they did?	94% Affirm the accuracy of the PPM report.
What do customers say they like about Delft Imaging Ghana?	Many rated "professionalism" followed by "promptness" and "communication."



(Left) Kumasi South Government Hospital
(Right) Client interview at Wechiau Government Hospital

4.5 Voices of Partners

We conducted a customer survey during the PPM for 2023 and received the following feedback:

The Easy DR system has made working easier. I can work faster and reduce patient waiting times.

Before we got the Easy DR system, the hospital had an analogue X-ray system. Having the Easy DR system was, therefore, very impactful. Image quality and resultant radiological diagnoses have greatly improved.

Frederick Damptey, Senior Radiographer
Kumasi South Hospital

The Easy DR X-ray system has benefited the community and other adjoining communities mostly in the diagnosis of TB screening in real-time.

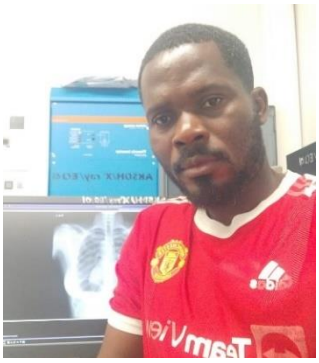
Vincent Anafo, Junior Radiographer
Bolgatanga Regional Hospital

The Easy DR makes work faster and easier with regard to attending to patients and clients.

Mohammed Atif Sidik, X-ray Operator
Wa West District Hospital

Easy detection of TB cases which has encouraged rapid response of the facility.

Cornelius Botchway, Clinical Engineering Manager
Effiduase Government Hospital



The EasyDR X-ray is helping the community and the hospital. TB cases are now treated in our facility.

Joshua Omega, X-ray Technician
Akatsi District Hospital

5 Conclusion

This whitepaper outlines the technical information of the EasyDR, a multipurpose stationary digital X-ray system based on the World Health Imaging Systems (WHIS-RAD). It offers guidance on selecting the most suitable system based on the clinical needs, local infrastructure, operational environments, human resources, and budget or total cost of ownership.

The advantages of the EasyDR are highlighted:

- **Meet the WHO WHIS-RAD specifications:**
  Provide high-quality images, safe to use, reliable and easy & simple to learn and operate.

- **Multifunctional:**
  The U-arm can be positioned both vertically and horizontally, enabling to perform all X-ray examinations at primary healthcare clinics and 95% at district hospitals.

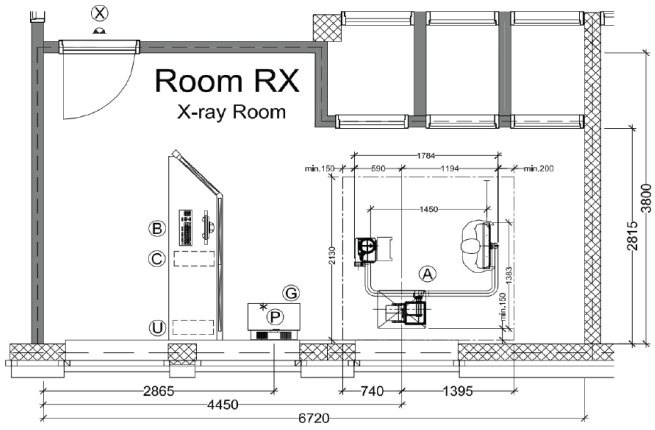
- **Robust and easy to install:**
  Installation time is only one day, and possible to install it in a small X-ray room. It can also be installed in a container, a truck, or a van to deploy hard-to-reach areas.

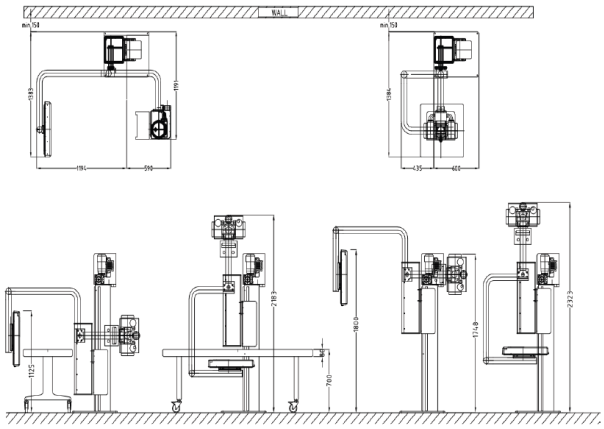
- **Easy to operate:**
  Relatively little experience is needed for the output of high-quality images thanks to the Automatic Exposure Control and automatically aligned detector and X-ray beam.

- **Proven solar-powered X-ray**:
  An integrated power pack enables continuous operation in case of grid power failures.

The case study of Ghana showcased 54 units of EasyDR installations across the country. Despite such a large-scale implementation, including in remote areas, the performance overview shows that support & service by Delft Imaging Ghana help ensure EasyDR's continuous operation with minimal technical challenges. Furthermore, the Planned Preventive Maintenance and periodic capacity building confirm high maintainability, uptime and constant patronage from the clients. The EasyDR systems contribute to a significant diagnostic impact on TB case findings, other general health examinations as well as the pandemic response, leading to a more robust health systems in Ghana. Additionally, the client surveys show that users have been pleased with EasyDR's ease of use, high performance, effectiveness in TB detection, and its role in the improving the quality of health services.

Annex: EasyDR Technical Specifications





EasyDR	Specification
	EasyDR (SID 145cm, chest screening and multipurpose system) Includes: • Canon CXDI-401G (GOS detector) • Canon CXDI-NE/RD software + control unit (PC) incl. generator integration • Mini-console + exposure switch • Operator display, 17" touch screen • Manual 3 knob collimation with LED (top/bottom separate knob) • Grid Unit 10:1 140cm 52 l/cm (removable) • Automatic Exposure Control (three field) • X-ray tube 150 kV, 300 kHU • Radiographic Generator 50kW/150kV Energy Assist* • HS-cable, 8 meter • Motorized movement (up/down and rotation) *Capacitor Assist generator, Single Phase 214VAC -/13%, 16A low power consumption.

References

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