DELFT IMAGING

September 2024

Delft Light Whitepaper

Ultra-Portable, Battery-Powered Digital X-ray for Decentralised Active TB Screening

www.delft.care

CONTENTS

ABOUT THIS DOCUMENT

Intended Audience

- Ministries of Health
- National TB Programs
- NGOs and Implementing Partners
- Private healthcare providers

Purpose

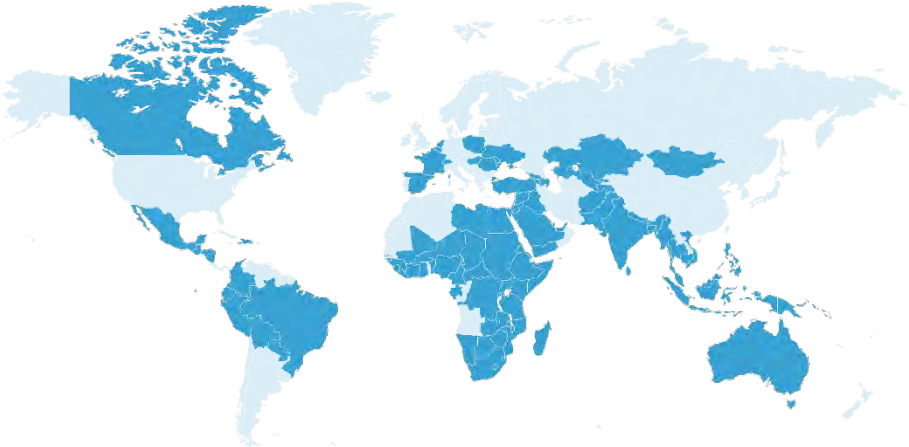
- Support planning, incorporating, and implementing ultra-portable digital X-ray systems for TB screening and triaging and for general radiographic examinations in resource-constrained settings.
- Assist in facilitating the practical implementation of Delft Light with/without CAD, considering:
  - Clinical needs
  - Local infrastructure
  - Operational settings
  - Human resources
  - Available budgets
  - Total cost of ownership

About Us

Delft Imaging is a B-Corp-certified social enterprise headquartered in the Netherlands with regional offices in Africa and Asia. We are committed to supporting the eradication of tuberculosis by promoting health equity through innovations. We provide reliable and sustainable AI-powered diagnostic imaging solutions in emerging countries.

As a total solution provider for TB screening, we offer integrated digital X-rays and AI-powered CAD solutions, as well as one-stop training, technical support services and project management.

Delft's Global Presence and Impact



80+ countries

2,300+ installations

1,000+ capacity building

31+ million impact

PRODUCT SUMMARY

Product name	**Delft Light**	
Certification	CE	
Components	Main *(29.5kg)*	• Backpack - Battery-powered X-ray generator/tube with two removable rechargeable batteries and a charger - Exposure switches • Detector Bag - Canon wireless (or wired) detector with a holder and a hanger, two batteries and a charger - Delft Light workstation (laptop) with Canon CXDI-NE Viewing Software • Tripod for X-ray generator with 360° rotation * *Different types/configurations, such as a detector stand, are available upon request.*
	Accessory	- Delft solar panel with power pack - Lead apron - Thyroid collar - 5 portable radiation warning signs - 5 portable pregnancy warning signs - Dosimeter (optional)
Intended use	• Chest • Diagnose injuries and fractures in general, trauma imaging	
Setup time	5 to 10 minutes.	
Exposure	400 exposures on fully charged batteries.	
Implementation setting	• Community outreach • Active TB case-finding • Facility-based screening • Non-facility-based screening • Prevalence surveys • Prisons/Correctional centres • Occupational health centres • IDP/Refugee camps etc.	
Use with CAD/AI	CAD4TB is a seamlessly integrated combination. Any other CAD software that accepts DICOM can be used.	
Power supply	Runs on batteries. No need for an electricity supply at the site.	
Support & Maintenance	Support & Maintenance package (1- or 3-year warranty extension) is available.	
Procurement	• Stop TB Partnership's GDF catalogue, Wambo • Direct at Delft Imaging	

KEY FEATURES & BENEFITS: Delft Light and CAD4TB as a total solution

Integration

Certification	Both solutions are CE-certified.
Technical Requirements	CAD4TB meets WHO's Target Product Profile. Delft Light meets WHO/IAEA technical specifications for portable X-ray systems.
Intended use	TB screening & triage: CE approval for adults and children aged 4 years and above.
Implementation Setting	• Community outreach • Active TB case-finding • Facility-based screening • Non-facility-based screening • Prevalence surveys • Prisons/Correctional centres • Occupational health centres • IDP/Refugee camps etc.
System Integration	CAD4TB can be pre-configurated on the Delft Light X-ray's workstation.
Deployment	Can operate at sites without an electricity supply or no internet connectivity.
Capacity Building	Integrated user training for X-ray & CAD4TB, including eLearning.
Installation	Integrated local installation support for X-ray & CAD4TB.
Contact Point	One-stop service and support contact for the total solution (X-ray & CAD4TB) via 24/7 helpdesk technical specialists in all time zones.
After-Sales Support & Maintenance	Local & remote maintenance and support by in-country service partner and Delft. Predictable lower cost of product ownership.
Procurement	Discount applies to the combined purchase of Delft Light and CAD4TB.

> *The use of the portable X-ray digital system in combination with compatible AI-powered Computer-Aided Detection (CAD) software solutions could significantly increase the diagnostic capacities of the system, efficacy and efficiency, and its appropriateness and advantages of use.*
>
> **WHO/IAEA, Portable digital radiography system technical specifications**

1. Guidelines and Policies on Using Portable Digital X-rays and AI for TB Screening

Chest X-ray (CXR) is a sensitive screening tool vital for the early detection of TB and is fundamental to achieving the targets outlined in the WHO End TB Strategy. Additionally, it is a crucial component of resilient and sustainable systems for health and future pandemic preparedness. However, its widespread utilisation was restricted by two major barriers: limited access to high-quality diagnostic digital CXR imaging and a shortage of radiologists, especially in resource-constrained settings[i].

The first barrier is now overcome through the introduction of portable digital X-ray devices. Compared to heavier-duty stationary systems fixed at health facilities, portable systems offer more flexibility in use options, making it easier to deploy them to various locations. In 2021, the WHO and IAEA published technical specifications for portable digital radiography systems and defined minimum technical requirements[ii].

The second challenge is addressed by Computer-Aided Detection (CAD), which interprets CXR accurately and improves case detection. In 2021, the WHO recommended using CAD in systematic TB screenings[iii].

Combining digital X-ray systems and CAD software can significantly improve the value of diagnostic imaging. Furthermore, portable systems present immense opportunities for community-based, decentralised active TB case finding to find the missing millions affected by TB.

Strategic documents by key stakeholders highlight the importance of CXR and CAD. **The Global Fund Strategy (2023-2028)**[iv] and the TB Information Note[v] underline the role of digital X-rays in early and accurate TB diagnosis. These documents place a strong emphasis on finding the 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. Also, X-rays are deemed valuable in the context of Resilient and Sustainable Systems for Health, Community System Strengthening and Pandemic Preparedness. They can be used for integrated and multi-disease screening and for diagnosing in relation to respiratory care and case management services.[vi]

The Stop TB Partnership's Global Plan to End TB 2023-2030[vii] highlights the need to leverage modern technologies. Solutions like CXRs with CAD enhance the rapid detection of presumptive TB and increase early diagnosis, including at sub-clinical stages. The plan highlights that digital CXRs are highly valuable in pulmonary TB screening in combination with confirmatory tests, especially in populations with high TB rates.

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

Delft Imaging is the pioneer of ultra-portable digital X-ray systems in a backpack. With our innovation CAD4TB, Computer-Aided Detection for TB, we have revolutionised TB detection in resource-constrained settings in support of finding the missing people with TB.

2. Delft Light Innovation Journey

The World's Only Total Solution Provider of X-rays and AI-powered CAD for TB

Delft's innovation journey began with the realisation that countries with high TB burdens and limited resources often lack access to X-ray services despite their critical role in screening for active TB and detecting other health conditions. We envisioned a robust, affordable, and user-friendly X-ray system that could be easily transported to hard-to-reach locations while producing high-quality images. Furthermore, we believed that combining portable digital X-rays with AI-enabled CAD software and using solar-power packs could significantly enhance the use and value of diagnostic imaging in resource-constrained settings. This integrated innovation could facilitate rapid and accurate TB screening, especially in outreach settings and at the primary healthcare level, where access to high-quality radiology services is limited.

Advances in digital imaging and software technologies have enabled the innovation of smaller, lighter, low-cost, battery-powered digital X-ray devices. These systems can produce high-quality images with low radiation doses, ensuring safety for both patients and health workers. We collaborated with Canon Medical Systems, Oldelft Benelux and local partners to introduce Delft Light to TB programmes.

The most widely used ultra-portable X-ray system by TB programmes

Since the first installation in Eritrea in 2018, Delft Light has gained traction for TB screening in Africa and Asia. Subsequently, Delft Light's global presence, alongside CAD4TB, has expanded significantly since the *introducing New Tools Project (iNTP),* supported by USAID and the Stop TB Partnership. As part of this initiative, we provided 55 Delft Light and 63 CAD4TB boxes, including installation and user training, in seven countries. These digital tools are now being deployed globally at scale with funding from the Global Fund and USAID, demonstrating a high impact on incremental TB case notifications.

A wide range of digital X-ray systems, including ultra-portable, mobile and stationary systems, has been designed mainly for TB screening and triage. This allows TB programs to select a suitable system for various settings. **Delft is the world's only total solutions provider, offering a wide array of X-ray systems integrated with AI-powered CAD4TB and solar-powered battery packs**. We have gained considerable experience deploying cutting-edge yet simple-to-use solutions in resource-constrained settings.

3. Delft Light

Delft Light is a battery-powered ultra-portable digital X-ray system. It comes with a powerful yet lightweight portable X-ray unit for high-quality X-ray images. It is easy to set up and especially suited for TB screening at/outside health facilities or in hard-to-reach areas.

Delft Light is CE-certified and meets WHO/IAEA technical specifications for portable digital X-rays (2021).

Advantages of the Delft Light

- **Higher Throughput**

  Reliably performs 400 exposures per day on fully charged batteries. Cost-effective and highly productive compared to a similar range of ultra-portable systems.

- **Multifunctional**

  It is ideal for chest X-rays but can also be used to image extremities and support trauma care through the imaging of injuries and fractures.

- **For Adults, Children and Infants**

  The additional adapter enables the screening of children and infants.

- **Fully Battery-Operated**

  The system, including an X-ray generator and a wireless (or wired) detector, runs on high-capacity, lightweight removable batteries that can be charged by the Delft portable solar panel or the grid.

- **Highly Durable**

  The X-ray system is robust and reliable for use in resource-constrained settings with high ambient temperatures and humidity.

- **Simple to Setup and Use**

  The system can be taken to multiple locations and easily be set up or dismantled in 5 -10 minutes. A laser pointer supports proper collimation in any surroundings.

- **Highly Sturdy and Portable**

  The complete system weighs 29.5 kg.

  The components are packed in sturdy, waterproof transport cases. The entire system can be easily transported to multiple locations by car, motorcycle, or boat for temporary use.

- **Powered by Clean Solar Energy**

  The Delft solar panel can charge all subcomponents of the Delft Light.

- **No Need for National Grid or Diesel Power**

  There is no need for access to the national grid or a diesel power generator for electricity supply at the site.

- **Radiation Safety**

  Delft Light can be safely used for TB screening, both for individual patients and radiology staff, when adequate precautions are taken.

- **Compatible with CAD/AI**

  CAD4TB can be pre-configurated on the Delft Light X-ray's workstation.

  Other CAD software can be used with Delft Light.

- **One-Stop Integrated Training, Installation Support and Service**

  Combined Delft Light and CAD4TB enable streamlined delivery, capacity building, helpdesk, and after-sales assistance for seamless implementation support.

- **Global Track Record**

  Delft Light is used in over 30 countries, making it the most widely used ultra-portable X-ray system by TB programmes worldwide.

3.1 General Description

Battery-operated X-ray unit

The battery-operated lightweight X-ray unit is designed to provide excellent performance and convenience in diagnostic imaging. Its total weight, including the battery, is only 7.2 kg, ensuring versatility in its usage.

The X-ray unit runs on a high-capacity Li-ion battery capable of over 200 exposures on a fully charged battery. **Delft Light includes two (2) batteries, allowing the system to capture 400 exposures.**

The unit is equipped with a Toshiba X-ray tube capable of producing X-rays of up to 90kV, ensuring high-quality imaging. It follows radiation protection standards, safeguarding patients and healthcare providers.

Enhanced Durability

The X-ray unit features an innovative impact-resistant construction, ensuring longevity even in high-throughput screening settings with frequent transportation. Its DR interface enables seamless connectivity and integration with digital imaging systems.

User-Friendly Features

- Operator-friendly design with a centred balance point, ensuring ease of handling during examinations in various settings.
- Hand switch to activate the collimator light.
- Collimator with format pre-adjustment, dual laser pointers and a spirit level.
- Digital display allows users to check and adjust exposure settings and control parameters such as mAs, sec., and kV.
- Battery charging status indicators.
- LED display for “X-RAY”, “READY”, and “ERROR” notifications.
- Five memory buttons simplify operation for quick and easy access to frequently used settings.
- Sound and light signals during exposure to enhance its usability in clinical practice.

Canon CXDI Wireless (or Wired) Detector

The Delft Light features the **Canon CXDI 703, a wireless digital X-ray detector**. Renowned for its robustness and superior image quality, this advanced flat panel detector converts X-rays into high-quality digital images while ensuring operational uptime.

In daily practice, detectors may accidentally fall or bump. However, the shock-resistant, robust design of the Canon CXDI 703 ensures an uninterrupted workflow. Furthermore, the user-friendly detector simplifies operation; its intuitive software streamlines the setup of various radiographic examinations. The integration of Canon CXDI-NE Imaging Software with the Delft Light X-ray unit ensures constant high-resolution images at the lowest possible radiation dose.

Canon NE Software and Work Station

Together with the CANON detector, we provide the **CANON CXDI NE software**, which is installed on the Delft Light workstation (laptop). The software allows for the fast and easy setup of any radiographic examination.

Key features include:

- Pre- and post-processing tools such as zoom, rotate, flip, and magnifier.
- Noise reduction and advanced edge enhancement, which improve the visualisation of details.
- Scatter correction feature reduces the effect of scattered radiation and lowers the required dose for X-ray examination by >50%. This is achieved by a superior level of post-image processing, allowing for the use of lower radiation exposure parameters (e.g. Kv, mAs).

Delft Solar Panel

The Delft Light can be recharged using the Delft solar panel with an integrated power pack. The internal battery can recharge all required subcomponents, including the X-ray tube and detector batteries, laptop, and CAD4TBbox. The integrated solar panel or the GRID can recharge the internal battery.

The power pack mitigates the risks of an unstable grid power supply with spikes in voltages that can cause faulty parts.

Delft Light Tripod with 360° Rotation

Delft Light comes with a lightweight, robust X-ray generator stand that can be easily adjusted, installed, and dismantled within minutes. The tripod is made of high-quality, corrosion-resistant aluminium, ensuring safety and stability to hold the X-ray generator.

Adapter for Comprehensive Exams, also for Children & Infants

With the additional adapter, this stand becomes ideal for various imaging applications, including chest X-ray exams and other body parts such as foot, arm, and ankle.

It is well-suited to screening children and infants, as the adapter allows the generator to rotate 360 degrees on both the X and Y axes.

Patient Registration and Image Exposure

Unique patient registration is an essential aspect of any TB screening project and can be done in different ways:

Barcode Scanner: The Delft Light can be equipped with a barcode scanner attached to the operator workstation. The barcode scanner acts like a keyboard, and when a unique barcode is scanned, the 'barcode number' appears on the patient information screen. This method has been used for the national TB prevalence study in, e.g. Zambia and Ghana. It prevents the need to enter the same information multiple times during the screening process.

DICOM Modality Worklist: The Delft Light offers the option to connect an external patient information system via the operator's laptop. Once registered, the participant or patient information can be retrieved on the operator workstation with a DICOM modality worklist connection.

3.2 Scientific Validation

Several studies and publications highlight Delft Light's operational effectiveness and reliability.

Publication Highlights

Improved TB Case Detection

Delft Light portable digital X-ray and CAD4TB, in parallel with the WHO 4-symptom screen (W4SS), achieved a lower pre-diagnostic loss of presumptive TB cases. Additionally, the W4SS + portable X-ray with CAD screen-based intervention was more efficient for TB case yield: four times the number of TB cases yield than symptom-only-based screening intervention.

[Babayi et al., Public Health Action, 2023]

Decentralised TB Screening

The technology was overall perceived as a tool to decentralise TB screening and triage in programmatic settings ranging from facility-based triage to hard-to-reach areas.

[Qin et al., PLOS ONE, 2023]

Community-Based Active Case Finding

TB screening using Delft Light Backpack X-ray and CAD4TB during community-based ACF in hard-to-reach Niger Delta communities of Nigeria showed a high TB prevalence among participants. Nationwide deployment of the instrument in hard-to-reach areas is recommended.

[Odume. et al., Public Health Action. 2022]

Radiation Safety of Ultra-Portable X-rays

Ultraportable X-ray devices can be safely used for TB screening when using adequate precautions.

In most cases, the total radiation dose of ultraportable X-ray devices can be kept below 1 mSv/year by employing basic radiation safety rules: 1. reduce time in the X-ray field, 2. increase distance to the X-ray source, and 3. use shielding measures (e.g. lead apron).

[Paulis. et al., 2024]

3.3 Deployment

Compared to stationary X-ray systems, Delft Light is compact and designed for easy transportation and set-up, making it suitable for use in various settings and locations.

Due to its nature, there is no 'standard' operational setup for the Delft Light. Therefore, it is crucial to consider where and how to use the system. The setup will always depend on the venue selected, the amount of space, patient flow, etc.

Examples of Delft Light Transportation

Car | Motorcycle | Boat | On Foot | Tricycles

By Car

On Foot

By Rickshaw

By Boat

Examples of Delft Light Setup and Power Supply

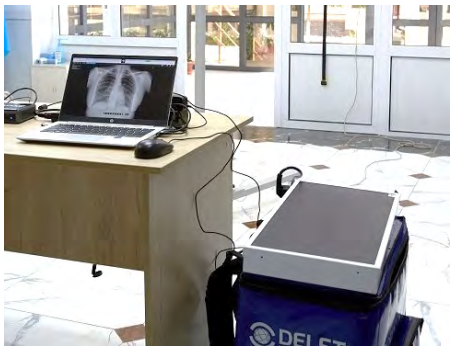
Health facilities	Community Centre	Prison	Tent	Solar Panel

Implementation in the field

Community outreach		
TB screening event		
Migrant screening		
Health facility		

3.4 Integration with AI-powered CAD Software

The integration of Delft Light with CAD4TB offers several distinct benefits and facilitates a more seamless implementation. Additionally, Delft Light is compatible with other CAD software.



Advantages of Delft Light with CAD4TB		
	Pre-configuration	CAD4TB can be pre-configurated on the Delft Light X-ray workstation (laptop).
	Streamlined Registration	Integrating patient data from CAD4TB into the DICOM Modality Worklist eliminates manual entry on the X-ray console.
	Results Display	Users can also see CAD4TB results on the X-ray workstation.
	Diagnostic Connectivity & Integration	TB screening data (case-based and aggregate) can be seamlessly sent to the National TB platform.
	Solar Power Pack	The Delft solar panel can charge both the Delft Light subcomponent and the CAD4TBbox.
	One-Stop Contact Point & Help Desk	A single point of contact and helpdesk supports the procurement, delivery, installation, training, support, and maintenance of Delft Light and CAD4TB. This ensures quick responses, short resolution times, and low total cost of ownership.

Procurement Channel

The Delft Light and CAD4TB can be procured via streamlined procurement channels such as the Diagnostics Catalogue of the Stop TB Partnership's Global Drug Facility (GDF) and Wambo.

4. Training, Support & Maintenance

What Delft offers	Benefit to clients
Capacity Building • Remote or in-person • eLearning • Offered in multiple languages	Access to qualified local personnel for operational sustainability
24/7 Helpdesk • Well-trained and experienced engineers • Different time zones	Swift query resolution for uninterrupted operations
Qualified Teams of Experts • Training, installation support, and reliable services & maintenance	Maximum uptime and efficiency
Global Service Network • Delft regional offices in Africa and Asia • Local service partners in 55+ countries	Predictable total cost of ownership

4.1 One-Stop Integrated Training and Support for Delft Light & CAD4TB

Procuring Delft's X-ray systems and CAD4TB as a total solution simplifies project management by receiving integrated training and installation support for both X-ray and CAD software.

Partners also benefit from unified delivery, after-sales support, and maintenance services, ensuring seamless implementation.

Single point of contact for X-ray and CAD4TB

Partnering with one supplier for total TB screening solutions offers TB programs **a single point of contact** for:

- Procurement & Supply Chain
- Project management
- Installation planning
- Warranty and maintenance contract management

The cost savings gained from a total solution will contribute to the **reduced total cost of ownership** for TB programs, ensuring the systems remain productive and impactful.

4.2 Capacity Building

We offer on-site and remote training programs that are integral to every 'digital X-ray project'. The Delft Light standard training includes remote theoretical and practical training sessions on system safety, utilisation, transportation, and maintenance.

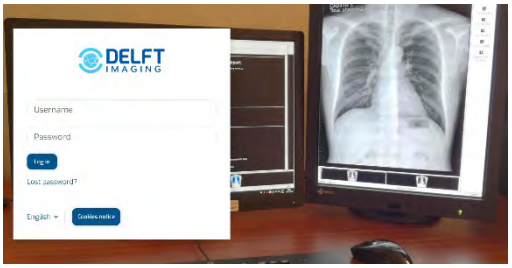
<Available languages for training and materials>

- English
- French
- Arabic
- Portuguese
- Russian
- Spanish

We can possibly accommodate other languages upon request.

(New) eLearning

We offer eLearning modules to support continuous capacity-building. The **eLearning platform** enables flexible access to essential resources for refresher training and onboarding new staff. With its offline accessibility, all trained participants can review the materials at any time, ensuring continuous reinforcement of their skills and knowledge.



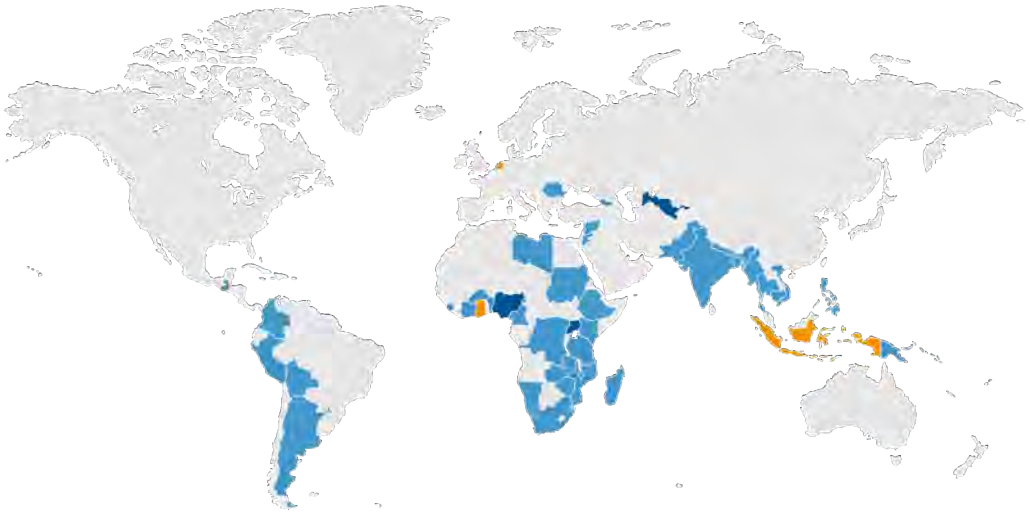
Module	Access	Content
Chest X-ray (40hrs)	Online	• Focusing on CXR interpretation, radiation safety, radiation procedures, TB identification in CXR, CAD/AI etc. • A certificate is provided upon completion. • The course is available in any language through Google Chrome's built-in translation.
Delft Light (2.5hrs)	Offline	• Focusing on system set-up, installation, operation, troubleshooting and more. • The offline platform is accessible via an app and can be downloaded on devices (phones, tablets, and laptops). • The application is available in English and possibly available in other languages.

4.3 Support & Maintenance

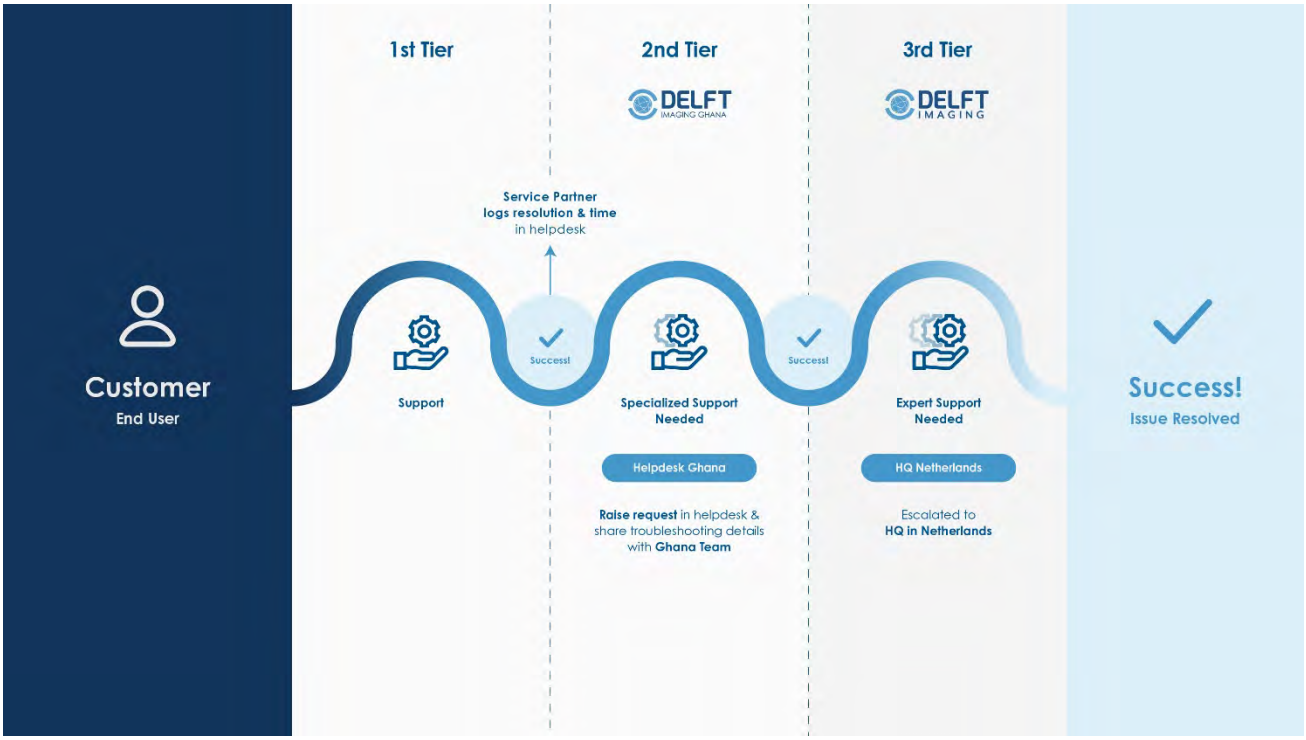
To address any reported issues promptly, we offer:

Service & Support		
24/7 Helpdesk	All time zones	Ensure troubleshooting and issue resolution within a maximum of five working days from the reporting day.
Delft's Regional Offices	Ghana Nigeria Indonesia	Professionally support clients' operations with web-based and on-site technical assistance for rapid response and instant issue resolution.
Local service partners	Over 55 countries	

Follow-Up Capacity Building		
Refresher Training	Online sessions <Available Language> - English - French - Arabic - Portuguese - Russian - Spanish	Prevent and minimise system failure risks, support maintaining the capacity of trained personnel and facilitate new staff onboardings.
Preventive Maintenance Session		We offer sessions (two times per year) to confirm the complete functionality of Delft Light.



Delft's Service Partners Locations



First-Tier

This is typically performed 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 and resolve minor software problems. They can also perform preventive maintenance routines such as cleaning and calibration.

Second-Tier

This is typically performed by trained (in-country) biomedical engineers or IT specialists from Delft's local service partners. 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-Tier

This is the manufacturer's support. In some cases, problems may not be easily identified or resolved promptly. For such issues, Delft Imaging has over 20 highly qualified and certified engineers who can be on-site within days. Also, our state-of-the-art global customer service centre is available for support. Most installed equipment and software can be monitored in real-time over the internet, enabling remote diagnosis of potential problems.

5. Considerations to Select Optimal Portable X-ray Systems

A range of ultra-portable digital X-ray systems is available. Each system has distinct strengths and benefits along with important considerations such as operational settings, human resources, maintenance, and total cost of ownership. Thus, it is advisable to consider the following points when selecting an ultra-portable X-ray system.

> *The decision of which fixed, mobile or portable equipment should be purchased should take into account many variables as for example, but not exclusively, the local epidemiological situation and health needs, the geographic context, the local health infrastructure, the trained and available health care workforce, as well as the characteristics of the health system (e.g. decentralisation of health services).*
>
> **WHO/IAEA, Portable digital radiography system technical specifications**

Programmatic Goal & Intended Use

When selecting an X-ray system, it is essential to consider the programmatic goal and a specific strategy, as there is a trade-off between portability, daily throughput, radiological exam coverage, and initial investment. Moreover, cost-effectiveness is crucial, considering initial and service costs and daily screening capacity.

The portable X-ray is optimised for Chest X-rays and can also be used for diagnostic imaging of injuries and fractures. However, the power of the X-ray generator should be considered. For CXR image quality, there are no significant differences between portable and stationary X-ray systems. Some studies indicate, however, the reduced image quality of lower power (Kv) X-ray systems for people with larger body sizes and overweight[ix].

Portable X-rays are primarily designed for field deployment; they are easily transported and set up in various locations, including hard-to-reach and resource-constrained areas where a stable power supply may not be available.

These systems can add great value in a decentralised screening approach. However, they may not be ideal for health facilities that require an X-ray system for a radiology department anticipating high throughput and/or requiring a wide range of radiology services. In such cases, a stationary or mobile digital X-ray system would be more technically suitable.

Ultimately, balancing the advantages and limitations of greater portability depends on project objectives and priorities.

Installation & Operation Settings

It is crucial to consider where and how to use an ultra-portable X-ray. It can be transported to multiple locations and used at health facilities or in almost any other venue, such as meeting rooms or under tents for temporary use, including event-based screening, prisons, occupational health, and screening campaigns in overcrowded areas. It is also an option to set it up in a van.

The set-up will always depend on the venue selected, the amount of space, patient flow, etc., as well as local radiation protection requirements. Some considerations for use are:

- Patient flow: where do patients enter/exit the room?
- X-ray beam direction: where does the X-ray beam point to? This may be a trade-off with the patient flow.
- Radiographer area: what is a safe distance for the radiographer? Is additional lead shielding available?
- Distance between the X-ray and detector: What is the minimum/maximum distance between the X-ray and detector stand?

Environments

The Delft Light is robust and durable. It is specially designed for sustained use in areas with high ambient temperatures and elevated humidity. However, environmental factors such as temperature and humidity should be considered.

Human Resources

In resource-constrained settings, the scarcity of human resources, such as qualified radiographers, healthcare professionals, X-ray technicians, and IT staff, can pose a significant challenge. Operating the Delft Light is simple and easy for radiographers since relatively little experience is required to produce high-quality images.

For portable X-ray transportation, it is necessary to consider personnel to carry the system to sites. Depending on the mode of transportation, one or two personnel are typically required to carry the equipment and accessories.

Capacity Building & Training

Healthcare professionals must receive appropriate training on operating and maintaining the system safely and effectively, minimising radiation exposure and complying with local regulations. Therefore, training and capacity building are essential for both theoretical and practical aspects of digital X-ray systems.

The Delft Light requires a basic level of radiology knowledge. Radiologists may not be required on-site when CAD software is used for TB screening and triaging.

Support & Maintenance

For optimal system uptime and seamless operation, a supplier should offer a comprehensive maintenance contract or extended warranty service agreement in collaboration with a trained local service partner. It is strongly advised that the maintenance plan be put in place, including provisions for inspection and corrective and preventive maintenance.

Budget & the Total Cost of Ownership

The costs associated with X-ray systems can vary greatly depending on the modalities and suppliers. Thus, selecting a system that balances needs and cost-effectiveness is essential, considering both initial expenses and daily operational capacity.

When selecting and budgeting X-ray systems (with/without CAD), it is essential to consider the total cost of ownership (TCO). This includes all direct and indirect costs related to the procurement, distribution, and operation of the device. Additionally, the economics per screen is another critical factor to consider.

Key factors in the TCO of the equipment include:

- Capital expenditure
- Training/installation costs
- Useful life of the equipment
- Necessary consumables
- Maintenance and service costs

For instance, if a daily screening capacity of over 300 X-rays is needed, 1 unit of Delft Light can serve this need. In contrast, other ultra-portable X-ray systems may require the TB program to procure 3 to 6 more units to achieve the same screening throughput.

6. Case Study

TB Screening Impact Stories by Stop TB Partnership using Delft Light and CAD4TB

Icddr,b, Bangladesh[x]

As of April 2023, Icddr,b together with the NTP have successfully screened over 32,689 individuals. Out of the total screened, over 5,060 individuals displayed abnormal chest X-ray results, and a total 1,452 individuals were diagnosed with TB.

The iNTP has successfully reached hundreds of individuals with TB who would have otherwise remained undetected, enabling them to access the care they need whilst reducing community transmission.

Bangladesh continues to implement these digital tools in eleven districts under the iNTP, and the National TB Program is developing plans for scale-up. The lessons learnt from the iNTP are being used by other districts across Bangladesh as part of broader efforts to adopt these new technologies.

Programme National de Lutte Contre la Tuberculose, DR Congo[xi]

As of June 2023, a total of 11,180 individuals had been screened in DRC. Among those screened, over 4,250 people displayed an abnormal chest X-ray. Altogether, this led to the diagnosis of 2,302 people with TB.

The iNTP screening activities have demonstrated significant potential in finding missing people with TB using ultraportable X-rays with CAD.

The success of the project has highlighted the effectiveness of using ultra-portable X-rays with CAD in the fight against TB. The PNLT plans to continue utilising the eight units and aims to procure additional digital X-ray systems with CAD software to extend screening and find more missing people with TB.

KNCV Nigeria, Nigeria[xii]

Active case finding using Portable Digital X-ray (Delft Light) with CAD4TB screened 127,994 people, identified 12,357 presumptive TB cases, and diagnosed 2,674 cases.

The W4SS + portable X-ray with CAD screen-based intervention was more efficient for TB case yield: four times the number of TB cases yield than symptom-only-based screening intervention. NNS (Number Needed to Screen) was 48, and NNT (Number Needed to Test) was 5.

KNCV Nigeria, Nigeria[xiii]

Since the beginning of implementation in Nigeria, the iNTP implementing partners from KNCV Nigeria and IHVN have screened over 130,000 individuals, with about 13,000 detected with presumptive TB. Over 3,200 people have been diagnosed with TB through this intervention.

This project has demonstrated the potential of ultraportable X-ray with CAD in a high TB burden country. As the intervention was concentrated in hard-to-reach areas and high-risk populations, the project has made care accessible for thousands of people who otherwise may be missed.

The high impact on incremental case notifications of this project confirms the need for scaling up these technologies nationwide.

National Tuberculosis, Leprosy and Lung Disease Program, Kenya[xiv]

In 2022, Kenya implemented a TB case-finding strategy using digital CXR with CAD4TB. This was piloted in 8 USG-supported health facilities.

A total of 9,427 clients were screened for TB using CAD4TB. From the total screened, 879 clients had a CAD score >60. 647 (79%) were subjected to Xpert MTB/RIF testing and 330 (51%) had a bacteriological confirmation for TB (Xpert positive). An additional 189 clients were clinically diagnosed with TB.

Overall, there was a 40% increase in case finding in the pilot sites and a potential 80% ($88) saving in cartridge cost per bacteriologically confirmed case. This FR includes a request for investments to procure additional digital CXR with AI to improve TB case finding among PLHIV as well as other populations.

Division of National Tuberculosis, Leprosy and Lung Disease Program, Kenya[xv]

Medical super-intendent Madiany sub-county**:**
"In a day we serve an average of 200-300 clients of which 10 are likely to be TB patients. Compared to last year, our TB diagnosis increased by 50%, meaning we were missing cases as a result of the absence of the machine".

The facility radiographer praises the efficiency, effectiveness and user-friendly nature of the portable machine, which involves taking X-ray images and utilizing the built-in AI for interpretation. *"This machine is superior to others, providing satisfaction when diagnosing patients, initiating treatment and witnessing their health improvement***".**

National Tuberculosis and Leprosy Programme, Uganda[xvi]

Uganda performed both facility and community-based activities to bring care to hard-to-reach areas and under-served populations. The use of digital X-ray and CAD is a major step forward in the fight against TB in Uganda. These technologies are helping to ensure that more people with TB are diagnosed and treated.

As of September 2023, under the iNTP, the NTLP has successfully screened over 5,500 individuals, with 962 individuals displaying abnormal CXR results. Of those who displayed abnormal CXR results, 591 individuals were diagnosed with TB.

The five ultra-portable X-ray and CAD systems from the iNTP have been fully integrated into the NTLP's screening programme.

National Tuberculosis Control Program (NTP), Vietnam[xvii]

Vietnam performed both facility and community-based activities to bring care to hard-to-reach areas and high-risk populations. The iNTP has successfully reached hundreds of individuals with TB who would have otherwise gone undetected without this project, potentially resulting in some losing their lives to TB and/or transmitting the infection to others.

As of March 2023, with support from USAID-funded Partners, the NTP has successfully screened more than 32,000 individuals. Over 3,500 individuals had abnormal chest X-ray results, and more than 450 individuals were diagnosed with TB, of which 279 were bacteriologically confirmed.

By detecting people with TB early, the iNTP project has allowed these individuals to access vital care, thus preserving lives and diminishing the likelihood of TB spreading within the community.

More Case Studies are Available at

Delft Live Webinar Series: Field Implementation & Insights

https://www.delft.care/impacted-stories/

7. Voices of Partners

"We are scaling up digital X-ray with AI for TB case finding thanks to the introduction and pilot of the Delft Light Backpack. The pilot led to what we have been able to do not only at KNCV Nigeria but also at the National Programme to help bridge the gap in TB case finding. Digital X-ray with AI has shown efficiency in TB case finding as the number needed to screen and test had reduced significantly.

- **Dr Bethrand Odume, Executive Director, KNCV TB Foundation, Nigeria**

"Despite limited access to radiology services for TB screening in Uganda, we introduced digital X-ray systems fitted with CAD in 2020. Since then, we have acquired 12 portable digital X-ray systems with CAD4TB and two mobile clinics equipped with digital X-ray, CAD and GeneXpert. We deployed them for outreaches targeting TB hotspots and high-risk populations. Additionally, for monitoring our work, we initially had paper-based systems.

- **Dr Turyahabwe Stavia, Assistant Commissioner - TB/Leprosy Control Division for the Ministry of Health, Uganda**

"Portability improves access to testing at lower-level health facilities and in communities. These devices allow for reduced radiation exposure and a cost-effectiveness of over 200+ screenings per day. This service reduces the time to diagnosis and the number of tests needed to diagnose. In a day, we serve an average of 200-300 clients, of which ten are likely to be TB patients. Compared to last year, our TB diagnosis increased by 50%, meaning we were missing cases as a result of the absence of the machine. This machine is superior to others, providing satisfaction when diagnosing patients, initiating treatment and witnessing their health improvement.

- **National Tuberculosis, Leprosy and Lung Disease Program, Kenya**[xviii]

That this tool - digital x-ray (Delft Light) helps the program to better its performance. There are 270 cases of TB that we were able to detect by using this X-ray. In tests with the molecular tests, those tools were used, were easy to install. After training, there was a real easiness to install them, and to operate them without any serious problems until the end of the second year. We had some issues at first. But we were easily accompanied to help to use it. And so the link between the x-ray, and the molecular tests were really beneficial.

- Dr Jean Pierre Kabuayi, Expert in TB Epidemiological Surveillance, Ministry of Public Health, Hygiene, and Prevention, DR Congo

In 2022, we received Delft Light and CAD4TB for the first time thanks to our partner USAID. So far, the systems have been deployed to screen over 3,000 people who live in remote areas and have challenges accessing TB services. These applications are especially efficient in remote, rural and mountainous areas, and we have been using the system without any issues. I hope that in the future we will expand such a comfortable device, which will be very useful to identify TB cases and contribute to treating patients in Tajikistan.

- Dr Nurov Rustam Majidovich, Director of the Republican Center for the Protection of the Population from TB of the Ministry of Health and Social Protection of the Republic of Tajikistan

After training our specialists, we noticed that screening people from remote areas using portable X-rays doesn't require additional expenses, other resources like films or other personnel. So even if you have one operator, it is enough, then sending several people will help reduce the cost of exams in remote areas. The system can work online and offline.

– Dr Akamal Umarov, Leading Radiologist & National Coordinator, Republican Specialized Scientific-Practical Medical Center of Phthisiology & Pulmonology, Ministry of Health, Uzbekistan

“With the cooperation with USAID and the StopTB Partnership, we received Delft Light ultraportable X-ray systems and CAD4TB last year and sent them to 10 provinces. During the pandemic, Vietnam experienced a significant reduction in TB notifications; therefore, the National TB Program of Vietnam strategised the optimised use of Gene Xpert and X-ray (2X) in detecting TB cases. Additionally, the 2X strategy has been expended to all TB health facilities besides the nationwide active case-finding at communities for high-risk groups. Thanks to CAD4TB, abnormal cases can be reviewed again by a doctor and referred to an Xpert test. Although it's still an early stage, the programme identified 102 TB cases of all forms out of screening over 6,569 people through ACF at communities and health facilities.

- **MPH. Ngoc Anh Le Thi, Program Coordinator and Senior Researcher at the Vietnam National Lung Hospital**

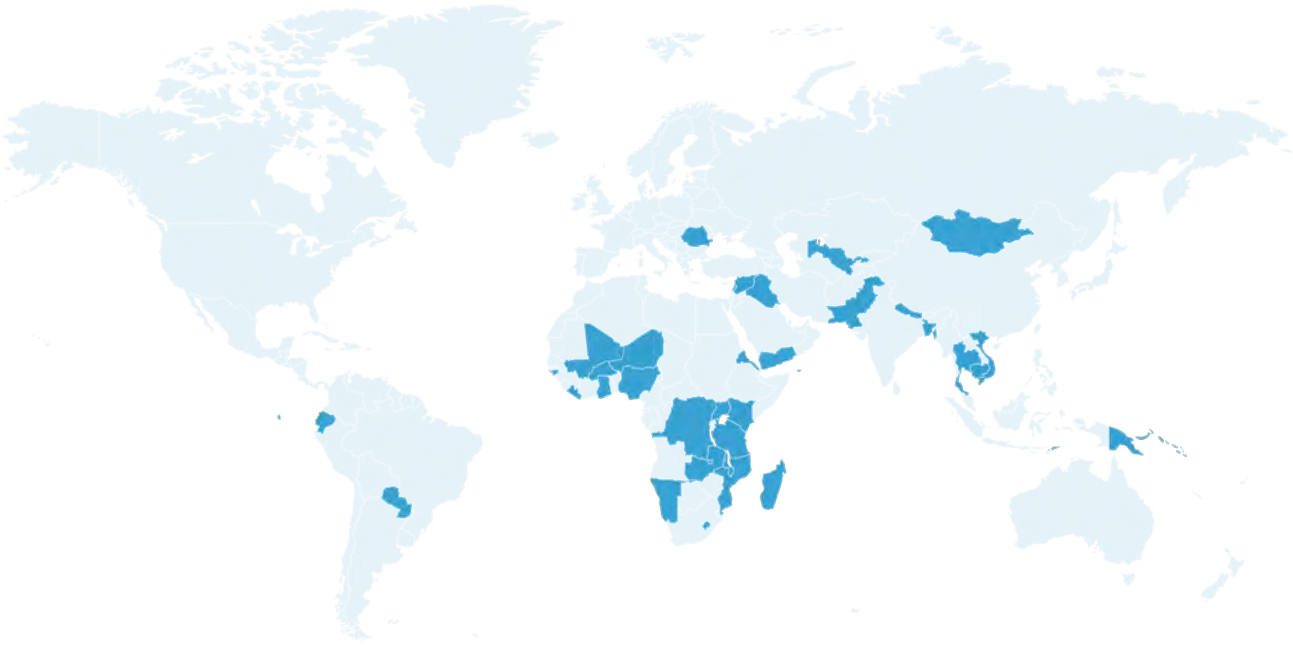
“In our experience, the Delft Light is portable and easy to set up. On a fully charged battery, they can easily do 200, sometimes up to 250, exposures. The operational hours for Delft Light and CAD4TB are up to 16 hours, no problem.

- **Dr Khay Mar Aung, The Cambodia Prevalence Survey Core Team**

“The Delft X-ray machine is very easy to transport and install. It does not require a constant connection to an electrical network because most prisons here (in Paraguay) don't have stable internet and electricity ... if you can, we suggest you get the CAD4TB box. We didn't buy that, so we have to work with unstable internet in prison, leading to work delay.

- **Dr Louis Gomez Paciello, Pulmonologist, PhD candidate, Prinose Project, Paraguay**

8. Delft Light Track Record



(as of August 2024)

Africa	Asia Pacific	Americas	Europe & Central Asia	Middle East
Burkina Faso	Bangladesh	Ecuador	Romania	Iraq
DR Congo	Cambodia	Paraguay	Tajikistan	Lebanon
Eritrea	Mongolia		Uzbekistan	Syria
Ghana	Nepal			Yemen
Guinea-Bissau	Pakistan			
Kenya	PNG			
Lesotho	Solomon Islands			
Liberia	Thailand			
Madagascar	Timor Leste			
Malawi	Vietnam			
Mali	Kiribati			
Mozambique				
Namibia				
Niger				
Nigeria				
Tanzania				
Uganda				
Zambia				

Annexe 1: Technical Specifications

X-ray Unit

- Inverter frequency: max. 150kHz
- Electrical power 1.35 kW @ 90 kV, 15 mA
- Tube voltage 40-90 kV (2 kV steps)
- Stationary Anode X-ray tube
- Exposure time range 0.01-1.0 sec (0.01 sec steps)
- Tube current: Range: 20 mA @ 40-60 kV, 15 mA @ 62-80 kV, 10 mA @ 82-90 KV
- Leakage 0.05 mA @ 90 kV
- Duty cycle 1:60 (one 0.2 sec exposure every 12 seconds)
- Dual laser positioning pointer: Class III-a laser diode
- Total filtration 2.5 mm Al @70kV
- Multi leaf collimator: two buttons and four blades
- Heat storage capacity 10.000 HU
- X-ray tube:Toshiba D-0814M
- Dimensions L x W x H:265mm x 220mm x 180mm
- Focus: 0.8mm x 0.8mm

- Battery type: Lithium Ion Battery
- One battery load ~ 200 exposures @ 90KV
- Charging time (empty to full): 4 hours. 'Low Battery' indicator/alarm on the display panel
- Supplied with all needed cables and connectors
- **Weight: 7.2 KG**

Delft Light Tripod

- Foldable, twistable, and rotatable stand
- High-quality corrosion-resistant aluminium stand
- Vertical travel range 50 – 170 cm
- Horizontal travel range unlimited
- Tube rotation 360 degree
- **Weight: 4.8 kg**

CANON CXDI X-ray Detector

- Purpose: general radiography
- Scintillator: CsI
- Effective imaging area 35x43 cm
- Image display time 1 second
- Pixel pitch: 140 um
- DQE: 74% @ 0lp/mm 3.5 µGy RQA
- Resolution: 3.5 lp/mm
- Grayscale 4096
- Scatter correction software (no need for GRID)
- Battery-type Lithium ion
  - Total capacity allows 200 chest X-ray exposures @ 90KV
- Charging time (empty to full) < 2.5 hours. Low battery /alarm in software (icon) and on an LED on the detector
- External Li-ion battery; second battery is included
- Equipped with internal shock sensors, very robust for a continuous, uninterrupted workflow
- Provided with 0.5 kg Detector hanger

Delft Light Workstation

- 15.6 Inch LED full HD widescreen colour display, with more than 2Mpixel.The X-ray workstation is fully integrated with the NE image management software
- Intel core i5 microprocessor 3.4 GHZ
- 8 GB RAM
- 1 TB SSD hard drive
- High-resolution images 1440 * 1440
- Storage capacity of more than thirty thousand (30.000 images).
- Display languages: English, French, Spanish, Japanese, Chinese, Portuguese, Italian, Dutch, German, and Russian, with the possibility of adding more languages upon request

- Powered by a built-in battery with ten (10) hours of autonomy time
- The workstation charger is Single Phase, 90VAC 240VAC, 50/60Hz. The plug type will be in compliance with the national standards and regulations applicable in countries of destination
- The charger of the Workstation has the functionality of a voltage stabilizer; it allows safe and stable operations at ± 20% of the locally, rated voltage. For extra safety, we recommend using Delft Light solar panel to charge the battery
- The charging time of the Canon NE workstation is (empty to full) 4 hours
- **Weight: 1.7 KG**

Canon NE software

- Image pre- and post-processing tools (clip, zoom, magnifier, invert, rotate, flip, annotations, measurements, digital collimation, etc.)
- Image viewing tools
- Alphanumeric annotation of images
- Interoperability with local and/or national Picture Archiving and Communication System (PACS)
- Secure: encryption of data and DICOM compliance

Delft Solar Panel

- Output 230 VAC @ 250 Watt
- Output 2 x USB, 5 Volt, 3,2 Amp
- Peak power 500 Watt
- Battery capacity 70 Ah, 259 Wh
- Water-resistant IPX4
- The Delft Solar Panel can also work as a UPS when the items are charged through the integrated power bank; it has a voltage stabilizer that can protect the batteries from voltage spikes
- Dimensions 550x300x50 mm
- **Weight 6 kg**

Annexe 2: Resource Kit

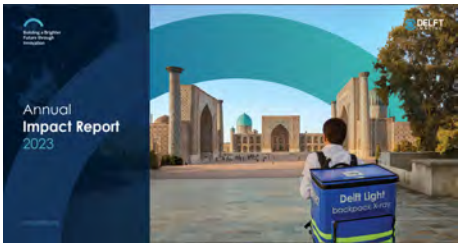
Delft Live Webinar Series for Field Implementation & Insights

https://www.delft.care/impacted-stories/

TB Screening Project Book

https://www.delft.care/presence-projects/

Annual Impact Report



https://www.delft.care/annual-reports/

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