Program Planning and Implementation Considerations

MODULE 3

Stop TB Partnership

Introduction

This module offers a menu of the key programmatic and procedural considerations steps to consider when designing and implementing a project to deploy ultra-portable X-ray systems with CAD software to screen and triage for TB.

Outline

- → Stakeholder framework and situational assessment
- → Site selection and preparation
- → General screening workflow
- → Key implementation considerations
- → What to expect from suppliers
- → Challenges and lessons learned from early users of CAD and UP-XR
- Summary

Learning Objectives

By the end of this module, participants should be able to:

- Engage key stakeholders from early stages of a CAD and UP-XR program.
- Perform a tailored situational assessment for a CAD and UP-XR program.
- Identify suitable sites and prepare for CAD and UP-XR field activities.
- Understand the human resource requirements of CAD and UP-XR programs.
- Understand the general screening workflow involving CAD and UP-XR programs.
- Be aware of key implementation considerations for CAD and UP-XR.
- Be aware of some challenges and lessons learned from pilot projects.

PROGRAM PLANNING AND SITE SELECTION AND PREPARATION

Stakeholder Framework

For more detail, see Section 4.3 of Stop TB's Practical Guide

Implementer and NTP/MoH should consider engaging the other important stakeholders for the implementation of ultra-portable X-ray systems with CAD software, such as:

National radiography, radiology, and medical associations or equivalent

Could be **opposing** the operation, so it is important to engage and sensitize them to ensure support for projects. Engagement should include radiographers, radiologists, chest specialists, and relevant clinical officers specialized in lung health.

National center for personal data

To address any regulatory concerns around the collection, storage, and processing of patient data, particularly by CAD.

National radiation/atomic energy regulatory authority or equivalent

To confirm whether the ultra-portable X-ray systems can be imported (from a radiological safety standpoint). Design radiation safety protection measures for patient and operator.

ICT companies/Internet providers

To ensure that a suitable Internet connection is provided for running CAD software and for data synchronization if using CAD online or hybrid.

Civil society and TB-affected community organizations

For active case finding activities and advocacy for sustainable funding of the intervention.

Medicines and medical devices agency or equivalent

To confirm whether the ultra-portable X-ray and CAD software are classified as a medical device in the country. If necessary, complete national registration.

Donors and international partners

Provide funding for system procurement and investigations as well as technical assistance on various aspects in the implementation.

Situational Assessment

As an initial step, a country situation analysis should be conducted to select possible sites for implementation to identify how CAD and UP-XR can **slot into** and **reinforce** the existing health system.

A situational assessment should cover the following:

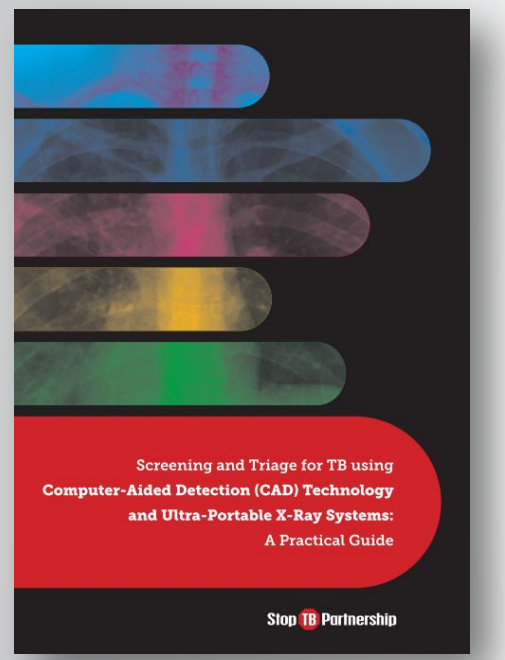
1. Existing public health interventions
2. The available literature on CAD and X-ray screening
3. National and district regulations and policy
4. Existing health system integration and capacity
5. Existing ICT infrastructure

Reviewing the existing situation should make it possible to:

- ➔ **Select possible implementation sites.**
- ➔ **Establish relationships with nearby facilities for:**
    1. Referral of people for confirmatory testing (such as community to facility, primary health care to facility, or diagnostic site to Basic Management Unit)
    2. Storing backup X-ray images and CAD software reading outcomes
- ➔ **Establish the roles and responsibilities of the NTP, local distributors, and implementing partners.**
- ➔ **Develop a costed operational plan for implementation.**

Site Selection and Preparation

Following completion of all implementation steps and prior to beginning X-ray screening, the site and staff should be evaluated for readiness.



The site should be evaluated for:

- Planning and HR
- Equipment, service, and maintenance
- Screening facility readiness
- Relevant procedures for patient registration, results reporting, and CAD maintenance
- Digital data and diagnostics connectivity
- Monitoring and evaluation
- Recording and reporting of results
- Capacity to train and assess competency of staff

A checklist for assessing site readiness can be found in Annex 7 of the Stop TB Partnership's Practical Guide.

Highlighted Considerations for Site Selection and Preparation

1. Patient management

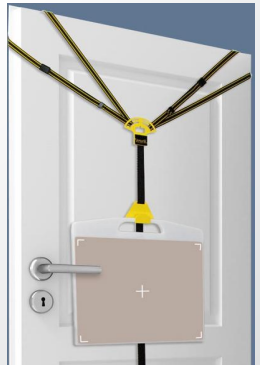
- How will a presumptive patient be registered?
- Do the X-ray and CAD results need to be printed for referral?
- Where will presumptive patients with an abnormal X-ray be referred for confirmation testing?
- Will sputum samples be collected onsite and transported to Xpert labs?
- What is the expected daily throughput of the site?
  Note: Ultra-portable X-ray systems are not ideal for sites anticipating high throughput (e.g., 300 scans per day).

2. Equipment requirement

- Are there sufficient sockets available for battery re-charging of essential devices: CXR detector, generator, PACS laptop?
- Is there an available electricity source to power the CAD4TB box and the router?
- Is there a place to hang the detector with the Versarix holder?
- Is there secured storage for the Delft Light backpack?
- Does the X-ray unit ensure an optimal environment:
  - Working: operating: 0–60 degrees Celsius, 5–95% RH (no condensation)
  - Storage: 0–60 degrees Celsius, 10–90% RH

3. Radiation safety and regulation

- Is Delft Light allowed to be used in open spaces/non-specialized facilities without lead wall shielding?
- Is there adequate space to perform X-ray exposure in compliance with relevant national regulatory requirements?
- What radiation safety equipment is required according to local authorities?
- Where do patients enter/exit the room /radiographer area? What is a safe distance for the radiographer? What is the maximum distance between generator and detector?



Stop TB Partnership

Human Resources

1. Identify and hire **X-ray technicians or radiographers** to operate X-ray systems, and **community health care workers** to conduct screening activities.
   Note: If CAD is used for screening and triage purposes, **radiologists might not be required** to be onsite, according to WHO recommendation.

2. Identify existing **biomedical and IT staff** (or hire new staff) to support the configuration, installation, maintenance, and support of ultra-portable X-ray systems and CAD software.
   Note: CAD projects may necessitate capacity building in this area.

3. Ensure sufficient **staff to transport** ultra-portable X-ray systems and necessary accessories, if necessary. A **minimum of two people** will be required.

4. For threshold selection (see Module 4), consultants with **operational research and statistics background** may be necessary.

5. Engage a **legal expert** to advise on how to best protect the patient information while allowing for necessary data flow.

Training and capacity building

Two trainings are recommended for end-users (clinicians, radiologists, radiographers) to become familiar with the product:

1. A **theoretical training** on CAD and X-ray using modules developed by the Stop TB Partnership/IDDS – *see next slide.*
2. A **practical training** specific to the CAD4TB and Delft Light by the manufacturer, included when procured from GDF.

Theoretical training for end users

Developed by Stop TB/IDDS, 5 theoretical training modules are freely available to any programme implementing CAD and X-ray (here).

- **Intended audience:** radiographers, radiologists, physicians, clinicians, X-ray technicians.
- **Overview:**
  - Inspired by this training, these modules offer tailored content on:
  - **Module 1:** Updated WHO TB screening guidelines
  - **Module 2:** Introduction to AI and ultra-portable X-ray
  - **Module 3:** Implementation considerations for end-users
  - **Module 4:** Introduction to CAD thresholds
  - **Module 5:** Connection to program and national systems.

Do’s and Don’ts for theoretical training

DO:

- Consider which end users would benefit most from this training.
- Present the modules with the help of the **accompanying facilitator manual**.
- **Customize** the modules to your context. For example including the national diagnostic algorithm, project M&E indicators, and overall screening strategy.
- Consider whether relative pros and cons of training **on-site or online.**
- Add or remove content to **tailor training to your intended audience**.
- **Engage local teams with experience** using the tools to share their experience or deliver training.

DON’T:

- **Expect practical training** on operation of the machines from this training – this will be covered by the manufacturer.

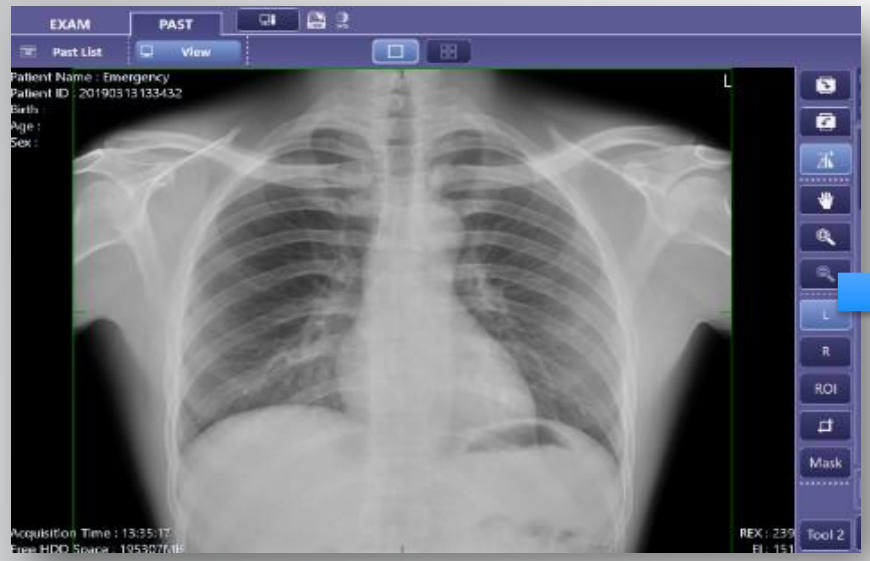
General Screening Workflow

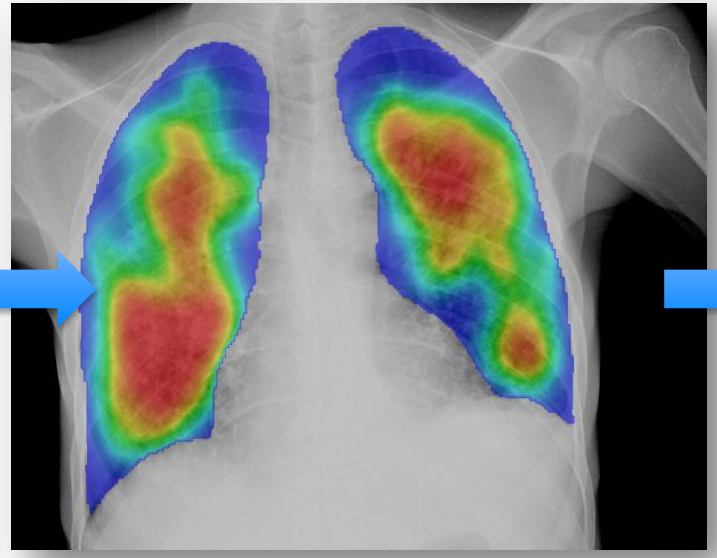
1. Outreach and promoting X-ray and CAD screening projects and identify presumptive patients who require X-ray examination as per national TB screening and diagnostic algorithm

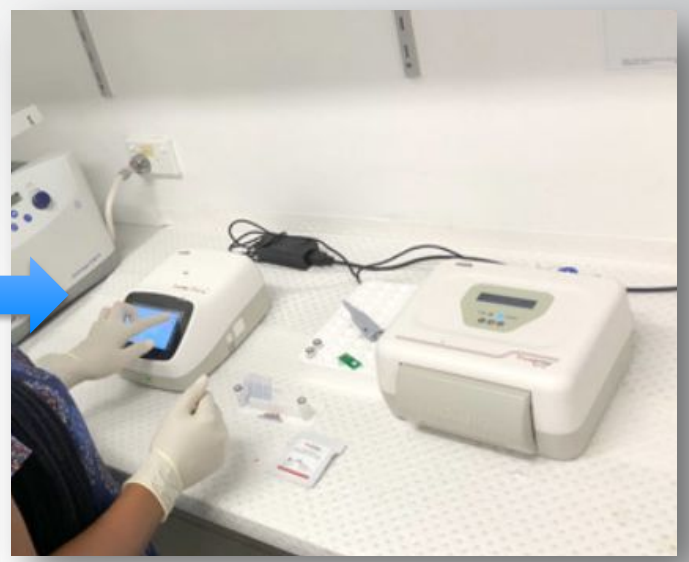
2. Presumptive patient screening and registration

3. Presumptive patient preparation and X-ray exposure

General Workflow







4. After the exposure, the detector receives the images and immediately transfers the X-ray image to the console PC using Bluetooth (or wired connection). The console laptop automatically processes and generates the X-ray image.

X-ray images may also be viewed on the tablet accompanying the CAD4TB box.

5. The X-ray is then automatically read by CAD4TB and generates results.

   CAD4TB results can be displayed on the console PC (online) or accompanying tablet (offline).

6. Post-screening referral and diagnostic and care provided, along with monitoring and evaluation (Module 5).

IMPLEMENTATION CONSIDERATIONS

Electricity and Power

Because of the limited battery capacity and charging options, ultra-portable X-ray may not be suitable for high throughput settings without power in the field.

The entire Delft Light system has **built-in batteries** so it can be operated in screening settings without access to electrical mains.

The charging requirements of the system are:

Generator battery	Capable of approximately 200 exposures. Recharging takes approximately 4 hours. **Note:** The battery must be **removed from the tube for charging** and inserted into the generator charger. This means that the X-ray generator **cannot be charged and operated** at the same time.
Detector battery	Capable of approximately 100 exposures per set of 2 batteries. A second set of batteries means up to 200 exposures are possible. Recharging takes approximately 2.5 hours. 
CAD4TB box	The CAD4TB box requires an AC connection to operate. It is **not** capable of storing its own power.

Electricity and Power

If implementers plan to deploy the systems for high throughput in an off-grid setting, external power sources are critical to ensure continued operation.

MobiSun solar panel and power bank

All system components (generator, detector, workstation, and CAD4TB box) can be recharged from a portable, water-resistant MobiSun solar panel with built-in power bank in settings without access to electrical mains.

- The solar panel power bank takes **16 hours to fully charge in direct sunlight.**
- There were some difficulties experienced by early users using the solar panel due to the difficulties and deficiencies of charging by sunlight.
- Alternatively, the solar panel's power bank can be charged from the electrical grid in **approximately 2.5 hours.**
- Solar charging cannot occur while the system is in operation.

Note: 12 second gap is required between exposures.

Portability and Setup

The full kit contains several components in addition to the X-ray generator and detector. The overall weight of a complete set can still be **too much for a single person** to carry.

The Delft Light comes with two bags for carrying the system:

- **Backpack** for the generator, detector, detector stand, console, CAD box, and accessories
- **Carrying case** for the generator stand

Photo credit: KNCV Nigeria

Delft Light component	Weight (kg)
X-ray generator	7.0
X-ray generator stand	8.0
X-ray detector (incl. batteries)	3.8
X-ray detector stand	0.4
Console laptop/workstation	1.5
Lead apron	3.0
Battery chargers	1.0
Solar panel/power bank	6.0
Carrying case (empty)	2.5
Delft Light total	**33.2**
CAD4TB Box	1
System total	**34.2**

Radiation Safety Policy

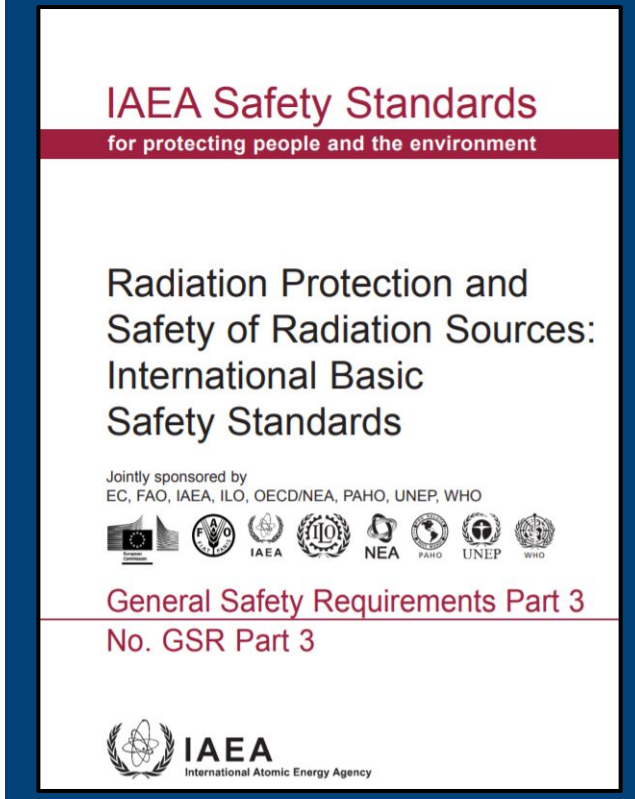
Radiography involves exposure to ionizing radiation. Although the risk remains low when the levels of radiation are controlled, precautions are needed to ensure the safety of health care workers and patients.

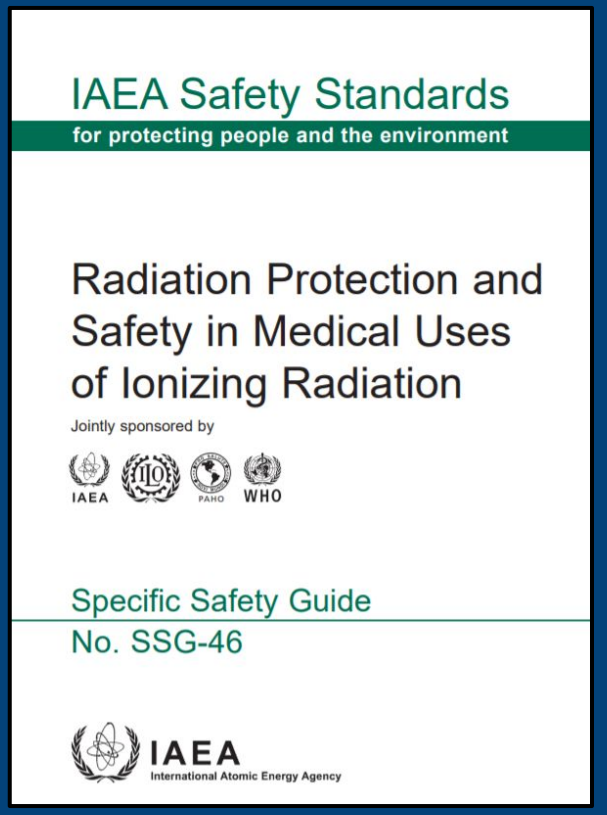
Local and international radiation safety regulations should be followed, especially when deployed in non-specialized facilities in the field.

The global benchmarks for radiation safety worldwide:

- Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards
- Radiation Protection and Safety in Medical Uses of Ionizing Radiation—Specific Safety Guide SSG-46

A necessary initial step is to scope the requirements of the local radiation authority.





Digital Data—Server and Storage

When using CAD in high throughput settings, large quantities of data are generated. Thought should be given to how that data will be stored securely.

Server

Options to consider include:

- Server type: physical or cloud server?
- Server location: in-country or not?
- Server purchase: from the CAD supplier or not?
    - Using the supplier-recommended cloud could result in lower costs, ease of access for server updates, as well as better physical and logistical security measures

Advantages: automatic back-up, accessible from different locations, scalable storage capacity

Disadvantages: costs and need for server admin (depending on choices of server), potentially less control over data security, and need for more robust legal protection

Physical Back-Ups

Options to consider include:

- External hard drives
- CD disks
- Pen drives/USBs

Advantages: can be inexpensive, more control over data security, back-up can occur without Internet connection

Disadvantages: manual, difficult to manage large volumes of data, possibility of damage/loss/corruption of storage device

Digital Data—Data Privacy and Security

Patient medical data are collected, stored, and transferred during CAD projects.
It is important that these data are kept **private** and **secure.**

Data privacy
is the right to restrict the use, access, disclosure, and dissemination of information.

Data security
comprises technological and non-technological mechanisms that limit the use, access, disclosure, and dissemination of information.

Restricting the use of digital data to a limited set of purposes necessary when using CAD technologies is essential for data privacy and security.

Patient data can be protected using technological and non-technological (legal) measures.

➔ For CAD companies in the GDF catalogue, the principal agreement stipulates that CAD companies can **only** use implementers' data to provide CAD services (i.e., to read CXR images and provide outputs).

Digital Data—Data Privacy and Security

Non-technological (legal) measures

As the legal data owner, there are two primary measures that can be used to ensure that the project's patient data are kept private and secure by CAD suppliers.

The Stop TB Partnership has produced templates of both agreements and accompanying instructions designed to maximize the data protection, privacy, and security of the patient data.

- **Data processing agreements (DPAs)** govern the legal rights and obligations of parties involved in the transfer, storage, and processing of personal data. Stop TB has created a DPA template to protect CAD implementers' data that manufacturers in the GDF catalogue are **required** to sign.
    - Access the template here and the instructions here.

- **Non-disclosure agreements (NDAs)** legally bind individuals and organizations to secrecy and confidentiality regarding shared information. Stop TB has created an NDA template to maximize data confidentiality.
    - Access the template here and the instructions here.

Both templates should be adapted in line with local legislation and regulation by a legal expert.

Digital Data—Data Privacy and Security

Technological measures (data de-identification)

Personally identifiable information (e.g., patient name) can be removed from CXRs before sharing them with CAD suppliers for processing and analysis.

The two primary methods to de-identify patient data in a DICOM file are:

Anonymization

- Removing identifying information like name, age, gender from header elements in a DICOM file, or replacing with random data.
- If the project links CAD output with other databases, a unique patient identifier system should be used.
- **Provides greater data privacy but does not allow for re-identification.**

Pseudonymization

- Modifying personal data so that they can no longer be attributed to a specific individual without the use of additional information (kept separately).
- The age/gender/name in the DICOM file is replaced with artificial identifiers.
- **Provides less data privacy than anonymization but allows for patient re-identification by authorized personnel.**

De-identification scripts should be set up with assistance of an IT specialist and CAD supplier engineer.

Further Considerations

Internet requirement: When using CAD products online or in hybrid mode, a **strong and stable Internet connection** is required for online mode because X-ray files are large (approx. 10–30 MB). If the intended use is in areas without reliable Internet access, it is important to purchase a CAD product that can analyze CXR images and generate results offline.

Privacy: Prospective sites should be assessed for suitability for mounting the detector in an area where **privacy** is available for anyone being screened who needs to remove any clothing with metallic components, or accessories, before taking a CXR.

What to Expect from Suppliers

- Onboarding training and installation, including system installation, theoretical and practical training on safety, use, transportation, and maintenance
- Monthly virtual support call
- Extended onsite/remote training with eLearning
- Threshold point calibration and troubleshooting
- Onboarding toolkit, including the IT, infrastructure, and human resource requirements for running CAD
- User manual capturing installation process, software update process, troubleshooting, and maintenance
- To be discussed in manufacturer’s training

CHALLENGES AND LESSONS LEARNED FROM EARLY USERS OF CAD AND UP-XR

Challenges and Lessons learned from early users

Interviews with six early implementers of CAD with UP X-ray identified through Stop TB's partner network revealed the following insights:

Reluctancy from radiologists and fear of being replaced by artificial intelligence can still exist → underscores the importance to **engage and sensitize medical professionals and associations**. Artificial intelligence has many use cases when used WITH human readers.

Image quality was described as **comparable to stationary machines** when taking images of most people.

Threshold score selection is difficult: Most new users just start with manufacturer recommendations or adjust in response to false positives. Once they gain experience, they do operational research.

Potential problematic behavior change: The potential for the **interpretation of CAD output as diagnosis** was a concern:

Although it is easy to integrate the CAD system with the PACS system, it is difficult to integrate CAD results with **the existing national TB database (e.g., DHIS2) or a project-specific electronic medical record system (e.g., openMRS).**

Challenges and Lessons Learned

Equipment fault and CAD reading error:

- Detector to the console connection: Bluetooth resulted in delayed or failed image transfer. A wire connection would make this more efficient, but the length of the wire can be limiting.
- The connection between the console and CAD laptops can also be a weak point. Some projects experienced loss in connection prior and fixed it by restarting the laptops.
- X-ray generator battery failed → new product, having a good service and maintenance contract is important.
- The detector battery is durable, but the battery life of the console laptop may not last with use. → new product, more actively engage Delft's client service
- Solar panel charges slowly without direct sunlight or in winter → charge it with electricity grid or replace with another power bank.

Manufacturer service: All projects reported positive experiences with the supplier's IT support system, but access to this service may be limited for implementers who work in settings without Internet connection.

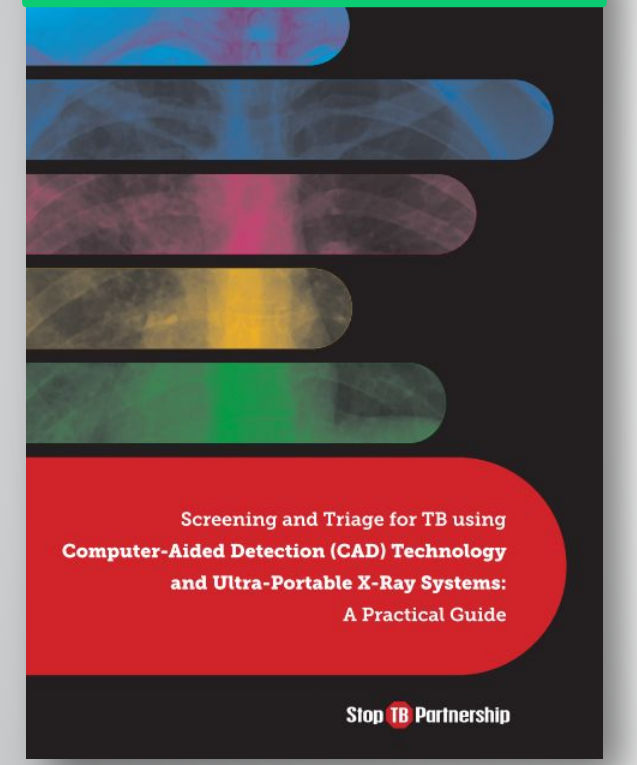
Summary

Summary

- When implementing CAD and UP-XR key considerations include:
  - Electricity and power
  - Portability and set-up
  - Radiation safety
  - Data management and privacy
  - Internet access
  - Availability of private spaces
- CAD suppliers provide installation, training, and technical help to support the smooth operation of CAD programs.
- Preparations for implementation include identifying key stakeholders, performing a situational assessment, and analyzing field site readiness and suitability.
- CAD and UP-XR projects require a blend of clinical, IT, scientific, and legal expertise.

Stop TB Partnership's CAD and X-ray Practical Guide

Click to access the guide



An invaluable resource for implementers of CAD and UP-XR:

Recommended reading:

- Chapter 3, Section 3.2: Implementation Considerations
- Chapter 4: Planning and Preparation

Templates and resources:

- Annex 5: Budgetary considerations for implementation
- Annex 6: Checklist to assess suitability of a CXR-CAD screening site
- Annex 7: Checklist to assess readiness of a CXR-CAD screening site
- Annex 8: Proposed indicators for monitoring the performance of CAD technology