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DIGITAL INNOVATION

# Digital Tomosynthesis

## Accuracy and Speed in Three Dimensions

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Radiographs are two-dimensional images generated by projecting a three-dimensional body onto an acquisition device called a detector, using X-rays. As projections, X-rays superimpose soft tissues, bones and different structures, bringing with them a high quantity of data but also flattening the three-dimensional information of the body.
DTS (*Digital Tomosynthesis*) is a software specifically developed to perform the tomosynthesis algorithm, which, using a sequence of projections acquired at different angles, guarantees a complete reconstruction of the volume to be examined.

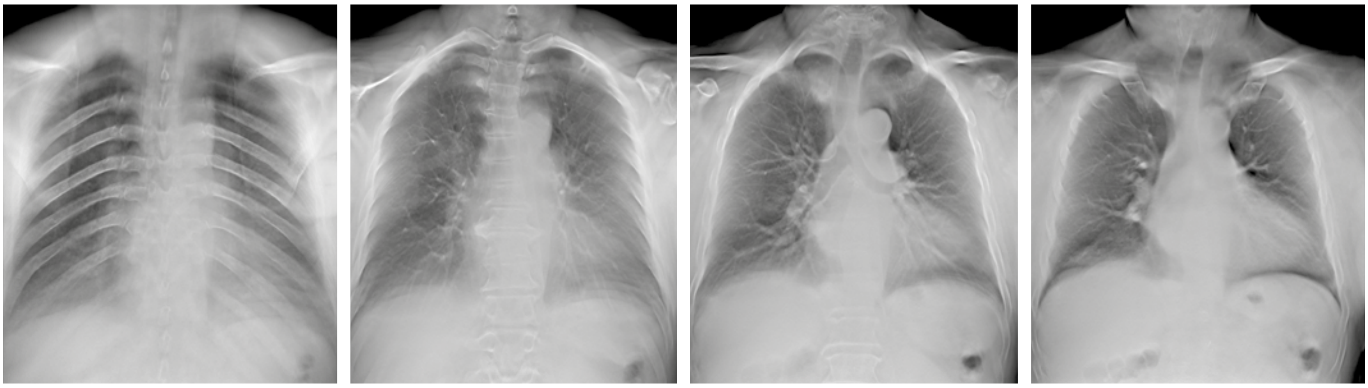


**Figure 1: Visible results** – The volumetric accuracy resulting from the implementation of the DTS algorithm guarantees fast and precise reconstructions, allowing you to focus on individual structures.


## Abstract

In **traditional X-rays,** body volumes are flattened in outputs that superimpose **soft tissue, bones and different structures in a single image**.
This **technical limit**, together with the **high costs** and **reduced portability** of computed tomography techniques, has oriented research towards **algorithm solutions** and, consequently, towards the development of **dedicated applications** capable of optimising execution, portability and the results.
This research has produced **DTS**, a **software** solution capable of executing the **digital tomosynthesis algorithm** and carrying out a **volumetric reconstruction** of the patient's body, guaranteeing clinical outcomes of high technical **quality**, hardware **portability** and - last but not least - economic **sustainability**.

**The multiple clinical applications of DTS** attest to these advances **[1]**. They include the realisation of:

- **chest** volumes, to improve identification of pulmonary nodules;
- volumes of the **head** and **neck**, for a better visualization of the paranasal sinuses;
- **dental** volumes, to obtain better spatial resolution;
- **breast** tomosynthesis, to detect lumps and calcifications of the breast area.

The **strengths** of DTS essentially consist in:
1. reconstruction **quality**;
2. execution **speed**;
3. multi-purpose **adaptability**;
4. hardware **compatibility**;
5. **reduced** implementation **costs**.

# Features and Operation

## Context

Because they are two-dimensional, **traditional X-rays** flatten three-dimensional body volumes by superimposing **soft tissue, bones and different structures** in a single image.
This **technical limitation**, together with the **high costs** and **reduced portability** of computed tomography techniques, has contributed to the **spread** of the **tomosynthesis algorithm** and the development of software capable of optimising its execution.

## Operational logic

By applying the tomosynthesis algorithm, the **DTS (*Digital Tomosynthesis*)** software aims to **reconstruct a volume**. How?
By knowing the **geometric configuration of the system**, it is possible to trace the **position of the source and detector** in space; DTS exploits these positions and the information present in the X-rays acquired at **different angles** to **reconstruct the volume** being examined.
The volume is provided to the user as a **list of images reconstructed** at a preset and configurable distance: **each image corresponds to a level**[1] of the reconstructed volume.

[1] The single level is also called "*layer*" or "*slice*".

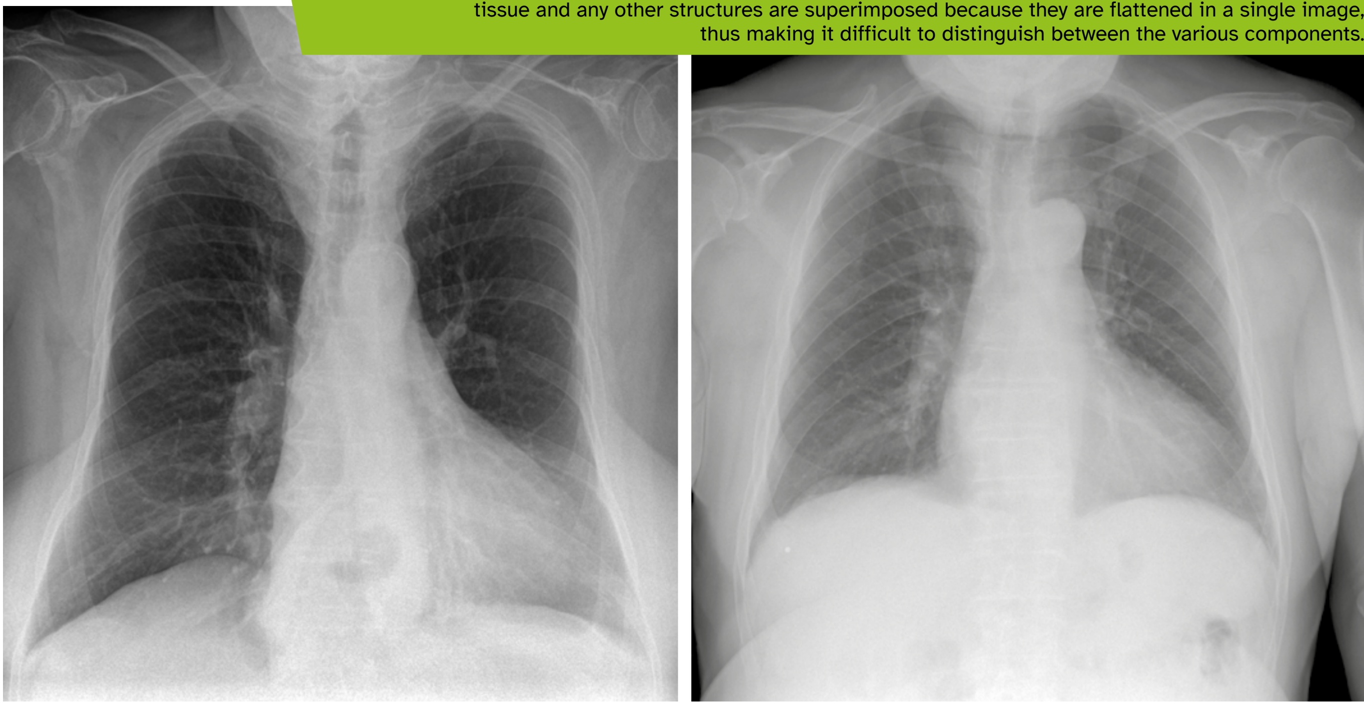


**Figure 2: Radiography** – In a 'classic' X-ray, regardless of the quality of the output, the soft tissue, bone tissue and any other structures are superimposed because they are flattened in a single image, thus making it difficult to distinguish between the various components.

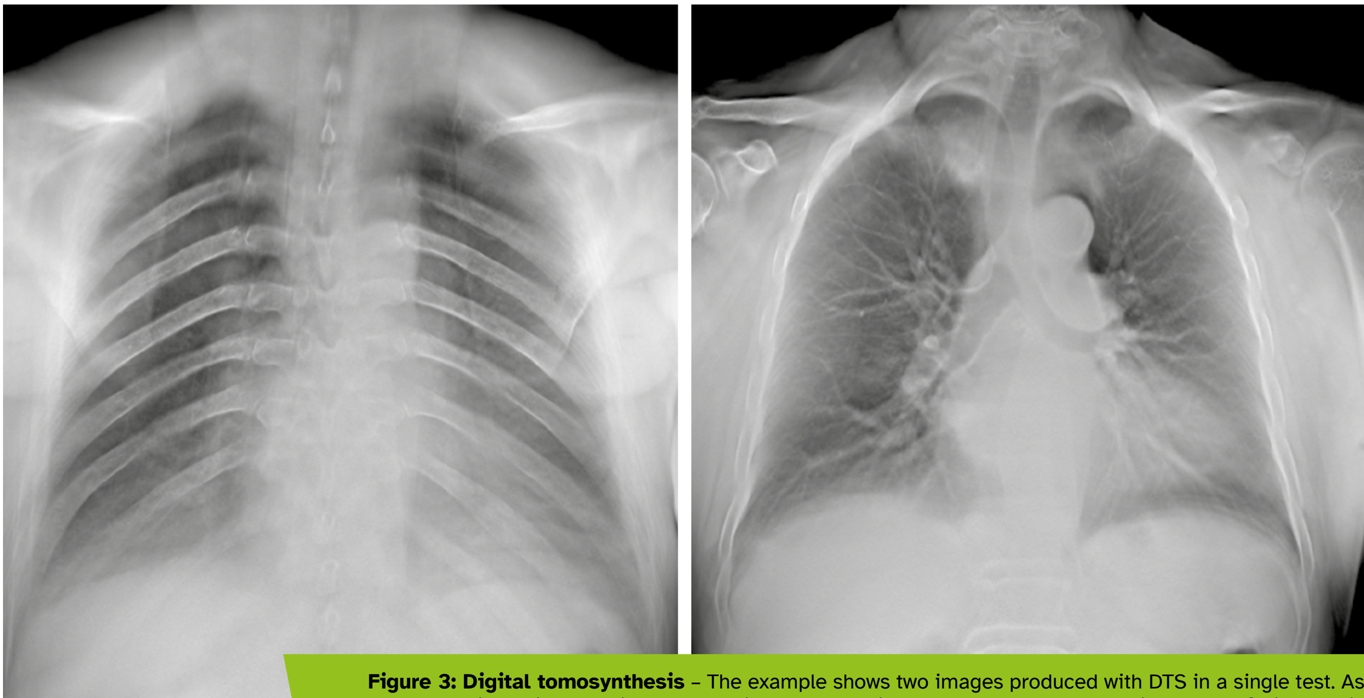


**Figure 3: Digital tomosynthesis** – The example shows two images produced with DTS in a single test. As can be appreciated, in each single 'synthetic' reconstruction, some structures (bone tissue vs. soft tissue) will be more visible than others, depending on the position inside the body and the source-detector angle.

# Methods of execution and application

## Single projections at different angles

For the tomosynthesis algorithm, **each individual projection is acquired at different angles** and therefore contains different points of view of the framed object. **By knowing the position** of the X-ray source, the detector and the volume, and exploiting the different viewpoints of the projections, **the volume is reconstructed in a three-dimensional space**.

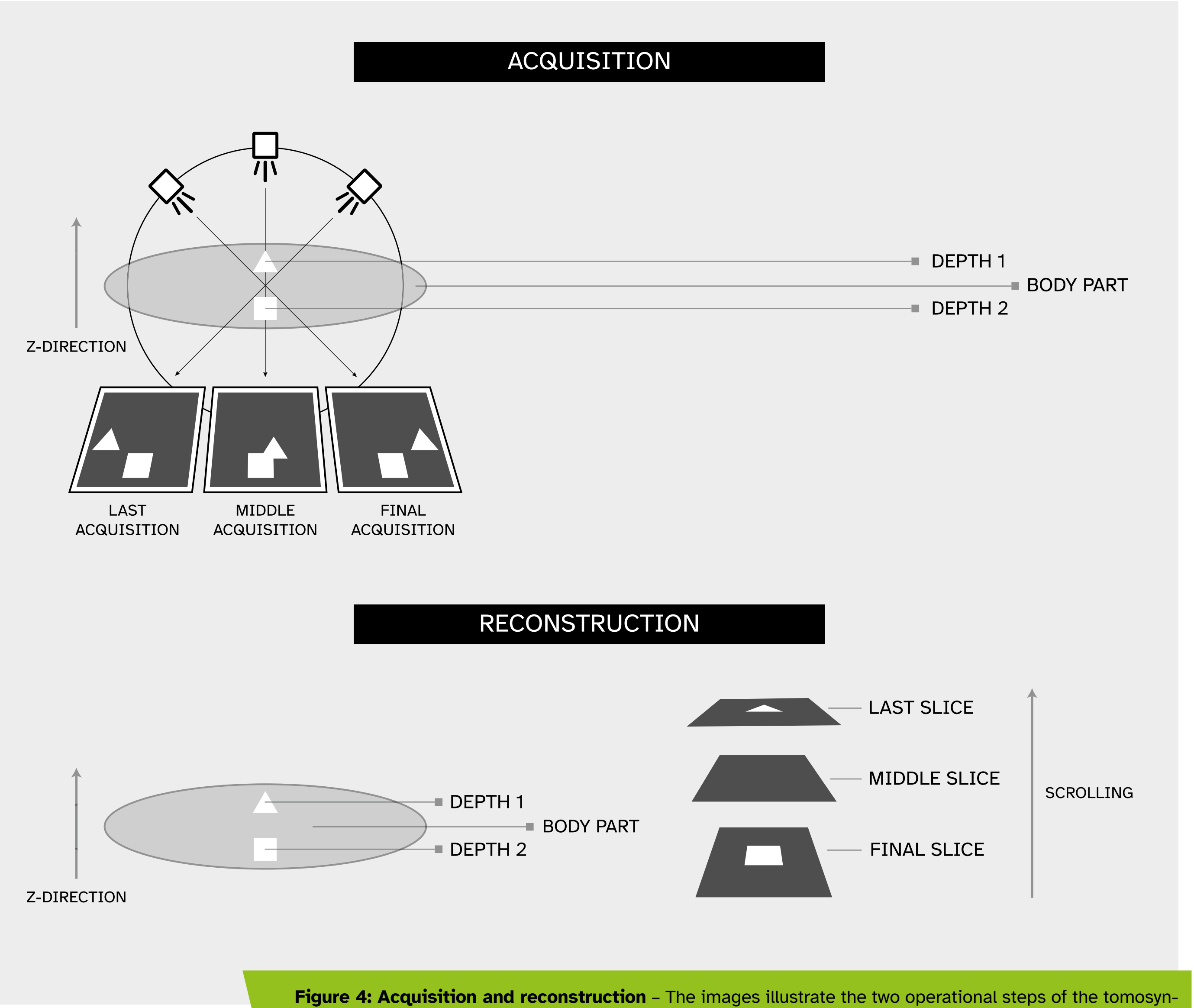



**Figure 4: Acquisition and reconstruction** – The images illustrate the two operational steps of the tomosynthesis algorithm: above, the acquisition process; below, the reconstruction process.

## Three-dimensional output

The **volume generated** by DTS can be **analysed layer by layer**, allowing the radiologist to observe the object in **three dimensions**, separating the structures at different heights into **different levels based on the position** inside the body.

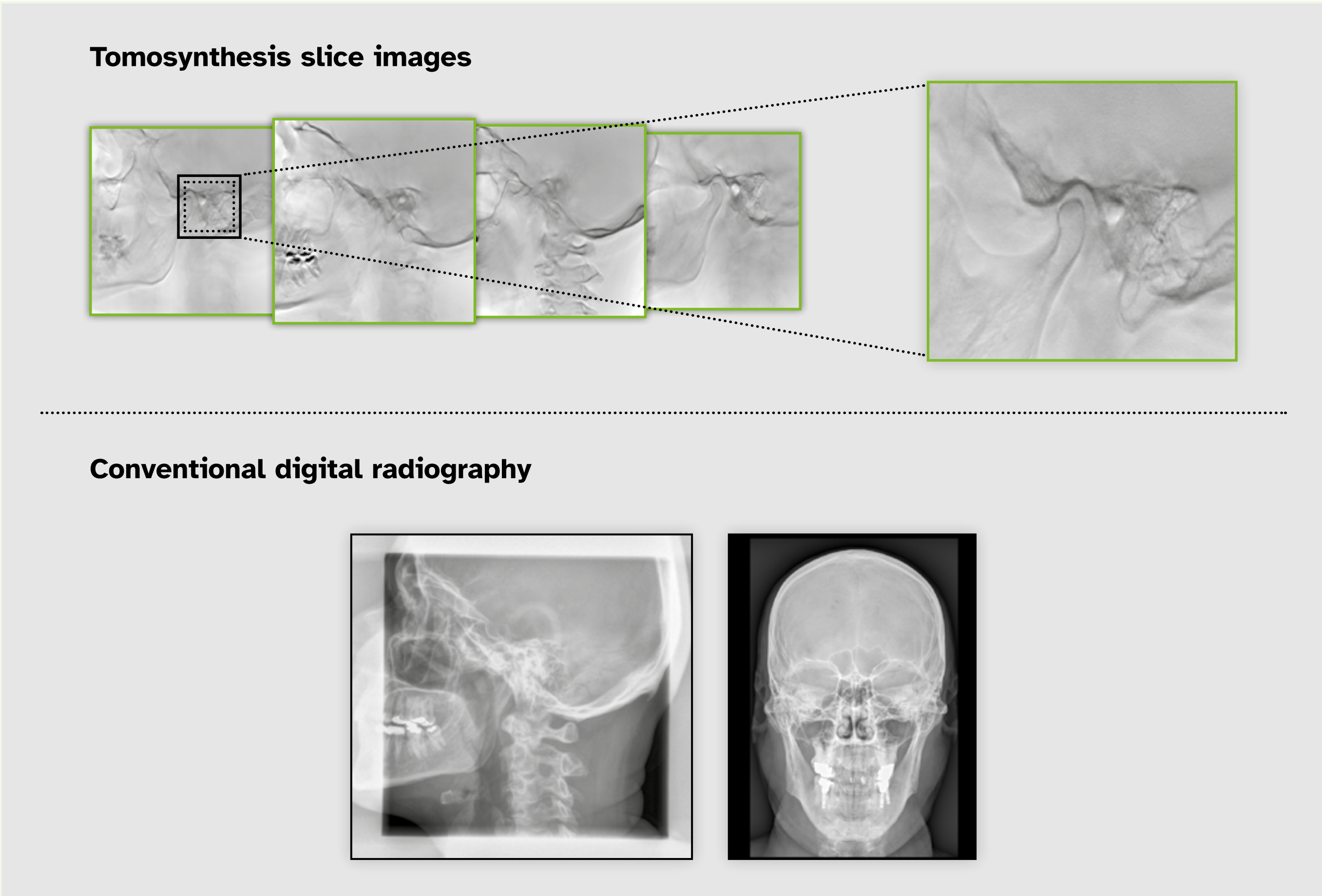



**Figure 5: Tomosynthesis and radiography compared (1)** – The individual tomosynthesis images allow greater visibility – and, in some cases, also a 'granularity' of detail – than in radiography **[1]**.

## Application methods

The algorithm has been designed to allow the user to choose between **two application methods depending on the operational context** and the actual test to be carried out:

- **tomosynthesis (DTS)**, useful for the volumetric reconstruction of any anatomical area;
- **breast tomosynthesis (DBT)**, which shares the same operating principle with DTS, but differs in terms of acquisition geometry **[2]**.

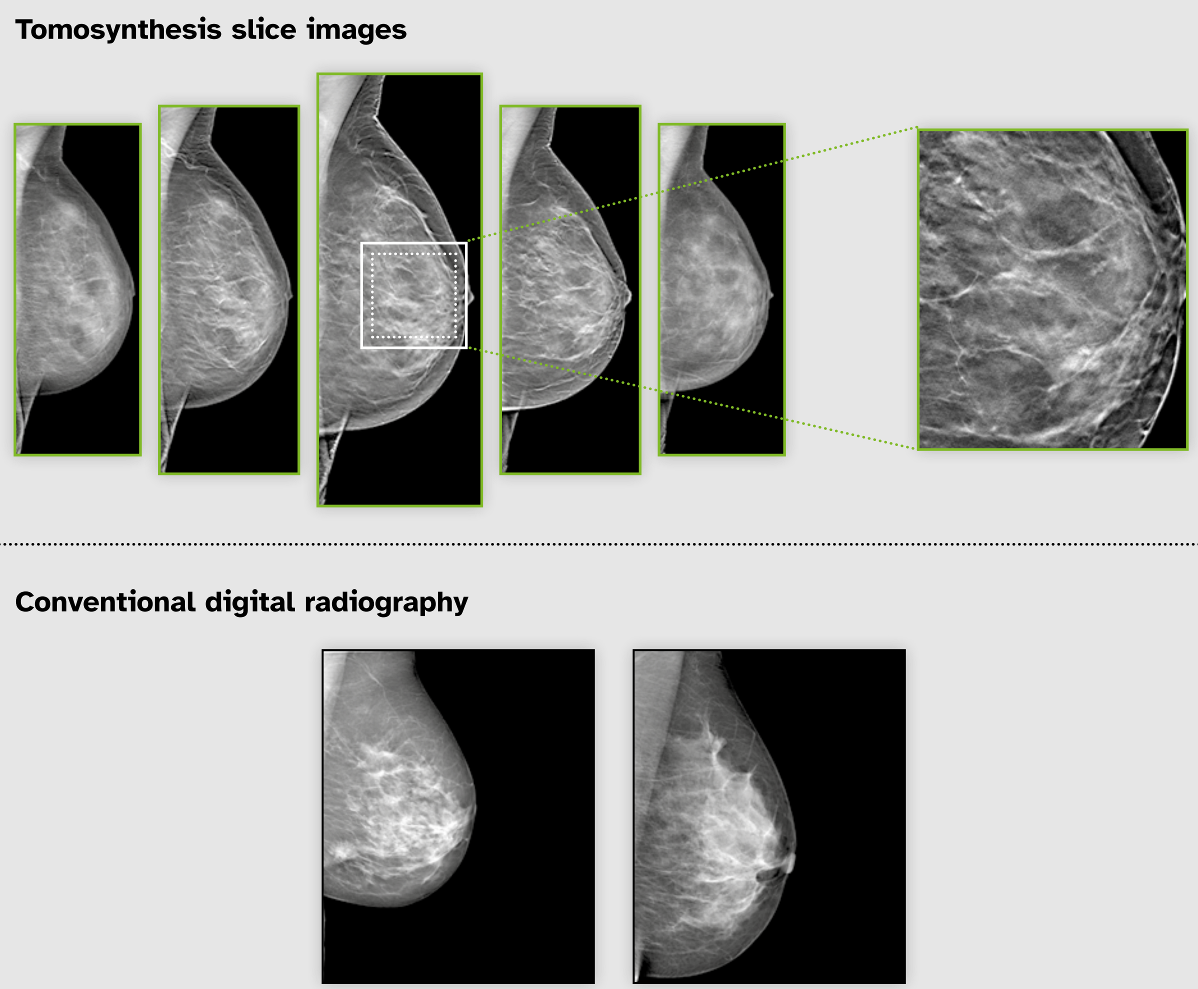



**Figure 6: Tomosynthesis and radiography compared (2)** – Even in the absence of bone structures or precisely because of it, the radiographic results in the breast region are not comparable to the amount of information provided by tomosynthesis.

# FOCUS

## Breast tomosynthesis o *Digital Breast Tomosynthesis* (DBT)

The need to **improve the diagnostic potential in the breast area** clearly emerges from the data: worldwide, breast cancer **is the most common cancer in women** and, with approximately 1.7 million new cases identified in 2012, it represents 25% of all cancers in women and 12% of all new cancer cases in the population as a whole **[3]**.

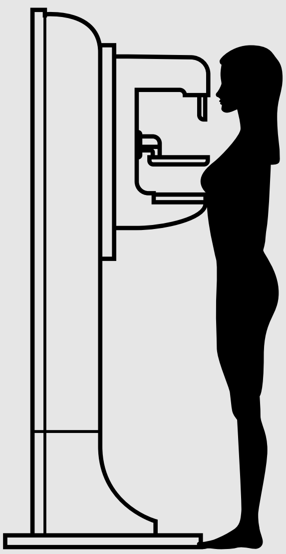


**Figure 7: Tomosynthesis in the standing position** – In breast tomosynthesis, the patient stands in front of the machine with her breast resting on the table. A compressor presses the breast in order to reduce the thickness and increase the surface area. The source rotates in an arc and the detector is stationary.

DBT has **a major impact in preventive screening for breast cancer**: the patient is exposed to a **limited dose of radiation and three-dimensional images** are acquired. This technology offers the possibility of **examining the breast layer by layer** and **improving the visibility of the structures** - including the early diagnosis of any tumour formations - which in classic digital mammograms would be superimposed **[4]**.

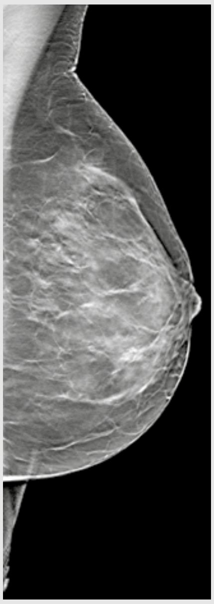


**Figure 8: Mammography and tomosynthesis** compared - Although conventional mammography (left) is still the diagnostic reference standard for the prevention of breast cancer, the tomosynthetic technique (right) allows for a stratigraphic study of the breast and therefore, in a significant number of cases, potentially more effective diagnostic outcomes **[5]**.

# Digital Tomosynthesis: flexible, fast and reliable

## Workflow fluidity

**DTS integrates seamlessly** with the acquisition SW by operating directly **within the** tomosynthesis workflow:

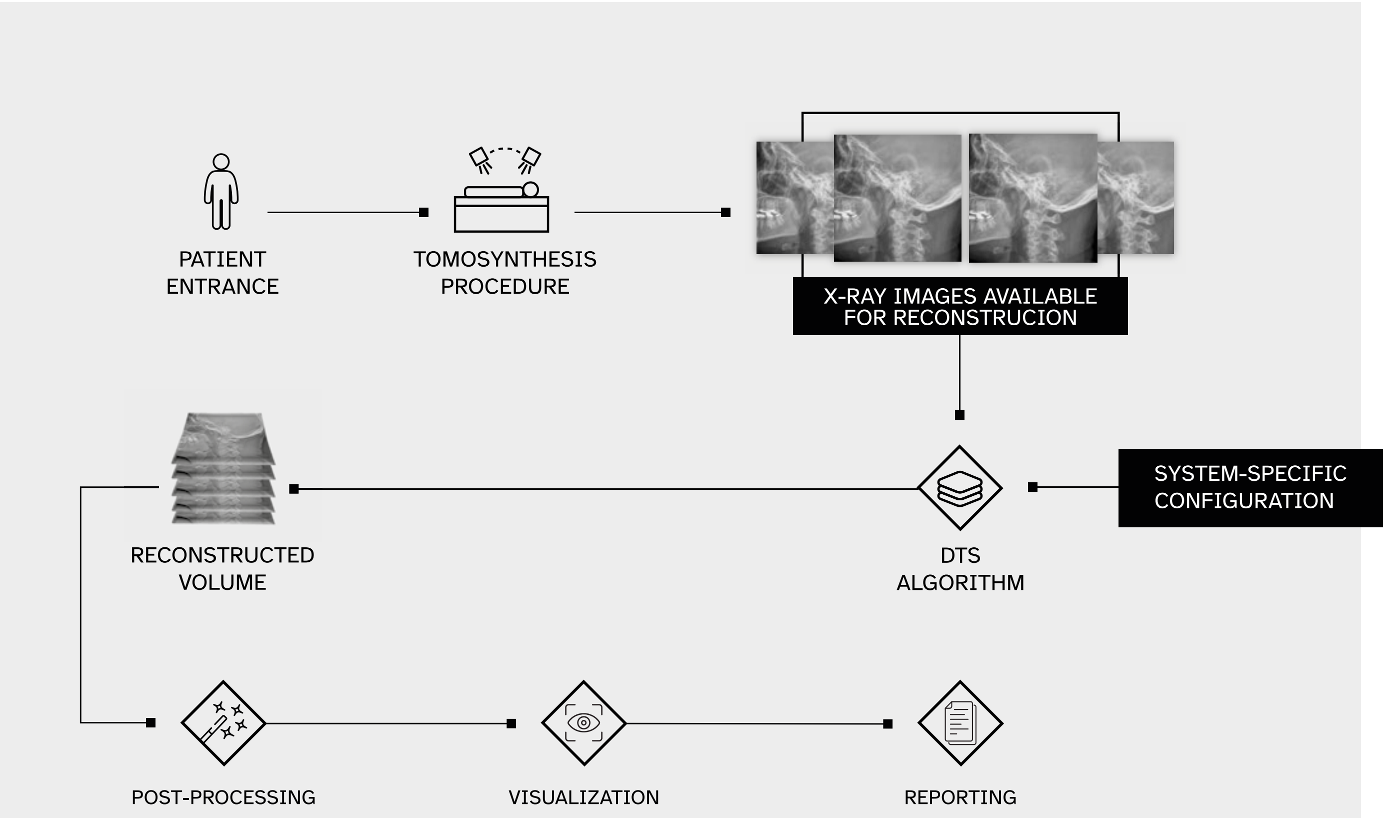



**Figure 9: The workflow** – Without any incumbrance or delays, once the system has completed the acquisition process of the X-ray projections, the images and the mechanical configuration are provided to the DTS algorithm, which reconstructs the three-dimensional volume in the form of a set of planes. The volume is provided to the user software, which will proceed with viewing for medical reporting.

## Speed of execution

The execution time of the DTS algorithm varies from **20 to 40 seconds** depending on the chosen configuration and the size of the input data[2].

[2] Test performed on real images with 2.4 GHz 16-core processor, 8GB GPU, 64GB RAM.

### Reconstruction quality

**What is the added value of such a flow?**
With DTS, the vertical position of structures that would otherwise be flattened in X-ray projections can be distinguished with certainty. In some pathologies (for example, nodules in a chest cavity obscured by the ribs) could be hidden, leading to possible doubts, diagnostic errors, or even missed diagnoses.

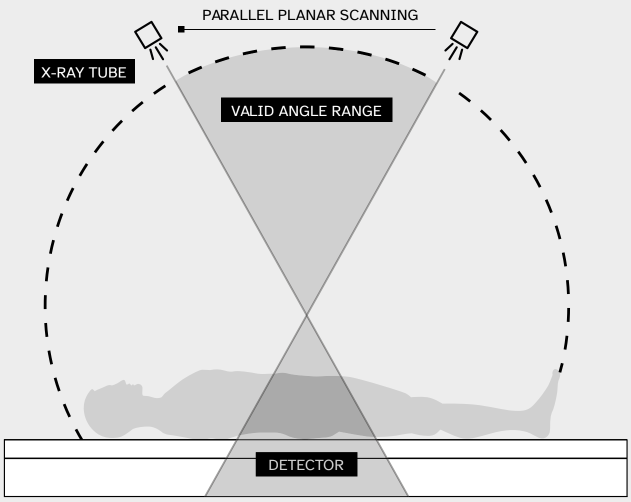
As proof of its reliability, DTS has been **certified as DTS C** (*Digital Tomosynthesis Certified*) **by the notified body TÜV Rheinland Italia (EC number: 1936)** in accordance with current laws[3].

## TS vs CT

### Comparing techniques

The operation of **tomosynthesis** (TS) resembles that of **computerised tomography** (CT). How do the two techniques differ?

**Tomosynthesis (TS)**
The angle of oscillation of the source typically varies - depending on the type of machine - from 20° to 60° with respect to the patient's body.




**Computerised Tomography (CT)**
Body images are acquired by means of a full 360° rotation around the patient's body.

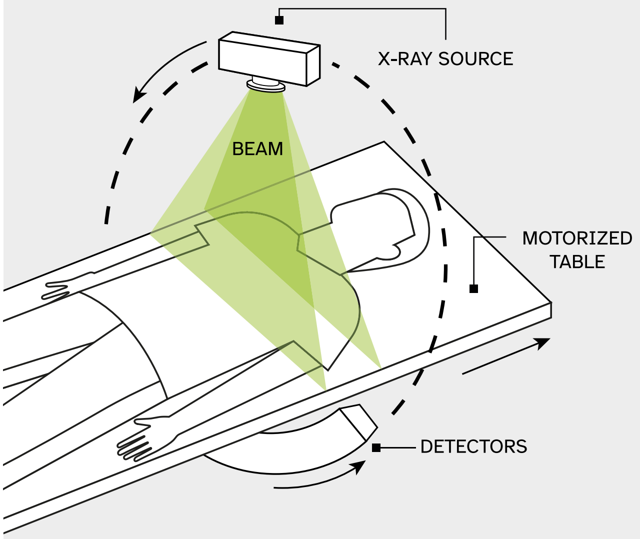



**Figure 10 and 11: TS and CT techniques compared** – In CT the X-ray source is opposite the detector and both rotate 360° around the table, whereas in TS, the source moves with a linear or arc trajectory only within the valid angular range, while the detector can either move linearly in the opposite way to the X-ray source (always within the valid angular range), or remain still.

[3] Request sent in accordance with Chapter I of Annex IX of *Regulation 2017/745 (EU MDR)*, as indicated in art. 52, paragraph 6 of the same.

**The** typical **angular range** of TS, within which approximately 10 to 30 projections are made, is therefore limited and well **below 180°**. So while in CT the reconstruction of the framed volume is faithful, in TS the spatial sampling is insufficient to guarantee an exact reconstruction of the volume, which will therefore contain artefacts linked to the operating principle.

## What about performance?

From the comparison illustrated above, **it might seem that TS performs less well** than CT. However, it is **worth contextualising** this assessment in a broader scenario, taking **several factors** into account:

1. The **artefacts** deriving from the operating principle of TS are **not limiting** for the purposes of medical diagnosis. **[1]**
2. TS guarantees greater **portability** because it can be **integrated into many X-ray machines**, which have **significantly lower costs** than CT machines.
3. TS **acquisitions** are **much faster** than CT and allow a first analysis of the body, **improving the workflow and diagnosis times**, especially in the screening phase **[6]**.

# The advantages at a glance

DTS therefore presents itself as **an algorithm that is not only high-performance, but also versatile.**

- Although each manufacturer has its own mechanical configuration, **DTS is independent** of the movement used **by the mechanical system** and able to adapt to **any type of geometry**.
- With the use of *filtered back-projection* (FBP) or *Iterative Algorithms*, DTS is **applicable for both classical tomosynthesis and breast tomosynthesis**.
- DTS can be **completely customised** to suit the customer's needs.
- DTS can be **run both with and without GPU support**[4] (see table below).

| | | | |
|---|---|---|---|
| DBT | Alg/HW | GPU | CPU |
| | Iterative | Supported | Not Supported |
| | FBP | Not Supported | Not Supported |
| Tomosynthesis | Alg/HW | GPU | CPU |
| | Iterative | Supported | Not Supported |
| | FBP | Supported | Supported |

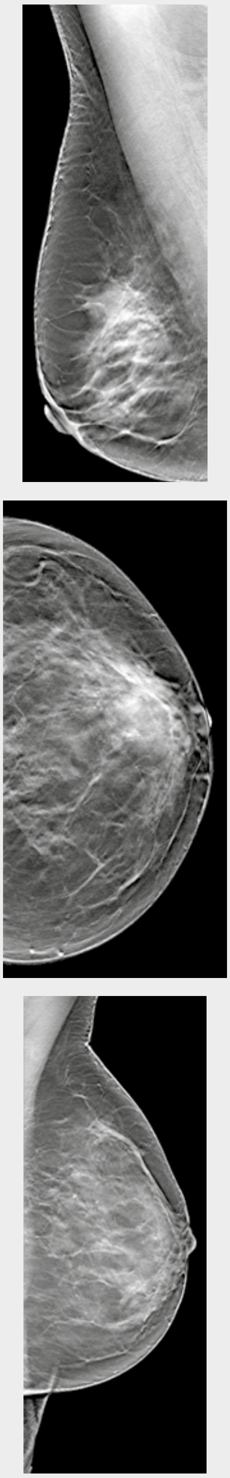
[4] To be able to perform a DBT (*Digital Breast Tomosynthesis*), it is necessary to have a GPU installed.

# Confidence: a test

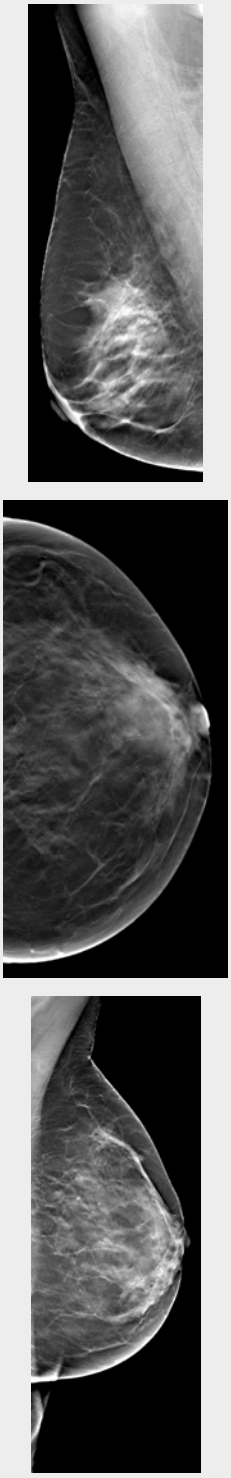
A **visual comparison between** the volume generated with **DTS and** the reconstruction of **a market leading competitor** is shown below.

The images show, for purely illustrative purposes, three levels extracted from **volumes reconstructed with DTS** (left) compared with the respective comparative references (right).

**Image generated with DTS**



**Comparative reference**



As can be seen **from** the images, **the results obtained with DTS** are **in line**, if not **superior, to the market standard**, especially **with** regard to **contrast levels** and **edge sharpness**.

## Conclusion

In light of the above, and considering the advantages in terms of **speed, portability and economy**, tomosynthesis is confirmed **to be useful** both for an **initial analysis** of the layers of the body and in the **diagnostic screening** phase of some pathologies.
**DTS** is therefore a **valid solution for managing both classic (TS) and specialised breast tomosynthesis (DBT)**, as it is able to adapt to all the mechanics and systems on the market.
DTS is a completely **configurable, versatile, efficient** software as well as certified with **the CE mark**.

**DISCLAIMER:** DTS does not provide any measurement function and cannot, in any case, replace the diagnosis of a professional. 3D reconstructions should be used by healthcare professionals to help make medical decisions.

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*Digital Tomosynthesis to Evaluate Fracture Healing: Prospective Comparison with Radiography and CT*; Ha AS, Lee AY, Hippe DS, Chou S-HS, Chew FS; DOI: 10.2214/AJR.14.13833 (accessed on 10 February 2024).

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**Specific**

**[1]** *Whole-Body Clinical Applications of Digital Tomosynthesis*; Machida H, Yuhara T, Tamura M, Ishikawa T, Tate E, Ueno E, Nye K, Sabol JM; DOI: 10.1148/rg.2016150184 (accessed on 10 February 2024).

**[2]** *Breast Tomosynthesis*; Philpotts LE, Hooley RJ; Elsevier, 2017.

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**[4]** *Pros and Cons for Breast Cancer Screening with Tomosynthesis: a Review of the Literature*; Kleinknecht JH, Ciurea AI, Ciortea CA; DOI: 10.15386/mpr-1698 (accessed on 10 February 2024).

**[5]** *Effectiveness of Digital Breast Tomosynthesis Compared With Digital Mammography: Outcomes Analysis From 3 Years of Breast Cancer Screening; McDonald ES, Oustimov A, Weinstein SP et al; DOI: 10.1001/jamaoncol.2015.5536 (accessed on 10 February 2024).*

**[6]** *Lung Cancer Detection with Digital Chest Tomosynthesis: First Round Results from the SOS Observational Study; Bertolaccini L, Viti A, Tavella C, Priotto R, Ghirardo D, Grosso M, Terzi A; DOI: 10.3978/j.issn.2305-5839.2015.03.41 (accessed on 10 February 2024).*

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