An Innovative Optical Imaging Technology for Early Breast Cancer Detection



DeHCA is a project with a dual objective:

An **innovative medical device** for the early diagnosis of breast cancer, characterized by:

- use of visible light **harmless** to human health
- **painless** and comfortable examination
- **functional** examination providing new information to the physician.

Innovative services in the territory:

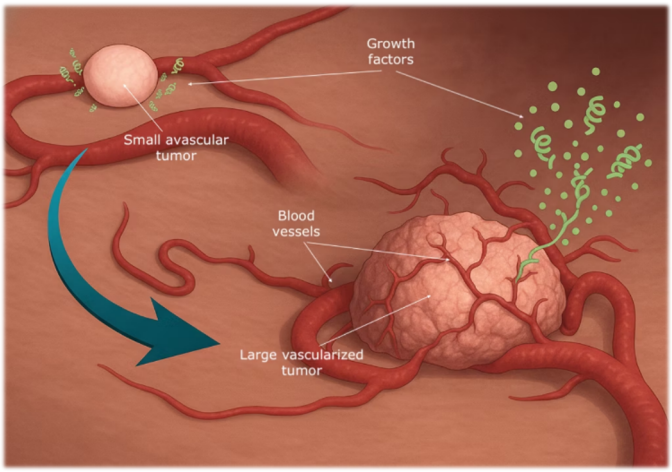
- prevention also for **dense breasts**, especially in younger women
- accessibility also in **local medical centers**, in a simple and affordable way
- **used alongside traditional morphological examinations** such as ultrasound and mammography, complementing them **through image integration** to achieve greater diagnostic completeness.

Novaura Srl
Via Podgora 13, 20122 Milano
P.IVA 13471500150
info@novaura.com

CONFIDENTIAL
© 2026 - Property of Novaura S.r.l.
Unauthorized reproduction or distribution, in whole or in part, of this document is prohibited.

Scientific basis

The DeHCA project is based on consolidated and widely validated scientific principles related to breast physiopathology. The technology focuses on identifying functional changes caused by tumors rather than structural changes in tissues.



Two mechanisms are particularly relevant:

Increased oxygen consumption – Tumor cells consume oxygen more rapidly than healthy tissue, generating a local accumulation of **deoxyhemoglobin**.

Neoangiogenesis – Tumors promote the growth of new irregular vessels that tend to concentrate blood with altered oxygenation.

Device operating principle

The device is an optical tomograph (DOT) that uses imaging at 640 nm to detect areas of abnormal oxygen consumption in the breast, often associated with pathological conditions and highlighted by the presence of excess deoxyhemoglobin; hence the name of the project: DeHCA is in fact an acronym for **De**oxy**H**emoglobin **C**oncentration **A**lteration.

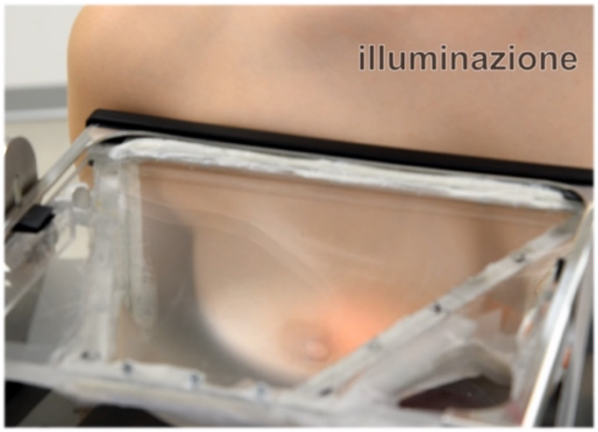
The DeHCA examination is carried out through the following procedure:

- a gentle and painless compression of the breast at low pressure (10 mmHg) causes local stasis of blood microcirculation in the tissues involved
- the presence of a tumor locally causes an increase over time in the concentration of deoxyhemoglobin within the neo-angiogenic vascular network
- the presence of deoxyhemoglobin generates areas of abnormal absorption of red light at 640 nm in the breast
- the device acquires, for a few tens of seconds, thousands of images over time through two special cameras that photograph the breast, illuminated in darkness by red light (to detect deoxyhemoglobin) and infrared light (to detect the 3D volume occupied by the breast)
- through complex mathematical algorithms, the abnormal absorption of red light is reconstructed.

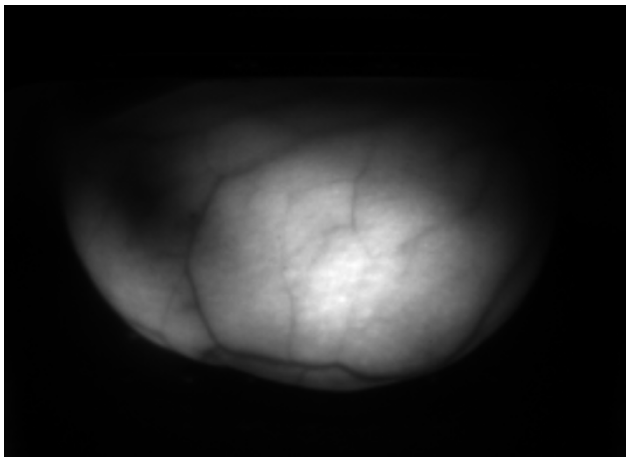


Novaura Srl
Via Podgora 13, 20122 Milano
P.IVA 13471500150
info@novaura.com

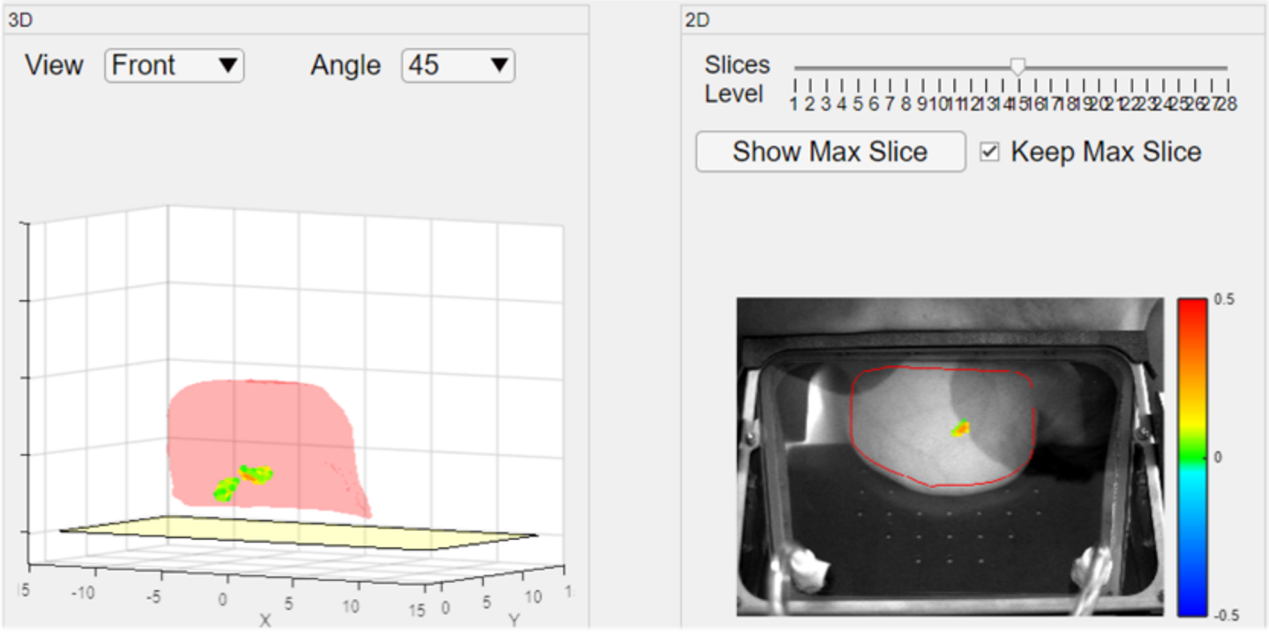
CONFIDENTIAL
© 2026 - Property of Novaura S.r.l.
Unauthorized reproduction or distribution, in whole or in part, of this document is prohibited.



The examination **is functional rather than morphological**: the Device generates a 3D image that, through a colour code, highlights within the breast volume the areas of abnormal oxygen consumption, which represent a new indication for possible subsequent morphological investigations.



If the exam highlights abnormal oxygen consumption in any volume of the breast, it is recommended to perform a **morphological examination**, for example an ultrasound examination, guided by the spatial indication provided by the DeHCA exam.



To optimize the functional and regulatory aspects of the DeHCA Device, it has currently been decided to **consider it composed of two separate Medical Devices**:

a. the image acquisition HW (CE certified Class I), which interfaces with the patient, manages the exam and collects and stores optical absorption images
b. the image processing SW (to be CE certified based on the results of clinical validation trials) that processes the images and provides 3D absorption maps that can be interpreted by the referring physician, both locally and remotely.

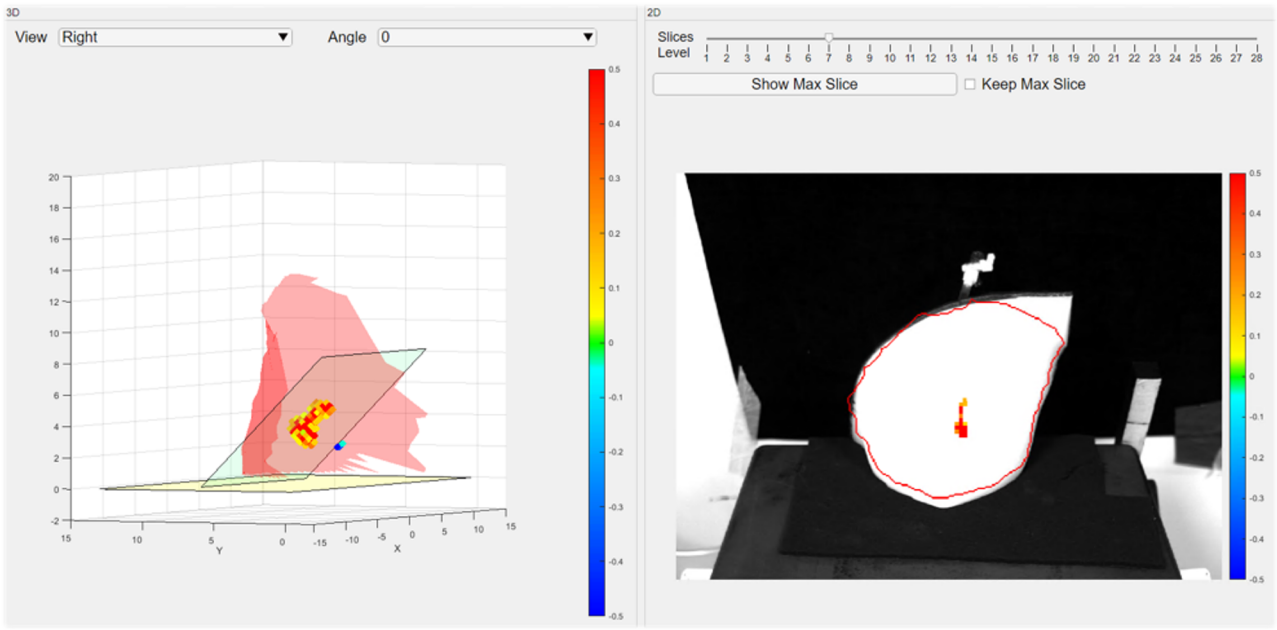
Novaura Srl
Via Podgora 13, 20122 Milano
P.IVA 13471500150
info@novaura.com

CONFIDENTIAL
© 2026 - Property of Novaura S.r.l.
Unauthorized reproduction or distribution, in whole or in part, of this document is prohibited.

Clinical results

Data collection

Data were collected through three different approaches:



- **laboratory tests** on technical aspects (pressure, timing, optical noise, etc.): numerous experiments were carried out in the laboratory to verify and document different aspects of development
- **simulations with phantoms**: several static and dynamic phantoms were created to simulate different aspects of the examination (optical and mechanical behaviour of breast tissues, breast morphology, exam dynamics, etc.)
- **clinical tests on volunteers** and patients: data were collected **from 262 patients.**

Technology optimization

Most of the data collected so far have been used during the different development phases to define and optimize the characteristics and performance of the DeHCA device.

The objective, with the support of clinicians, has been to correlate the optical maps generated by the device with possible pathologies and, through dedicated software, provide a 3D visualization of the optical scan allowing physicians to easily and directly identify possible suspicious areas.

User Experience

The numerous tests with patients and volunteers were also used to understand the requirements of practicality, efficiency and ergonomics that must be satisfied during the examination.

Novaura Srl
Via Podgora 13, 20122 Milano
P.IVA 13471500150
info@novaura.com

CONFIDENTIAL
© 2026 - Property of Novaura S.r.l.
Unauthorized reproduction or distribution, in whole or in part, of this document is prohibited.

Demonstration of effectiveness

The tests performed on patients were carried out using progressive versions of HW and SW necessary to improve performance. For this reason, the currently available data refer to samples of limited size and are therefore not yet sufficient to definitively demonstrate the clinical validity of the Device.

Once the reference version of the Device has been defined and its performance and optimal conditions of use have been objectively evaluated, it will be possible to make it fully available to clinicians, who will thus have a new tool in the fight against cancer.

Project history

The project originated and developed starting in 2016 from an original intuition by Danilo Gennari, which led to two patents for the realization of an innovative applicator dedicated to breast optical imaging.

During development several original competencies were developed related to the specialized aspects of the DeHCA Device, including:

- dynamic low-pressure air control
- mathematical methods for 3D reconstruction of DOT images
- HW and SW methods for minimizing and compensating patient movement
- development of static and dynamic phantoms for device calibration
- methods for reducing and filtering optical noise.

A CE-certified experimental device **(DeHCA Theia)** has been developed whose purpose is to provide 3D maps of abnormal red-light absorption in breasts with pathology.

This is the current **level of development of the Device (TRL 7):**



- **the pressure regulation system** on the breast works correctly and laboratory tests show that the pressure exerted on the breast (and transmitted inside it) is properly controlled and follows the patient's movements
- **the image acquisition system** is complete and functioning, **and the resulting electronic and optical noise** is adequate for correct image processing
- **the DOT image reconstruction algorithms** function correctly in tests carried out on phantoms, showing areas with different light absorption
- in tests carried out with volunteers and patients, some artifacts emerged due to **displacement and/or deformation of the breast** (compatible with the theoretical analysis of light absorption and the measurements made on phantoms), for which various HW and SW methods of containment and/or compensation have been implemented

CONFIDENTIAL
© 2026 - Property of Novaura S.r.l.
Unauthorized reproduction or distribution, in whole or in part, of this document is prohibited.

- **in tests carried out with patients** with tumors, **the tumor is detected correctly**, with exceptions when macroscopic displacements or deformations of the breast under examination occur
- tests with patients also show that the **anatomical profile of the illumination plate** still needs to be further improved to avoid artifacts in large breasts
- in the clinical use of the machine, there is still ample room for improving the ergonomics of the device, as well as its design.

Project Developments

The current stage of project development is being carried out through the Open Innovation approach, which involves the participation of multiple subjects and entities (Universities, Research Centers, Industry, Medical Device Manufacturers, etc.) that can contribute, with different roles and objectives, to the many activities required.

The immediate objectives are:

1. **to create a team** that covers all the necessary activities
2. **to reach a final version of the device** in order to achieve the target performance
3. to achieve complete **Proof of Concept** through validation of its clinical performance
4. to achieve the **Project exit** by transferring the intellectual property to a manufacturing company capable of bringing the device to market.

The **following improvements** to the Device have been identified as being functional to achieving the desired result:

1. complete compensation for motion artifacts through examinations on healthy women
2. acquire multiple 3D images of the breast to compensate for possible deformations
3. include breast deformation in DOT processing
4. optimize the morphology and inclination of the illumination plate with respect to the final result
5. “smooth” 3D modeling of the breast.

Organizational structure

The Organizational Structure that the project must equip itself with in order to achieve the set objectives must include the following aspects:

Scientific Committee:

- It is composed of scientists from different disciplines (medicine, engineering, mathematics, etc.) who must guide and verify the correct scientific approach in the development of the project.

Laboratories:

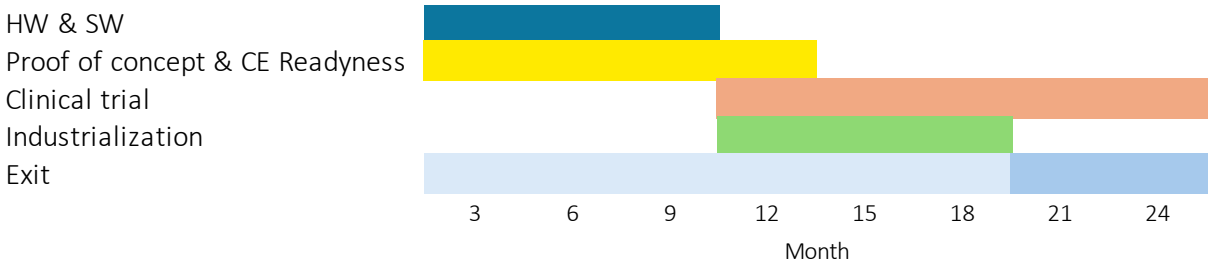
1. Pressure system/applicator development – Must optimize the performance of the system that regulates pressure inside the applicator
2. Mechanical engineering – system – Provides for the re-engineering of the system, making it more suitable for the target industrial model
3. DOT algorithm development – Must optimize image processing to highlight suspicious areas in the best possible way

CONFIDENTIAL
© 2026 - Property of Novaura S.r.l.
Unauthorized reproduction or distribution, in whole or in part, of this document is prohibited.

4. Phantom development – Must continue to develop static and dynamic phantoms for the verification of laboratory performance
5. Electronics and system testing – Must fine-tune the Device for clinical use
6. SW development – image acquisition, User Interface, integration with DOT, remote analysis, implementation of AI algorithms for improving and extending functionality
7. Industrial Design – must improve and optimize the user experience.

Business overview

From the moment the new working team is established, a first phase of completion of Device development and a second phase of clinical tests are envisaged. The two phases should have a total duration of 12/24 months, during which the device will not be sold, but it will be possible to set up the commercial structure.



- Global breast imaging market: $4.1 billion (CAGR 8.5%)
- Theoretical accessible European market: >14,500 devices (> €1 billion)
- Primary target: 80 million European women (35–49 years old) who do not access traditional screening programs
- Target DeHCA market price: €85,000
- Novaura first target share: 5% (715 devices, > €60 million potential revenues).

Project Economics

- Investment sustained up to the current phase: approximately €8.6 million, TRL7 (2017–2025)
- Estimated investment up to industrialization: €1.5 million (final development and validation)
- Project duration: up to 30 months
- Value-enhancing milestone: validated clinical Proof of Concept, CE Mark
- Expected exit: sale of IP or industrial licensing agreement within 24 months.

For further details, a business plan and a detailed roadmap of the operational phases are available.

Novaura Srl
Via Podgora 13, 20122 Milano
P.IVA 13471500150
info@novaura.com

CONFIDENTIAL
© 2026 - Property of Novaura S.r.l.
Unauthorized reproduction or distribution, in whole or in part, of this document is prohibited.

Acknowledgements

- San Raffaele Hospital, Milan
- European Institute of Oncology (IEO), Milan
- Italian League for the Fight Against Tumors (LILT), Gravedona
- National Cancer Institute – Pascale Foundation, Naples
- Valduce Hospital, Como
- Politecnico di Milano
- University of Milan.

A bibliography related to the aspects described above is available upon request.

If you would like to participate in the DeHCA Project, please write to dehca@novaura.com



Novaura Srl
Via Podgora 13, 20122 Milano
P.IVA 13471500150
info@novaura.com

CONFIDENTIAL
© 2026 - Property of Novaura S.r.l.
Unauthorized reproduction or distribution, in whole or in part, of this document is prohibited.