MammoWave.
The first breast test towards a paradigm shift in breast cancer prevention

UBT SRL
Benefit C.

Video: www.youtube.com/watch?v=lGF5x67ep3Y&feature=youtu.be

https://www.ubt-tech.com/en/home/

Speaker: Gianluigi Tiberi (Co-founder, Head of R&D)

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No 830265, No 872752, No 793449, No. 101017098, No. 101097079

PIONEERING MICROWAVE IMAGING

UBT Srl (benefit company) develops **microwave imaging** to meet existing **needs for safer imaging techniques providing patented, novel, cost-effective, accurate alternatives to current devices**

MammoWave: Allowing all women to be screened to detect **breast cancer**
Stage of development: TRL 9 (CE marked)

+AI

C E MARK

BrainWave: allowing pre-hospital **brain stroke** detection and classification
Stage of development: TRL 6 (clinical trials)

+AI

+AI

Top4 life-science start-ups in Italy 2015

Umbria StartCup 2015 Winner

Medtec start-up academy 2017 Winner

SME Instrument
Phase 1 winner 2017
Phase 2 winner 2018

Individual, Research and Innovation Staff Exchange

FET PROACT 2020

Winner of the EEN Award 2021

Hello Tomorrow Finalist

MISSION CANCER

MAMMOWAVE: A LONG JOURNEY

2012

2015

2016

2018

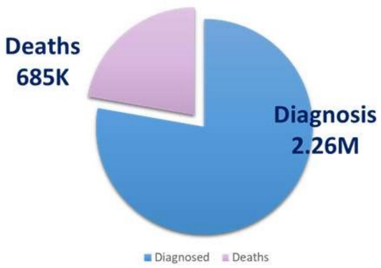
2020/21

Screening for all women!

Patents

- ✓ Tiberi G, Raspa R (2012). Patent n. WO 2014045181: “Apparatus for testing the integrity of mammary tissues”. Granted in Italy, China, EU and USA.
- ✓ Tiberi G, Raspa R (2018). Patent n.102018000004591: “Device for microwave measurement of a dielectric discontinuity of a material”. Granted in Italy and EU (+ PCT).

World stats (2021)



THE PROBLEM

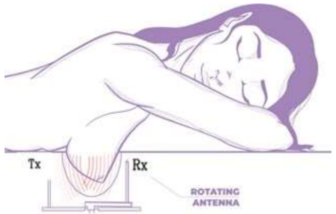
Breast Cancer (BC) is the No.1 cancer-related cause of death in women

30% of BC are now diagnosed in women aged under 50

THE SOLUTION

MammoWave - revolutionary breast cancer (BC) screening device based on safe microwaves instead of x-rays

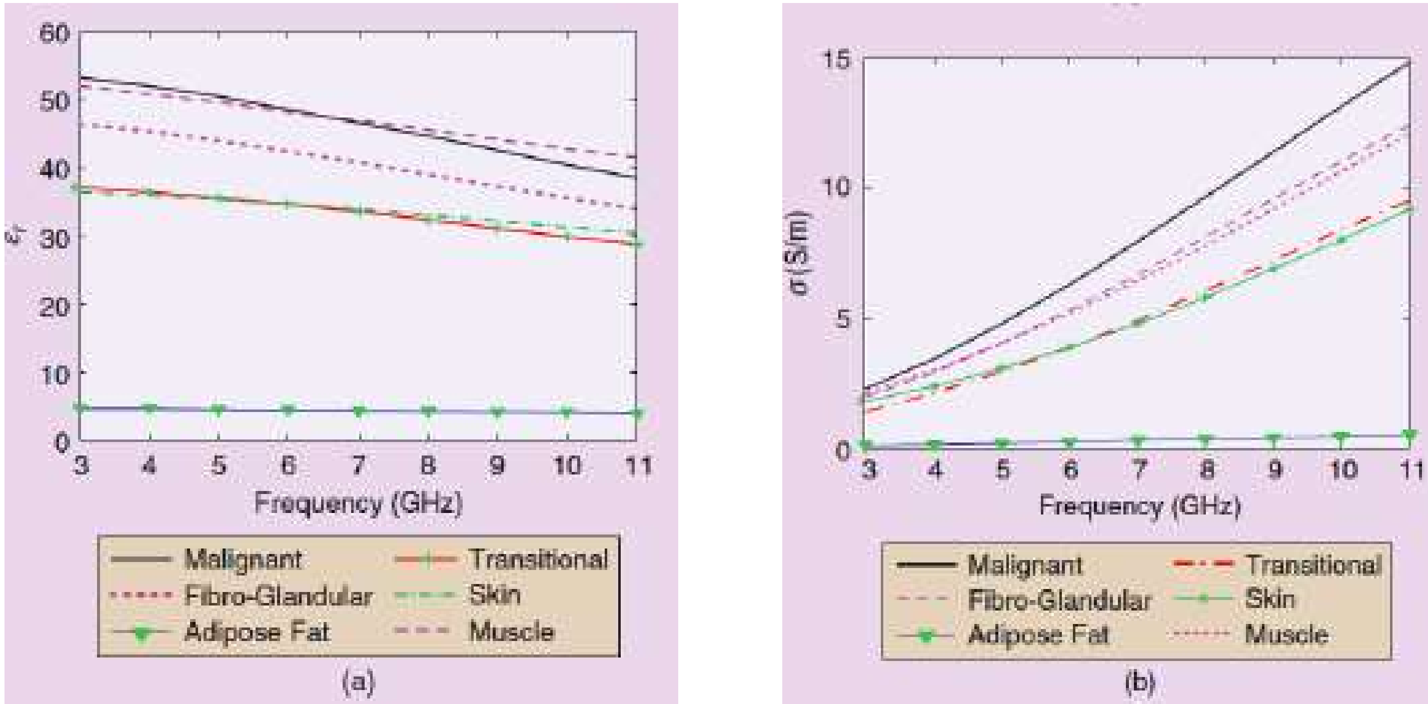
IP protected in EU, USA & China



Innovative medical imaging technology based on the use of safe, low power (<1 mW) microwaves and validated through international, multicentric clinical trials

MAMMOWAVE: HOW IT WORKS

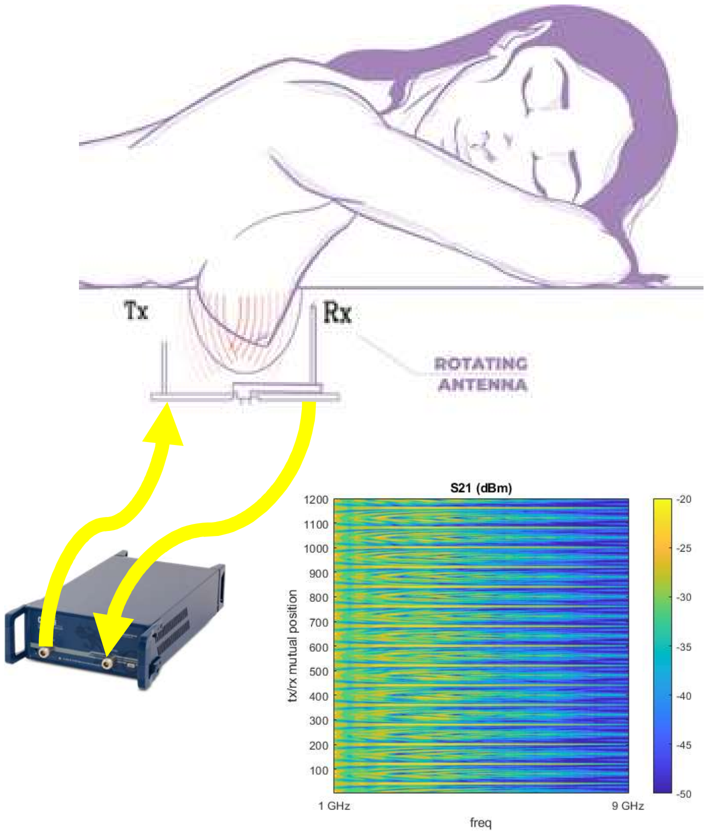
Microwave imaging can be applied to breast cancer detection due to the contrast in the dielectric properties at microwave frequencies of normal and malignant tissues



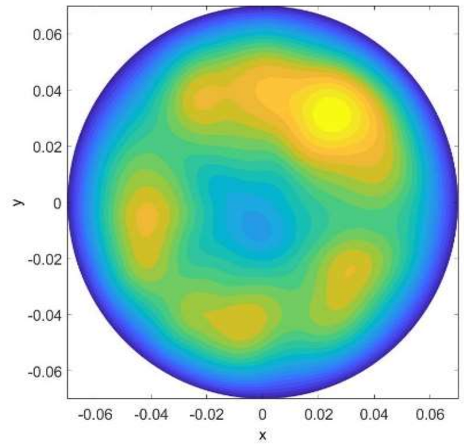
Dielectric constant and conductibility of breast tissues
Source: Microwave Imaging for Breast Cancer, Nikolova, N.K., IEEE Microwave Magazine, 2011


UBT
MAMMO WAVE

MAMMOWAVE: HOW IT WORKS

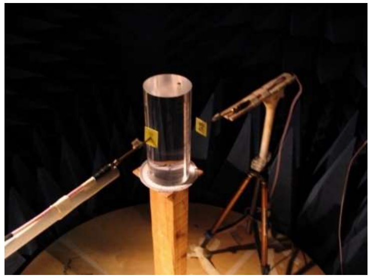


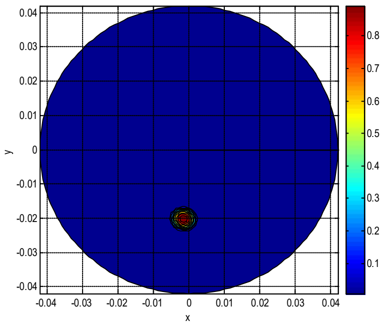
- Contrast in the dielectric properties at microwave frequencies, f=[1-9GHz]
- Images are maximum intensity projection coronal maps (2D) of dielectrics homogeneity of breast tissues
- Images are given in arbitrary units
- Images are normalized to average
- Images' parameters, i.e. features, are introduced to quantify the non-homogenous behaviour of the image.
- Capability of discriminating between breast with finding and breast with no finding

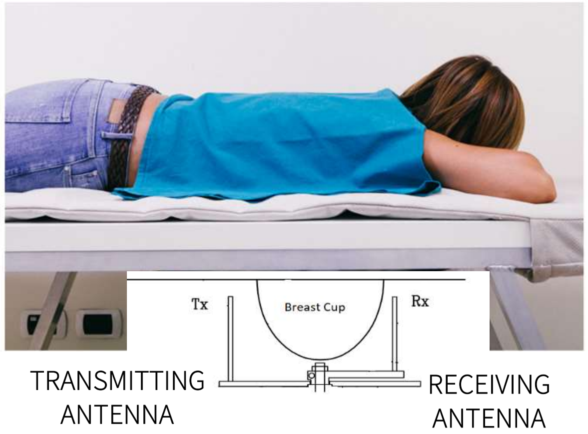


MAMMOWAVE: HOW IT WORKS

Huygen's principle theory*







Clinical trials

Conventional breast exams constituted by echography and/or mammography or magnetic resonance imaging

The radiologist reviews the conventional exams

Gold standard- Output of the radiologist study: breast with no radiological finding (NF) and breasts with radiological findings (WF)

The subject undergoes MammoWave microwave imaging exam: MammoWave data are collected

MammoWave images are obtained and analyzed

MammoWave classification of breast with no radiological finding (NF) and breasts with radiological findings (WF)

Comparison

* G. Tiberi et al, IET Microwaves, Antennas & Propagation, 2011,

* N. Ghavami et al, IEEE Transactions on Antennas and Propagation, 2012

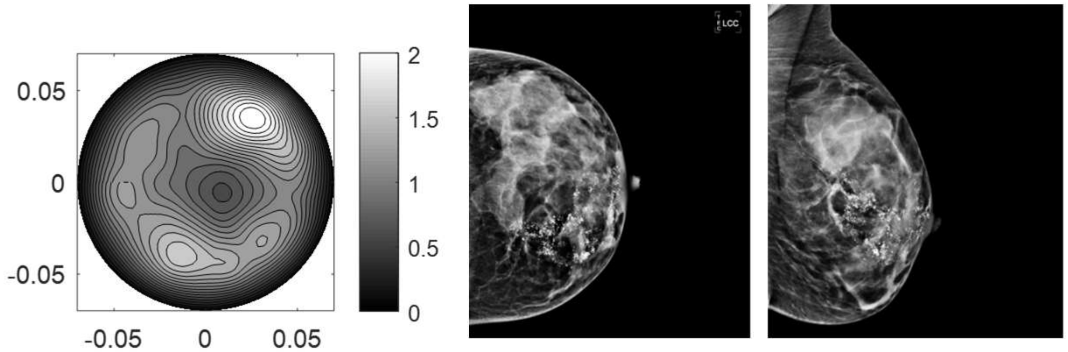
CLINICAL TRIALS

- Feasibility trials on 150 women: **completed**.
- Sponsored trial on 353 women: (https://clinicaltrials.gov/ct2/show/NCT04253366), activated thanks to H2020 Smeinst2: **Completed** at European Hospitals.

MAMMOWAVE: FEASIBILITY CLINICAL TRIALS RESULTS

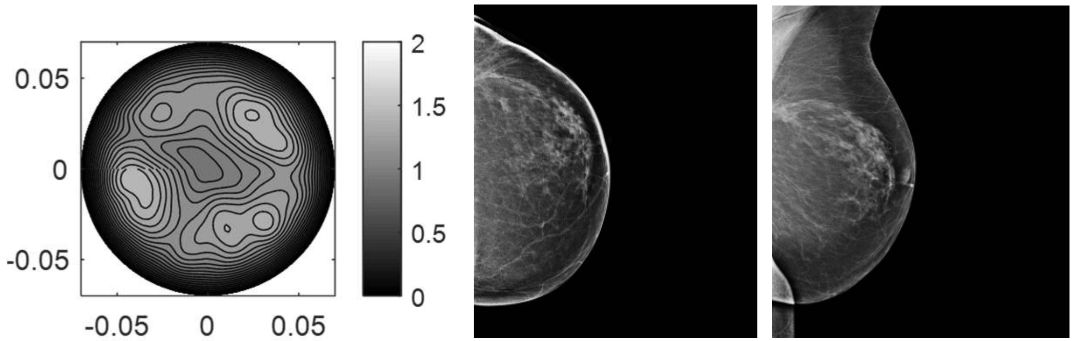
As an example, microwave images are given for: (a) heterogeneously dense breast with carcinoma located in the inner quadrants
The correspondent mammography images are given in (b, c)

(a) (b) (c)



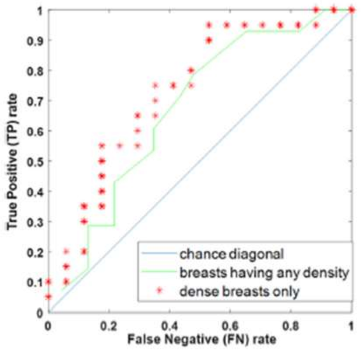
As an example, microwave images are given for: (d) scattered fibroglandular healthy breast
The correspondent mammography images are given in (e, f)

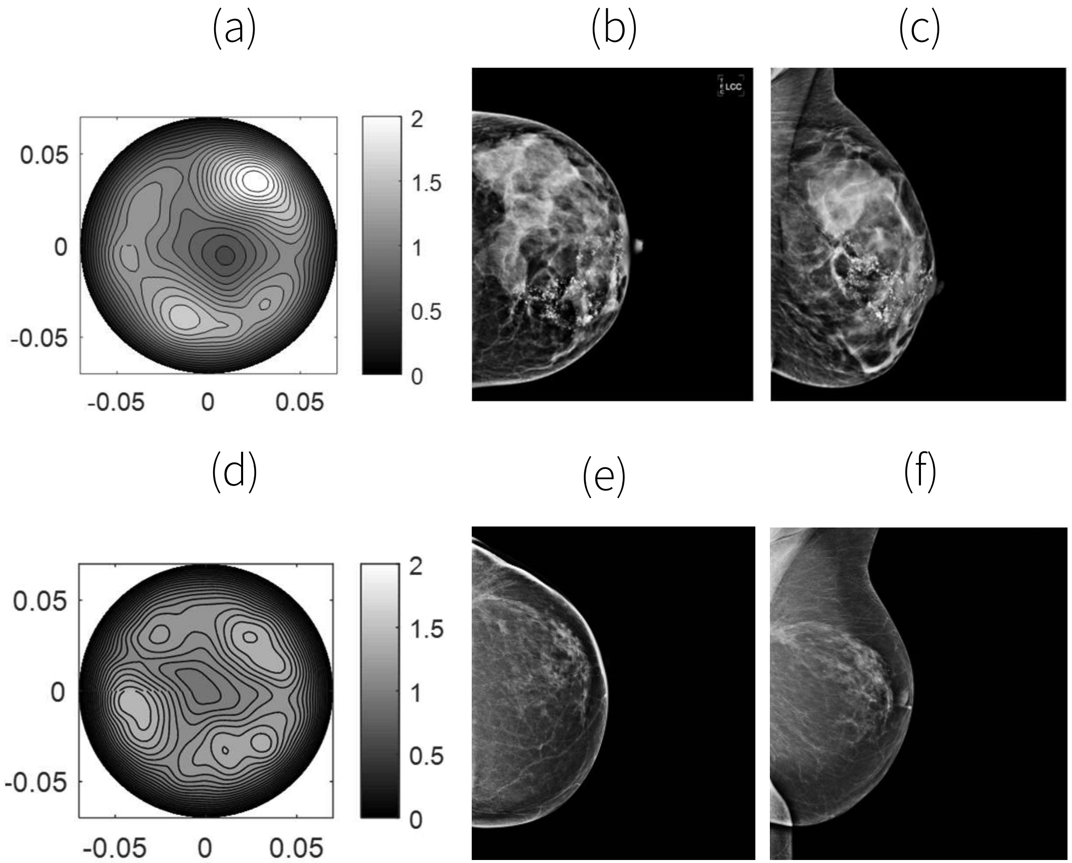
(d) (e) (f)



MAMMOWAVE: FEASIBILITY CLINICAL TRIALS RESULTS

Mammowave images' parameters, i.e. *features*, are introduced to quantify the non-homogenous behaviour of the image.
As an example of parameters, we may consider the images' PEAK





An appropriate **combination of features and thresholds** has been selected during feasibility clinical trials and then prospectively used for classification (statistical significance was set at $p<0.05$)
and then
it has been **used in the prospective clinical trial**

MAMMOWAVE: PROSPECTIVE CLINICAL TRIAL H2020

Conventional radiologist study output is used as Reference Standard. Specifically, each breast is classified into one of the two groups:

breasts with no radiological finding (NF);

breasts with radiological findings (WF), i.e., with benign or malignant lesions.

For an additional evaluation (retrospective), each breast is classified (using the Reference Standard) also into one of the two groups:

breasts with confirmed (by histology) malignant lesion;

breasts without any findings or with benign findings.

Comparison Versus MammoWave output (**both** feature&thesholding based **and** AI augmented)

Scientific evidence on recent H2020 Trials

Radiological WF vs NF (i.e. BI-RADS1): Image parameters and thresholds, **prospective,** algorithm (*thresholds have been fixed after a calibration phase involving 15 NF volunteers and using the median)

Study summary

353* subject enrolled (180 in Toledo, 110 in Genoa, 63 in Milan).
Results will be presented at ECR2023 and have been submitted to PLOSONE (under review)

	TOTAL
Breasts without radiological finding (NF)	230 (93 dense)
Breasts with radiological finding(s) (WF)**	377 WF (197 dense)

*Including 15 patients enrolled for the preliminary phase

**Including 117 confirmed cancers

	All breast types
Accuracy	72.5% (95%CI: 0.68-0.77)
Sensitivity	82.3% (95%CI: 0.78-0.87)
Specificity***	48.6% (95%CI: 0.40- 0.58).
	Low density breasts
Accuracy	72.0% (95%CI: 0.66-0.78)
Sensitivity	89.6% (95%CI: 0.84-0.95)
Specificity	33.8% (95%CI: 0.22-0.45)
	High density breasts
Accuracy	73.3% (95%CI: 0.67-0.80)
Sensitivity	75.0% (95%CI: 0.68-0.82).
Specificity	68.7% (95%CI: 0.56-0.82)
	Histology-confirmed breasts cancer
Sensitivity	82.2% (95%CI: 0.78-0.87)

***This value of specificity is consistent with having set the threshold references equal to the median values of NF breasts recruited in the initial phase

AI augmented

Principal component analysis (PCA) is implemented on the raw data signals engaging support vector machine (SVM) with radial basis function (RBF) kernel.

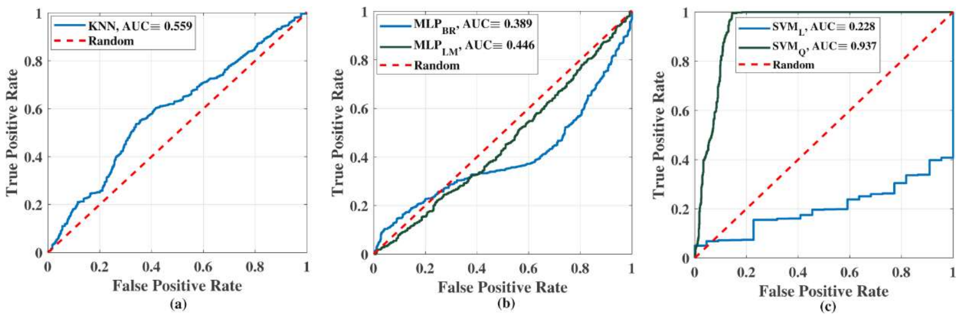

SCIENTIFIC REPORTS

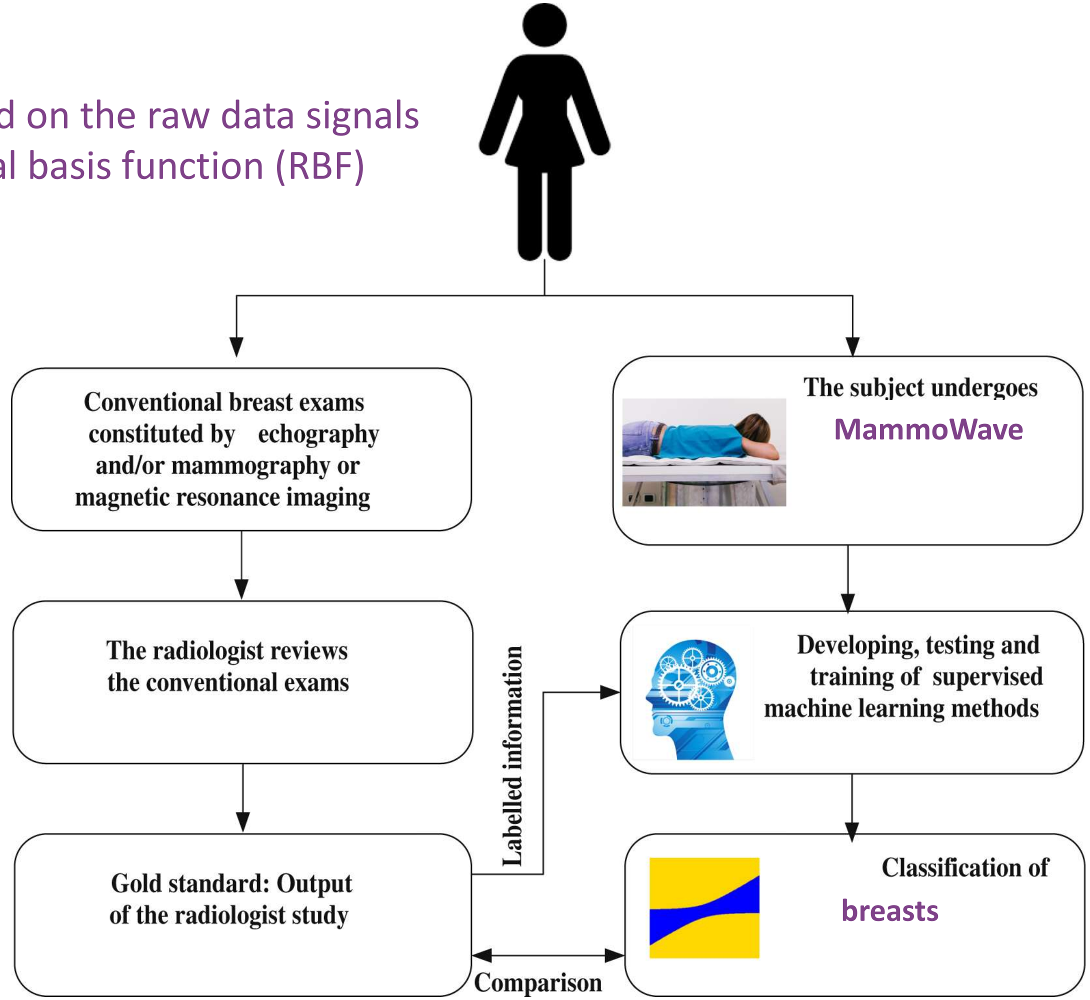
OPEN

Machine Learning Approaches for Automated Lesion Detection in Microwave Breast Imaging Clinical Data

Received: 11 September 2018
Accepted: 4 July 2019
Published online: 19 July 2019

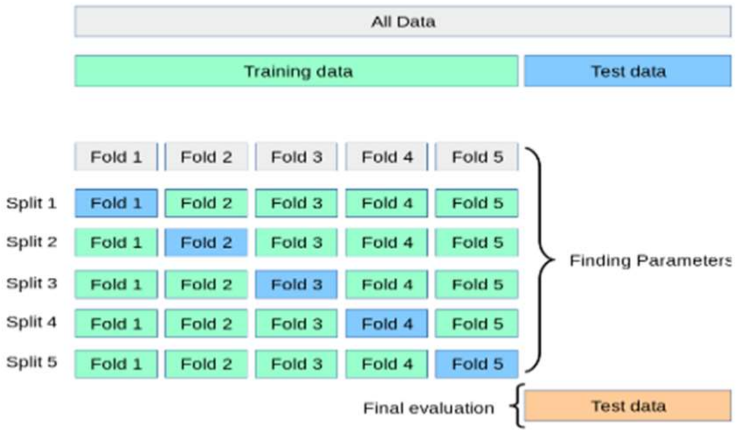
Soumya Prakash Rana[1], Maitreyee Dey[1], Gianluigi Tiberi[1,2,3], Lorenzo Sani[2], Alessandro Vispa[2], Giovanni Raspa[2], Michele Duranti[4], Mohammad Ghavami[1] & Sandra Dudley[1]

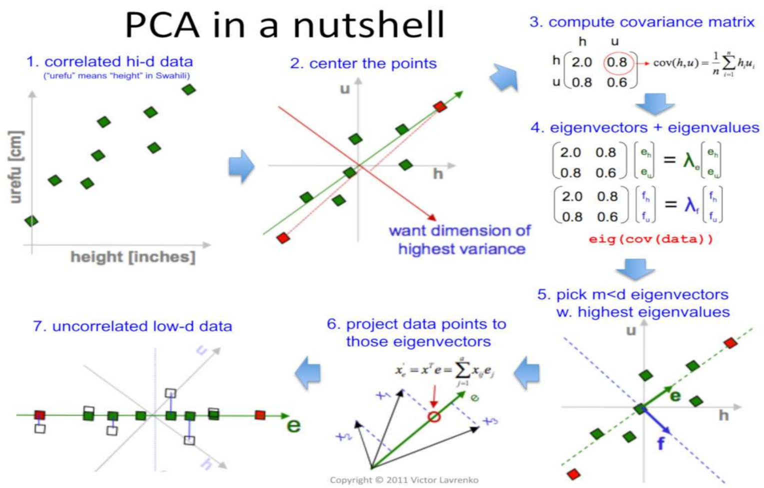




AI augmented

Supervised learning





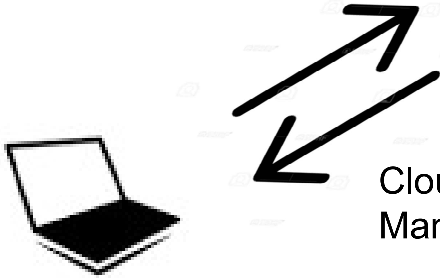
Features selection

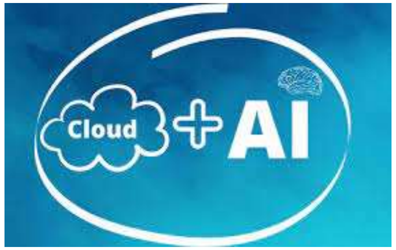
<u>Raw data:</u> Principal component analysis (PCA) is applied fixing the number of components to 100 (95% of data variance)
<u>Rad./stat. features:</u> Feature selection algorithm cuts redundant and highly correlated (>0.9) features, reducing them from few thousands to few hundreds
Up to 90% sensitivity and 90% specificity (retrospective), also in dense breasts (Papini et al, EuCap 2023)

Currently tested prospectively within an ongoing sponsored clinical trials (ClinicalTrials.gov Identifier NCT05300464), activated thanks to H2020-FETPROACT-2020-01

UBT
Umbria Bioengineering Technologies
Benefit Company

MAMMOWAVE: The Operability





Cloud platform to allow real-time/high speed remote MammoWave data processing (anonymized)

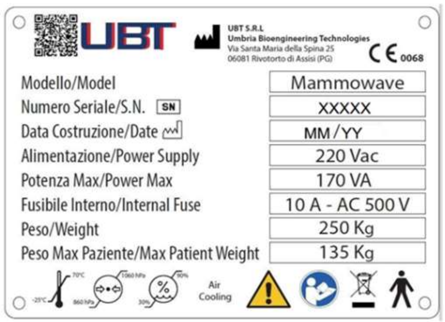
MammoWave output, augmented by AI, **will then be sent back to the clinical specialist in 10 min.**
MammoWave output will be:

- **with anomalies, i.e. suspicious findings: WSF**
- **no anomalies, i.e. no suspicious findings: NSF**

Database enhancement will lead to performance improvement

Possibility time-tracking for each breast

MAMMOWAVE: The Operability



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CE 0068

Modello/Model	Mammowave
Numero Seriale/S.N. SN	XXXXX
Data Costruzione/Date	MM / YY
Alimentazione/Power Supply	220 Vac
Potenza Max/Power Max	170 VA
Fusibile Interno/Internal Fuse	10 A - AC 500 V
Peso/Weight	250 Kg
Peso Max Paziente/Max Patient Weight	135 Kg

Air Cooling

<u>Installation requirements</u>

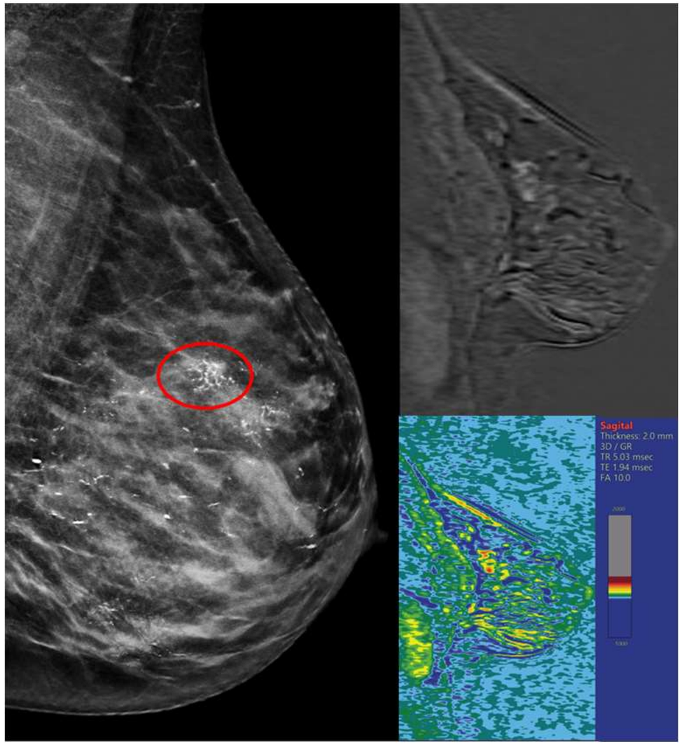
Weight: 250 Kg

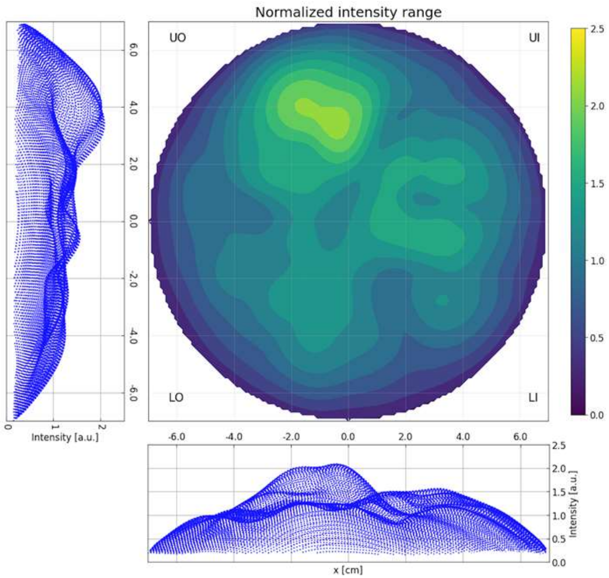
Power supply is multi voltage 100-240Vac 50/60Hz

MammoWave is simple to install and use. It can be placed in any structure as it is free of X-rays, so it does not need any requirements to shield the environment.

Medical device IIa-CE marked

Example #1



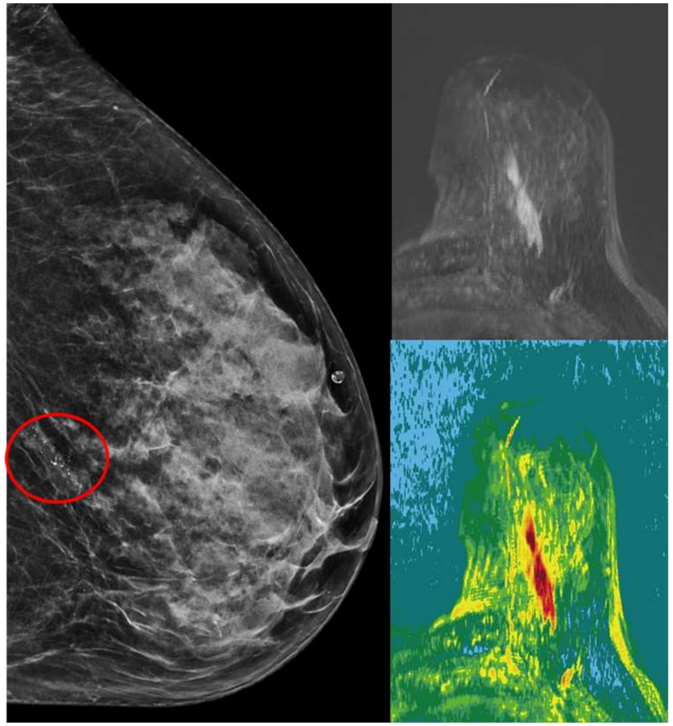


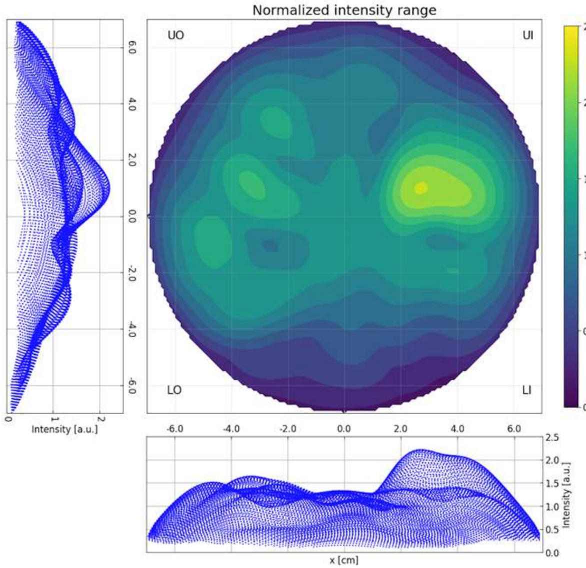
M2ME_i	2.220	WF
MAX_n	2.220	WF
VAR_p	0.196	WF
MAD0_p	0.352	WF
VAR_r	1.750	WF

Female, 37 years old, high-grade microcalcifications.
BI-RADS density: C
Ductal Carcinoma In Situ confirmed.

Report + AI: probably with suspicious findings (WSF)

Example #2





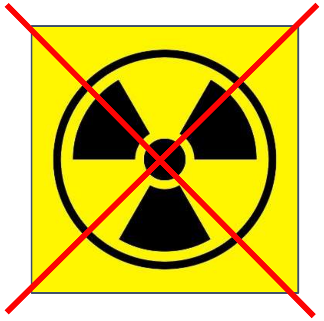
M2ME_i	2.220	WF
MAX_n	2.220	WF
VAR_p	0.152	WF
MAD0_p	0.324	WF
VAR_r	1.000	WF

Female, 66 years old, microcalcifications.
BI-RADS density: D
Intraductal carcinoma, interval cancer confirmed.

Report + AI: probably with suspicious findings (WSF)

MAMMOWAVE: VALUE PROPOSITIONS

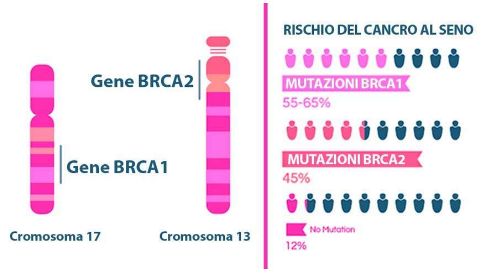
The first breast test towards a paradigm shift in breast cancer prevention



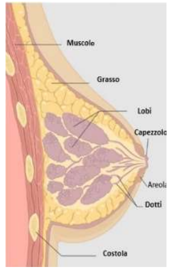
No Radiations

No breasts compression

Accessible for women of all ages



Perfectly suitable with BRCA gene mutation



High performance with dense breasts

MARKET OPPORTUNITY:
Making regular BC screening accessible to more than twice as many women

67.5 million

Women in the EU currently included in x-rays based mammographic BC screening programs

Market with intense competition

99 million

Women under 50 y.o. currently excluded from regular mass screening programmes

New market, with UBT being first mover

MAMMOWAVE: The Mammoscreen Study

HORIZON-MISS-2021-CANCER-02-01 Develop new methods and technologies for cancer screening and early detection

UBT has been awarded (with 15/15) a “Horizon Europe Mission On Cancer” grant of 6M (+1M by UK) within a consortium:

The project (acronym: Mammoscreen, https://cordis.europa.eu/project/id/101097079) will generate evidence regarding the use of MammoWave as BC screening technique **in population-based programs promoted by National Health Systems**. The clinical trial (multicentric, prospective) will involve **10,000 women in 10 recruitment centres located in many European countries** (enrollment started in Feb 2024).

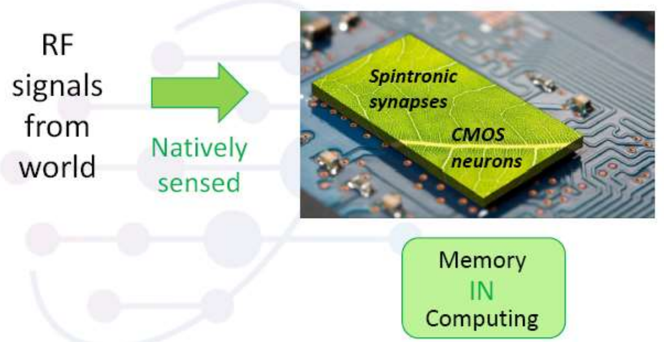
MammoWave® - The EU Radiospin Study

Hardware AI, the AI of the future

UBT participates in an EU consortium, granted (3.7M) with a H2020 FET-PROACT, for working on a Hardware AI (UBT will have the exclusive patent for the Healthcare sector).

https://cordis.europa.eu/project/id/101017098

RadioSpin embedded RF neural chip



Energy / 100
Speed x 100

→ Several breakthroughs

> Accuracy of Mammowave!

Dedicated clinical trial
ClinicalTrials.gov Identifier: NCT05300464
Recruitment Status: Recruitment ongoing
Participant enrolled so far: 400

Expected publication of the results on 400 participants : 2 months (prospective), 12 months (RadioSpin AI evaluation)

Publications (selection)

Álvarez Sánchez-Bayuela D, Fernández Martín J, Tiberi G, et al, Microwave imaging for breast cancer screening: protocol for an open, multicentric, interventional, prospective, non-randomised clinical investigation to evaluate cancer detection capabilities of MammoWave system on an asymptomatic population across multiple European countries, 2024, BMJ Open, 10.1136/bmjopen-2024-088431, https://bmjopen.bmj.com/content/14/11/e088431

Mehran Taghipour-Gorjikolaie, et al, AI-based Hierarchical Approach for Optimizing Breast Cancer Detection using MammoWave Device, 2024, Biomedical Signal Processing and Control, https://doi.org/10.1016/j.bspc.2024.107143

Sánchez-Bayuela DÁ, Ghavami N, Tiberi G, Sani L, Vispa A, Bigotti A, et al. , 2023, A multicentric, single arm, prospective, stratified clinical investigation to evaluate MammoWave's ability in breast lesions detection. PLoS ONE 18(7): e0288312 https://doi.org/10.1371/journal.pone.0288312

L. Papini et al., Breast Cancer Detection using Machine Learning Approaches on Microwave-based Data, 2023 17th European Conference on Antennas and Propagation (EuCAP), Florence, Italy, 2023, pp. 1-5, doi: 10.23919/EuCAP57121.2023.10133340 https://ieeexplore.ieee.org/document/10133340

Sani L et al, Breast lesion detection through MammoWave device: Empirical detection capability assessment of microwave images' parameters, PLoS ONE 16(4), 2021, https://doi.org/10.1371/journal.pone.0250005

Soumya Prakash Rana, et al, Machine Learning Approaches for Automated Lesion Detection in Microwave Breast Imaging Clinical Data, Scientific reports,9(1), 2019, 10510. doi:10.1038/s41598-019-46974-3, https://www.nature.com/articles/s41598-019-46974-3

Ghavami, N.; Tiberi, G.; Edwards, D.J.; Monorchio, A., UWB Microwave Imaging of Objects With Canonical Shape, IEEE Transactions on Antennas and Propagation, Volume: 60 , Issue: 1, Publication Year: 2012 , Page(s): 231 – 239, https://ieeexplore.ieee.org/document/6018277

G. Tiberi, N. Ghavami, D. J. Edwards, A. Monorchio, UWB Microwave Imaging of Cylindrical Objects with Inclusions, IET Microwaves, Antennas & Propagation, Volume: 5, Issue: 12 Publication Year: 2011 , Page(s): 1440 – 1446, https://digital-library.theiet.org/content/journals/10.1049/iet-map.2011.0033

OUR TEAM: THE MOST STRATEGIC ASSET

ISO 13485

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Mary Terry
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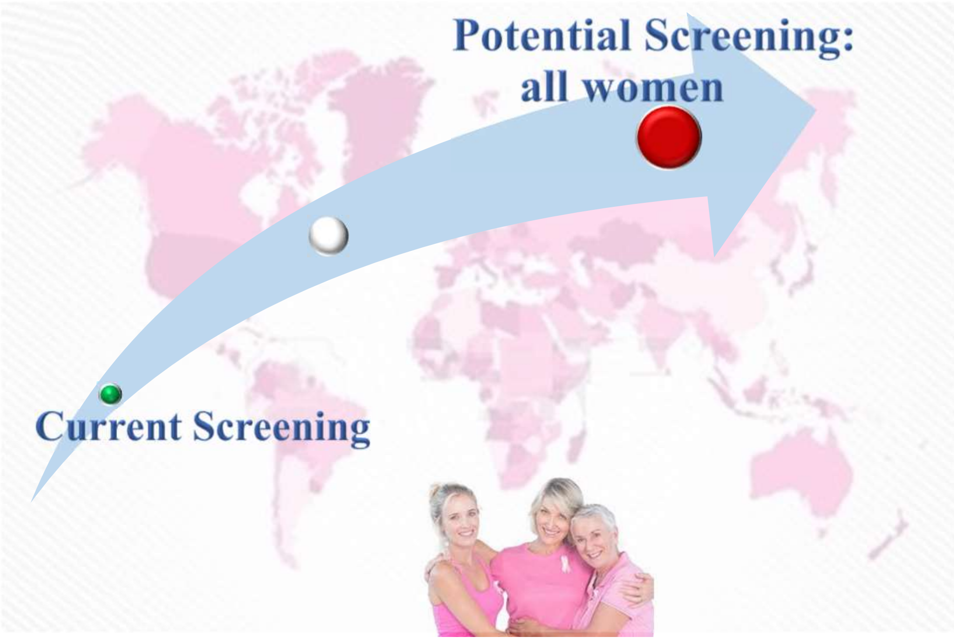

Mass screening is the most effective way to fight breast cancer.
We want to make a difference, allowing all women to be screened!

Many thanks!

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