

Vaginal Tactile Imager

Biomechanical mapping, transvaginal, with report



Innovation for:

- Urogynecology
- Physiotherapy
- Gynecology
- Cosmetic Gynecology

Regulatory approvals:

- FDA (USA)
- CE (Europe)
- TGA (Australia)

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INTRODUCTION

Many of pelvic floor disorders, including pelvic organ prolapse and incontinence are related and manifested in the mechanical properties of pelvic organs and tissues. Therefore, mapping a response to applied pressure within the pelvic floor and measuring pelvic floor function opens new possibilities in biomechanical assessment of vaginal and pelvic floor conditions.

DEFINITIONS

Tactile Imaging is a medical imaging modality translating the sense of touch into a digital image. The tactile image is a function of $P(x,y,z)$, where P is the pressure on soft tissue surface under applied deformation and x , y and z are the coordinates where P was measured. The tactile image is a pressure map on which the direction of tissue deformation must be specified [1].

Functional Tactile Imaging translates muscle activity into dynamic pressure pattern $P(x,y,t)$ for an area of interest, where t is time and x and y are coordinates where pressure P was measured. It may include: (a) muscle voluntary contraction, (b) involuntary reflex contraction, (c) involuntary relaxation, and (d) specific maneuvers.

Biomechanical Mapping = Tactile Imaging + Functional Tactile Imaging

VAGINAL TACTILE IMAGER (VTI)

The (VTI) probe is equipped with 96 pressure sensors, motion tracking and temperature controllers. The VTI allows acquisition of the pressure response patterns during tissue/structure deformations from vaginal walls along the entire vagina to visualize vaginal and pelvic floor support structures, and to record pelvic floor muscle contraction patterns. The VTI software provides data visualization, analysis, information and reporting tools. The acquired data can then be used for quantitative biomechanical assessment of the vaginal and pelvic floor conditions.

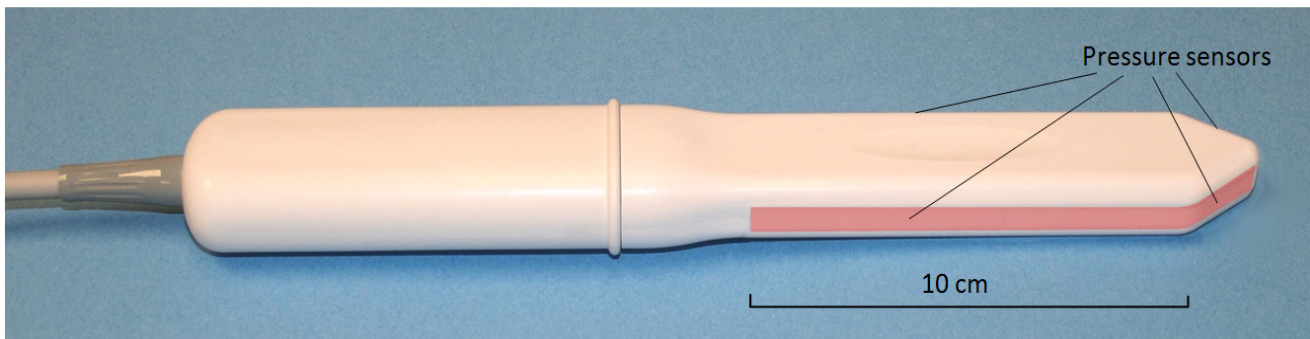


Figure 1. VTI probe. Pressure/tactile sensors are aligned on the outer surfaces of the probe (highlighted in the image).

Indications for Use

The VTI obtains a high resolution mapping of pressures and assesses the strength of pelvic floor muscles within the vagina. It is used in a medical setting to acquire the pressures and store the corresponding data. It also provides visualization, analysis tools and information. The real time data as well the analysis information can then be viewed with an intention of assisting in the diagnosis and evaluation. The device is intended for use by physicians, surgeons and medically trained personnel.

CPT Code (AMA)

The VTI examination procedure has the new Category III CPT code 0487T "Biomechanical mapping, transvaginal, with report".

Patents

9,861,316; 8,840,571; 8,419,659; 8,187,208; 8,142,368; 8,069,735; 8,052,622 and counting.

Table 1. VTI examination includes 8 tests.

Test No.	Procedure	Output
Test 1	Probe insertion	Tactile image for vaginal anterior and posterior compartments along the entire vagina (resistance, force, work, tissue elasticity)
Test 2	Probe elevation	Tactile image for anterior and posterior compartments which related to pelvic floor support structures (pressure and pressure gradients for specified locations)
Test 3	Probe rotation	Tactile images for left and right sides along the entire vagina (force and pressure values for specified positions/locations)
Test 4	Valsalva maneuver	Dynamic pressure response from opposite sites (anterior vs posterior) along the entire vagina (pressure changes, pressure peak displacements).
Test 5	Voluntary muscle contraction	Dynamic pressure response from opposite sites (anterior vs posterior) along the entire vagina (pressure changes; maximum pressure values).
Test 6	Voluntary muscle contraction (sides)	Dynamic pressure response from opposite sides (left vs right) along the entire vagina (pressure changes; maximum pressure values).
Test 7	Involuntary relaxation	Dynamic pressure response from opposite sites (anterior vs posterior) along the entire vagina (pressure changes/slope).
Test 8	Reflex muscle contraction (cough)	Dynamic pressure response from opposite sites (anterior vs posterior) along the entire vagina (pressure changes; pressure peak displacements).

The software calculates 52 biomechanical parameters for pelvic floor characterization. Figure 2 shows Test 5 results.

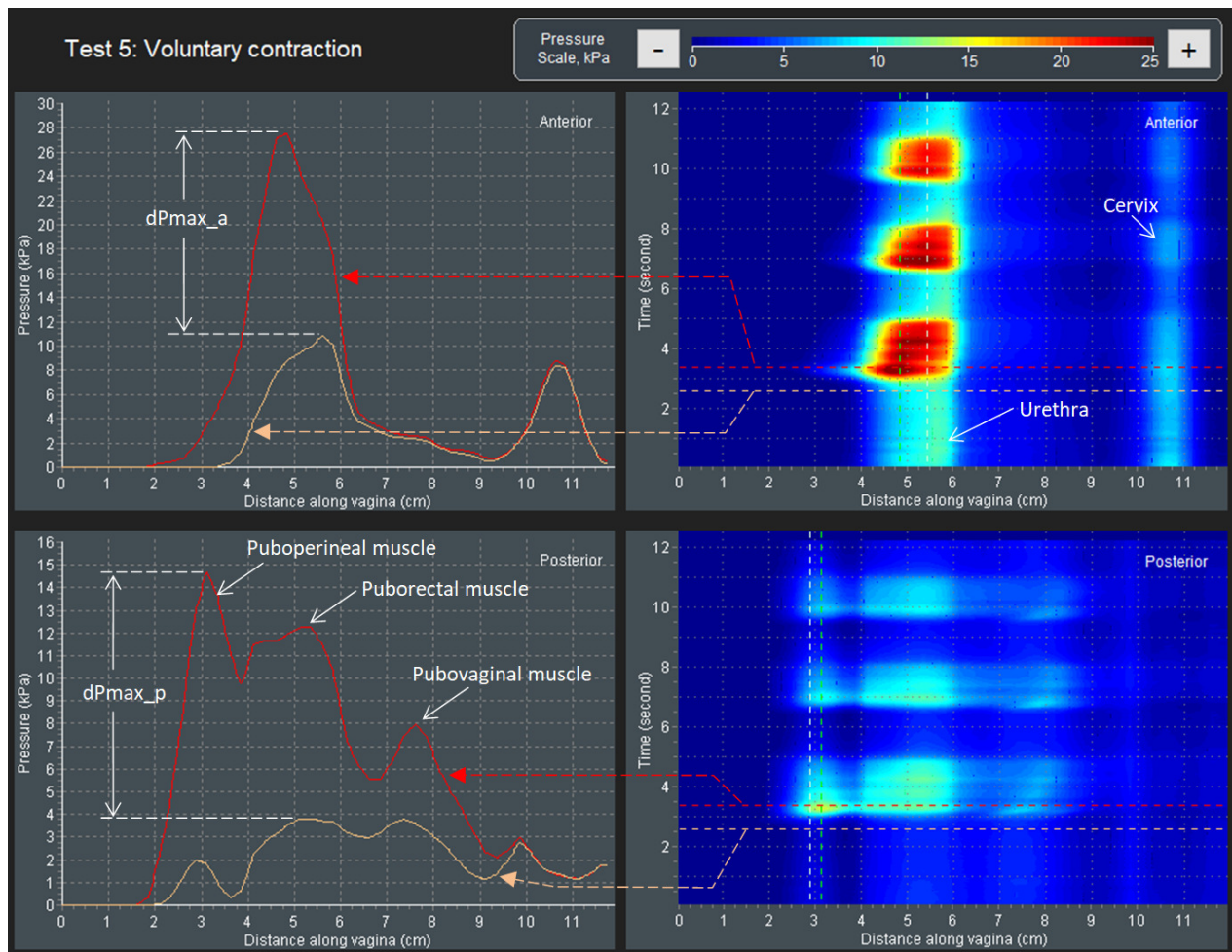


Figure 2. A dynamic pressure patterns acquired during the voluntary muscle contraction for anterior and posterior compartments (Test 5).

Figure 3 presents the VTI Examination Report for Tests 1-6 with basic images/graphs and parameters.

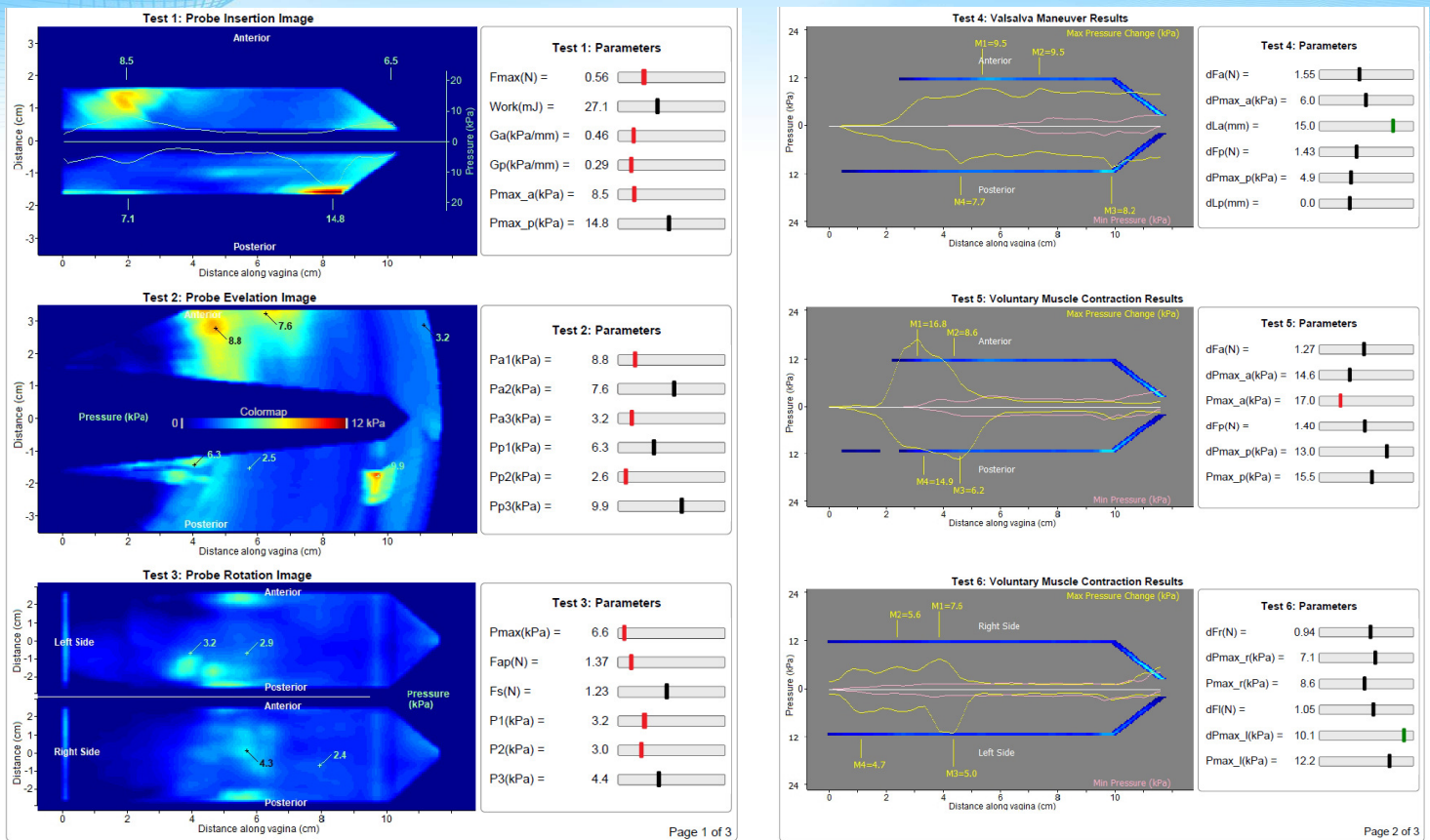


Figure 3. VTI Examination Report for Tests 1-6. Red bar means the parameter value is in lower 25%, black from 25% to 75%, and green is in upper 25% of the entire parameter range (from diseased to normal conditions).

SELECTED PUBLICATIONS

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