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Echopulse

Product Data 2013

General Overview

The Echopulse device is a high-precision device, specially designed and manufactured by Theraclion to treat benign tumors such as breast fibroadenomas and thyroid nodules, using High Intensity Focused Ultrasound (HIFU).

The main components are:

- Visualization and Treatment Unit (VTU)
- Integrated ultrasound scanner
- Arm and scanning motors
- Coupling and cooling system
- Patient motion detector
- Touch screen user interface

A patient bed and a set of cushions are necessary to perform the treatment. These elements are not provided by Theraclion.

A 4-Step Procedure

Preparation

- Device preparation and coupling and cooling set-up
- Patient installation
- Patient sedation/anaesthesia

Visualization

- Manual positioning of the treatment probe over the area to be treated and target visualization
- High-precision 3D electronic target centring

Planning

- Target outlining on the real-time ultrasound imaging
- Planning of HIFU target sites

Treatment

- Sequential treatment delivery (Pause & Pulse)
- Real-time view of HIFU pulses
- Continuous ultrasound monitoring



HIFU

The equipment is based on focused ultrasound technology. HIFU is a process that allows the delivery of a large amount of acoustic energy to a focal point. This acoustic energy is converted into heat (80°C-95°C) into the selected area to produce necrosis of targeted tissue.

-The millimetric precision of HIFU delivering ensures efficacy and patients' safety.
-The liquid conductive cooling prevents skin heating.

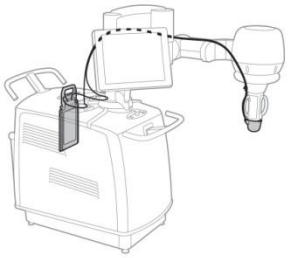
General Features

Safety
▪ No ionizing radiation ▪ Smart cooling and coupling technology ▪ Built-in diagnostic imaging ▪ Integrated and real-time ultrasound imaging ▪ Real-time patient monitoring and control (treatment can be stopped at all time) ▪ Patient motion detection ▪ Energy delivery control ▪ Built-in control safeties ▪ Emergency stop button ▪ Company certificated ISO 13485 and Echopulse CE marked for thyroid nodules and breast fibroadenomas
Efficacy
▪ Alignment of the therapeutic beam with ultrasound imaging ▪ Pre-visualization of focused pulses ▪ Real-time view of HIFU pulses ▪ Millimetric treatment precision ▪ Coupling kit to optimize image quality
Cost-effective
▪ Conscious sedation / local anaesthesia ▪ A 1h treatment procedure on average ▪ Minimal staff required

Not approved for sale in the US.

Key Components

EPack



Before each treatment a new EPack must be installed on the device.

EPack replacement is secured through RFID management.

The cooling system consists of a cooler, two pumps and a disposable set of tubing and pouch containing 500ml of fluid.

It allows:

- Ultrasound waves to be transmitted without loss or distortion
- To protect the skin from the heat of HIFU waves

The pump circulates the fluid in a closed circuit between the pouch and the VTU. A temperature sensor located in the VTU ensures that the fluid in the VTU will be properly cooled. Internal pressure is adjusted accordingly.

Echopulse User Interface

The touch screen user interface is intuitive and easy to use. Mounted on an articulated arm, the screen is easily reachable and orientated by the operator.

Real-time imaging enables the operator to monitor the treatment and see its progress.

It is possible to suspend or modify the treatment parameters at any time.

The main functions of the user interface are:

- To guide the operator for kit installation
- To outline the key anatomical structures
- To determine parameters for imaging, positioning and energy
- To outline the target and select areas to be treated
- To launch and monitor the treatment in real-time

Visualization and Treatment Unit (VTU)

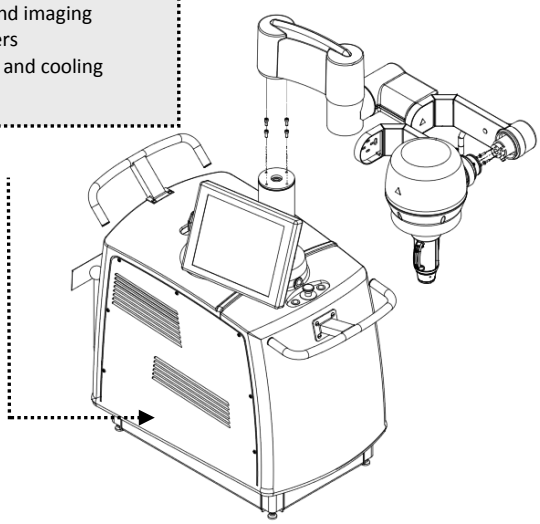
The VTU is composed of:

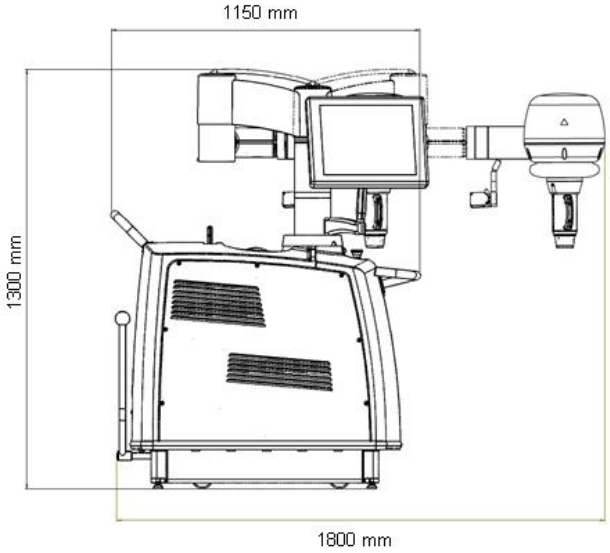
An ultrasound probe enabling real-time imaging of the region of interest.
To perform sagittal and transversal imaging of the target, the VTU rotates around its acoustical axis. The rotation of the VTU can be performed manually or controlled by the software during the planning phase.

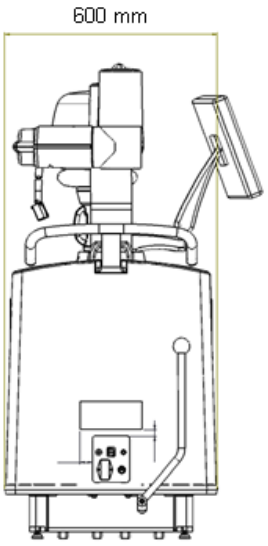
An HIFU transducer is also embedded within the same treatment head, in-line with the imaging probe, in order to ensure optimal treatment safety and efficacy.

Schemes

- Ultrasound imaging
- Computers
- Coupling and cooling system







Technical Data & International standards

SYSTEM	PARAMETER		SPECIFICATION
General Specifications	Reference		THC800154-D THC800154-E
	Equipment designation		High Intensity Focused Ultrasound Therapy Equipment
	Medical application		Ablation of tissues by external application
	Classification 93/42/EEC		Equipment class IIb
	Treatment duration		1 hour (average)
	Total weight Model THC800154-D Model THC800154-E		350 kg ± 20 kg 370 kg ± 20 kg
	Dimensions	Length	1150 mm
		Width	600 mm ± 5 mm
		Height	1300 to 1800 mm ± 20 mm
	Power consumption		1 kW
	Recommended preventive maintenance cycle		6 months
	Environmental conditions for transport and storage		4 °C to 65 °C
	Environmental conditions of operations		15 °C to 30 °C
Arm	Type		6 degrees of freedom
			Weight compensation
			Electromagnetic friction brakes
Electronic cabinet	Type		Mobile on 4 wheels
Control computer	Monitor		19" Touch screen
Epack	Reference		THC900800
VTU	HIFU	Transducer	Piezoelectric
		Type	Automatic depth compensation feature
		Frequency	3MHz (central)
		Typical maximal treatment depth	24 mm
		Typical maximal acoustic power	125 W
	Imaging probe	Type	128 elements linear array 38 mm wide
		Default mode	B-mode
		Frequency range	7.5 MHz - 12 MHz
		Default image depth	5 cm
		Typical frame rate	12 frames/s
	Head		Motorized movements (R, x, y, z)
			xy range: ± 25 mm
		Robotic	z range: ± 10 mm

Main standards applied	**IEC 60601 Ed.3.0** Medical Electrical Equipment
	ISO14971 Medical Devices - Application Of Risk Management To Medical Devices
	IEC 62304 Medical device software - Software life cycle processes
	IEC 62366 Medical devices - Application of usability engineering to medical devices
IP classification	**IP 20**
Device Certification	**CE marked for thyroid nodules and breast fibroadenomas**