



EchoStation

The Bone Densitometry of the future

EchoStation is the first radiation free solution for the early diagnosis of Osteoporosis at the axial sites.. A breakthrough echographic medical device for bone characterization and micro-architecture assessment through an innovative approach that enables the scanning of the reference sites: Lumbar Vertebrae and Proximal Femur.





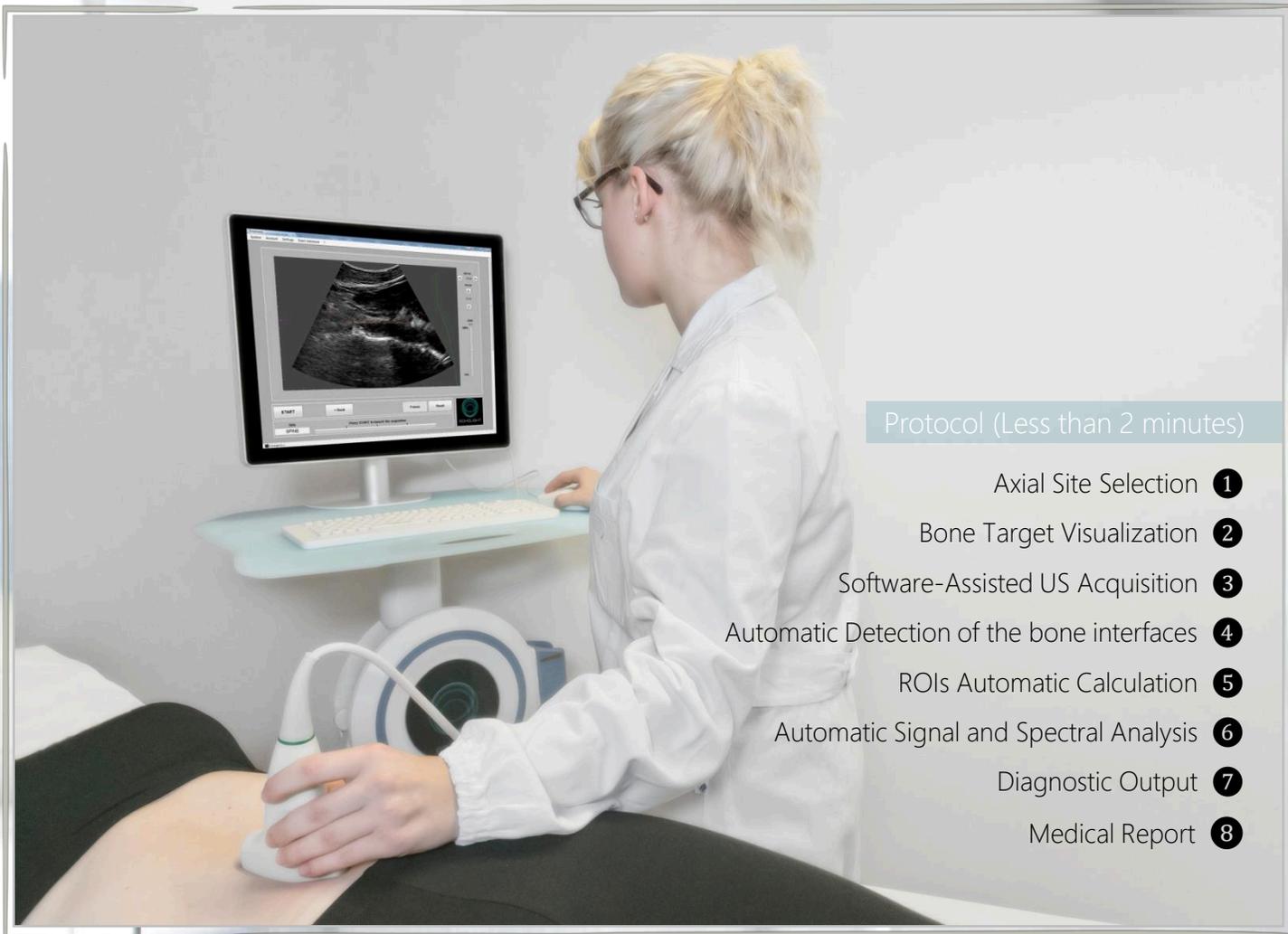
R.E.M.S. Method

The peculiar feature of the proprietary R.E.M.S. (Radiofrequency Echographic Multi Spectrometry) method is the exploitation of RF signals acquired during an echographic scan of the target bone structure to determine the internal bone architecture through detailed comparisons with reference spectral models. Ultrasound scans are performed by EchoS equipped with a convex transducer operating at 3.5 MHz, allowing the simultaneous acquisition of conventional B-mode images and corresponding unprocessed RF signals.

A person wearing a white lab coat is operating a medical device. The device has a circular probe with a blue and white design, labeled 'ECHOUGH-1'. The person's hand is resting on a light blue surface of the device. The background is a blurred clinical setting.

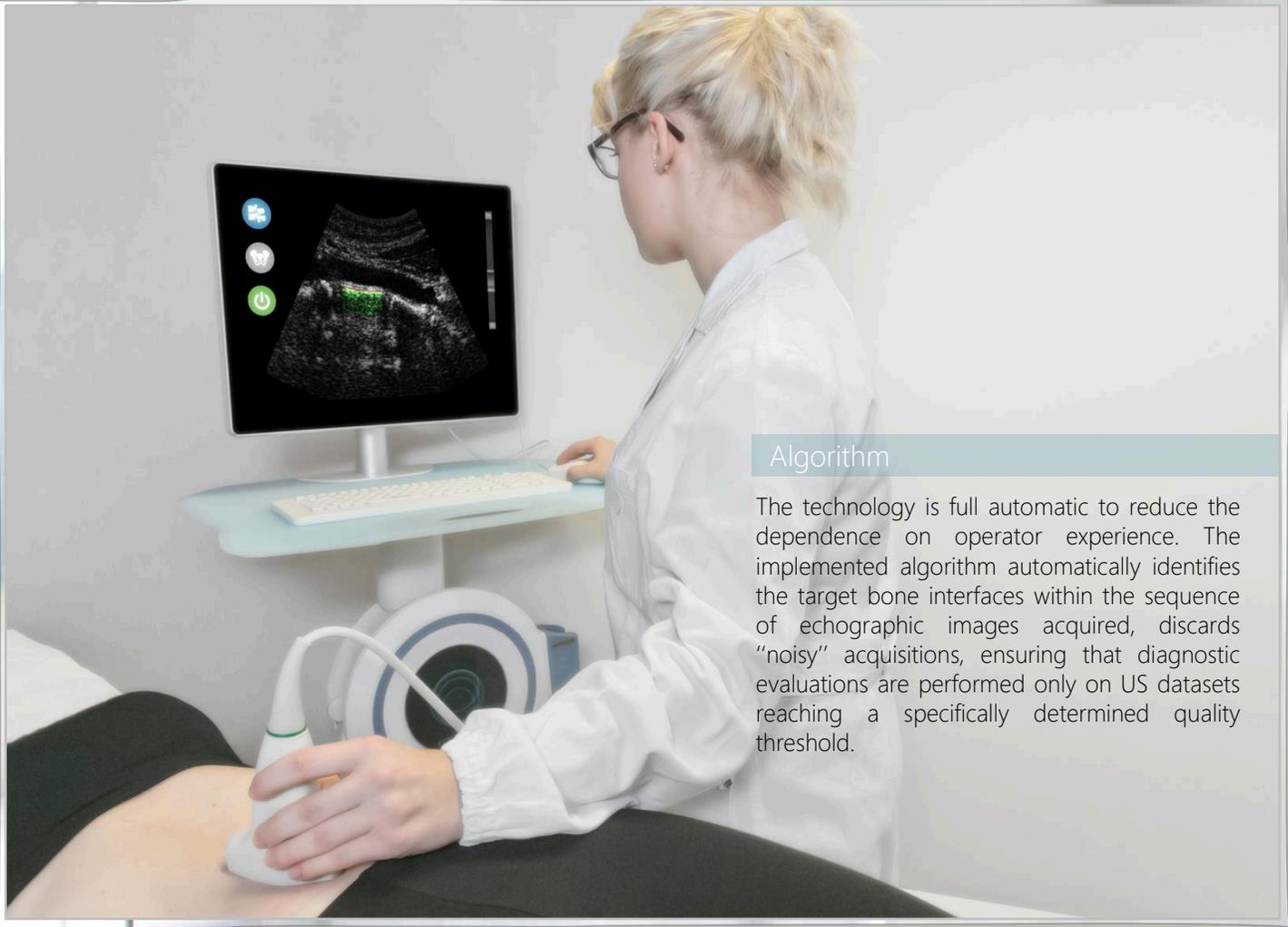
Innovative Approach

The method is natively integrated with US imaging, since, on one hand, the regions of interest (ROIs) for diagnostic calculations within the investigated bone are automatically identified exploiting both morphologic details and RF spectral features, and, on the other hand, the simultaneous acquisition of several RF scan lines for each image frame provides a solid and reliable statistical basis for subsequent spectral processing and the final diagnostic output.



Protocol (Less than 2 minutes)

- 1 Axial Site Selection
- 2 Bone Target Visualization
- 3 Software-Assisted US Acquisition
- 4 Automatic Detection of the bone interfaces
- 5 ROIs Automatic Calculation
- 6 Automatic Signal and Spectral Analysis
- 7 Diagnostic Output
- 8 Medical Report



Algorithm

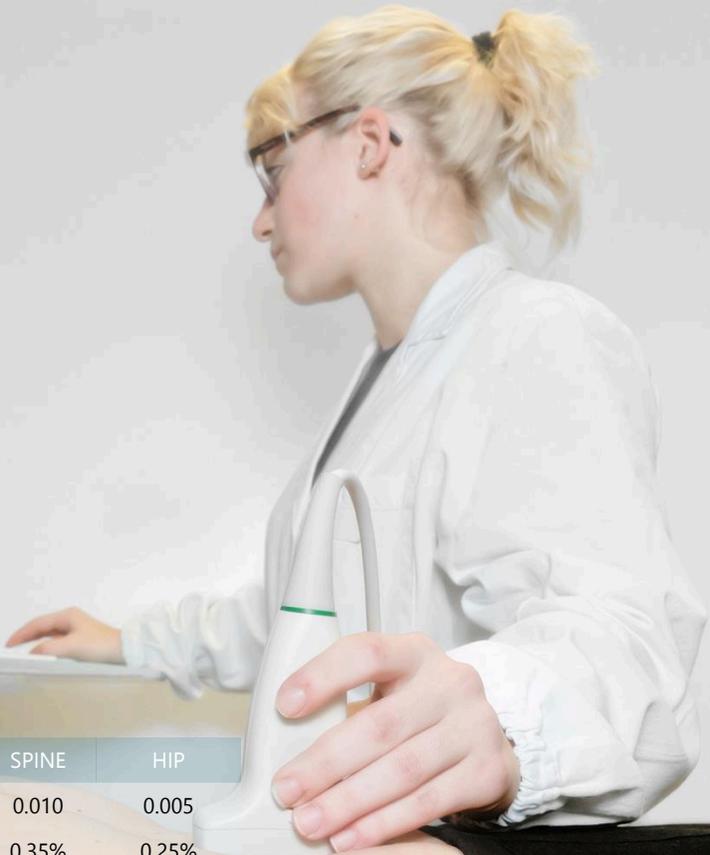
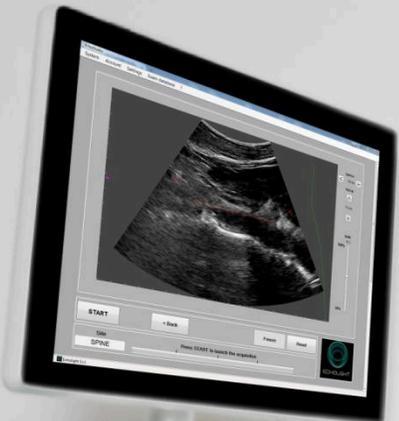
The technology is full automatic to reduce the dependence on operator experience. The implemented algorithm automatically identifies the target bone interfaces within the sequence of echographic images acquired, discards "noisy" acquisitions, ensuring that diagnostic evaluations are performed only on US datasets reaching a specifically determined quality threshold.

Database

Database includes around 10.000 subjects from 30 to 90 years, grouped into 5-y intervals and split into three subgroups based on BMI value. The subjects underwent the following diagnostic examinations: DXA scan of lumbar spine and/or proximal femur, TBS calculation where applicable, echographic scan with EchoS system and FRAX[®] questionnaire. Data were used to calculate the corresponding pairs reference spectral models for the following bone conditions: "osteoporotic/healthy" and "frail/non-frail". BMD values derived from O.S. calculation were compared with the results of DXA measurements, while F.S. values were evaluated against FRAX[®] predictions of 10-year probabilities of a generic osteoporotic fracture.

The image shows a computer monitor displaying a medical database interface. The interface is divided into several sections:

- Table:** A table with columns for ID, Family name, Name, Birth, Gender, BMI, Age, and Menopause age. The table contains several rows of data, with some rows highlighted in blue.
- Form:** A form for entering patient information, including fields for Family name, Name, Date of birth (dd/mm/yyyy), Gender, Age (years), Ethnicity, Menopause age (years), Other pathologies, Notes, and Contacts. There are also buttons for "Save changes" and "Cancel".
- Buttons:** "Save changes" and "Cancel" buttons are located at the bottom of the form.



QUANTITATIVE PERFORMANCE	SPINE	HIP
SMALLEST DETECTABLE DIFFERENCE (SDD) [g/cm ²]	0.010	0.005
INTRA-OPERATOR REPEATABILITY (RMS-CV) [%]	0.35%	0.25%
INTER-OPERATOR REPEATABILITY (RMS-CV) [%]	0.54%	0.41%
DIAGNOSTIC AGREEMENT WITH DXA	93.1%	94.2%



ECHOS

Clinical Validation

In collaboration with the Italian National Council of Research, Echolight has carried out international multi-center studies for the clinical validation of the proprietary technology in the most important reference centers for the diagnosis of osteoporosis under the lead of its scientific advisory board and scientific committee.

Patent

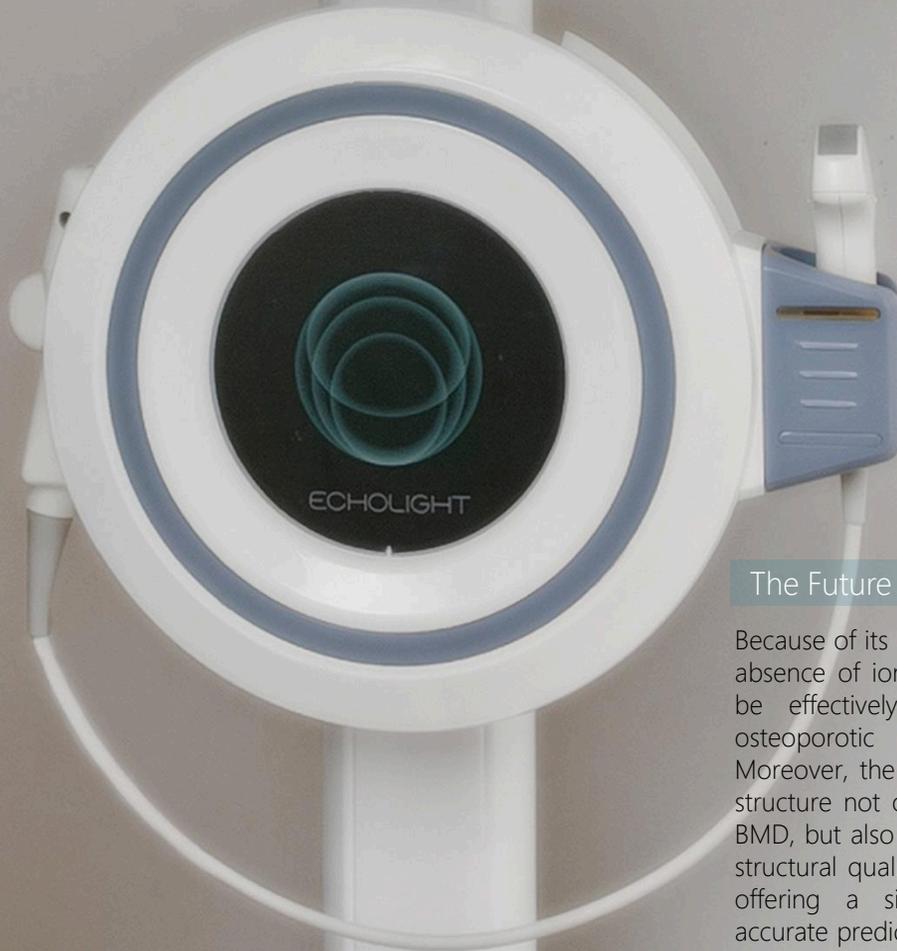
ITALIAN PATENT

“Apparato ad ultrasuoni per valutare lo stato della struttura ossea di un paziente”
(Patent N. 0001405771, filed date 16/05/2011 and granted date 24/01/2014).

INTERNATIONAL PATENT APPLICATION (PCT)

“Ultrasound apparatus for assessing the quality of a patient's bone tissue” (WO2012156937)
- Europe (EP2709533)
- South Korea (KR20140035932)
- Cina (CN103648401)
- USA (US2014155748)



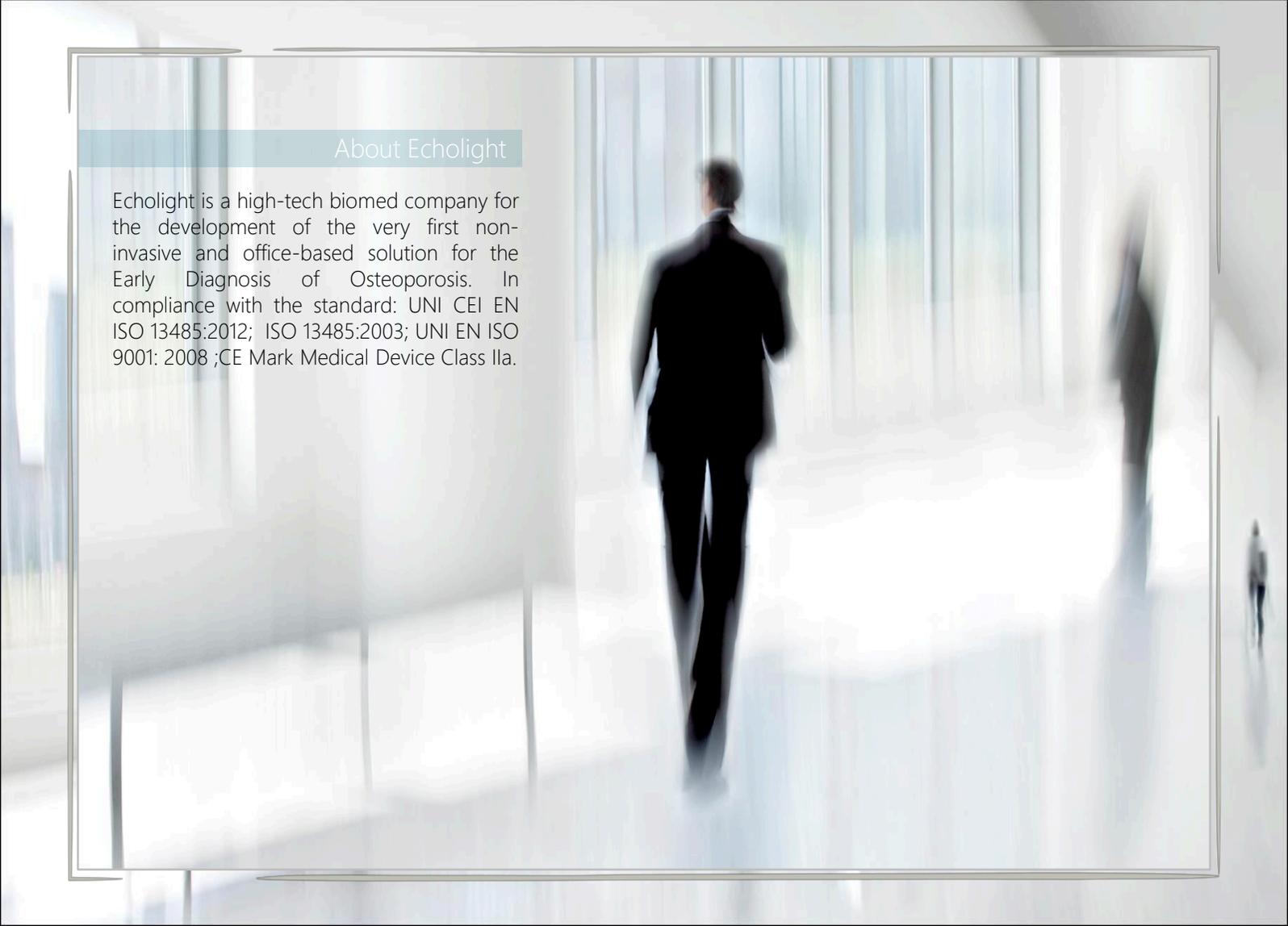


The Future State-of-the-art

Because of its accuracy levels and the complete absence of ionizing radiation this method can be effectively employed for diagnosis of osteoporotic disease at an earlier stage. Moreover, the US assessment of internal bone structure not only gives information related to BMD, but also provides further insights into the structural quality of bone and its real strength, offering a simultaneous, independent and accurate prediction of fracture risk.

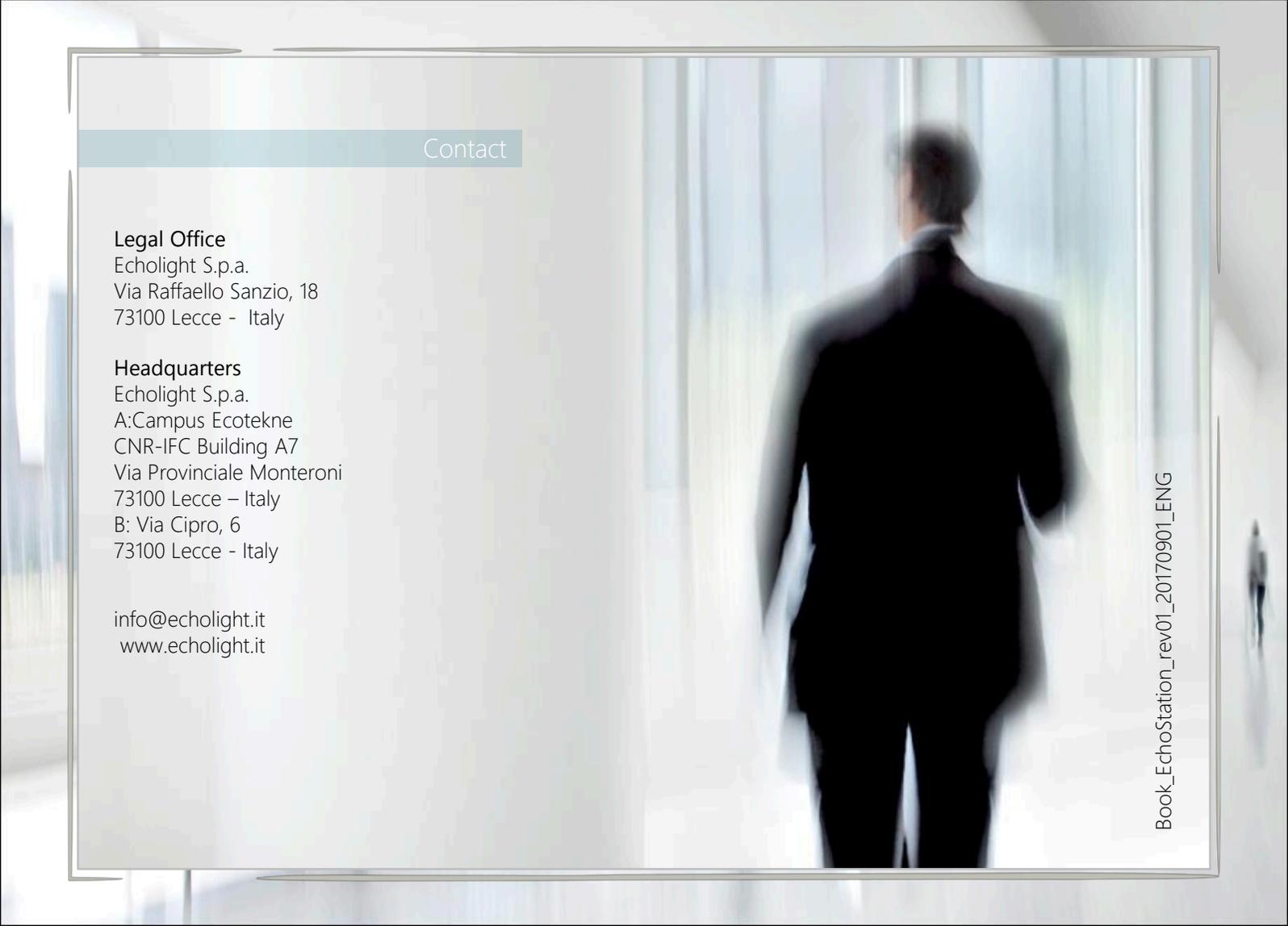
Key Advantages

	DXA	QUS	EchoStation
Radiation Exposure	YES	NO	NO
Axial Sites	YES	NO	YES
Bone Density Assessment BMD (g/cm ²)	YES	NO	YES
Bone Quality Assessment	NO	??	YES
FRAX Index	YES	NO	YES
Body Composition Index	YES	NO	YES
Operator Independent	NO	NO	YES
Accuracy	HIGH	LOW	VERY HIGH
Primary Care	NO	YES	YES
Cost	HIGH	VERY LOW	LOW
Operator Certified Needed	YES	NO	NO
Dedicated Shield Room	YES	NO	NO
Maintenance Costs	YES	NO	NO
Diagnostic Tool	YES	NO	YES
Prevention, Monitoring and Follow-up	NO	NO	YES



About Echolight

Echolight is a high-tech biomed company for the development of the very first non-invasive and office-based solution for the Early Diagnosis of Osteoporosis. In compliance with the standard: UNI CEI EN ISO 13485:2012; ISO 13485:2003; UNI EN ISO 9001: 2008 ;CE Mark Medical Device Class IIa.



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We see different things.



ECHOLIGHT