


DBM SONIC *Bone Profiler*®

Technical Data Sheet

Manufacturer	IGEA S.P.A. Via Parmenide 10/a Carpi, Modena, Italy Quality System in compliance with ISO 9001; ISO 13485
Destination	Densito-structural bone tissue evaluation
Investigation	By Ultrasounds
Frequency	1,25 MHz
Electrical requirements	110 - 230 Vac 50-60 Hz
Dimensions	L36 x W48 x H32 cm
Safety and quality standards	In accordance to the norm IEC 601-1, IEC 601-1-2, IEC 601-1-4 Marked  0051, according to the norm CEE 93/42 for medical device, under the surveillance of IMQ
Transportable	The device has got an electronic calliper (for taking measurements) connected to the central computerised unit.
Dedicated Software	The system is endowed with a devoted software, projected in Windows environment, for the clinical and registry data management, that it allows the storage of several exams and the comparison among different measures of the same patient performed in different moments.
Self diagnosis	The device is able to self-check whether a calibration drift has been occurred and warns the user of the problem.
Execution time of the measurement	About 3 minutes, 10 minutes included receiving the patients. In one hour time it is possible to perform 8 to 10 measures.
Site of measurement	Distal metaphysis of the II, III, IV,V finger phalanxes of the hand.
Measurement acquisition	<ul style="list-style-type: none"> • Automatic: the system automatically acquires the data once the calliper is applied on the phalanx and slightly rotating it on the site. At the end of the measurement session the system processes the acquired data, according to precise internal criteria, in order to catch the correct signal. • Manual: during the measurement process the data are always visible, and the user can decide which signal freezes and acquires.
Parameters	<ul style="list-style-type: none"> • <i>Amplitude Dependent Speed of Sound</i>: AD-SoS: velocity of the ultrasound beam through the phalangeal bone tissue, depending on the amplitude of the signal. • UBPI (<i>Ultrasound Bone Profile Score</i>): Calculated on the graphic trace parameters. It gives information about bone structure. It allows to better recognize subjects having altered bone structure, and to find out subjects at high risk of osteoporotic fracture. • BTT (<i>Bone Transmission Time</i>): The parameter BTT does not depend on soft tissue thickness, but on bone tissue thickness and quality only. BTT is the ideal parameter to follow-up drugs therapy and dietary adjustments. • T-Score and Z-Score. • Ten years risk of fracture evaluation.

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Available Curves (normative data)	<ul style="list-style-type: none">• Curve of the ultrasound velocity (AD-SoS) vs age for women, men and children.• Curve of the ultrasound velocity (AD-SoS) vs months since menopause (<i>menopausal curve</i>)
In vivo reproducibility (CV%)	0,5%
Standardized Reproducibility (SCV%)	2,2%
Ability to discriminate between normal and pathologic subjects	<ul style="list-style-type: none">• sensibility: 81,5%• specificity: 79,3%
Ability to predict the risk of fracture	High risk of fracture (Odds Ratio): 1,5% for each standard deviation of AD-SoS decrease
Monitoring of the therapies	<p>The system enable the monitoring of drug therapies effect through the BTT. A 4-year longitudinal study has demonstrated that women under HRT treatment keep an good level of BTT, while control group of women show a lower value of the parameters.</p> <p>A 2-year longitudinal study has demonstrated DBM Sonic Bone Profiler to be able to identify the effect of Alendronate therapy, in post-menopausal subjects with osteoporosis, as well as lumbar BMD.</p>