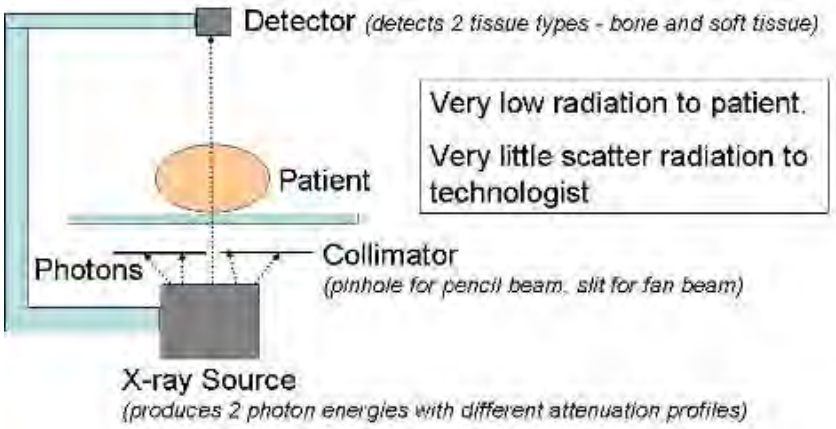
OSTEO Pro DEXA

Use of ultrasonic wave harmless to human body

WHAT IS DUAL ENEGERY

What is DEXA?

It is the most popularly used method to measure bone density and was developed in the middle of the 1980s DEXA has the advantages of outstanding correctness, short scanning time, and low radiation quantity. It is the perfect equipment for diagnosing osteoporosis and for evaluating the appropriate treatment



Very Low radiation
to patient & operator

Very Little scatter radiation
to technologist

03 OSTEOPRO DEXA

CE CERTIFICATION

GRAND-DUCHE DE LUXEMBOURG

snch

Société Nationale de

Certification et d'Homologation s.a.r.l.

Notified Body

Organisme Notifié - Benannte Stelle

N° 0499

EC Type Examination Certificate

Certificat d'examen CE de type - EG-Baumusterprüfbescheinigung

according to Annex III of directive 93/42/EEC on Medical Devices

conformément à l'Annexe III de la Directive 93/42/CEE relative aux dispositifs médicaux

gemäss Anhang III der Richtlinie 93/42/EWG über Medizinprodukte

Manufacturer: B.M.Tech. Worldwide Co., Ltd.

Fabricant:

Hersteller: #1001, 1002 Jungang Industria 5-Cha 138-6 Sangdaewon-dong, Jungwon-gu Seongnam-si, Gyeonggi-do, Korea

Certificate No.: 1144651-00 Valid until: 2016-08-18

No. du certificat: Valide jusqu'au:

Bescheinigung Nr: Gültig bis:

Device identification: X-Ray Bone Densitometer

Identification du dispositif:

Produktidentifizierung: OsteoPro

GMDN: 37661

We hereby declare that a type examination has been carried out on the listed device(s) in accordance with the requirements of Annex III (4) of the Directive 93/42/EEC on medical devices. We certify that the type conforms to the relevant provisions of the aforementioned directive.

Nous déclarons qu'un examen de type du/des dispositif(s) mentionné(s) a été réalisé selon les exigences de l'Annexe III (4) de la Directive 93/42/CEE relative aux dispositifs médicaux. Nous certifions que le type est conforme aux exigences applicables de la Directive mentionnée ci-dessus.

Hiermit bestätigen wir, daß ein Baumuster der aufgelisteten Produkte geprüft wurde gemäß den Anforderungen des Anhangs III (4) der Richtlinie 93/42/EWG über Medizinprodukte. Wir bestätigen, daß das Baumuster den anwendbaren Bestimmungen der oben erwähnten Richtlinie entspricht.

Luxembourg, 2011-08-19

Claude LIESCH

Directeur

GRAND-DUCHE DE LUXEMBOURG

snch

Société Nationale de

Certification et d'Homologation s.a.r.l.

Notified Body

Organisme Notifié - Benannte Stelle

N° 0499

EC Certificate - Production Quality Assurance System

Certificat CE - Système d'assurance de la qualité de la fabrication

EG-Bescheinigung - Produktions-Qualitätssicherungssystem

according to Annex V of directive 93/42/EEC on Medical Devices

conformément à l'Annexe V de la Directive 93/42/CEE relative aux dispositifs médicaux

gemäss Anhang V der Richtlinie 93/42/EWG über Medizinprodukte

Manufacturer: B.M.Tech. Worldwide Co., Ltd.

Fabricant:

Hersteller: #1001, 1002 Jungang Industria 5-Cha 138-6 Sangdaewon-dong, Jungwon-gu Seongnam-si, Gyeonggi-do, Korea

Certificate No.: 0343497-05 Valid until: 2014-01-23

No. du certificat: Valide jusqu'au:

Bescheinigung Nr: Gültig bis:

Date of last audit: 2010-11-09

Date du dernier audit:

Datum des letzten Audits:

Scope: see annex to this certificate

Champ d'application: voir l'annexe de ce certificat

Anwendungsbereich: siehe Anhang dieser Bescheinigung

We hereby declare that the manufacturer's quality system was audited in accordance with the requirements of Annex V of the Directive 93/42/EEC on medical devices. We certify that the quality system meets the requirements of the aforementioned directive. The present certificate is subjected to the surveillance required by Annex V Section 4. For placing on the market of Class IIb or Class III devices, an EC Type Examination Certificate according to Annex III is required.

Nous déclarons que le système qualité du fabricant a été audité selon les exigences de l'Annexe V de la Directive 93/42/CEE relative aux dispositifs médicaux. Nous certifions que le système qualité remplit les exigences de la Directive mentionnée ci-dessus. Le présent certificat est soumis à la surveillance exigée par l'Annexe V Point 4. Pour la mise sur le marché de dispositifs de la Classe IIb ou de la Classe III, un certificat d'examen CE de type est requis conformément à l'Annexe III.

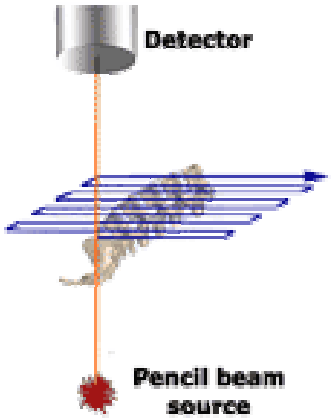
Hiermit bestätigen wir, daß das Qualitätssystem des Herstellers bezüglich wurde gemäß den Anforderungen des Anhangs V der Richtlinie 93/42/EWG über Medizinprodukte. Wir bescheinigen, daß das Qualitätssystem den Vorgaben der oben erwähnten Richtlinie entspricht. Die vorliegende Bescheinigung ist der Überwachung nach Anhang V Abschnitt 4 unterworfen. Für das Inverkehrbringen von Produkten der Klasse IIb oder der Klasse III ist eine EG-Baumusterprüfbescheinigung nach Anhang III erforderlich.

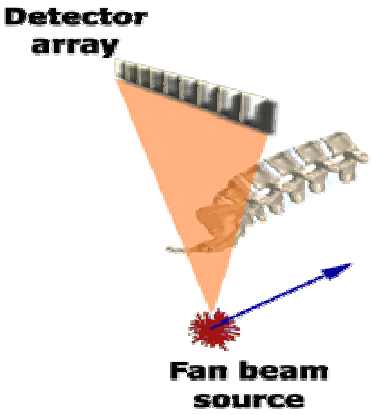
Luxembourg, 2011-08-19

ISO/IEC 17021

03 OSTEOPRO DEXA

1. COMPARISON



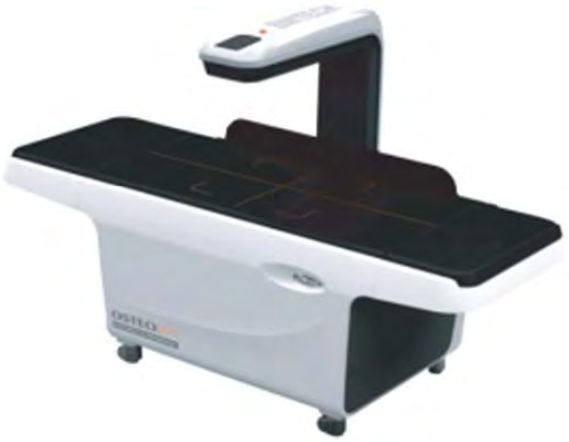


	Pencil beam type	Fan-beam type
Accuracy	★ Higher Accuracy: Higher Bone mineral and body composition	Accuracy of body composition measurement in small subjects
Scan time	Scan Time: 3~5 min. OSTEOPro DEXA -Spin : >2min, Dual Femur: >3min and Forearm: >1.35min	★ Faster Scan Acquisition Scan Time: 1~2 min. Short scan time due to its ability to process more data.
Resolution	Good image quality Improved geometrical resolution	★ Better Image Quality ※ detect conditions such as osteophytes and abnormality of spine
Radiation Rose	★ Lower Iraadiation Dose ~1μ Sv	Low Patient Dose ~10μ Sv
Price	★ Lower Price	Higher Price

03 OSTEOPRO DEXA

2. STRONG POINT

OSTEO | pro DEXA



Foddering Cover /Attractive design / Small Foot Print / light of weight
Fast measurement time, High Quality but Competitive price

✣ ✹ Maximizes even the constricted space with its foldable wings and it is suitable for Small and middle side Clinic and hospital

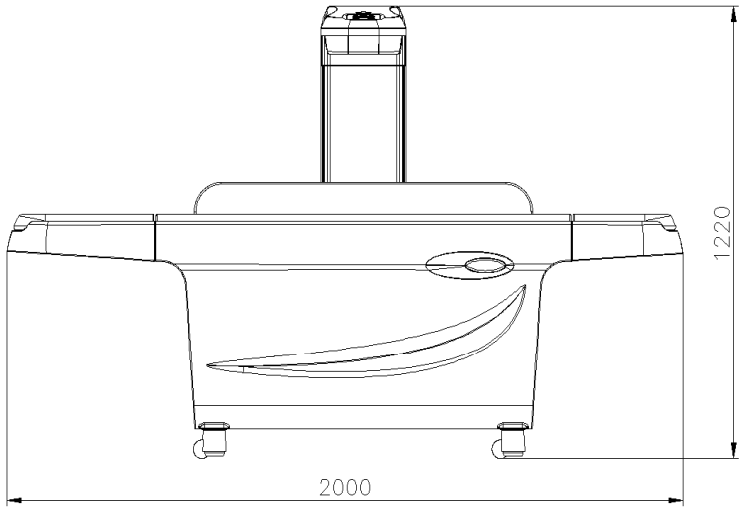
✣ ✹ Assures high-speed scanning and consumes brief span of measuring time

✣ ✹ Penetrates both private and public hospitals because of its competitive price in the industry's without sacrificing quality and performance

3. SPECFICATION

Classification	Description
Scan Method	Pencil beam
Measurement Part (Measurement Time)	AP spine (Normal : 2' 22"), Femur (Normal: 1' 58") Forearm (Normal : 1' 35") Non-stop Scan (AP Spine, Femur 4' 30") Non-stop Scan (AP Spine, Dual Femur 6' 28")
Measurement Method	Single Scan(AP Spine, Femur(R/L), Forearm(R/L)) Non-stop Scan (AP Spine, Dual Femur) Possible to measure three parts at a time
Reference Data	Standardized Data of WHO
Reproducibility	<1% CV
Correction of Special Parts	A user can add or delete the bone and tissue possibly reducing the error while calculating BMD such as fracture, implant, or operation part.
Auto ROI	Automatically distinguishing the ROI (interest area) after the measurement is ended
Radiation Exposure Quantity	No more than 10mRem at a time
System Linkage	DICOM support
Multi-Output Function	The result value, information on the examined person, and trend are outputted
Trend Comparison	Comparison of the trend data for each part

4. DIMENSION



OSTEOPro DEXA Dimension and weight

Net weight with demission : 200x810x120CM

120kg

Gross weight with demission : 140x95x145CM

250kg

OSTEOPro DEXA Composition

OSTEOPro system unit (Excl. Computer System),

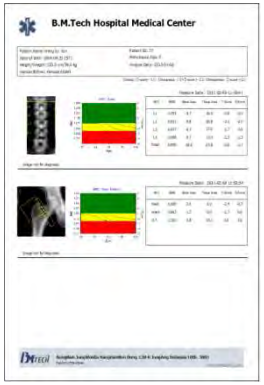
Software installation CD

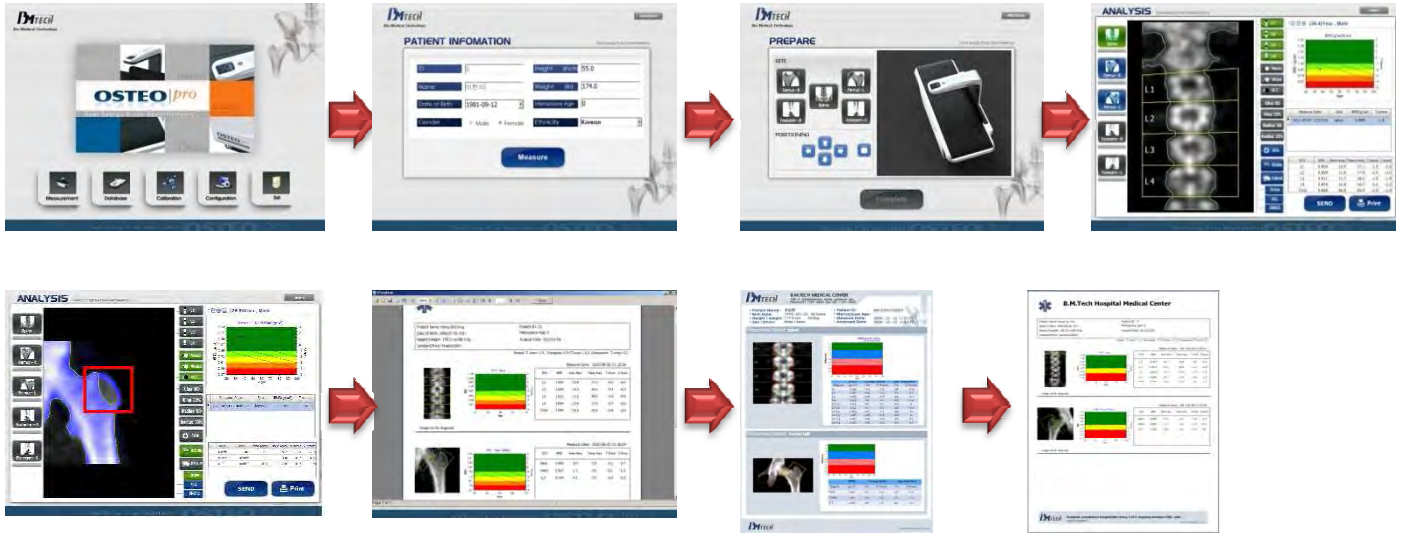
- Measurement assistance
  (2EA for Spain and Femur)
- QC Phantom
- Operating (User) manual & Service manual
- Power cable &LAN cable for communication

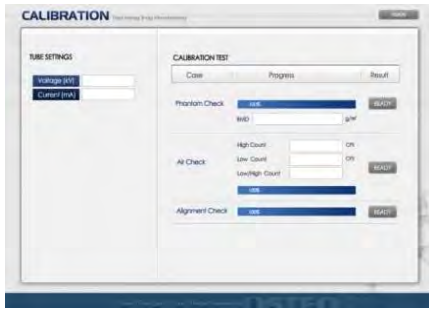
03 OSTEOPRO DEXA

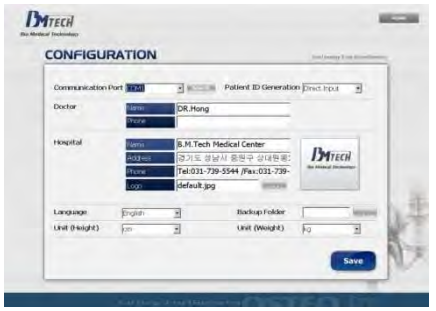
5. SOFTWARE

Osteoporosis

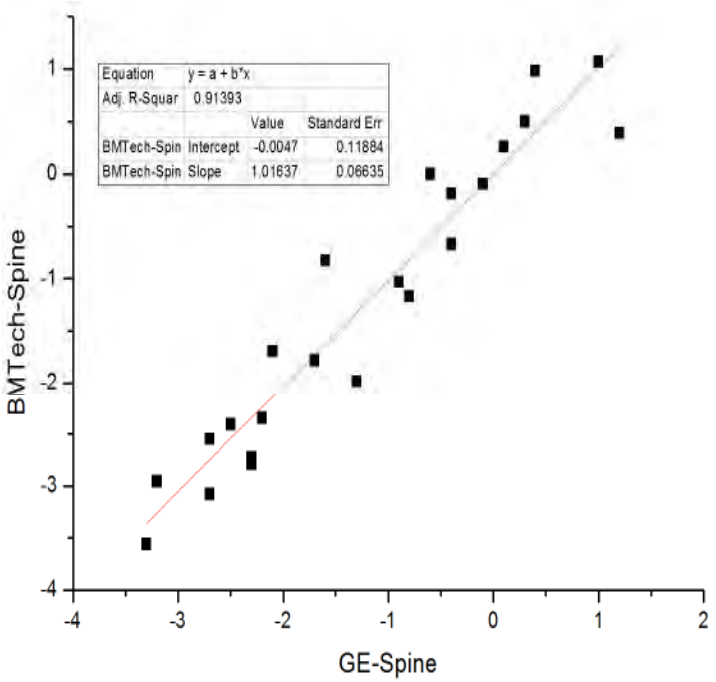


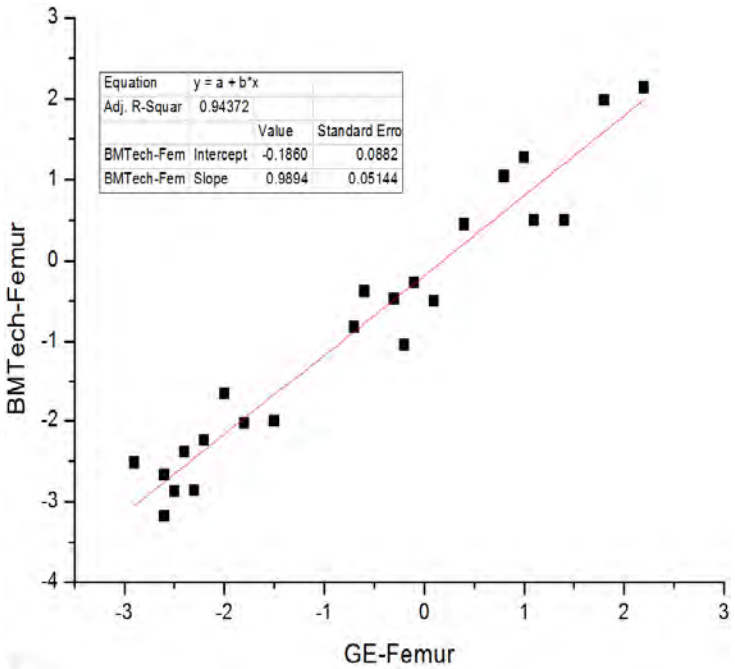






6. CLINICAL REPORT





The Analysis graphs correlate T-Score of three measurement sites (namely AP Spine, Femur, and Forearm) produced by OSTEOPro DEXA and Lunar DEXA (GE). Based on the results between these two sets of values, it could be inferred that there are few differences between OSTEOPro DEXA and Lunar DEXA (GE) in AP Spine, Femur, and Forearm.

7. COMPARISION TO GE

Model		OsteoPro DEXA (BMTech)	DPX PRO (GE)
Scanning Method		Pencil Beam	Pencil Beam
Radiation Dose		Less than 1%	Less than 1%
Appearance			
Measurement	Measurement Site	AP Spine ,Femur ,Dual Femur,Forearm	AP Spine ,Femur ,Dual Femur,Forearm
		-	Whole Body ,Body Composition
		On Scan / DICOM	On Scan / DICOM
	Measurement Time	150 sec. (AP Spine)/120 sec (Femur) 240 sec (Dual Femur)/95 sec(Forearm)	215 sec (AP Spine)/221 sec (Femur) 443 sec (Dual Femur)/286 sec (Forearm) 1337 sec (Total Body)
		On Scan for Spine, Dual Femur (~5min)	On Scan for Spine, Dual Femur (~10 min)
	Parameter	T-Socre, Z-Score, % Young Adults & Age-Match	T-Socre, Z-Score, % Young Adults & Age-Match
	Precision	< 1% CV	< 1% CV
Device Spec.	Dimension	2000 x 810 x 1220mm/120 Kg	2420 x 1030cm X 1208mm/ 272 Kg
	Voltage&Frequency	230/240 VAC ± 10%, 50Hz/ 60Hz/500VA	230/240 VAC ± 10%, 50/60 Hz /400VA
Computer	Required Window	Windows XP, Window 7, VISTA	Windows XP Professional