Preliminary echnical data



MEDIX DR 2D-FanBeam Whole Body Densitometer



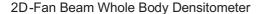


2D-Fan Beam Whole Body Densitometer

Acquisition chain parameters

Dual Emission X-ray Absorptiometry (DEXA) 2D-FanBeam with X and Y kinematics

Multisite (L x W)	Customizable scan area
Scan window size	Adjustable to patient's morphology
Acquisition windows	
Method	Dual Energy Xray Absorptiometry (90/110 kV)
Туре	2D Fan Beam technology
Acquisition method	
Table type	Fixed for all exams including the Whole Body mode
Scanning type	Motorized arm with X and Y kinematics
Maximum scan area	200 x 65 cm
Scanning method	Rectilinear scan
Scanner	
LOCALIZATION	Above the patient
Detector pixel pitch Localization	-
Specification Detector pixel pitch	Photon counting, energy sensitive 1.1 mm x 16 mm
Material Specification	cdTe (1mm)
Type of detection	
Quantity Type of detection	1(2D array 4 x 64 pixels) Direct detection
Detector	1/ 2D owner A v 64 pixels
Size	72 mmx8 mm
Height	30 mm
Material	Brass
Detector Collimator	
Shutter	4 mm lead
Tubepatient distance	270 mm
Collimator-patient distance	77 mm
Size	18 mm×2.5 mm
Material	Lead
Tube Collimator	11
Energy splitting	Filtering: samarium 200 μm + aluminium 2mm
Focal point dimension	0.6 x 0.6 mm
X-ray beam	fan type
Anodecathode direction	Horizontal
Anode angle	12°
Localization	Under the patient
X-ray tube Type	Tungsten fixed anode
waximum tupe current	Z.4 IIIA
Maximum tube current	2.4 mA
Cooling system High voltage	Immersion in oil + cooling fans 110 kV
X-ray continuous generator Manufacturer	High frequency monoblock IMD
V roy continuous generator	High fraguancy manablests





Diagnostic tools

Advanced Morphometritools Fracture risk information using Hip Structural Analysis (HSA)

Examination sites

AP spine (L1- L4)

Forearm: Ultradistal, Mid-radius and Distal (1/3)

Hip: Total Hip, Femoral neck, trochanter, intertrochanter, Ward zone

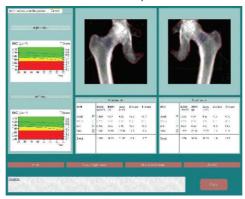
Total Hip: Combined examination of the left and right hip

In-Row Scan: Combined examination of the lumbar spine and of the left or right hip

Whole body: total or local (left arm, right arm, left ribs, right ribs, t spine, I spine, pelvis, left

leg, right leg, head)

Twin Hip



Diagnostic tools

Calculation of Bone Mineral Density (BMD), Bone Mineral Content (BMC), surface, T-score and Z-score

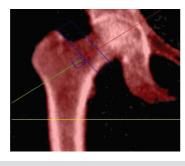
Advanced Morphometric tools (surface, distance and angle): Bone can be measured on every type of examination (spine, hip, forearm)

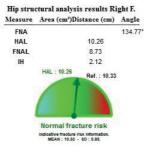
Automated Hip Structural Analysis (HSA): Hip Axis Length (HAL), Femoral Neck Axis Length (FNAL), Intertrochanter to Femoral Head Center Distance (IH) and Femoral axis versus Neck axis Angle (FNA)

Fracture risk information using Hip Structural Analysis (HSA)

FRAX tool to evaluate probability of osteoporotic fractures

Fracture risk information





Diagnostic tools

Whole body examination: Total BMD, Total BMC, surface, local BMD, local BMC, Tscore, Zscore and body composition

Digital Vertebral Assessment (DVA): Provides a low dose, lateral image of the spine (to view all the vertebrae of the spine). The deformation or compression is precisely diagnosed, measured and classified. This analysis can be either automatic using the Genant's semi-quantitative classification, or manual using the Genant's visual classification (L4 - T2)

Lateral spine BMD: To measure the bone density of the vertebrae of the lumbar spine from a lateral angle and without spinal backbone Paediatrics: To measure the BMD (spine and whole body) and the whole body composition

Orthopaedics: To measure the BMD around the prosthesis (ex: Gruen zone selection). Enables a smart implant management. Available for hand, forearm, elbow, shoulder, spine, hip, AP knee, lateral knee, feet. Automatic detection of ROI for hip, knee and lateral knee examinations



2D-Fan Beam Whole Body Densitometer

Analysis

Manual and automatic analysis for all exams

Multisite	Bone Mineral Density (BMD) expressed in g/cm ² , stands for the mineral density of the bones
	Bone Mineral Content (BMC) expressed in g, stands for the mineral mass of the bones
	Area expressed in cm ² , 2D projection of the bone
	T-score = Difference between the patient's values and the mean value of a young population of healthy subjects of the same gender and from the same ethnic background as the patient, divided by the standard deviation of a young population of healthy subjects
	Z-score = Difference between the patient's value and the mean value of a population of healthy subjects of the same age, divided by the standard deviation
Whole body	Total Bone Mineral Density (BMDt)
	Local Bone Mineral Density (BMDI)
	Area
	Body Composition
	Fat mass
	Leanmass
	Bone mineral mass
	Total and local body composition
	Color mapping for visualizing the fat areas
	T-score
	Z-score
Orthopaedic	Bone Mineral Density (BMD)
	Bone Mineral Content (BMC)
	Area
	Automatic ROI selection (ex: Gruen zone), for hip, knee and lateral knee
Paediatric	Bone Mineral Density (BMD)
	Bone Mineral Content (BMC)
	Area
	Body composition
	Z-score
	Skeletal age comparison
Reference curve	Displays the BMD according to the age for the examined region(s). It enables to supply T-score and Z-score values a diagnosis values
Morphometry	Quantitative morphometry (areas, lengths, angles). ex: Automatic Hip Structural Analysis (HSA)
Specification of the clinical data	
Bone Mineral Density (BMD)	± 1.0% in vivo (± 0.5% in vitro)

2D - Fan Beam Whole Body Densitometer



Software

New user friendly interface Evolutionary software

Software tools

Patient follow-up graphs

Advanced Morphometric tools (distance, angle and area) ex: hip length axis

Calculation of standardized BMD (comparison to NHANES III normative data)

Easy scan repositioning from PC method

Customizable user interface (colours, trend, results, print out, etc.)

Multi-user (different profiles can be configured: operator, physician, etc.)

Reference population (reference normality curve): Caucasian, Asian, NHANES-III, African, Turkish, Hispanic, Japanese and Koren

Personalized multiple reference populations (normality curves editor)

Patient's data follow-up: Data base importation from another device + Previous data input

Customizable automatic/semi automatic database archiving

Multi-report for comparative purposes

Customizable reports (header, footer, predefined forms, letters, etc.)

Detailed colour print out of reports (bone + reference curve + analysis report + operator comments + patient and physician letters + followup), configurable by the physician

Email reports sending

Automatic and customizable letter (patient and physician)

Image display tools: Contrast, brightness and zoom

Density display in colour scale

Multi-language software: Chinese simplified, Czech, German, English, Spanish, French, Italian, Polish and Turkish (other languages can be translate)

Help menu

DVO recommendations (Certified by DachVerband Osteologie)

Optional software tools

Telemaintenance software: network connection required

Touch screen

Storage

CD, DVD or external hard drive

Connectivity

DICOM compatibility (Output HIS, RIS, PACS (options))

Push & Print: Storing, printing and transferring patient's data

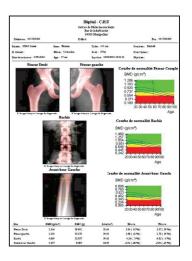
Worklist (option) To manage the patient list

Workstation mode (option): Possibility to connect from multiple distant workstations and access to device data

Multi-user mode (option): Login, logout and rights management

Formatused to export image data: .jpg or .pdf

Multi report





2D-Fan Beam Whole Body Densitometer

Examination parameters

Automatic and manual selection of the Region Of Interest (ROI) Low dose adapted to patient morphology

Doses

Examination time and pixel size

Hip	Pixel size	Examination time	Scanning speed
Fast	1 mm	30 s	220 mm/s
Accuracy	0.5 mm	60 s	220 mm/s

AP Spine	Pixel size	Examination time	Scanning speed
Fast	1 mm	30 s	280 mm/s
Accuracy	0.5 mm	60 s	280 mm/s

Lateral Spine	Pixel size	Examination time	Scanning speed
Fast	1 mm	30 s	250 mm/s
Accuracy	0.5 mm	60 s	250 mm/s

DVA	Pixel size	Examination time	Scanning speed
Fast	1 mm	60 s	280 mm/s
Accuracy	0.5 mm	2 min	280 mm/s

Forearm	Pixel size	Examination time	Scanning speed
Fast	1 mm	30 s	220 mm/s
Accuracy	0.5 mm	60 s	220 mm/s

Whole body	Pixel size	Examination time	Scanning speed
Fast	2 mm	3 min	260 mm/s
Normal	1 mm	5 min	260 mm/s
Accuracy	1 mm	8 min	260 mm/s

Body composition: 3 min, achieved at the same time of the Whole body exam

Total hip: 1min
In Row Scan: 1 min

Patient positioning

Laser light

Easy scan repositioning from PC method

Method of examination

Preregulated exam modes: Exam parameters adjusted automatically based on patient's morphology (Thinness, Health and Overweight)

Personalized: Motor drive speed (mm/sec) and selectable image height and width

Automatic and manual selection of the Region Of Interest (ROI) = Intelligent Scan Acquisition

IntelliScan: Smart reduction of the scan window and of the examination time

Specifications of the clinical parameters

Age grouping 15–95 years old (4-18 years old in paediatric mode)
Weight < 210 kg

Calibration and quality control

Quality control using external phantom

Quality control trend plotting integrated to the software

Control by internal reference between each scan





Computerparameters

Minimal computer configuration	
Operating system	Windows XP, Vista, Seven, 8, 8.1 or Windows 10
Processor	Processor dual core1GHz
RAM	1 GB
Hard disk	100 GB
CD Romor DVD drive	For updating software
Archiving	CD, DVD burner or external hard drive
Monitor	SVGA resolution 1024x768
Printer	Color
Connectivity	2 LAN port for communication and DICOM (LAN for DICOM can be supplied by USB to LAN converter)

Environmental data and electrical specifications

Environmental data	
Operating temperature	20 to 28 °C (68 to 82.4 °F)
Operating humidity	20%- 80% (withoutcondensation)
Pressure	0.8 – 1.2 Bar
Storage temperature	10 to 40°C (50 to 104°F)
Storage humidity	20%- 80% (withoutcondensation)
Radioprotection	No external shielding required
Electrical specifications	
Voltage-Current	110 VAC- 10 A
	210 - 230 VAC - 5 A
Frequency	50/60 Hz
Power consumption	560 W

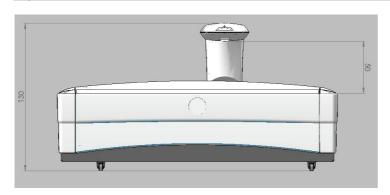
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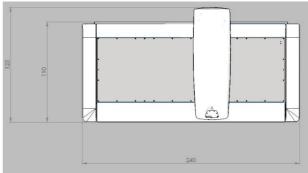


Physical description

Dimensions and weight	
Dimensions	L 240 x W 125 x H 130 cm (L 94" x W 49"x H 51")
Examination table	L 240 x W 110 cm (L 94" x W 43")
Mattress	L 208 x W 72.5 cm (L 82" x W 28")
Patient table lowest height	60 cm (24")
Weight	250 kg (521 lbs)

Physical characteristics





Room layout

