QCT PRO™

Bone Mineral Densitometry Software

User's Guide

Version 5.1 – Revision 20130102

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Regulatory Compliance Information

Product Components

QCT PRO 3D Spine Analysis Module
QCT PRO 2D Spine Analysis Module
QCT PRO CTXA Hip Analysis Module
CT Calibration Phantom
QA Phantom
Bolus Bags
CT Table Pad Set
QCT PRO PACS Option

Model Numbers

10000-40000

Manufacturer

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Contacting Mindways

Mindways provides technical support and sales information through channels as described in the following table.

Service	How to Contact	Availability	Description
Toll-Free Phone	877 MINDWAYS 877 646 3929	8am-5pm Central Time US and Canada Only	Technical support and sales information
Phone	+1 512 912 0871	8am-5pm Central Time	Technical support and sales information
Fax	+1 512 912 0872	Submit: 24 hours daily Response: 1 working day.	Submit technical questions via fax along with preferred contact information.
Technical Support E-mail	support@qct.com	Submit: 24 hours daily Response: 1 working day.	Submit technical questions via e-mail.
Sales E-mail	info@qct.com	Submit: 24 hours daily Response: 1 working day.	Submit sales or product information queries via e-mail.
Web	www.qct.com	24 hours daily	Provides access to product information and technical literature. Technical support queries may also be submitted.

General Safety Precautions

Warning: United States Federal Law restricts this device to the sale, distribution, and use by or on the order of a physician.

The QCT PRO BMD application modules are intended for use as an accessory to a CT scanner. The QCT PRO documentation contains information regarding the installation of QCT PRO and optional BMD modules for use with your CT scanner, including instructions for verifying compatibility with your CT scanner, and directions for calibrating and monitoring the performance of your installed system. These instructions should be followed to assure the safe and effective use of these products.

The QCT PRO BMD application modules are intended for use with CT calibration phantoms that provide a calibration reference relative to aqueous K2HPO4.

Warning: the alternate use of different calibration phantoms in serial patient studies should be avoided.

While the QCT PRO BMD application modules do not deliver or control the delivery of ionizing radiation to a patient, these modules are used to analyze CT images that are derived as the result of delivery of ionizing radiation to a patient through a CT scanner. The CT scanner manufacturer's guidelines for the safe use of the CT scanner should be adhered to at all times.

Each QCT PRO BMD application module includes a user's guide containing operational instructions specific to each BMD application module. These instructions include guidelines for estimating appropriate patient exposure when acquiring CT image data intended for analysis within a specific BMD application module. Adherence to these guidelines will often result in the use of an exposure below that which might be used for studies intended for radiologic interpretation in the same anatomical region, thereby reducing patient exposure to ionizing radiation. Adherence to these guidelines will also reduce the risk associated with having to repeat a study due to the acquisition of data not suitable for analysis within a specific BMD application module.

Warning: There may be practical patient-size limits for QCT PRO BMD studies. Such limits depend on anatomical site and CT model, and will typically be limited by either scan field-of-view (SFOV) or x-ray tube output of your CT scanner. See BMD module-specific documentation for further information.

Warning: When the user selects a reference database and uses the software to plot population bone mineral versus age, the user does so at their own risk.

Note: Addenda to the QCT PRO documentation, including the QCT PRO BMD application modules may be included with the device documentation. Please review any such addenda for up-to-date information regarding the installation and use of QCT PRO and the QCT PRO BMD application modules.

Indications for Use

Intended Use

Warning: United States Federal Law restricts this device to the sale, distribution, and use by or on the order of a physician.

The QCT PRO BMD application modules are intended to provide estimates of bone mineral content (BMC) and/or bone mineral density (BMD) at central anatomical sites as defined below:

The *3D Spine* application module is intended to provide BMD estimates, expressed in grams/cm^3 of equivalent K_2HPO_4 density, for trabecular bone within any combination of one to three vertebral bodies in the spine in the range of T11 to L4, as medically necessary as determined by a physician.

The *2D Spine* application module is intended to provide BMD estimates, expressed in grams/cm^3 of equivalent K_2HPO_4 density, for trabecular bone within any combination of vertebral bodies in the spine in the range of T11 to L4, as medically necessary as determined by a physician.

The *CTXA Hip* application module is intended to provide estimates of bone mineral content (BMC), expressed in grams of equivalent K_2HPO_4 mass, and bone mineral density (BMD), expressed in grams/cm^2 of equivalent K_2HPO_4 density, within the proximal femur as medically necessary as determined by a physician.

Common applications of each of the QCT PRO BMD application modules include the detection of low bone mass conditions, and monitoring bone loss or gain over time as might result from response to a specific treatment regimen or from natural aging processes. Specific indications and contraindications for use are provided in the following sections.

Indications for Use

Clinical indications for central BMD estimates include:

- Conditions where low estrogen levels in women may increase bone resorption, including spontaneous menopause at any age, ovariectomy, secondary amenorrhea from hyperprolactinemia, excessive exercise or nutritional deficiency, or use of GnRH agonists for endometriosis or other medical indications.
- Conditions where the diagnosis of osteopenia is suggested by other means, such as x-ray.
- Conditions known to induce bone loss, such as prolonged immobilization, alcoholism, intestinal malabsorption, or treatment with calcium-wasting diuretics.
- Conditions where bone loss may be induced by treatment with or high endogenous levels of corticosteroids.
- Patients with primary hyperparathyroidism in whom surgery is being considered, to determine if there is low BMD.
- Monitoring the effectiveness of therapy for preventing bone loss for the above conditions. At the present time, there is no evidence that serial BMD measurements need to be made in women receiving adequate estrogen therapy.
- Other conditions deemed appropriate as determined by a physician.

Clinical conditions where central BMD estimates may be useful, but in which care must be taken in interpretation of the results:

- Patients with chronic renal disease, especially those undergoing maintenance hemodialysis.
- Patients recently started on high-dose corticosteroid therapy.
- For the *3D Spine* and *2D Spine* modules, patients with severe lumbar scoliosis, where there may be significant regional variation in BMD within the vertebral body.
- For the *3D Spine* and *2D Spine* modules, patients with severe vertebral osteophytes, where there may be significant regional variation in BMD within the vertebral body.
- For the *CTXA Hip* module, patients with severe osteoporosis in which thinning of the proximal femur cortex may cause difficulties in the analysis.

Contraindications for Use

Clinical conditions where BMD estimates should not be used:

- Patients who have recently had another radiological procedure that includes the introduction of high density contrast material (barium, iodine, thorotrast, thorium) or radio-opaque catheters and tubes.
- Patients who are pregnant or may be pregnant.

Patient Conditions That May Affect Results

The following are examples of conditions that may influence the accuracy and/or precision of BMC and/or BMD estimates derived with the QCT PRO BMD application modules. It is recommended that the presence of such conditions be clearly noted in the patient report.

- Recent introduction into a patient of contrast materials, such as barium, iodine, thorotrast or thorium.
- External objects, such as clothing fasteners, jewelry, ECG leads or ostomy devices.
- Internal objects, such as Harrington rods, bone implants, surgical staples or other foreign bodies.