

## Frequently Asked Questions

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**❖ What is the OsteoGram?**

- ✓ The OsteoGram is a patented, FDA cleared system that measures bone mineral density (BMD) at the middle phalangeal bones of the hand. A hand x-ray is taken using either digital or standard x-ray equipment, then analyzed using the OsteoGram.

**❖ What are the components of the OsteoGram system?**

- ✓ The DICOM OsteoGram system consists of a proprietary software CD, a security key and a hand template. The film-based OsteoGram system consists of a computer with proprietary software, security key, monitor and a flatbed radiograph scanner.

**❖ Some publications refer to OsteoGram “service”. Is it different from the on-site system?**

- ✓ CompuMed started the OsteoGram central-lab service in 1991, and then made it available as an automated on-site based system in 1999. The service (which is still available) and the automated system (that requires no special training to operate) give identical results.

**❖ What is the precision (reproducibility) of OsteoGram?**

- ✓ The OsteoGram precision is >99%, which means precision error of <1%.

**❖ How accurate are the OsteoGram results?**

- ✓ The OsteoGram accuracy is >95% (an accuracy error of 4-5 %). This is based on comparing the OsteoGram to the ultimate test for bone mineral measurement, which is ashed bone weight in cadaveric studies. The correlation coefficient ( $r$ ) is another way of expressing this comparison. On a scale of one this correlation is 0.98.

**❖ How does the OsteoGram compare to ultrasound heel machines?**

- ✓ Ultrasound BMD testing has poor precision and unknown accuracy (Table 1, page 22); hence, its proper usage is in bulk screening not diagnosis. The OsteoGram has excellent precision and excellent accuracy. In addition to screening, it can be used for diagnosing osteoporosis, monitoring bone mass change over time as well as predicting fracture risk.

❖ **How does the OsteoGram compare to DXA?**

- ✓ The precision and accuracy of the OsteoGram are comparable, if not superior, to DXA (Table 1 below). Studies show correlation coefficient ( $r$ ) between the two methods as high as 0.8 - 0.9.

Technique and Site	Precision (Error)	Accuracy (Error)	Radiation Dose ( $\mu$ Sv)	Exam Time (minutes)	Operator Qualification
DXA, hip	1-2%	4-8%	1-6	15	Needed
DXA, spine	1%	4-8%	3	15	Needed
DXA, forearm	<1-2%	4-6%	0.1	7	Needed
Ultrasound, calcaneus/tibia	<1-4%	N/A	N/A	3	N/A
<b>OsteoGram RA, fingers</b>	<b>&lt;1%</b>	<b>4-5%</b>	<b>0.001</b>	<b>3</b>	<b>N/A</b>

*Table 1: Bone mineral density techniques comparison based on recent scientific articles and manufacturer literature*

❖ **What are the indications for OsteoGram use?**

- ✓ The OsteoGram can be used as an aid to physicians for diagnosing osteoporosis, monitoring bone mass change over time as well as predicting fracture risk.

❖ **If the OsteoGram can analyze one x-ray exposure of the fingers then why the need for two exposures?**

- ✓ For Quality Assurance (QA) purposes, the technology of the OsteoGram was developed for two exposures. This QA process consists of two stages. The first QA stage serves in verifying x-ray equipment. The second QA stage verifies the consistency of results between the two exposures for each analyzed bone. In rare cases where one of two exposures is not suitable for analysis and an assessment is still needed, the OsteoGram can adequately analyze one x-ray exposure. To obtain the best results, the OsteoGram should always be used with two valid exposures.

- ❖ **Can any x-ray film be used with the film based system?**
  - ✓ X-ray films must be size 8"x10", green sensitive, double emulsion and speed of 100 to 400.
  
- ❖ **Can any x-ray cassette be used?**
  - ✓ X-ray cassettes must be size 8"x10", green sensitive, double sided screens and compliant with the speed of film used.
  
- ❖ **There are instructions suggesting different x-ray settings (techniques) for the two required exposures when using the film-based system. Is this crucial?**
  - ✓ It is crucial to obtain a developed radiograph with a background gray shade of 1.1 optical density (OD) for each exposure. The acceptable range is 0.9 to 1.3 OD. The previously recommended difference of 10 kV between the settings of the two exposures is not necessary; using the same kV setting for both exposures gives the same results as the different kV, as long as the required gray shade of 1.1 is met in both exposures. Hint (for film & filmless): starting with the technique (settings) used to acquire hand/fingers x-ray in the facility, for OsteoGram: use the same kV and only 50% of mAS. (Yes, that makes the OsteoGram radiograph lighter than the common radiograph & that is what's needed).
  
- ❖ **Some patients have had hand x-rays taken for various reasons, can these x-rays be used with the OsteoGram?**
  - ✓ Not unless CompuMed's aluminum wedge was present near the hand when the x-ray was taken.
  
- ❖ **Can the OsteoGram measure bone density at the hip or spine?**
  - ✓ No; the OsteoGram was developed to measure BMD of middle phalangeal bones of the hand.
  
- ❖ **Is it necessary to measure bone density at the hip or spine to diagnose osteoporosis?**
  - ✓ The OsteoGram precisely and accurately measures phalangeal BMD, which has been proven to be a significant indicator of BMD at other sites of the body.
  
- ❖ **Is it necessary to measure bone density at the hip or spine to assess hip or spine fracture risk?**
  - ✓ The OsteoGram has been specially tested for this purpose. Studies in late 90's showed that the OsteoGram can be used with high reliability for spine and non-spine fracture risk prediction.

- ❖ **What expertise is needed to take a hand x-ray for the OsteoGram?**
  - ✓ Any health care professional who's allowed to take standard hand x-rays qualify.
  
- ❖ **What expertise is needed for an operator to run the analysis on the developed hand x-ray?**
  - ✓ No special expertise needed since the program is automated.
  
- ❖ **Why should I obtain an OsteoGram instead of utilizing other BMD devices?**
  - ✓ Cost effective
  - ✓ Uses existing either standard or digital x-ray equipment
  - ✓ Minimal radiation burden on patient's periphery (other techniques expose the central body to high radiation)
  - ✓ Reliability of results (best precision and accuracy)
  - ✓ Approved technology with more than 10 years of experience performing the test in a central lab
  - ✓ High correlation to known methods (e.g., DXA)
  - ✓ Minimal footprint
  - ✓ Rapid - one minute of perform analysis
  - ✓ Requires no special training to operate
  - ✓ Reimbursable by Medicare and most private insurers