



# Quality Control and Assurance

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LECTURE 4

# Learning objectives: Precision, Quality Control, Quality Assessment and Cross Calibration

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Phobias and  
Irrational fears



# DXA Quality Control Processes

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## Instrument QC

Pre-Scan calibration

Weekly phantom scanning

Monthly phantom scanning

Service log entries

Scanner preventative maintenance by manufacturer

Precision testing by the technologist

You must scan patients on a scanner with a database that represents their demographics. Therefore, it is imperative that you do the DXA scans preferably at the same clinic, same scanner, using the same technologist every time.

# Optimum Situations

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Limit number of scanning personnel

Daily calibration and/or QC of system

Weekly QC (not all systems will use this)

Precision study

Have you done one yet?

# Limiting Personnel

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“looks good on paper”

- Not always practical in today's world

Try to match tech to machine to patient

Try to be consistent in scanning protocols by setting down rules for facility

- You should have written work instruction

# Daily Calibrations

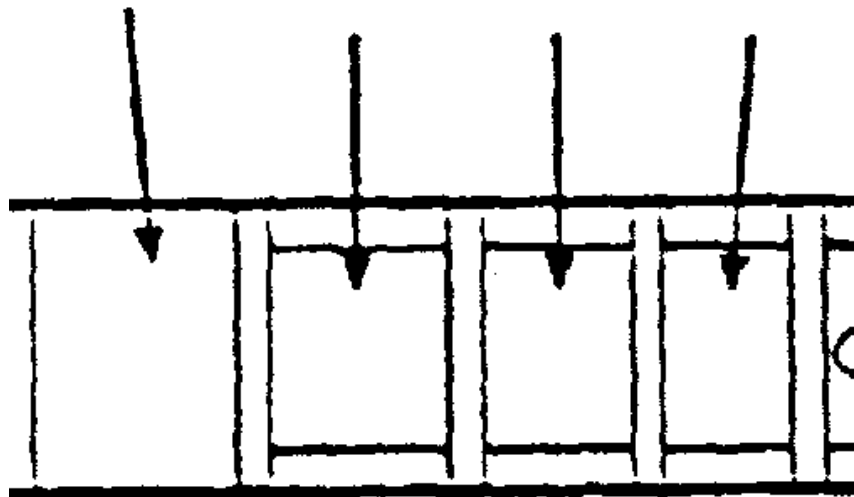
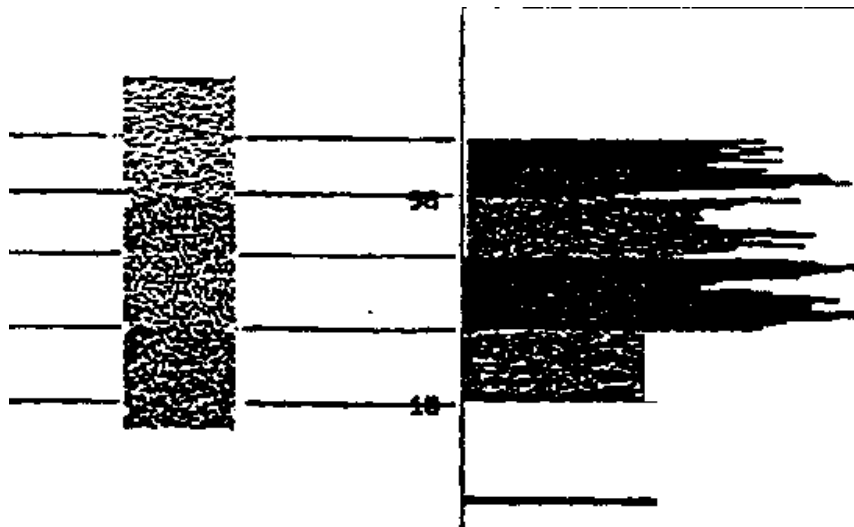
All DXA scanners utilize some kind of consistent calibration tool.

- Calibration box
- Anthropomorphic spine phantom
- Step-wedge phantom

# Phantoms/Standards

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Step-wedge



# Phantoms/Standards

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Anthropomorphic phantom

Resembles anatomy which is being evaluated





## Results from Phantom Scan

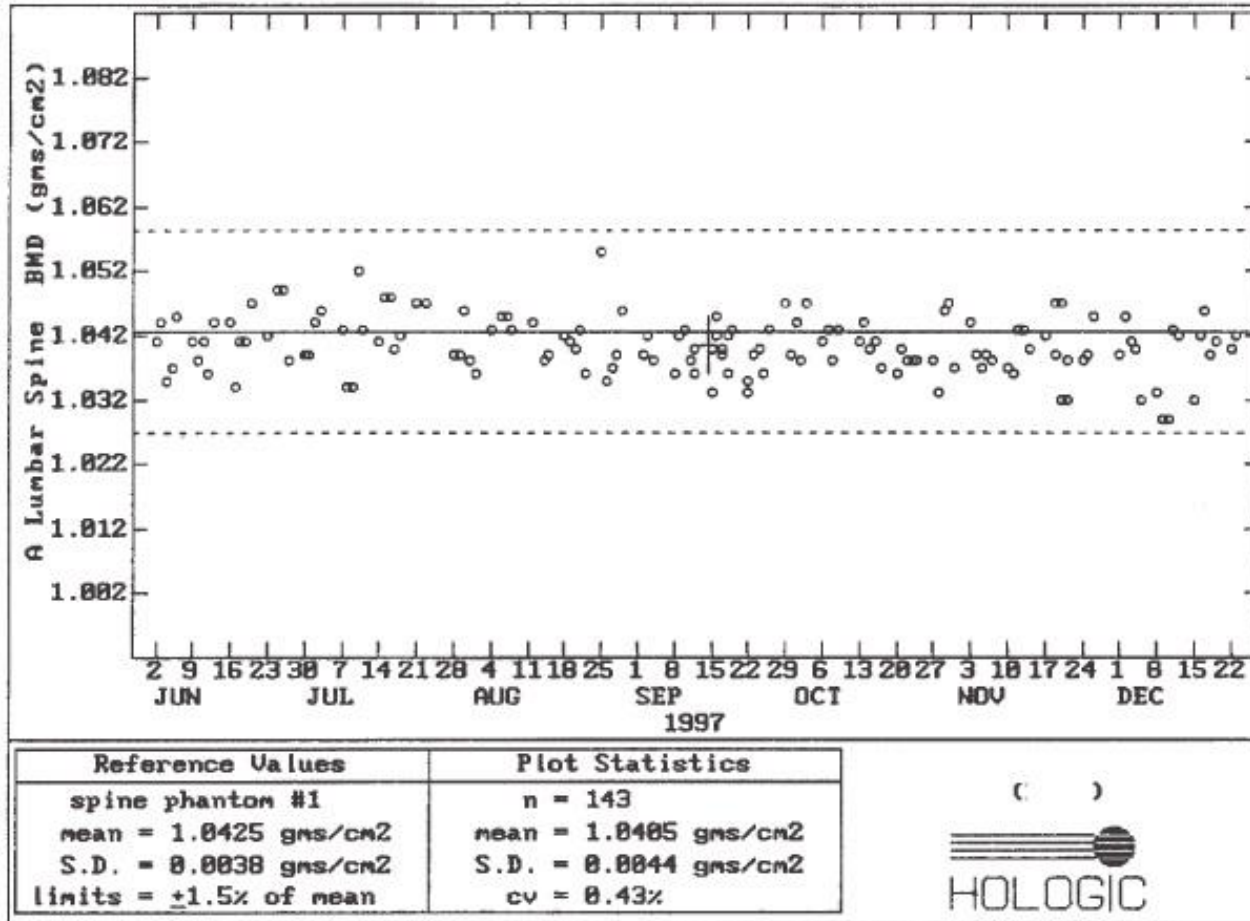
### Area measurement

- Bone Mineral Content (BMC)
- Bone Mineral Density (BMD)

BMD is plotted on QA graph

This BMD should fall  $\pm 1.5\%$  of established BMD of system

# Results from Phantom Scan



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## Results from Phantom Scan

What do you do with this information?

- Print the QC scan
- Check this printout
- Initial or sign off on it
- Place in QC book for facility
- These steps document you are visualizing your QC Scan and not just running them to get going on your day.

## Daily Calibration Process

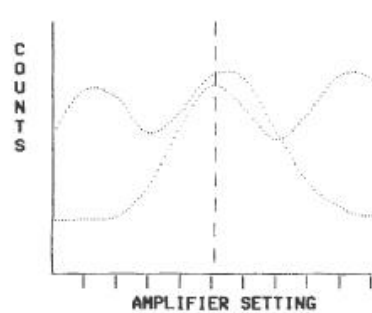
“Wakes up the machine”

Verifies and evaluates:

- Internal machine mechanics
- Electronics of scan table
- Function of laser light
- Detector system for the dual beam
- CV for the scan

QUALITY ASSURANCE RESULTS

X-Ray Voltage (kVp)	76.0	Date	02/26/98
X-Ray Current (μA)	150.0	System	1



DETECTOR		
AMPLIFIER SETTING	COUNTS LOW keV	COUNTS HIGH keV
220	41718	566
270	62826	934
320	59491	2483
370	42653	16576
420	52944	45827
470	78582	65478
520	68755	54464
570	43482	39683
620	18819	52320
670	6986	78416
720	2714	68669

PROCEDURE	VALUE	EVALUATION
Lights	-	Pass
Peak Setting	475 units	Pass
Background (Low keV)	0 cps	
Background (High keV)	1 cps	Pass
Beam Stop Action	-	Pass
Percent Spillover	7.56 %	Pass - Good
Chi Square	5	Pass
Air Counts (Low keV)	762830 cps	Pass
Air Counts (High keV)	445833 cps	Pass
Air Ratio	0.58	Pass
Transverse Mechanics	12386/12389 steps	Pass
Longitudinal Mechanics	19720/19721 steps	Pass
Tissue Value	1.309	Pass
Collimation Ratio	3.865	Pass

	1	2	3	4	5	MEAN	SD	%CV
LARGE BM	267.8	267.2	265.9	266.5	267.6	267.0	0.69	0.26
WIDTH	498	502	501	502	499	500	1.62	0.32
MEDIUM BM	200.4	198.6	197.8	197.2	196.3	198.0	1.41	0.71
WIDTH	429	433	432	432	428	431	1.94	0.45
SMALL BM	143.6	142.4	141.4	140.3	142.5	142.1	1.12	0.79
WIDTH	365	364	364	363	363	364	0.75	0.21

Courtesy GE-Lunar, Madison, Wis.

# Daily Calibration- GE Lunar

Where does the baseline come from?

Machine is brought to facility

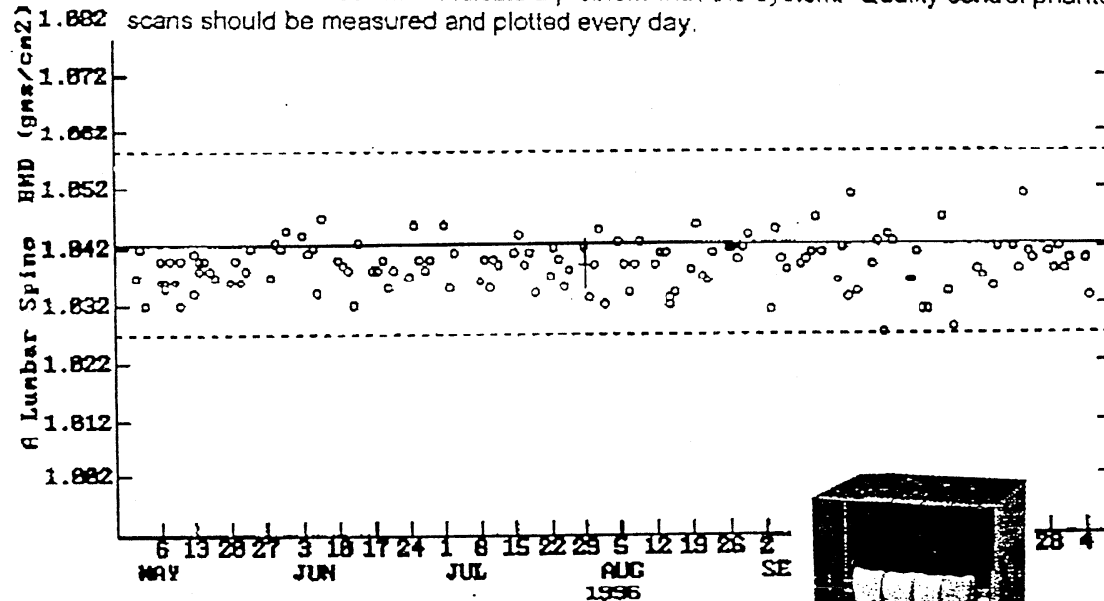
Taken out of boxes and assembled

Baseline scans are performed

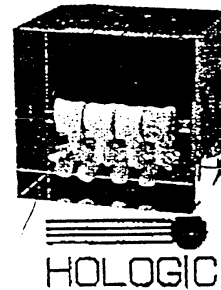
- Typically, 10 phantom scans without repositioning phantom
- Scans are averaged to produce a mean
- Range of performance or CV is calculated from mean
- Data is entered by engineer into system

Quality Control Hologic 2000

The quality control data base has a solid black line (mean) determined at the time of installation. Dashed lines indicate a +/- 1.5% range of variation around the mean. BMD values outside these limits indicate a problem with the system. Quality control phantom scans should be measured and plotted every day.



Reference Values	Plot Statistics
spine phantom #1716	n = 135
mean = 1.8425 gms/cm2	mean = 1.8389 gms/cm2
S.D. = 0.0038 gms/cm2	S.D. = 0.0042 gms/cm2
limits = +/- 1.5x of mean	cv = 0.41%



# Scan QC Information Baseline



What can change  
from day to day?

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Operators

The patient

Machine performance or  
fluctuation

- Changes in phantom  
measurements





# Measuring Precision

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BMD can vary due to:

Site measured

- PA Lumbar
- Hip
- Forearm

# Measuring Precision

## Type of densitometer

- Manufacturer
- Model of machine
- Age of Software

## Operator

- Experienced vs. Inexperienced

## Method of measurement

- RA, DXA, QCT, QUS

## Precision Study

### What is accuracy?

- When does it occur?
- How is it affected?

### What is precision?

- When does it occur?
- How do we measure it?

Does the BMD measurement produced by your machine reflect the true value of your patient's BMD

Or—"Do you have what we say you have?"

Would it match results from a core biopsy of your patient?

Accuracy

Provides amount of BMD for region



Allows us to assign

T-Score

Z-Score

Accuracy

Occurs first time you measure a patient's BMD



We assign a classification of BMD



Is affected by:

Type of device

Positioning of patient

Patient prep

Skill of technologist

Analysis process

Accuracy



# Accuracy

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Do you ever drop the ball in some of these critical areas?

Sure, we do

What can you do differently?

- Get some training
- Make changes as you grow in your skills

Reproducibility of results?



Can you duplicate the measurement the next time the patient comes back?



What can you do to help achieve this goal?

Look at previous scans

Compare them for performing your analysis

Duplicate, duplicate, duplicate

Precision



# Types of Precision Studies

## In Vitro

- Related to design of instrument
- Appropriate and timely maintenance of system
- Evaluated using a phantom

## In Vivo

- Based upon operator skills
- This can be more difficult to measure
- Uses live subjects, not a phantom

## Precision Occurs

When patient returns for serial measurements

Involves an in-house precision study

Perform one in your facility prior to doing follow-up measurements

## Precision Study

\*\*\*Make sure it is legal in your state to perform study with live subjects



Document the patient has consented to be involved in study

Develop a document for your facility which the patient will sign verifying they understand the following:

- They will be participating in a study
- They will receive some additional exposure with additional scan

Yours will be a short-term study

Complete all scans within one month

Perform a study for each area your facility measures

Analyze the data to find the precision of positioning and analysis process

# Precision Study

# Terminology

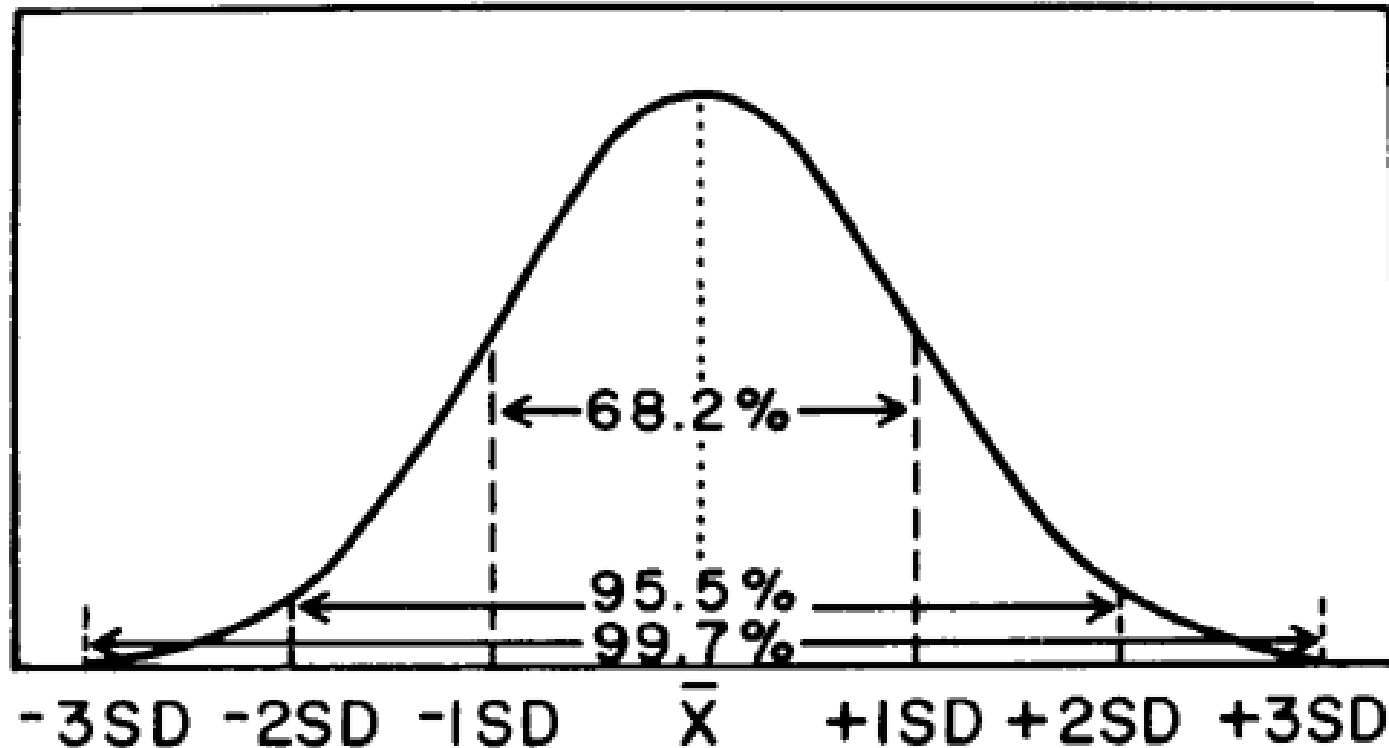
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## Mean

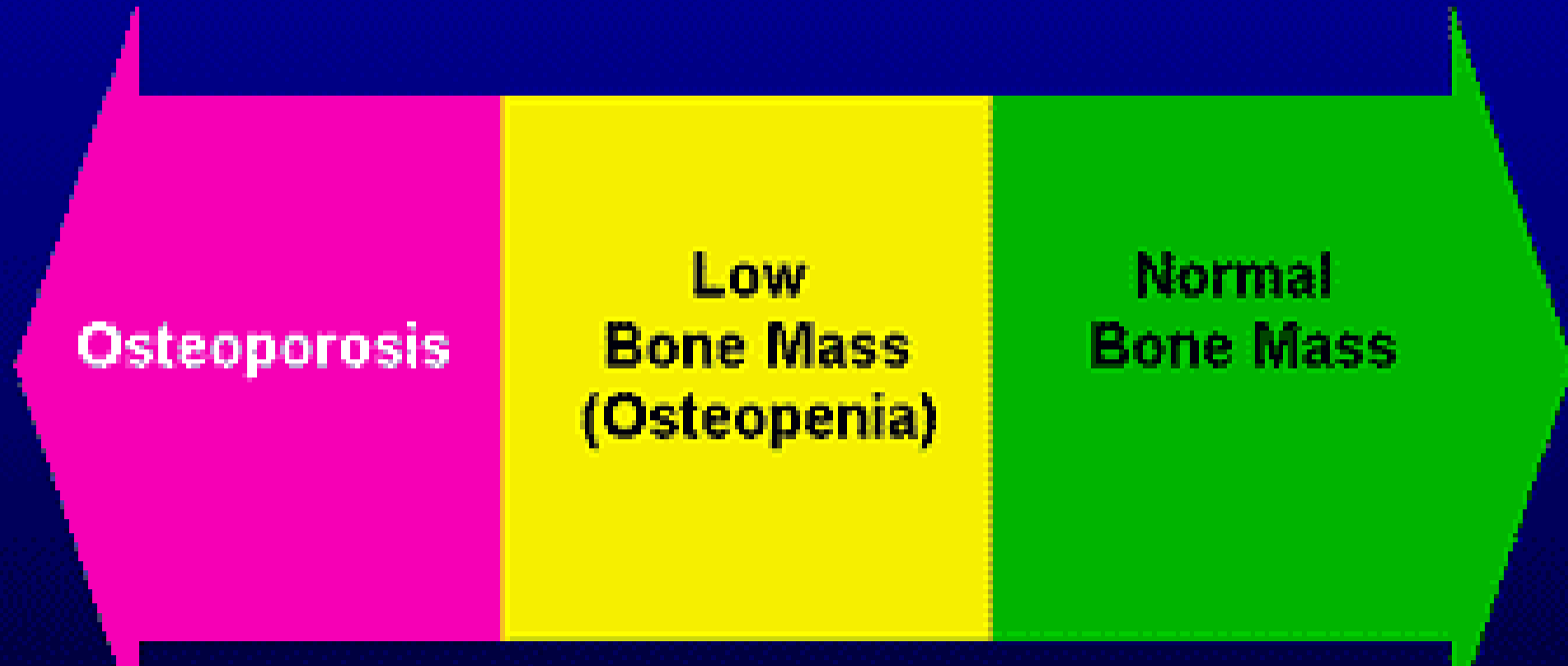
- Average value of a group of measurements

## Standard Deviation (SD)

- Standard variation or deviation from mean value



Correlates with life time fracture risk for Caucasian Women



How is the SD used in BMD?

# CV

## Coefficient of Variation (CV)

- SD as expressed as a percentage of the mean
- $CV = 100 \times (SD / \text{Mean})$

Smaller CV, the better the precision of the result or value

I.E.- a CV of 2% is better than 5%

Why should we  
measure  
precision?

Doesn't the manufacturer do it?

Can't I use their data?

Manufacturers uses:

- Phantoms or healthy individuals
- Highly skilled technologists



What's  
happening in  
my facility?

## Older patients

- Degenerative changes
- Medication changes
- Loss of a site to measure

## Newer operators

- Learning the ropes
- Do not know all the ins and outs of machine

Prior to performing serial measurement on patients



New technologist



Changes to equipment which may affect BMD

New machine

New x-ray tube

New software

Moving a machine  
to new location

When do we  
measure  
precision?

# How do we do it?

Within one month

Same technologist

Same site

- 30 patients -2 times
- 15 patients -3 times

The individual values and the average value for each of the 3 scans on patients 1 through 14 are shown in table 1.

PATIENT	SCAN 1	SCAN 2	SCAN 3	MEAN ( $\bar{x}$ )
Patient 1	1.010	1.019	1.100	1.043
Patient 2	0.925	0.940	0.918	0.928
Patient 3	1.164	1.160	1.170	1.165
Patient 4	0.999	1.010	1.008	1.006
Patient 5	0.900	0.920	0.905	0.908
Patient 6	0.955	0.960	0.960	0.958
Patient 7	1.000	1.010	1.150	1.053
Patient 8	0.875	0.849	0.869	0.864
Patient 9	0.898	0.920	0.901	0.906
Patient 10	1.111	1.009	1.100	1.073
Patient 11	0.964	0.949	0.960	0.958
Patient 12	1.000	0.985	0.992	0.992
Patient 13	1.200	1.185	1.205	1.197
Patient 14	1.165	1.170	1.180	1.172

Table 1. The Individual and Mean Values for AP Spine Studies on 14 Patients



# A Question

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WHAT IF WE HAVE MORE THAN ONE TECH?

# Precision Study

Use precision calculation formula

Use ISCD precision calculation software

Study will provide basis to determine amount of change in BMD on serial exams to be declared significant

Precision Study for DEXA L-Spine (Endocrine Clinic of Southeast Texas) 9/2/98

BMD (gm/cm2)	-(Mean)	Difference	Difference Squared
1.094	-1.11725	-0.02325	0.000540563
1.081	-1.11725	-0.03625	0.001314063
1.086	-1.11725	-0.03125	0.000976563
1.082	-1.11725	-0.03525	0.001242563
1.119	-1.11725	0.00175	0.00003063
1.104	-1.11725	-0.01325	0.000175563
1.101	-1.11725	-0.01625	0.000264063
1.126	-1.11725	0.00875	0.000076563
1.121	-1.11725	0.00375	0.000014063
1.145	-1.11725	0.02775	0.000770063
1.133	-1.11725	0.01575	0.000248063
1.160	-1.11725	0.04275	0.001827563
1.112	-1.11725	-0.00525	0.000027563
1.121	-1.11725	0.00375	0.000014063
1.116	-1.11725	-0.00125	0.000001563
1.106	-1.11725	-0.01125	0.000126563
1.138	-1.11725	0.02075	0.000430563
1.124	-1.11725	0.00675	0.000045563
1.138	-1.11725	0.02075	0.000430563
1.140	-1.11725	0.02275	0.000517563
1.138	-1.11725	0.02075	0.000430563
1.117	-1.11725	-0.00025	0.000000063
1.105	-1.11725	-0.01225	0.000150063
1.116	-1.11725	-0.00125	0.000001563
1.125	-1.11725	0.00775	0.000060063
1.107	-1.11725	-0.01025	0.000105063
1.110	-1.11725	-0.00725	0.000052563
1.118	-1.11725	0.00075	0.000000563
31.283			
		Sum of squared differences	0.009847264
		Divided by 27	0.000364713

Standard deviation: 0.019097473 gm/cm2

Coefficient of variation: 0.017093285 or 1.7%

preciscalcadv

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# ISCD Advanced Precision Calculating Tool

*This calculator is intended for use by advanced bone densitometrists only. It may be considered for special clinical practice situations and for clinical research. Please note that the ISCD recommends expressing precision as RMS SD, and LSC at the 95% confidence level. Using this calculator, you may:*

1. Calculate precision error with as many as 50 patients.
2. Express precision error as RMS SD (absolute value in  $g/cm^2$ ), CV, or %CV.
3. Express LSC (Least Significant Change) with a choice of confidence levels.

Instructions: Enter BMD measurements to 3 decimal places for at least 15 patients scanned 3 times each, or 30 patients scanned 2 times each. Precision and LSC must be calculated separately for each skeletal site and ROI (L1-L4, total proximal femur, femoral neck, etc.). BMD results from as many as 50 patients may be entered. The calculator does the rest.

Patient	Scan 1	Scan 2	Scan 3	SD	SD sq	CV	CV sq	Skeletal Site / ROI Tested:
1								
2								
3								
4								
5								
6								
7								
8								
9								
10								
11								
12								
13								
14								
15								
16								
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47								
48								
49								
50								

n = 0 (Number of Patients)

Sum = (Sum of SD sq)

Sum / n = (Sum of SD sq / n)

SqRT = (Square Root of above)

RMS SD =  $g/cm^2$  (Root Mean Square SD)

CV = (Coefficient of Variation)

%CV = % (% Coefficient of Variation)

LSC based on at least 15 patients with triplicate scans:

Advanced Calculator

Ready

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CV = (Coefficient of Variation)

%CV = % (% Coefficient of Variation)

LSC based on at least 15 patients with triplicate scans:

**LSC with Different Levels of Confidence**

Precision	95%	90%	85%	80%	Units
RMS SD					$g/cm^2$
CV					
%CV					%

LSC based on at least 30 patients with duplicate scans:

**LSC with Different Levels of Confidence**

Precision	95%	90%	85%	80%	Units
RMS SD					$g/cm^2$
CV					
%CV					%

DEVELOPED BY: E. Michael Lewiecki, M.D., FACP, CCD for ISCD

Advanced Calculator

Ready

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# How do you use the data?

Take the precision error for the site measured and subtract it from the amount of BMD change from the previous scan

This is your clinically significant BMD change.

# For example

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If your BMD error for the system and your scanning personnel is:

5% error for the L-Spine

10% error for the Total Hip



# For example

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Your patient's BMD in the L-Spine has changed 6.5% and 15% in the Total hip since the previous BMD measurement

How much of this BMD change is clinically significant?

# DXA Cross Calibration

# Machine Cross Calibration

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Should be performed when adding a new DXA machine to your facility.

When replacing an old DXA scanner of the same manufacture.

When getting a software upgrade.

When replacing an x-ray tube (Use the precision study from the x-ray tube that went out).

# ISCD Machine Cross Calibration Tool

Bone GLSC calibration calculator - Compatibility

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## ISCD DXA Machine Cross Calibration Calculating Tool

Generalized Least Significant Change Calculating Tool: version alpha 3  
Copyright: John A. Shepherd, Ph.D. and Ying Lu, Ph.D., UCSF, 01/06/06

DATE: \_\_\_\_\_  
CLINIC: JSC  
ROI: \_\_\_\_\_

SYSTEM 1 DATA		SYSTEM 2 DATA	
Manufacturer: Hologic	Model: Discovery	Manufacturer: Hologic	Model: Horizon
Serial no.: 49368	SW Version: 13.5.2.1	Serial no.: 100183	SW Version: 13.5.3

Simple Precision Calculator Results for SYSTEM 1		Simple Precision Calculator Results for SYSTEM 2	
RMS SD = 0.005 g/cm <sup>2</sup> (Root Mean Square SD)	RMS CV = 0.007 % (Coefficient of Variation)	RMS SD = 0.006 g/cm <sup>2</sup> (Root Mean Square SD)	RMS CV = 0.009 % (Coefficient of Variation)
%CV = 0.727 %		%CV = 0.884 %	

System 1 LSC based on 15 patients with triplicate scans:		System 2 LSC based on 15 patients with triplicate scans:	
Levels of Confidence		Levels of Confidence	
System 1 LSC	95% 90% 85% 80% Units g/cm <sup>2</sup>	System 2 LSC	95% 90% 85% 80% Units g/cm <sup>2</sup>
absolute LSC		absolute LSC	
CV LSC		CV LSC	
%CV LSC		%CV LSC	

System 1 LSC based 30 patients with duplicate scans:		System 2 LSC based 30 patients with duplicate scans:	
Levels of Confidence		Levels of Confidence	
System 1 LSC	95% 90% 85% 80% Units g/cm <sup>2</sup>	System 2 LSC	95% 90% 85% 80% Units g/cm <sup>2</sup>
absolute LSC		absolute LSC	
CV LSC		CV LSC	
%CV LSC		%CV LSC	

### CROSS-CALIBRATION TOOL RESULTS

Below is automatically calculated after entering your cross-calibration data into the scan1 columns for System 1 and System 2 below  
Have your FIELD SERVICE TECH use the equation below to cross calibrate your System 1 database before importing to System 2

System 2 = **-0.012** + **1.030** \* System 1

where the  
slope = **1.030** r-value = **0.982** no of patients used: **29**  
Intercept = **-0.012** RMS Error = **0.003**

Heel BMD 29 Summary PELV BMD Spine BMD Left Total Hip BMD Left Femur Neck BMD Left Trochanter BMD

Bone GLSC calibration calculator

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### Patient Cross-Calibration Data

DATE: \_\_\_\_\_  
CLINIC: JSC  
ROI: \_\_\_\_\_

SYSTEM 1 DATA		SYSTEM 2 DATA	
Make: Hologic	Model: Discovery	Make: Hologic	Model: Horizon
Serial no.: 49368	SW Version: 13.5.2.1	Serial no.: 100183	SW Version: 13.5.3

Enter UN CROSS-CALIBRATED DATA from System 1 scans below				Enter UN CROSS-CALIBRATED DATA from System 2 scans below			
Patient	Scan 1	Scan 2	Scan 3	Patient	Scan 1	Scan 2	Scan 3
1	0.716	0.724		1	0.728	0.725	
2	0.584	0.581		2	0.594	0.610	
3	0.532	0.537		3	0.531	0.540	
4	0.789	0.788		4	0.796	0.794	
5	0.664	0.668		5	0.638	0.633	
6	0.549	0.549		6	0.581	0.565	
7	0.796	0.795		7	0.830	0.836	
8	0.650	0.650		8	0.652	0.649	
9	0.536	0.531		9	0.535	0.541	
10	0.613	0.619		10	0.624	0.608	
11	0.588	0.570		11	0.598	0.598	
12	0.619	0.616		12	0.592	0.600	
13	0.770	0.766		13	0.771	0.781	
14	0.619	0.619		14	0.639	0.636	

Heel BMD 29 Summary PELV BMD Spine BMD Left Total Hip BMD Left Femur Neck BMD Left Trochanter BMD