Med-Imaps SA PTIB Hôpital Xavier Arnozan Avenue du Haut-Lévêque F – 33600 PESSAC Tel. +33 (0)5 57 10 28 56 www.med-imaps.com



TBS CALCULATOR USER GUIDE

User Guide version 2.0 This User Guide is based on TBS Calculator version 2.0

Société Anonyme au capital de 461 120€ RCS Bordeaux 491 084 216 000 10



Table of contents

l. Ove	erview	3
Α.	Intended use	3
В.	Prerequisites	3
C.	Input data	3
1.	Compatible devices	3
2.	Compatible DXA software	1
3.	Data source	4
D.	TBS calculation	4
E.	Output data	4
F.	Performances and limits	5
1.	Performance testing	5
2.	TBS and soft tissues6	3
3.	Output standardization6	3
G.	Regulation	3
II. Hov	v to use TBS CALCULATOR?	7
Α.	Software activation	7
1.	Product activation in Research Centers7	7
2.	Product activation for Contract Research Organization	3
В.	Software configuration	9
C.	Input data10)
1.	Add folders containing scans10)
2.	How to retrieve X-calibration parameters?11	
3.	List of folders	2
D.	Output data12	2
E.	Files processing	3
F.	Results delivery14	1
G.	View output file14	1
Η.	Troubleshooting15	5



I. Overview

A. Intended use

TBS Calculator <u>is a software</u> intended <u>for use</u> as an investigational tool only.

It computes the antero-posterior spine DXA examination files and calculates a score: Trabecular Bone Score (TBS). The TBS is derived from the texture of the DXA image and has been shown to be related to bone microarchitecture and fracture risk. This data provides information independent of BMD value.

B. Prerequisites

TBS Calculator is intended to be installed on a PC with a configuration equal to or higher than:

- Processor: 1 GHz;
- RAM: 1 GB;
- Disk space: 1GB free;
- Operating system: Windows XP, Windows Vista or Windows 7.

C. Input data

The software is able to analyze scans from several devices. All most recent scanners from GEHC Lunar and Hologic companies are compatible with TBS Calculator.

1. Compatible devices

Manufacturer	Model
GEHC Lunar	iDXA
GEHC Lunar	Prodigy
GEHC Lunar	Prodigy Compact
GEHC Lunar	Prodigy Pro
GEHC Lunar	Prodigy Pro Compact
GEHC Lunar	Prodigy Advance
GEHC Lunar	Prodigy Advance Compact
GEHC Lunar	Prodigy Primo
GEHC Lunar	Prodigy Primo Compact
HOLOGIC	Discovery A
HOLOGIC	Discovery C
HOLOGIC	Discovery W
HOLOGIC	Discovery SL
HOLOGIC	Discovery Ci
HOLOGIC	Discovery Wi
HOLOGIC	QDR 4500 A
HOLOGIC	QDR 4500 C



HOLOGIC	QDR 4500 W
HOLOGIC	QDR 4500 SL
HOLOGIC	Delphi A
HOLOGIC	Delphi C
HOLOGIC	Delphi W
HOLOGIC	Delphi SL

2. Compatible DXA software

TBS calculator has been validated for the analysis of the DXA scan files created by the following DXA software:

- GEHC Lunar enCORE, versions 8.0 to 14.1
- Hologic QDR Workstation, versions 12.3 to 12.7
- Hologic APEX, versions 1.0 to 4.0

3. Data source

The scans to be analyzed must be stored in specific folders. In each folder, scans must originate from the same center and the same DXA scanner.

D. TBS calculation

TBS is calculated using a specific algorithm that is optimized for each scanner model.

In order to be able to compare TBS values calculated from scans acquired on different scanners, a X-calibration must be done.

This X-calibration is a linear correction that will be applied on TBS output values. It is defined by a slope and an intercept value. By default, those parameters are, respectively, set to 1 and 0 in the software. They should be modified by the user if he intends to calculate TBS score on data providing from different scanners.

E. Output data

TBS Calculator software stores the calculated TBS values in a Microsoft Excel compatible file (CSV formatted). This file contains one row per scan and the following columns:

- Scan date
- Scan mode
- BMD analysis date
- TBS analysis date
- Patient ID
- Patient's First name
- Patient's Last name
- Patient's height
- Patient's weight
- Patient's Body Mass Index
- Patient's date of birth
- Patient's age
- Patient's sex
- Patient's ethnicity
- L1 BMD (g/cm²) If not measured, "N/A" is displayed



- L2 BMD (g/cm²) If not measured, "N/A" is displayed
- L3 BMD (g/cm²) If not measured, "N/A" is displayed
- L4 BMD (g/cm²) If not measured, "N/A" is displayed
- Mean BMD Spine $(g/cm^2) = \Sigma(BMD_ixSurface_i)/\Sigma(Surface_i)$ of measured and not excluded ROI
- L1 TBS If not measured, "N/A" is displayed
- L2 TBS If not measured, "N/A" is displayed
- L3 TBS If not measured, "N/A" is displayed
- L4 TBS If not measured, "N/A" is displayed
- Mean TBS Spine (of measured and not excluded ROI)
- L1 measured TRUE or FALSE
- L2 measured TRUE or FALSE
- L3 measured TRUE or FALSE
- L4 measured TRUE or FALSE
- L1 excluded TRUE or FALSE
- L2 excluded TRUE or FALSE
- L3 excluded TRUE or FALSE
- L4 excluded TRUE or FALSE
- L1 Surface (cm²) If not measured, "N/A" is displayed
- L2 Surface (cm²) If not measured, "N/A" is displayed
- L3 Surface (cm²) If not measured, "N/A" is displayed
- L4 Surface (cm²) If not measured, "N/A" is displayed
- ----- GE-Lunar devices only
- Combined Spine vertebra For ex. "L1-L4"
- L1 BMD T-score If not measured, "N/A" is displayed
- L2 BMD T-score If not measured, "N/A" is displayed
- L3 BMD T-score If not measured, "N/A" is displayed
- L4 BMD T-score If not measured, "N/A" is displayed
- Combined Spine BMD T-score If there aren't 2 adjacent vertebra available, "N/A" is displayed
- L1 BMD Z-score If not measured, "N/A" is displayed
- L2 BMD Z-score If not measured, "N/A" is displayed
- L3 BMD Z-score If not measured, "N/A" is displayed
- L4 BMD Z-score If not measured, "N/A" is displayed
- Combined Spine BMD Z-score If there aren't 2 adjacent vertebra available, "N/A" is displayed
 ------ End of GE-Lunar devices only
- X-cal Slope
- X-cal Intercept
- Input Folder
- Input File
- Center name
- Study phase
- Device Model
- Device serial number

F. Performances and limits

1. Performance testing

Ex vivo studies carried out from bony pieces of human cadavers have enabled us to assess the exactness of the TBS parameter from statistical correlations established with the Parfitt's "standard" 3D parameters that characterize the bone microarchitecture. Significant statistical correlations have been established between the TBS parameter and the 3D parameters of connectivity density, intertrabecular spacing and the number of trabeculae. These levels of correlation proved to be stable among several sub-set samples, and strong for independent evaluations lead from several aforementioned bone densitometers.



The reproducibility of the TBS parameter has been assessed according to a standard methodology based on experiments carried out on a set of vertebrae of human cadavers for devices listed in paragraph I.B.1, see page 3.

2. TBS and soft tissues

It is worth remembering that the patient's acquisition must be carried out with the acquisition mode recommended by the manufacturer and corresponding to his/her corpulence. As a consequence, it is important that his/her weight and height be updated at each examination.

Warning: In order to escape from the influence of soft tissue in extreme cases, the TBS algorithm takes into account the acquisition mode used for the realization of the DXA examination as well as the patient's BMI based on the values of Weight and Height.



Erroneous Weight and/or Height values (typing mistake on the part of the operator) may bias the TBS values in an uncontrolled manner; thus, it is recommended to systematically check the exactness of the patient's Weight and Height values reported in the DXA examination;



With GEHC-Lunar DXA scanners, TBS values computed from scans acquired in thin and thick mode may be biased; thus, **it is recommended not to take into account those values.**



In extreme cases where patients have a body mass index below 15 kg/m² or over 35 kg/m², it is possible that the TBS values be biased; thus, it is recommended not to take into account TBS values for patients with BMI below 15 kg/m² or over 35 kg/m².

For the case of a patient of normal corpulence presenting a more significant distribution of fat on the abdomen (case of an android type repartition), the DXA acquisition mode recommended by the manufacturer may be the "Thick" mode whereas the BMI is normal; in this specific case the probability that the TBS values are biased in an uncontrolled manner is high (for example, an excessively low TBS value). Thus, it is recommended to use more often the acquisition mode that is more logically adequate with the BMI value and to switch to the thick or thin modes only when extremely necessary (for example: in doubt about the accuracy of the BMD value for a thickness value of a patient in the excessively high or low acquisition zone).

3. Output standardization

TBS values are standardized so that, whatever bone densitometer brand and model is used, they can be plotted on a unique reference graph.

Thus, average TBS scores produced by all devices and models are identical. Therefore, due to technological differences between the scanner models and brands, two TBS scores obtained for a patient on 2 different scanner models must not be compared.

Moreover, patient follow-up should always be performed on the same bone densitometer.

G. <u>Regulation</u>

TBS iNsight[®] is not considered as a medical device since it is intended for investigational use only.



II. How to use TBS CALCULATOR?

A. Software activation

Once installed, the TBS Calculator software must be activated before any DXA scan can be analyzed. Activation may be done using a specific license file that has to be imported into the software and allows computation of TBS scans from one or several DXA scanners or it may be done online for users that have purchased a permanent web account.

1. Product activation in Research Centers

The software is intended to analyze clinical data of known research centers. It is restricted to some scanners with known serial numbers.

The list of authorized DXA scanners is included within the TBS Calculator license file, which also defines a validity period: it may be unlimited or limited to a couple of months.

TBS Calculator v2.0.0.0	
Welcome in TBS Calculator v2.0	.0.0
User name :	
Password :	
	Log in
<u>Activate your</u>	product
Configure the	e software
	ascendys
	VourSwins ♥ Medical Partner

Click on "Activate your product..." in order to import your license.

TBS Calculator v2.0.0.0	
Activate TBS Calculator v2.0.0.0 with a license file.	
License file name : Choo Activate Cancel	ose
 Suppress current license 	ascendys



Click on the Browse button, then select the license file that your retailer has sent you and then click on "Activate". The list of DXA scanners with corresponding validity period and number of DXA scans that can be analyzed, if limited, is displayed.

* "Suppress current license..." allows you to switch to online mode (you must have a user account to access online mode)

Your software lice	ense:			
Densitometer type	Serial number	Status	Expiration date	Available exams
Hologic Discovery	A 45009	Available	03-07-2013	1000
GE-Lunar iDXA	200024	Available	06-07-2013	992
 This product is in Activate your product 	ntended for inve	estigation only.		

Then click on "Next" to select the input data folder.

2. Product activation for Contract Research Organization

A specific work mode has been designed for Contract Research Organizations: a connected work mode, where the number of authorized DXA scanners is not limited while the number of analyzed scans is limited as well as the validity period of the analysis.

TBS Calculator v2.0.0.0	
Welcome in TBS Calculator v2.0	.0.0
Liser name :	
= Fassword.	
	Log in
Activate your	product
= Configure the	porting the second seco
	Sollware
	ascendus

Enter your user name and password and then click on the "Log in" button in order to be identified by the system.



Λ

Your computer must be connected to internet when you log in and when you analyze scans.

For each TBS Calculator user, an account in the TBS Calculator web platform is created when the contract is signed. Then for each study signed by the CRO with its clients, a corresponding order must be sent to Ascendys with the following information:

- Study name (an id that will be used to make it possible to analyze the corresponding scans)
- Number of scans to analyze in the study
- Study date start
- Study duration

Then, when you log in, the list of studies will be displayed with the corresponding information:

- Study name
- Number of scans analyzable
- Study date ends

	Status	Nb exams available	Date end
STUDY #1	Available	100	21/12/2012
STUDY #2	Not available	930	09/12/2012
STUDY #3	Available	474	21/12/2012

Select the study you want to analyze and click Next.

B. Software configuration

The name of the Center or of the company can be displayed in the first page of the software. In order to enter it, please click on "Configure the software...".



TBS Calculator v2.0.0.0	
Continue configuration	
Cente	er name : Osteoporosis Research Center
 Outp 	ut file format : Excel 2003 👻
- 001	
■ CSV	Tile Separator : System default (recommanded)
	Save

The output data will be populated in a MS Excel compatible file, which can be chosen between Excel 2003 (.xls) and comma separated values (.csv).

If CSV format is selected, the cell separator can be forced to a different value than that configured in Windows operating system.

C. Input data

The scans to be analyzed must be stored in specific folders. In each folder, all the scans must originate from the same scanner.

1. Add folders containing scans

When clicking on the "Add folder" button, a window is displayed where the user must indicate:

Folder:		
C:\QDR\Data		
Include subdirec	tories	
Parameters:		
Device model:	Hologic Discovery A	•
Center name:	Vienna Osteoporosis center	
Study phase:	Baseline	
Comments:	Denosumab 12 months	
Y-Calibration:		
Slope (a1):	1	
1. ()		

- Folder path
- Device model
- Center name (where the scans come from optional)
- Study phase (optional)
- Comments (to indicate a treatment or any relevant information optional)
- Center name, study phase and comments are not mandatory, but they will be reported in the output file and can be used to sort data in this file.



• X-calibration slope and offset. This information is necessary if output data from several devices have to be compared. X-calibration parameters will allow standardization of the TBS output values.

If DXA scans are not all in the same folder, check the "Include subdirectories" checkbox so that all scans contained in the selected directory and in all its subdirectories are taken into consideration.

2. How to retrieve X-calibration parameters?

The process to obtain X-calibration parameters is different whether you own TBS iNsight software or not.

a. Users who own TBS iNsight Software

X-calibration parameters can be read in the TBS iNsight software:

RSiNsiah	t					
	-				æ 🗌	
					7	
atabases	Filter the disp	layed patients	Clini	ical routine : 221 ex	camination(s) ou	it of 221
Clinical routine	Filtering activ	ated				
Berlin - DH	Last name:		Date of birth: All		*	
Berlin - Felsenb	First name:	Date	of acquisition: All		*	
Cound Autom	Comm.:		Gender: All		 Marke 	ed
	Last name	First name	Date of birth	Acquisition	TBS L1-L4	
	Last name	First name Fasbeter	Date of birth 27/05/1925	Acquisition 04/04/2011	TBS L1-L4 1.025	1
	Last name Adrien	First name Fasbeter Isabelle	Date of birth 27/05/1925 15/11/1965	Acquisition 04/04/2011 23/02/2011	TBS L1-L4 1.025 1.331	
	Last name Adrien Aguer Aguer	First name Fasbeter Isabelle Rosario	Date of birth 27/05/1925 15/11/1965 01/12/1949	Acquisition 04/04/2011 23/02/2011 09/02/2011	TBS L1-L4 1.025 1.331 1.496	
	Last name Adrien Aguer Ahmed Albert	First name Fasbeter Isabelle Rosario Bernadette	Date of birth 27/05/1925 15/11/1965 01/12/1949 09/10/1950	Acquisition 04/04/2011 23/02/2011 09/02/2011 28/03/2011	TBS L1-L4 1.025 1.331 1.496 1.356	
	Last name Adrien Aguer Ahmed Albert Amiliat	First name Fasbeter Isabelle Rosario Bernadette Jeanne	Date of birth 27/05/1925 15/11/1965 01/12/1949 09/10/1950 02/08/1928	Acquisition 04/04/2011 23/02/2011 09/02/2011 28/03/2011 02/03/2011	TBS L1-L4 1.025 1.331 1.496 1.356 1.147	
	Last name Adrien Aguer Anmed Ahmed Mahert Amiliat Amiliat	First name Fasbeter Isabelle Rosario Bernadette Jeanne Jeanne	Date of birth 27/05/1925 15/11/1965 01/12/1949 09/10/1950 02/08/1928 02/08/1928	Acquisition Image: Comparison of the system 04/04/2011 23/02/2011 09/02/2011 28/03/2011 02/03/2011 02/03/2011 02/03/2011 02/03/2011	TBS L1-L4 1.025 1.331 1.496 1.356 1.147 1.157	
	Last name Adrien Aguer Albert Ahmed Albert Amiliat Amiliat Amiliat	First name Fasbeter Isabelle Rosario Bernadette Jeanne Jeanne Yvette	Date of birth 27/05/1925 15/11/1965 01/12/1949 09/10/1950 02/08/1928 02/08/1928 09/07/1942	Acquisition Image: Comparison of the system 04/04/2011 04/04/2011 23/02/2011 09/02/2011 28/03/2011 02/03/2011 02/03/2011 02/03/2011 14/04/2011 14/04/2011	TBS L1-L4 1.025 1.331 1.496 1.356 1.147 1.157 1.203	
	Last name Adrien Aguer Aguer Ahmed Ahmed Ahmiat Amiliat Amiliat Amiliat Amiliat	First name Fasbeter Isabelle Rosario Bernadette Jeanne Jeanne Yvette Marcelle	Date of birth 27/05/1925 15/11/1965 01/12/1949 09/10/1950 02/08/1928 02/08/1928 09/07/1942 17/08/1937	Acquisition 04/04/2011 23/02/2011 09/02/2011 28/03/2011 02/03/2011 02/03/2011 14/04/2011 11/03/2011	TBS L1-L4 1.025 1.331 1.496 1.356 1.147 1.157 1.203 1.214	
	Last name Adrien Adrien Aguer Albert Ahmed Amiliat Amiliat Amiliat Amiliat Amiliat Amiliat Amiliat Adrien Amiliat Amiliat Adrien Amiliat Amiliat Amiliat Adrien Amiliat Amiliat Amiliat Amiliat Amiliat Amiliat Amiliat Amiliat Amiliat Amiliat Amiliat Amiliat	First name Fasbeter Isabelle Rosario Bernadette Jeanne Jeanne Yvette Marcelle Claude	Date of birth 27/05/1925 15/11/1965 01/12/1949 09/10/1950 02/08/1928 09/07/1942 17/08/1937 04/07/1945	Acquisition 04/04/2011 23/02/2011 09/02/2011 28/03/2011 02/03/2011 02/03/2011 14/04/2011 11/03/2011 01/02/2011	TBS L1-L4 1.025 1.331 1.496 1.356 1.147 1.157 1.203 1.214 1.016	

Click here to open TBS configuration window



The calibration report will be displayed and contains the X-calibration equation parameters:





b. Users who do not own TBS iNsight Software

For users who do not own TBS iNsight software, the X-calibration parameters can be:

- Obtained by scanning a TBS phantom and sending scans to Med-Imaps for processing;
- Calculated from a large number of scans (analysis of the shift and / or drift of TBS values of the center as compared to normal population);
- Left to default values (since X-calibration parameters are usually close to 1 (slope) and 0 (offset).

3. List of folders

One can enter as many folders as necessary: one for each scanner, or one for each group of patients...

TBS Ca	culator v2.0.0.0							
🖻 In	out data							
	Select folders	containir	ng DEXA s	scans				
	Path	Center	Phase	Comments	Device	Subdirectory	Slope	Intercept
	E:\Données\				GE-Lunar Prodigy		1	0
	Add folder		Change fol	der		Delete folder	F	Free the list
								~
				Back	Next		-	acconduc

The input data folders can be modified or deleted using the corresponding buttons.

D. Output data

The results will be stored in a file. The user must indicate where to store it:



TBS Calculator v2.0.0.0		X
Cutput data		
Select the destination	n folder and the name of the file containing TBS result	s
Output file:	C:\data\TBS_Output.xls	
	Anonymize patients data	
	Back Next	medimaps

Depending on the output file format, one Excel file with 2 sheets or two CSV files will be created for each analysis: one containing the files that have been analyzed and one containing the rejected files. Some files will be rejected since:

- They are not DXA files;
- They do not contain a spine exam;
- BMD analysis has not been performed;
- They have been acquired on a scanner which serial number is not in the authorized list.
- They are encrypted (enCORE files);
- The TBS Calculator software cannot read them.

The output data will be anonymized, which means that the first and last names of the patients will be replaced by the word "REMOVED".

E. Files processing

There are 3 steps at this stage:

- Building the list of files to be analyzed;
- Checking if files can be analyzed;
- Calculating TBS.

In the data analysis window, a progress bar will indicate the number of scans analyzed and those still to be processed.

The "Abort analysis" button may be pressed at any time in order to abort analysis.



TBS Calculator v2.0.0.0			
🕏 Data analysis			
Press button to start data ana	lysis:	Process	scans
Listing scans to be processed			_
Analysis in progress			
Status:			
Number of files read:	35 / 140		
Number of files analysed: Number of files ignored:	21 / 35 14 / 35		
Back	View output	Close	medimaps

F. <u>Results delivery</u>

Once analyzed, the results will be made available to the user after a final check of the number of available scans analyzes of the corresponding license or study.

Users whose number of scans analyzes is limited will have to confirm that they accept to be debited of the corresponding number of scans before to be able to view the results.

G. View output file

Output file is a Microsoft Excel compatible file. The "View output button" allows opening that file in Microsoft Excel application, provided it is installed on the PC that runs this software. Otherwise, any spreadsheet and even text editors can open this file.

NB: if the output file is XLS formatted, unexpected values and values beyond accepted range are outlined using a specific color. For example, BMI values over 35 appear in an orange cell and values over 60 appear in a red cell. TBS values under 0 or over 2.0 appear also in red cells.



0.) 🖬 🤊 -	(**) ₹	1000	-		TBS	_Output.xls	[Mode d	e compatik	oilité] -	Microsoft Excel				-			• X
	Accueil	Insertion	Mise en j	page F	ormules	Données	Révision	Affic	hage	Complé	ments						۲	- 🖷 X
	Coller 🛷	Arial	• 9 •	A A		= ≫- = := :=	Sta	ndard • % 0	00 *0 0 •00	Mis con	e en forme Me ditionnelle ▼	ettre sous forme de tableau *	Styles de cellules *	ile Insére Suppr Forma	er * rimer * at *	Σ - Α 	ier et Recl trer ≠ séle	hercher et
Pres	se-papiers 🕞		Police	G.	Ali	gnement	Ga .	Nombr	re G	5		Style		Cellu	les		Édition	
	A1 • Scan date																	
	А	В	С	D	E	F	G	Н	- I	J	K	L M	N	0	Р	Q	R	S 🔺
1	Scan date	Scan mode	BMD analysis date	TBS analysis date	Patient ID) First name	Last name	Height (cm)	Weight (kg) (BMI (kg/m²)	Date of birth	Age Sex	Ethnicity	L1 TBS	L2 TBS	L3 TBS	L4 TBS	Mean Spine TBS
2	18-août-11	THICK	27-nov-12	10-déc-12	W09	Janet	Haight	161	109	42,4	08-juin-41	70 FEMALE	WHITE	1,076	1,180	1,163	1,196	1,154
3	01-oct-12	STANDARD	27-nov-12	10-déc-12	W44	Jordice	Strand	168	61	21,8	05-sept-55	57 FEMALE	WHITE	1,156	1,286	1,289	1,235	1,242
4	19-juil-11	STANDARD	27-nov-12	10-déc-12	W21	Patricia	Kuntz	157	56	22,7	25-mai-50	61 FEMALE	WHITE	1,452	1,635	1,623	1,548	1,564
5	24-sept-12	STANDARD	27-nov-12	10-déc-12	W43	Linda	Michael	164	64	24,1	05-mai-42	70 FEMALE	WHITE	1,205	1,322	1,316	1,359	1,301
6	24-juil-12	STANDARD	27-nov-12	10-déc-12	W39	Kathy	Dutilly	154	56	23,6	28-juil-51	61 FEMALE	WHITE	1,334	1,415	1,422	1,357	1,382
7	03-nov-11	STANDARD	27-nov-12	10-déc-12	W13	Jill	Jones	167	60	21,6	04-avr-55	57 FEMALE	WHITE	1,326	1,370	1,326	1,354	1,344
8	04-mai-12	STANDARD	27-nov-12	10-déc-12	W25	Margaret	Mayer	158	63	25,2	20-déc-49	62 FEMALE	WHITE	1,321	1,375	1,316	1,502	1,378
9	1/-avr-12	STANDARD	27-nov-12	10-dec-12	VV27	Jackie	Larson	160	67	26,1	17-sept-39	73 FEMALE	WHITE	1,085	1,297	1,272	1,339	1,240
10	26-janv-12	STANDARD	27-nov-12	10-dec-12	VV42	Fumiko	Miyazaki	159	47	18,5	13-aout-37	74 FEMALE	ASIAN	1,208	1,314	1,309	1,335	1,292
11	12-dec-11	STANDARD	27-nov-12	10-dec-12	VV33	Pat	Cibula	158	56	22,2	05-aout-48	63 FEMALE	VVHITE	1,289	1,407	1,345	1,379	1,355
12	22-dec-11	STANDARD	27-009-12	10-dec-12	0000	Jan	Cibula	101	54	20,7	24-mars-43	69 FEIVIALE	WHITE	1,301	1,357	1,421	1,423	1,375
13	24 juil 10	STANDARD	27-HUV-12 27 pay 12	10-dec-12	VVUZ	Fumileo	Misezeki	104	10	20,1	12 poût 27	76 EEMALE		1,220	1,200	1,317	1,413	1,302
14	3 1-juii-12 18-jany 11	STANDARD	27-nov-12	10-déc-12	W/10	loan	Mareball	171	47	25.0	02-oct 34	76 FEMALE	WHITE	1,220	1 197	1 320	1,241	1,202
16	10-jd11-11	STANDARD	27-nov-12	10-déc-12	W/02	Holon	Henriche	164	70	20,0	05-mars-42	69 FEMALE	WHITE	1 1/3	1 233	1,303	1,154	1.226
17	05-déc-11	STANDARD	27-nov-12	10-déc-12	W16	Mary	Neckyatal	160	64	25.0	29-sent-46	65 FEMALE	WHITE	1 041	1 304	1 239	1 470	1 264
18	03-jany-11	THICK	27-nov-12	10-déc-12	W09	Janet	Haight	161	110	42.6	08-iuin-41	70 FEMALE	WHITE	1 111	1 097	1 154	1 224	1 147
19	10-mars-11	STANDARD	27-nov-12	10-déc-12	W14	Marian	Matthews	159	48	18.8	29-mai-48	63 FEMALE	WHITE	1,196	1.364	1.311	1.433	1.326
20	17-mars-11	STANDARD	27-nov-12	10-déc-12	W03	Marilyn	Martz	159	50	19.8	11-sept-43	68 FEMALE	WHITE	1.266	1.336	1.287	1.350	1,296
21	31-janv-12	STANDARD	27-nov-12	10-déc-12	W39	Kathy	Dutilly	153	58	24,6	28-juil-51	61 FEMALE	WHITE	1,302	1,411	1,407	1,343	1,366
22	14-avr-11	STANDARD	27-nov-12	10-déc-12	W14	Marian	Matthews	160	48	18,6	29-mai-48	63 FEMALE	WHITE	1,227	1,334	1,327	1,380	1,317 🗸
14 4	Analyzed / Rejected /									•								
Prêt															100 %			
				-						-								

TBS Calculator output file, XLS formatted: Analyzed scans

H. Troubleshooting

Some files contained in the input folders may have been rejected during the files processing. The reasons may be:

- The file contain no Spine exam
 - Select only scan files with a spine acquisition
- The file cannot be read by TBS Calculator, because it has been crypted and or compressed by enCORE software. If so, a message indicating "Unable to use file: Unable to read patient data. [Object reference is not set to an instance of an object" will be displayed in the rejected files sheet (if .xls formatted) or file (if .csv formatted).
 - Open enCORE software and
 - Untick the Compression and Encryption options (User Options > Systems > Exam files Options)

Optio	ns de fichier examen 📃	3
	HIPAA Sécuriser nom de fichier Comprimer fichiers d'examens Encrypter fichiers d'examen	
	OK Annuler	

- Re-analyze the scans.
- The file has been acquired by a DXA scanner that is not included in the scanners listed in the license.
 - Select only scan files acquired by DXA scanners for which you have a license or contact your retailer to get an extension of your license with additional scanners.



ſ	🕞 📊 🔁 🗟 🥉 📅 🔹 Output_TEST.xls [Mode de compatibilité] - Microsoft Excel							
	Accueil Insertion Mise en	page Formules A [*] A [*] ≡ ≡ ≡ ▲ ≡ ≡ ≡	Donné E	es Révision Affichage Développeur Équipe Standard				
Pres	se-p 😼 Police	🕞 🛛 Alig	inement	Nombre 🖼 Style Cellules Édition				
	A17 🗸 🔿 f 🖈			×				
	А	В	С	D				
1	Folder	Input file	Status	Message				
2	C:\DXA Scans\Patients\Hologic\QDF	PA06823A.P0H	Error	Unable to use file: File does not contain Spine exam: HIP				
3	C:\DXA Scans\Patients\Hologic\QDF	PA06823A.P0V	Error	Unable to use file: File does not contain Spine exam: HIP				
4			_					
5	C:\Docs\Projets\Etudes\Ostéoporos	2h7selb1v.dfs	Error	No license activation available for Bone Densitometer # 14323.				
5	C:\Docs\Projets\Etudes\Osteoporos	2xzxbkb1v.dfs	Error	No license activation available for Bone Densitometer # 14223.				
	C:\Docs\Projets\Etudes\Osteoporos	47eUgkb1v.ats	Error	No license activation available for Bone Densitometer # 14323.				
9	C:\DXA Scans\Patients\GE-Lunar\Pi	00r2ilb1v.dfs	Error	Inable to use file: Unable to read natient data. Il a référence d'objet n'est pas définie à une instance d'un objet				
10	C:\DXA Scans\Patients\GE-Lunar\Pi	028baib1v.dfs	Error	Linable to use file: Linable to read patient data. ILa référence d'objet n'est pas définie à une instance d'un objet				
11	C. Drev Counter allenta OE-Eurary	02009/01/010	21101	ondore to doe me, ondore to read patient data, parterence d'objet n'est pas denne à dre instance d'un objet.				
14 4	🕨 🖌 Analyzed 🖉 Rejected	7	1					
Séle	ctionnez une destination et appuyez sur	ENTRÉE ou cliquez su	ur Coller	· □ □ 100 % (

TBS Calculator output file, XLS formatted: Rejected scans



MED-IMAPS TECHNOLOGICAL PLATFORM FOR BIOMEDICAL INNOVATION HOPITAL XAVIER ARNOZAN AVENUE DU HAUT-LEVEQUE 33600 PESSAC FRANCE Phone: +33 557 102 856

> After-sales service: Email: support@tbsinsight.fr Tel: +33 557 102 872



III. Appendices

A. <u>Revisions history</u>

Revision	Date	Author(s)	Comment	Status
2.0	07 Dec 2012	Christophe LELONG	First version, which is an update of the TBS - Clinical Data Analyzer User guide, v1.8	

B. Validations history

Revision	Date	Author(s)	Comment
2.0	12 Dec 2012	Christophe LELONG	ОК