

ADDENDUM

# BIODEX SOFTWARE

## FOR BALANCE SYSTEM SD AND PORTABLE BIOSWAY

VERSION 2.0

950-440  
950-441  
950-444  
950-460  
950-461




**m-CTSIB Defaults**

**Group** General Population 17-72, 30 sec trial

**Age Range** 17 - 72

**Choose Default Conditions**

	Mean	SD
Eyes Open Firm Surface	0.35	0.14
Eyes Closed Firm Surface	0.73	0.20
Visual Conflict Firm Surface	0.67	0.19
Eyes Open Foam Surface	0.54	0.12
Eyes Closed Foam Surface	1.65	0.45
Visual Conflict Foam Surface	1.15	0.26

Cancel                      Restore Defaults                      OK

# BIODEX

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*Balance System SD*



*Portable BioSway*

**This software can be used with the following products:**

- 950-440 Balance System SD, 115 VAC
  - 950-441 Balance System SD, 230 VAC
  - 950-444 Balance System SD, 100 VAC
  
  - 950-460 BioSway, with Tabletop Stand and Case, 115V/230V 50/60Hz
  - 950-461 BioSway, with Tabletop Stand, 115V/230V 50/60Hz
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# 1. CTSIB Progress Report

Version 2.0 Software offers the ability to display and/or print a graph over time for each condition of a CTSIB test from multiple tests. Test results can be compared to previously recorded baseline test or to selected normative data ranges.

CTSIB results can also be exported to Biodex Concussion Management software version 2.0, so that CTSIB test data does not have to be re-entered.

## Report Selection

1. Report is selected from Patient Management the same as current progress reports are selected.
  - If a Patient has more than one CTSIB test in the patient record, the CTSIB **<Progress Report>** button is available.
2. Select specific conditions.
  - For example: Progress Report for conditions #1 and #4 only.
3. Baseline values can be compared to either normative data values or to a previous baseline test if available.
  - Different normative data values. The software includes normative data from two populations and protocols. Should additional normative values become available, either self generated or from another third party, these normative data values can be added to a table as they become available. E.g., Men's Hockey, Women's Soccer, etc.
  - Baseline test value is a CTSIB test from an initial screening or previous test for the selected patient. The clinician can select a *Baseline Upper Limit*, which is a value for a "window" of how close to baseline a follow-up test is expected to be. A baseline upper limit is a value of 5, 10, 15, or 20%. 15% is the suggested upper limit. The rationale for 15% is explained in the appendix.
4. Only data from same conditions will be compared.
5. Report will be limited to display and print up to four conditions.
6. Comments cannot be entered to the Progress Report. Any comments will have to be hand written. This is explained in the *Adding Comments* section.

**Note:** It is very important to recognize that for a non-CTSIB progress report, when different normative data groups are used, the normative data group should be selected as the default group in configuration for the target group being tested at that time. To ensure proper normative data comparisons, it will be necessary to make sure the appropriate default group is selected in configuration.

CTSIB normative default values as set in configuration.

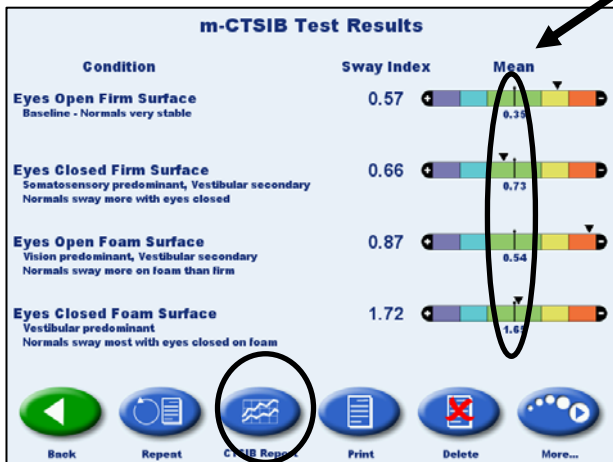


Figure 1.1

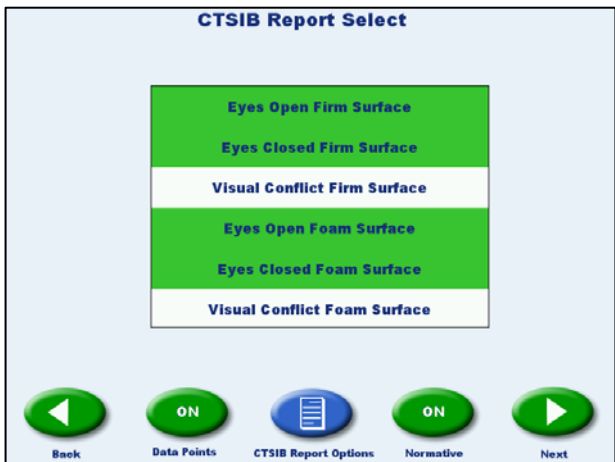


Figure 1.2

Choose to compare follow-up tests to % Baseline or to Normative Data.

Only for a CTSIB Progress Report can normative data groups be selected “on the fly”.

These values represent 2 standard deviations above the mean for each condition and are also the dash lines on the report.

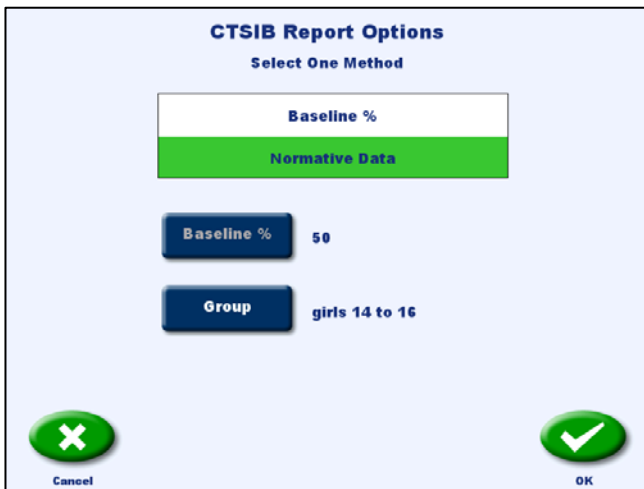


Figure 1.3

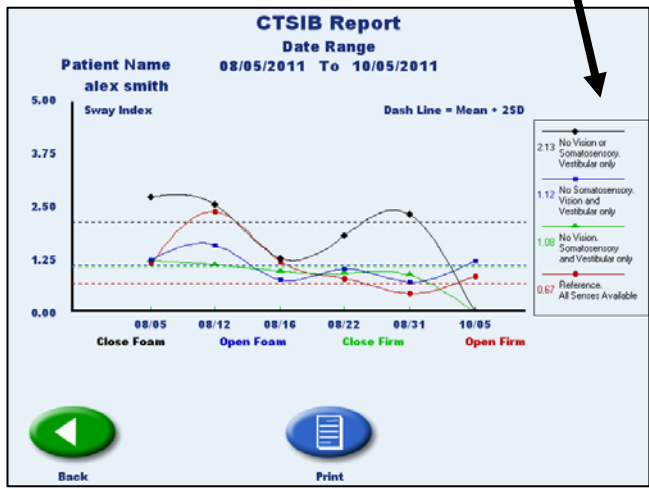


Figure 1.4 – Shows CTSIB report compared normative data, without data points on.

## 1.1 Selecting or Entering Normative Data Groups and Values

### Follow screen navigation:

Utilities >> Configuration >> Enter Access Code, to >> m-CTSIB Defaults

**Note:** It is very important to recognize that for a non-CTSIB progress report, when different normative data groups are used, the normative data group should be selected as the default group in configuration for the target group being tested at that time. To ensure proper normative data comparisons, it will be necessary to make sure the appropriate default group is selected in configuration.

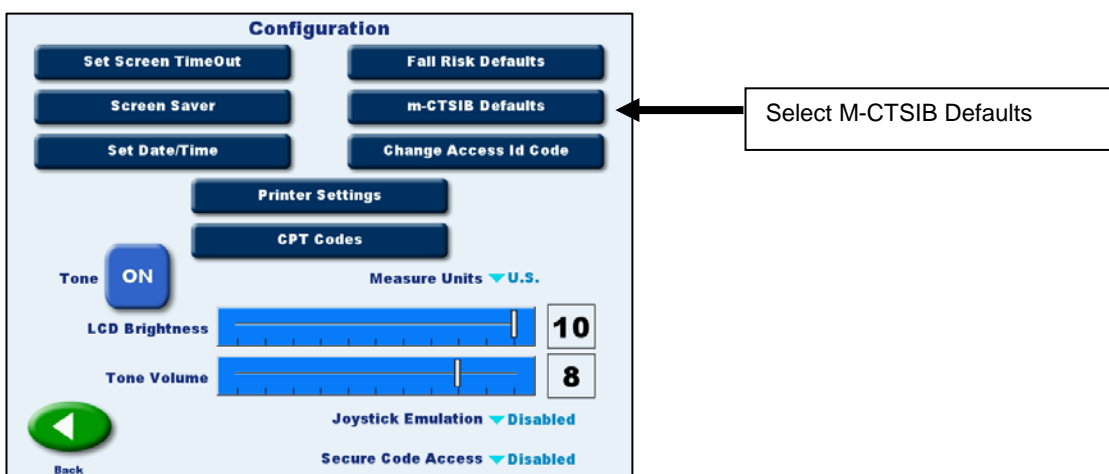


Figure 1.5

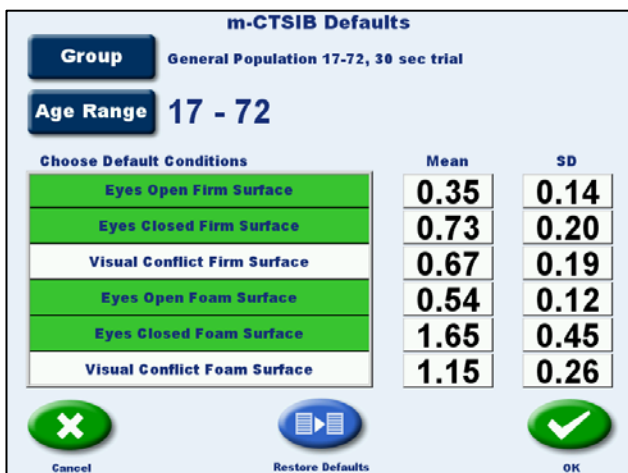


Figure 1.6

## New Groups and Normative Data can be added

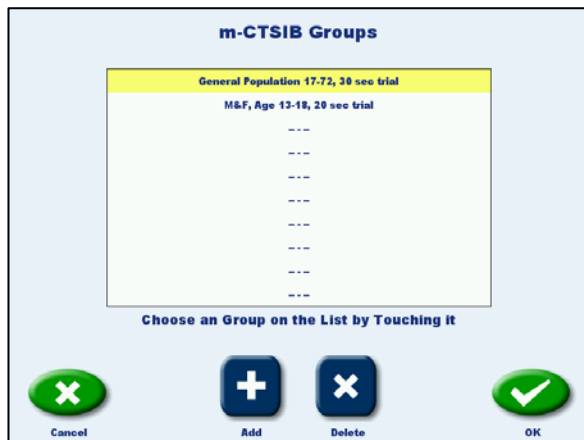


Figure 1.7

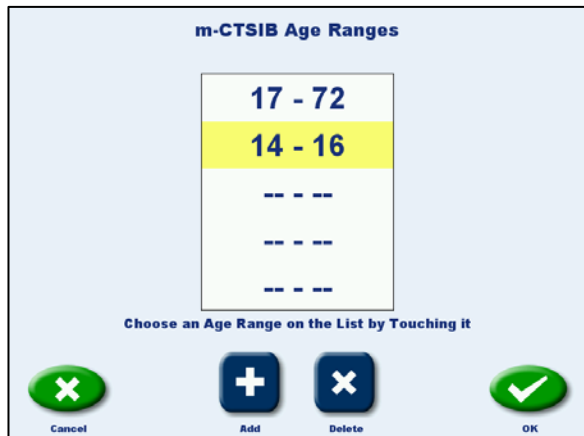


Figure 1.9

Select an existing group or add or delete a group. See Figure 1.7.

To create a new group name, press <Add>. To remove a Group press <Delete>. See Figure 1.7.



Figure 1.8 Keyboard support is offered in all screens for entering text and numeric values.

Add or delete specific age ranges for the selected group. Again use either Add or Delete. See Figure 1.9.

Enter group-specific Sway Index Mean and Standard Deviation (SD).

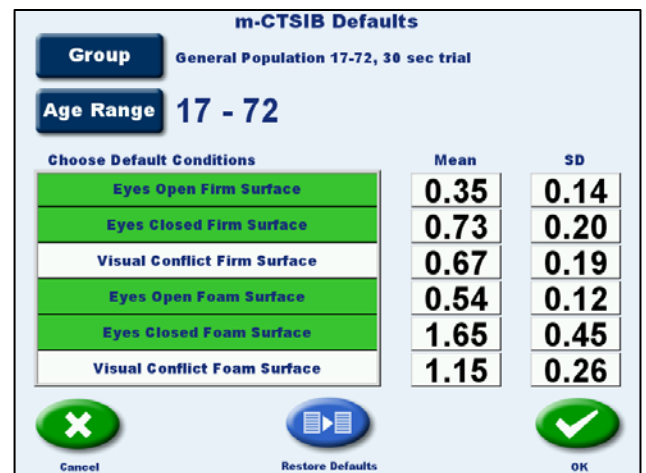


Figure 1.10

# CTSIB Report

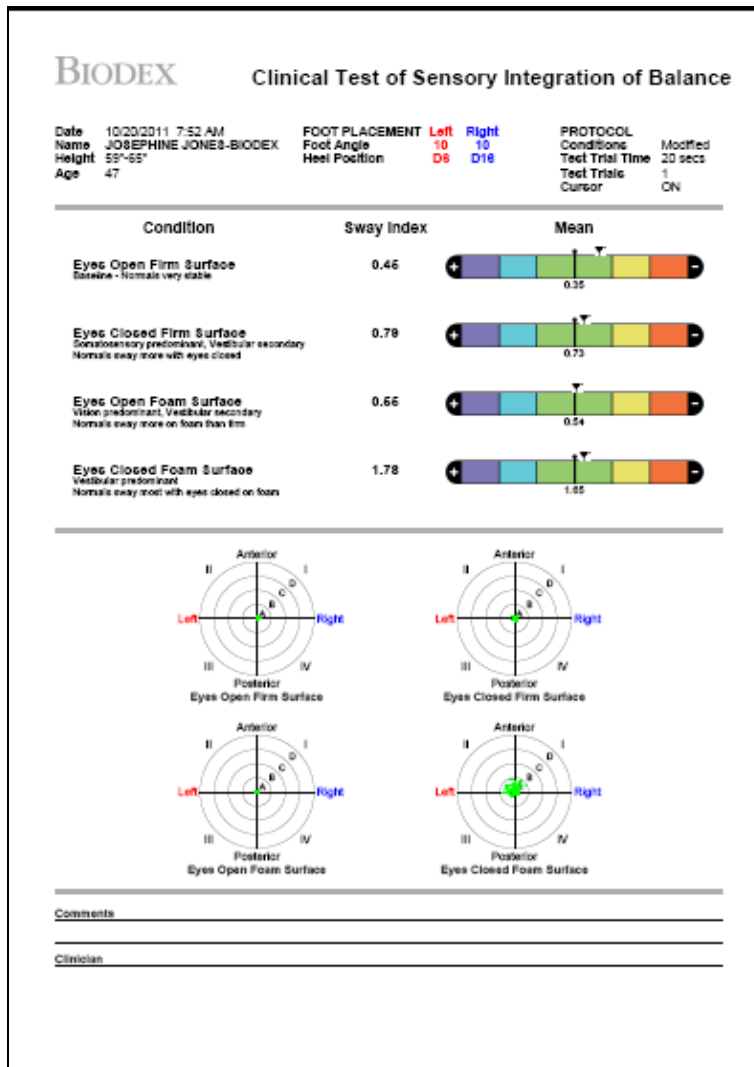


Figure 1.11

Scores are indicated relative to the selected normative value mean. The segments represent standard deviations. The first segment on either side of the mean is 1 SD. Second segment represents 2 SD, Third segment represents 3 SD. Beyond the third segment represents an outlier.



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## 2. Expanded Normative Data Selection

There are two pre-loaded default normative data selections pre-loaded in the software.

### 1.) General Population

The initial study for a general population of healthy community dwelling adults.

Age 17 to 72. N=100. Single trial, 30 second protocol for each condition.

The menu selection in the software says: *General Population 17-72, 30 sec trial*

The six CTSIB-condition mean values are:

		<u>Mean</u>	<u>SD</u>
1. Eyes Open	firm	.35	.14
2. Eyes Closed	firm	.73	.20
3. Visual Conflict	firm	.67	.19
4. Eyes Open	foam	.54	.12
5. Eyes Closed	foam	1.65	.45
6. Visual Conflict	foam	1.15	.26

Details for these normative data are described in the manual.

### 2.) Student Athletes

The new normative data is for a population of student athletes, male and female, age 13-18.

The data was collected by Carolinas Medical Center, Charlotte, NC, Department of Sports

Medicine & Special Events at four special events during the 2011 summer. Raymond F.

McKenna, PT, PhD, Clinical Associate Professor, Stony Brook University School of Health

Technology and Management, Department of Physical Therapy State University of New York,

provided the data analysis.

These are the normative data for a protocol that is (1) 20-second trial, no shoes. Male and

Female age: 13-18. N= 1440

The menu selection in the software will be: *M&F, Age 13-18, 20 sec trial*

		<u>Mean</u>	<u>SD</u>
1. Eyes Open	firm	.43	.12
2. Eyes Closed	firm	.66	.21
3. Eyes Open	foam	.74	.19
4. Eyes Closed	foam	1.85	.41



# 3. Adding Comments

Comments can be added when viewing test results immediately following the completed test (see Figure 3.1), or after a patient test has been recalled through Patient Management (see Figure 3.2).

Select <More> to edit or add Comments and CPT code (see Figure 3.3).

Add Comments immediately following tests:

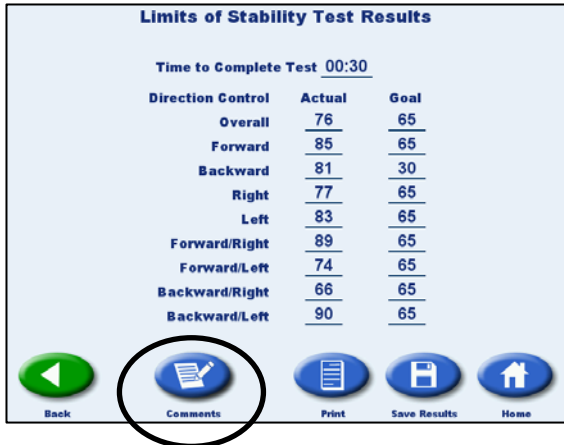


Figure 3.1

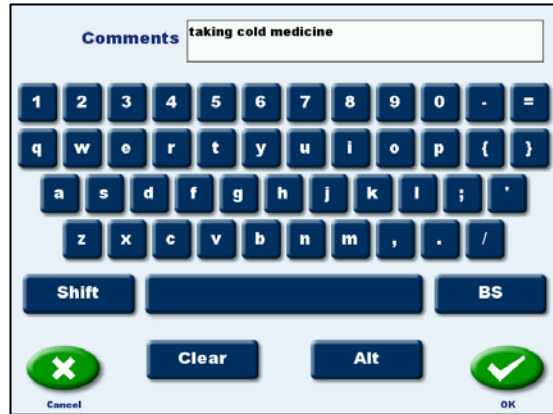


Figure 3.2

Add Comments via Patient Management after selecting patient test record:

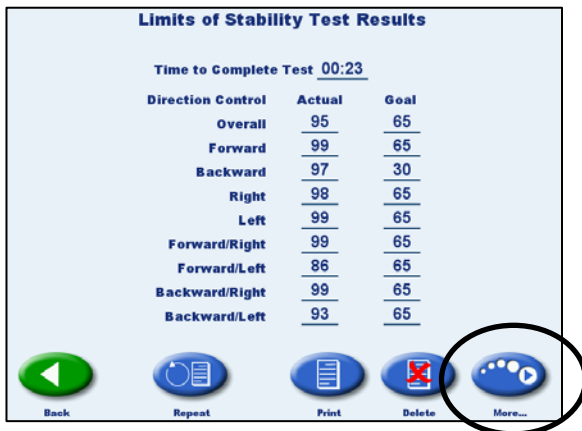


Figure 3.3

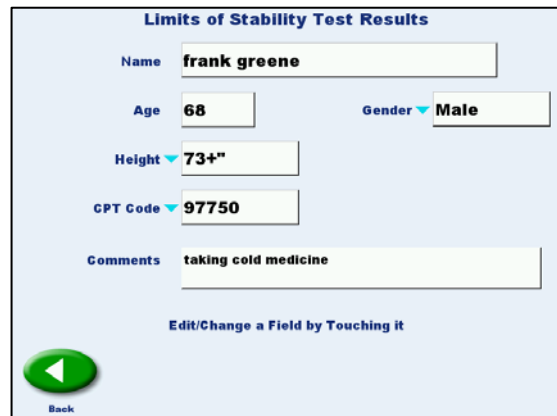


Figure 3.4

Code and comments appear on printed report (see Figure 3.5).

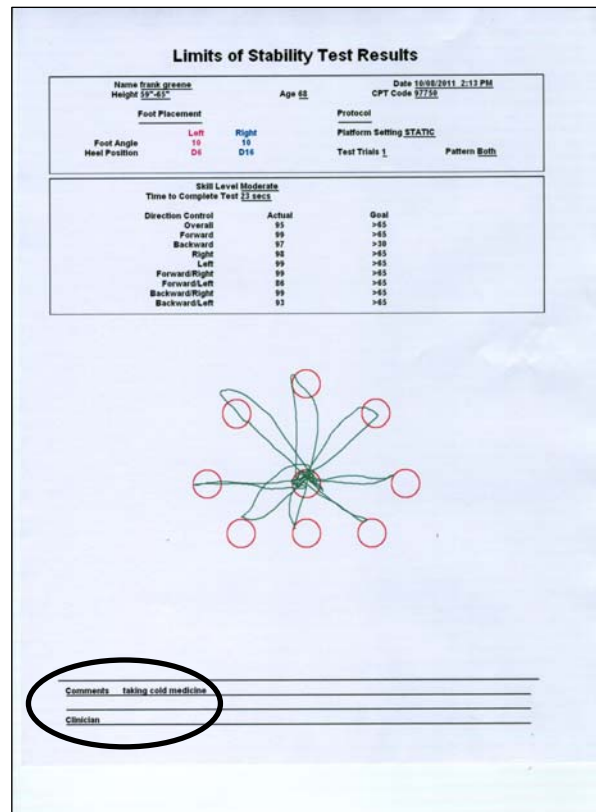


Figure 3.5

## Adding comments to a CTSIB report

Comments and CPT code can be added at the time of reviewing the test results or after recalling test results from Patient Management. Press the <More> button (see Figure 3.6). These will appear on printed individual session report, **not on a CTSIB progress report**.

Touch <Comment> field and keyboard screen will present for typing (see Figure 3.7).

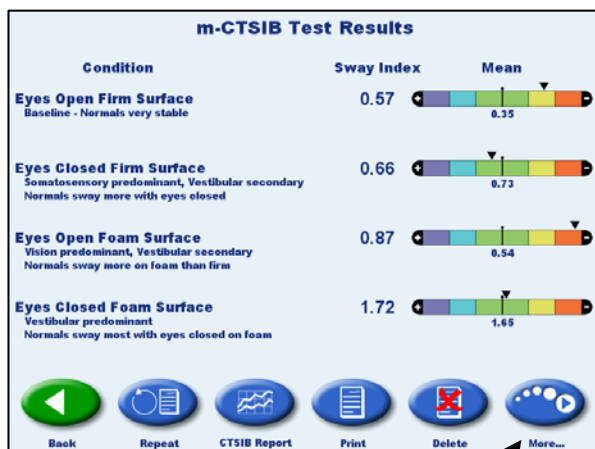


Figure 3.6

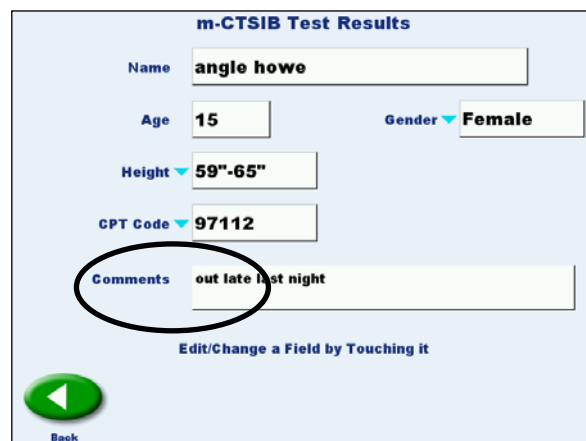


Figure 3.7

## 4. Assign CPT Codes

Include CPT Codes to a test or training session

To enable CPT code selection, or to create or edit, **follow screen navigation:**

>>Utilities, >>Configuration, >>enter Access Code.

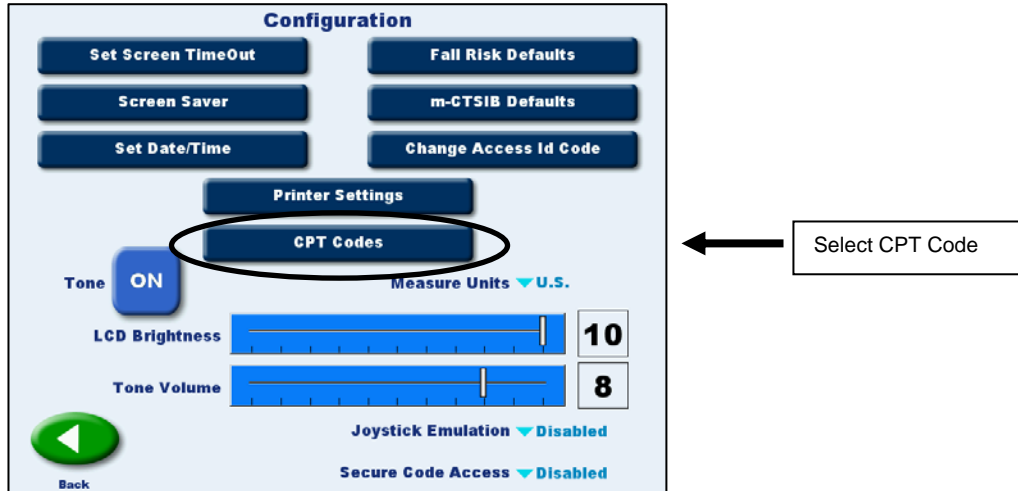


Figure 4.1

CPT Codes can turn On/Off (defaults to Off) and has a factory default list of 5 codes with the ability to add/delete for 10 codes total, each with a length of 10 max.

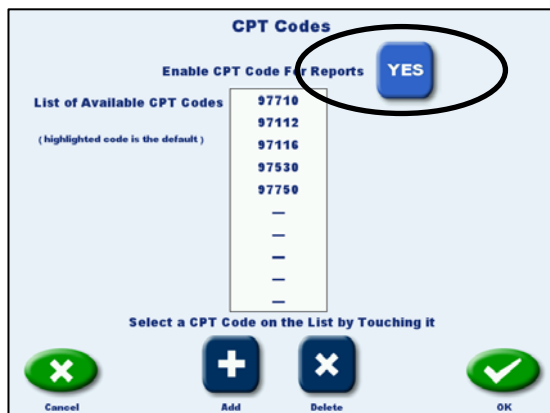


Figure 4.2 Enable, Add or Delete CPT Code.

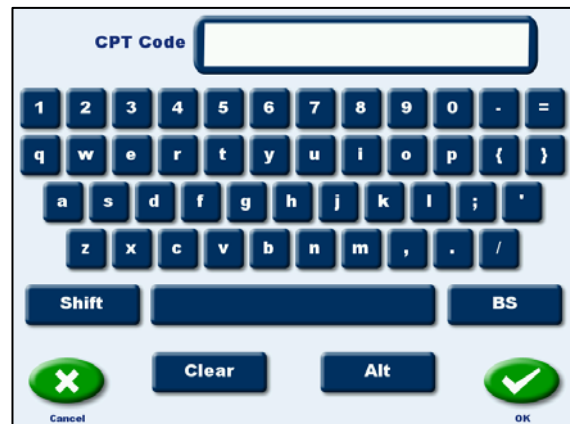


Figure 4.3 Create CPT Code.

Once set up, the ability to assign a CPT Code to the Training or Test is presented in the User Setup Information screen (see Figure 4.4). The CPT code can also be added or changed after a patient test has been recalled through Patient Management.



Figure 4.4

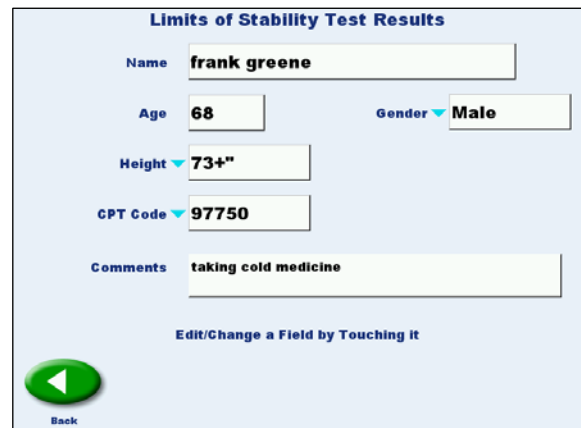


Figure 4.5

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## 5. Ethernet Printing: Wireless and Wired

Wireless printing feature will allow the Balance System SD or Portable BioSway to send all printed reports generated to a PCL compatible wireless printer.

### Materials Needed

*In order to enable wireless printing, you will need the following:*

- Wireless printer that is PCL compatible
- 802.11 b/g Wireless adapter. This can be purchased locally.
- ClientVB program install in the ClientVB directory
- Balance System SD or BioSway program version that supports wireless printing
- A wireless network configured and active in close proximity to the Balance System SD or BioSway. (This may require WPA or WEP password information for this network.)

### 5.1 Setup Wireless Adapter

1. Plug the wireless adapter into a USB port on the Balance System SD or BioSway display.
2. A screen will present to select the preferred wireless network. Select the network and Press **<Connect>**.
3. Exit the wireless adapter setup by pressing **<OK>**.



Figure 5.1

### 5.2 Setup Printer

1. Connect the wireless printer.
2. Select the preferred Wireless network and press **<Connect>**.
3. Write down the IP address of the Printer (see printer instruction, how to read IP address).

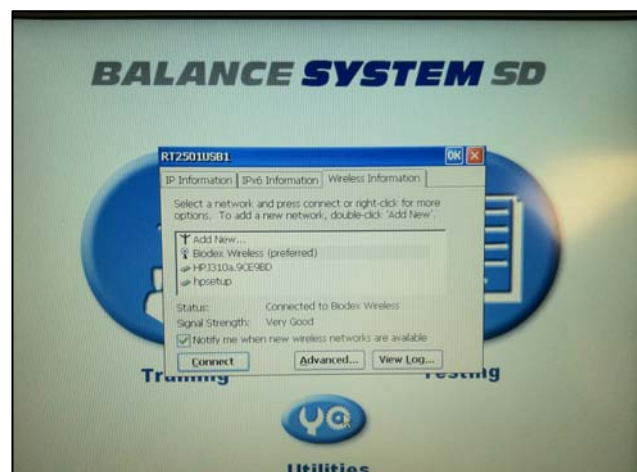


Figure 5.2

## 5.3 Setup Balance System SD or BioSway Wireless Printing

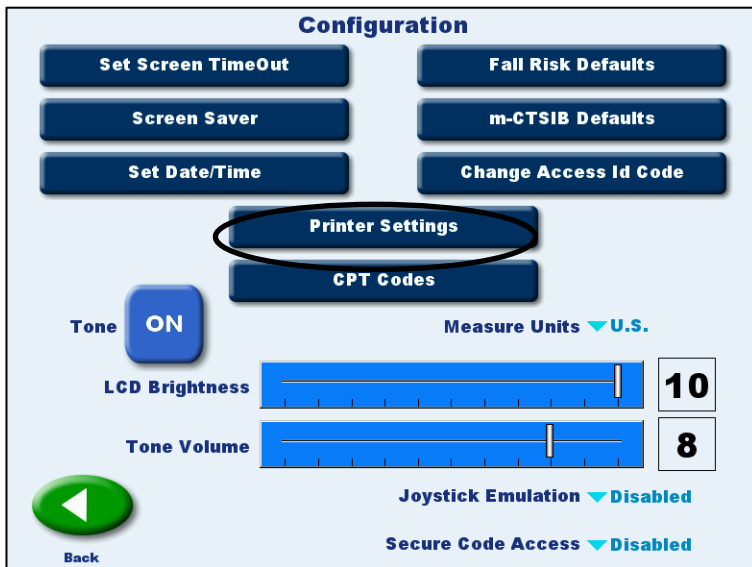


Figure 5.3

**Follow Screen Navigation:**  
>>Utilities,  
>>Configuration,  
>>enter Access Code.

Select <Printer Settings> (see Figure 5.3).

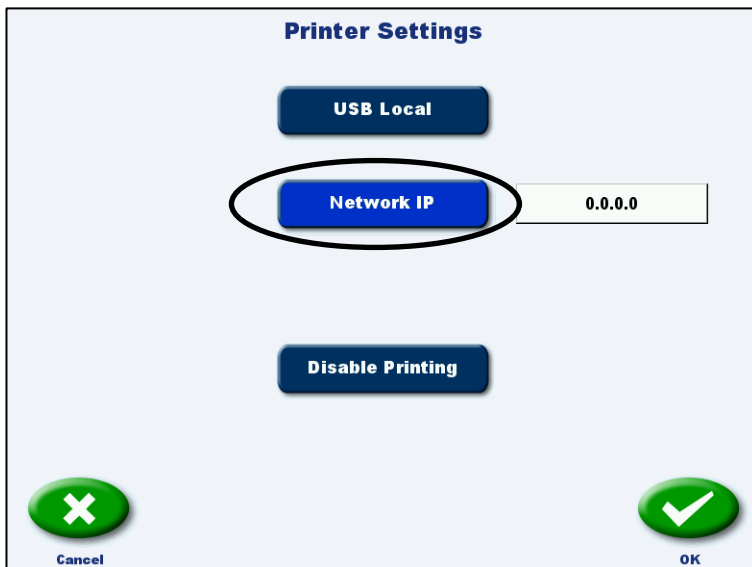
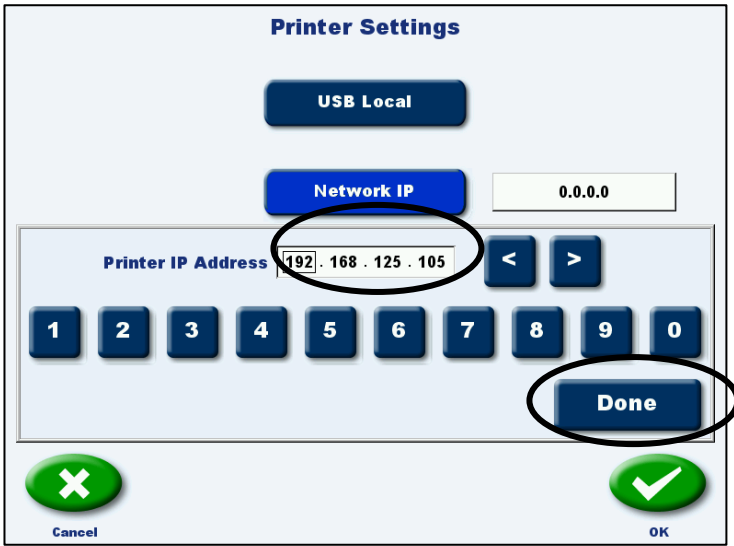


Figure 5.4

Note: The product is shipped with UBS local printing as the default.

Select <Network IP> (see Figure 5.4).

Follow the instructions for locating the IP address of your wireless printer. These instructions will be found in your printer manual or help menu.



Enter the IP address and press <Done> (see Figure 5.5)

IP Address will show in the window (see Figure 5.6).

Figure 5.5

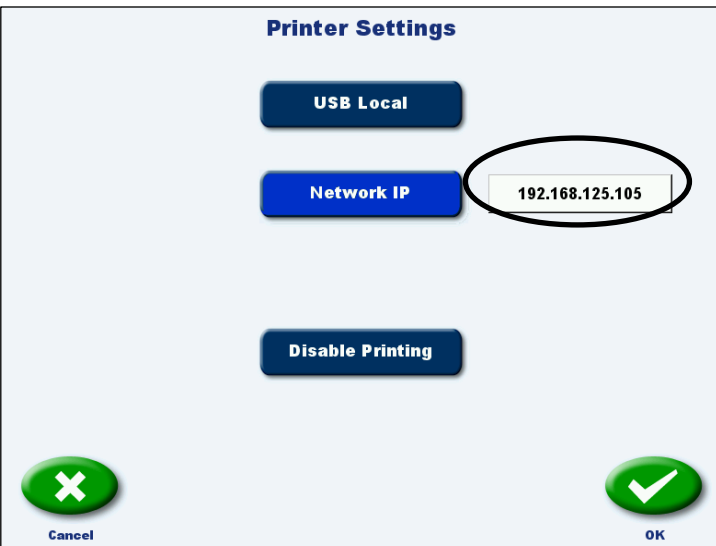


Figure 5.6

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Ethernet wired connection is noted as item #6.



**Figure 5.7** The printer power cable should be plugged into the AC receptacle on the rear base of the display support post. The printer USB cable should be plugged into the USB port on the back of the display.

1. Reset Button
2. Remote CRT Monitor Connector
3. PS 2 Connector
4. Ethernet Activity Lights. Green indicate connectivity; Yellow indicates activity.
5. Auxiliary Com Port (Serial Port)
6. Ethernet Connector (RJ 45)
7. PCB Activity Lights. Green indicates comact flash activity; Yellow indicates power on.
8. USB Connectors (suggested to use one of these for printer)

## 6. USB Flash Drive

### 6.1 Export Data File Process

Use this utility to export or import specific patient files. One patient or multiple patients selected from a specific time frame can be exported.

**Follow screen navigation:**

>>Utilities, >>Patient Management, >>enter Access Code.

1. First select the Option. Option allows selection of patients within a specific time frame.

2. Touch <Option> to select:

- Prior to:
- From/To:
- From:
- All:
- Only New:

3. Then choose Export Option:

- <Export Serial> - requires serial cable connection.
- <Export USB> - Place a USB thumb drive into an available USB port.



Figure 6.1 - Select Multiple Export.

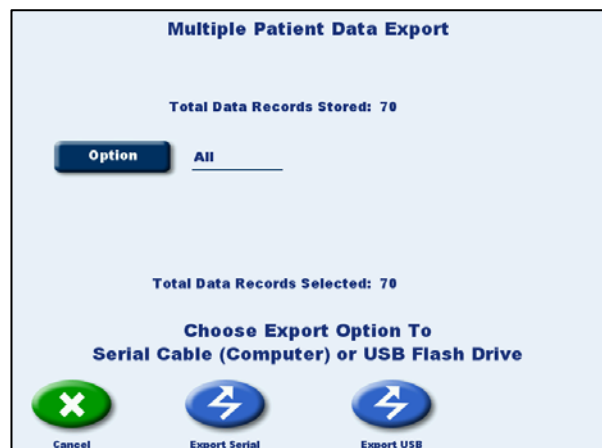


Figure 6.2 - Choose Export Option.

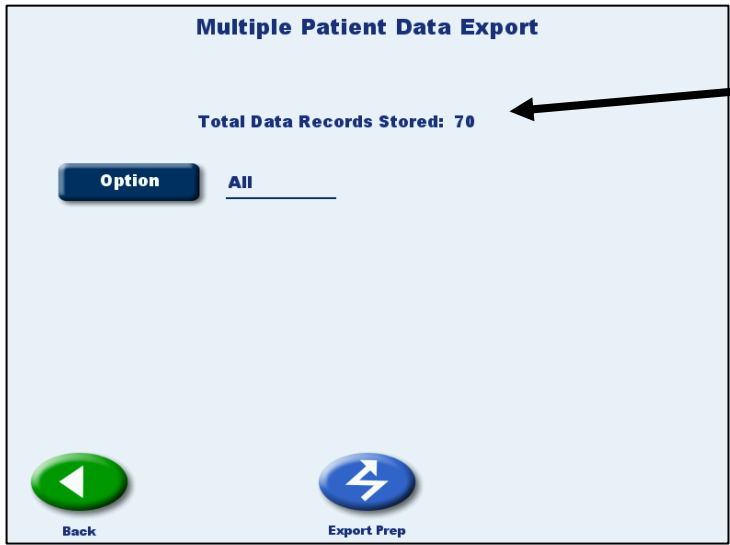


Figure 6.3 – Shows that 70 records were exported and stored into the flash drive.

Patient files are exported onto the USB Flash Drive. The file will be labeled BalResultsData.bio. Each exported file will be provided a unique file name. The number of export records and the date of export will also be noted.

**Note:** When you export patient data, it is recommended that you make a note of the file name and what was exported. This will be helpful at a later date when selecting a specific file to import.

Patient Data File Import - USB Flash Drive		
File Name	Test Results	File Date/Time
BalResultsData.bio	14	06/20/2011 5:38 PM
BalResultsData_01.bio	14	06/20/2011 5:38 PM

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Figure 6.4 – An example of file name and description on the USB flash drive.

## 6.2 Import Data File Process

Have the USB Flash Drive with the target BalResultsData.bio file plugged into a USB port on the display.

Select <Import> from the Patient Management screen (see Figure 6.5).

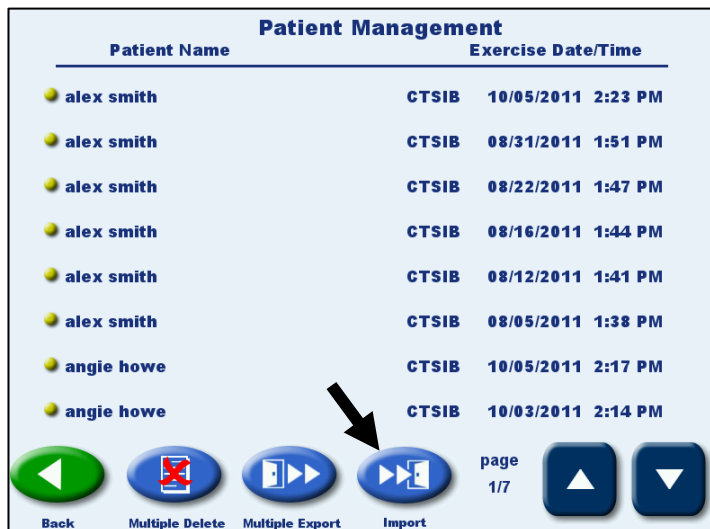


Figure 6.5

You are then presented with the screen to select the desired BalResultsData.bio file. Select the desired file by touching the <Yellow> button (see Figure 6.6).

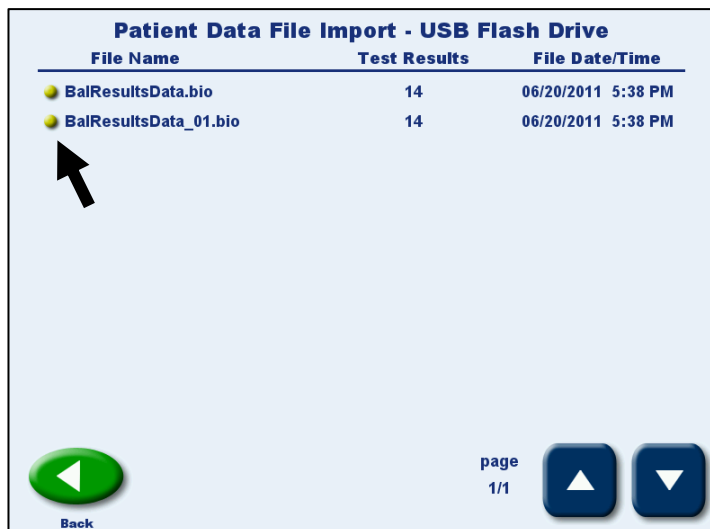


Figure 6.6

This screen is to confirm that the intended file was correctly selected. Press <Yes> to proceed. (See Figure 6.7).

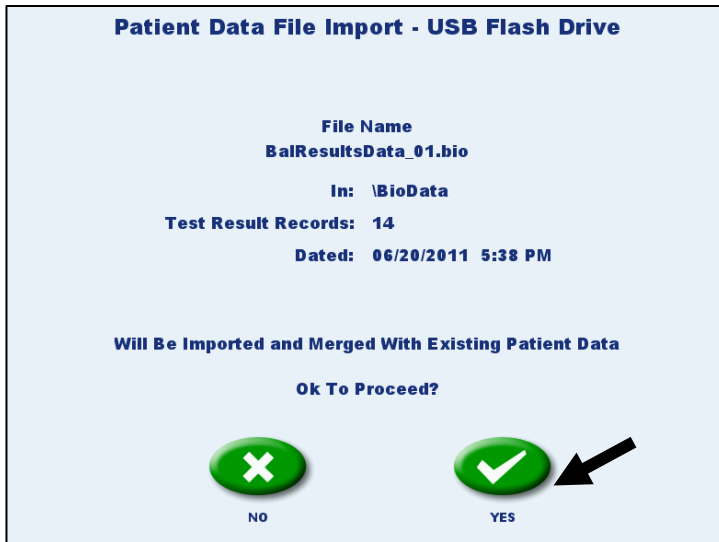


Figure 6.7



Figure 6.8

Files are now imported. Press <OK> to return to Patient Management screen (see Figure 6.8).

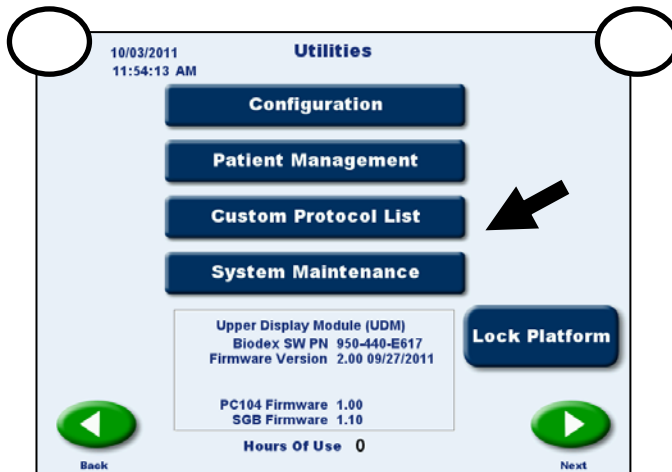
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## 6.3 Backup and Restore Data

This utility provides a complete system backup and restore. It also backs up and restores the firmware. It is ideal for when a display must be replaced. It is an advanced, hidden utility.

### To access System Maintenance:

At the Utilities screen – 1. tap the Top Right corner, 2. tap the Top Left corner, then 3. tap the Top Right corner again. System Maintenance will then appear. Select it. (See Figure 6.9).



1. Tap top right corner,
2. then tap top left corner,
3. then tap top right corner again.

Figure 6.9

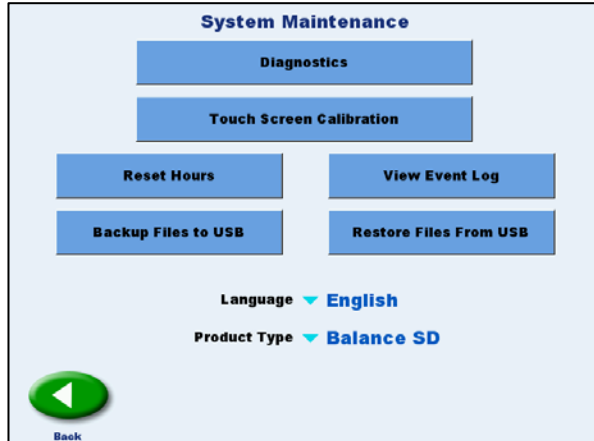


Figure 6.10

1. Insert the USB flash drive for intended data to backup or restore into the USB port.
2. Select <Backup Files to USB> or <Restore Files from USB>.



Figure 6.11 Screen shown when Backup is complete.



Figure 6.12 Screen shown when Restore is selected.

- Once Restore is complete, the display must be reset (see Figure 6.13).
- Usage will then resume from the main menu.



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## 7. Appendix

### Rationale for 15% Baseline

- Geurts, et al, showed a test variability difference between controls and TBI patients of 18%.
- Guskiewicz, et al, noted an average difference of 6% between baseline variability and day 5 post injury.
- Lehman, et al, in the paper *Quantitative Evaluation of Sway as an Indicator of Functional Balance in Post Traumatic Brain Injury* noted a standard error of measure for normative values of 17%

Considering Guskiewicz was using values considerably larger than what are presented with CTSIB results, test variability between 6% and 18% appears reasonable. This is how we arrived at 15% as the default baseline limit.



### USB keyboard support

Keyboard support is possible in all screens for entering text and numerics. Simply plug in any USB compatible keyboard and use it for data entry.

### References:

1. Geurts ACH, Ribbers GM, Knoop JA, LimbeekJ van. Identification of static and dynamic postural instability following traumatic brain injury. Arch Phys Med Rehabil 1996; 77:639-44
2. Guskiewicz KM, Ross SE, Marshall SW, Postural Stability and Neuropsychological Deficits After Concussion in Collegiate Athletes. J Athl Train 2001; 36(3):263-273
3. Lehmann JF, Boswell S, Price R, Burleigh A. DeLateur BJ, Jaffe KM, Hertling D,: Quantitative Evaluation of Sway as an Indicator of Functional balance in Post-Traumatic Brain Injury. Arch Phys med Rehabil 1990;71:955-62

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