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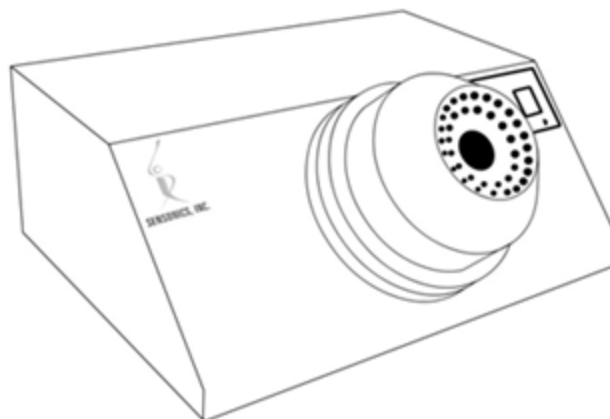
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# **SELF-ADMINISTERED COMPUTERIZED OLFACTORY TEST SYSTEM (SCOTS):**



## **OPERATION & ADMINISTRATION MANUAL**

**MODEL 40CHRA**



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# Congratulations...

...on your purchase of Sensonics' 40 Channel Self-Administered Computerized Olfactory Test System (SCOTS), an automated test system for evaluating the sense of smell. This manual provides information you will need for utilizing your new device for assessing odor identification and detection thresholds.

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# INSTRUCTIONS

## **\*Please read and save these Instructions**

This Owner's Manual covers operating procedures for your 40 Channel Self-Administered Computerized Olfactory Test System (SCOTS) and the use of its software. DO NOT operate this device without first reading and understanding this manual. Caution and common sense must be exercised when installing, operating, and/or maintaining this device. If questions arise regarding the installation or use of the SCOTS, please contact customer support service at Sensonics International [856-547-7702].

The first section of the manual explains the system and its installation. The second section discusses the software options that allow you to configure your system according to your needs. The system comes preconfigured with standardized settings, but you may wish to use different settings for your particular needs.

### **WARNING**

After each use wipe the dome with a clean cloth or a paper towel dampened with ethyl alcohol. Do not allow water or other liquid to drip into the dome outlet nozzle vents. (Part E)

Do not open the cover of the olfactometer. There is a risk of electrical shock that could result in serious injury or death. The inside of the machine should only be accessed by a qualified technician. There are no user serviceable parts inside.

Do not store or use gasoline or any other flammable or explosive gases, vapors or liquids in the vicinity of this device.

Do not attempt to open or change the contents of the odorant dome. The odorant dome should only be filled or recharged by Sensonics International. Use of solids, liquids, or gases other than those provided by Sensonics International could result in serious injury or death.

Do not attempt to download/upload other software to your unit. Each unit has been programmed to read and analyze the data from each participants' tests. The addition of other software can make your system inoperable.

**Always use with a grounded outlet and 3-prong plug**

# **Part 1:**

## **Taking Tests**

# CONFIDENTIALITY ISSUES

As with any psychometric instrument, only qualified professional personnel should administer the *Threshold* or *CB-SIT* test. Furthermore, test results and the administration manual should never, under any circumstances, be given to anyone not professionally engaged in the scientific or medical evaluation of the sense of smell.

# STARTING A TEST

Before each test, whether the test in question is the odor identification (*cB-SIT*) or detection threshold (*Threshold*) test, the patient (or subject) will be prompted to enter his/her demographic information.

- A. *If the patient has already taken either test:* he or she can enter his/her first name, last name, and zip, and select his/her information from the list.
- B. *If the patient has not taken either test,* he or she will need to enter the demographic information into the system. The on-screen prompt will guide the patient through the process.

The program does not require the patient to enter all of the requested information, and does not prevent the patient from taking the test if certain fields are not filled out. The patient also has the option to *skip* this section. If the patient skips everything, he/she will be entered into the system as *ANONYMOUS*.



# TAKING THE THRESHOLD TEST

To begin the *Threshold* test, click on the *Threshold* button on the main screen.

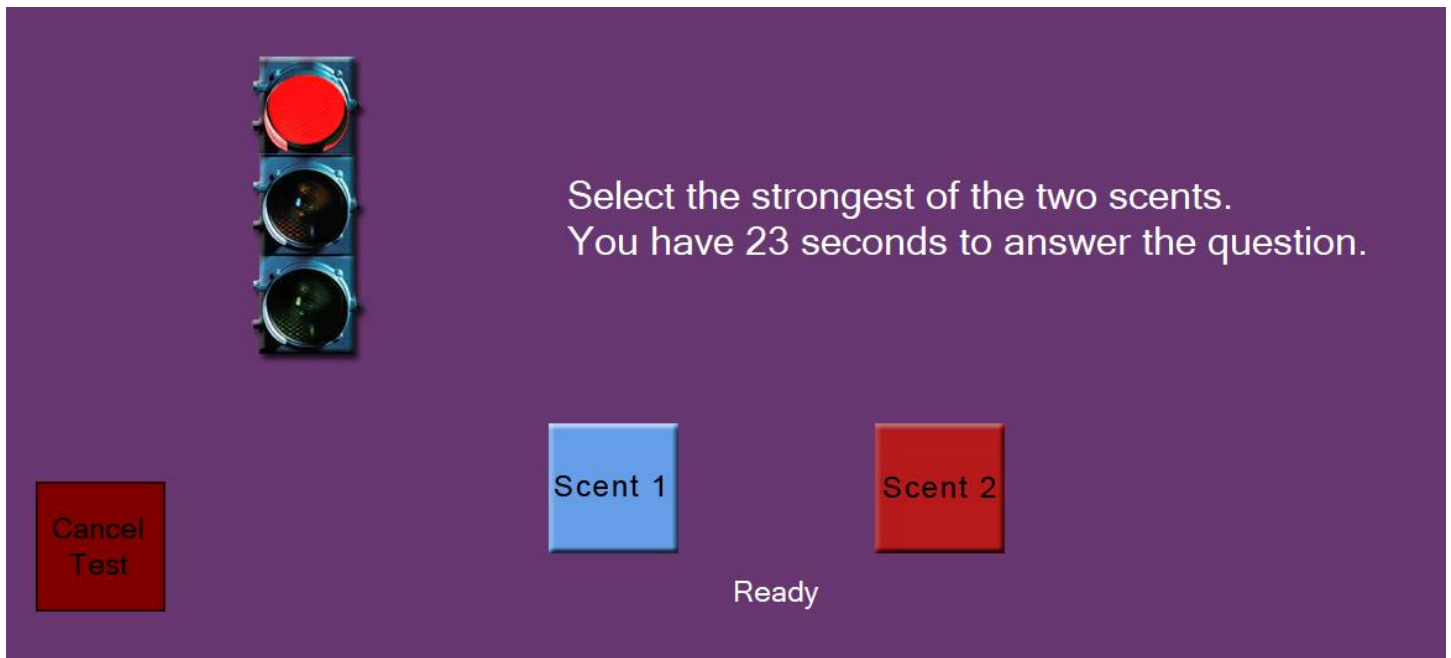
At the beginning of the test, the patient will be prompted to click a button to begin. Once the test has begun, the following procedure will be followed:

1. The first scent will be released from the dome. The nose should be positioned ~3 inches from the center hole of the dome.
2. A pause for a pre-determined amount of time will occur (default is 6 seconds).
  - a. This interval duration can be changed via *Configuration* window as described in the *Settings and Configuration* section of this manual.
3. The second scent will be released.
4. The patient then has a pre-determined amount of time to select the option to indicate whether the first or the second scent was strongest. The default period is 60 seconds.

NOTE THAT THE PATIENT MUST PROVIDE AN ANSWER EVEN IF IT IS A GUESS OR THEY SMELL NOTHING.

  - a. If the patient provides their answer within the time limit, the test will proceed.
  - b. If the patient does not provide an answer within the time limit, the test will end, and the partial test results will be saved and marked as incomplete.
  - c. This interval duration can be changed via *Configuration* window as described in the *Settings and Configuration* section of this manual.
5. After a pre-determined pause (default = 10 sec), the next set of pairs of successive odors are released and the patient is again asked which is stronger, the first or the second.
  - a. The pause duration (time between the sets of paired presentations) can be changed via *Configuration* window as described in the *Settings and Configuration* section of this manual.

This process will be repeated until the patient is informed that the test has been completed. The amount of time required to complete the test will vary from patient to patient. The test score, which is automatically computed, is the average of the last four of seven total staircase reversals.



## TAKING THE cB-SIT TEST

To begin the *CB-SIT* test, click on the *CB-SIT* button on the main screen. This is a 12-stimulus forced-choice odor identification test.

- If you receive a message saying "*There are currently no tests in the database*", the *Configuration* window will open.
  - Click on the tab which says *Threshold* or *CB-SIT* – the third tab from the left.

- Configuration**

Database Patient Information Tests Text Prompts Administrators Dome Serial

This tab will allow you to set and change various test options for the CB-Sit and Threshold tests.

Controls under the 'General Options' box apply for both tests. Other controls are test-specific.

---

**General Options**

Delivery Time: 3.5 Instant Feedback: No  
Inter-Scent Delay: 4.0 Laterality: Bilateral  
Inter-Trial Delay: 5 Malingering Detection: No  
Answer Limit: 30 Continuous-Testing Delay: 30

☐ Randomize Laterality ☐ Continuous Testing

**Identification Special Options**

Show Text / Images: Both  
Randomize Sequence: No  
Show Choices: No

---

**Threshold Calculation Options**

Number Of Infections: 7 Repeat Limit: 3 Starting PEA: -6.0  
Randomization: Pseudo Random

Pseudo Random Order:  
1,2,2,1,1,2,1,2,1,1,2,1,2,1,1,2,2,1,1,2,1,2,1,2,2,2,  
1,1,2,1,2,2,2,1,1,2,1,2,2,1,2,2,1,2,1,1,2,2,1,2,1,  
2,1,1,1,2,2,1,1,1,2,1,2,2,1,2,1,1,2,2,1,2,2,1,2,2,  
1,2,2,1,2,2,1,2,1,1,2,2,2,1,2,1,2,2,2,1,1,1,1,2,2,1,2,1,  
2,1,1,2,1,1,2,1,1,2,2,1,1,1,2,1,1,1,2,1,1,2,2,1,1,2,1,  
2,1,1,2,2,1,1,2,1,2,1,2,1,2,2,2,1,1,2,1,2,2,1,2,2,2,1,2,  
1,2,2,2,1,1,1,1,2,2,1,2,1,2,1,1,2,1,1,2,1,1,2,2,1,2,1,1,  
1,1,2,1,1,1,2,1,2,2,1,1,2,2,1,1,2,1,1,1,2,1,1,1,1,1,1,  
2,1,2,2,1,1,2

---

**Identification Tests**

BSIT

Test Type: BSIT

Question # 0

Choice A  
Choice B  
Choice C  
Choice D

Set Test

Create Test

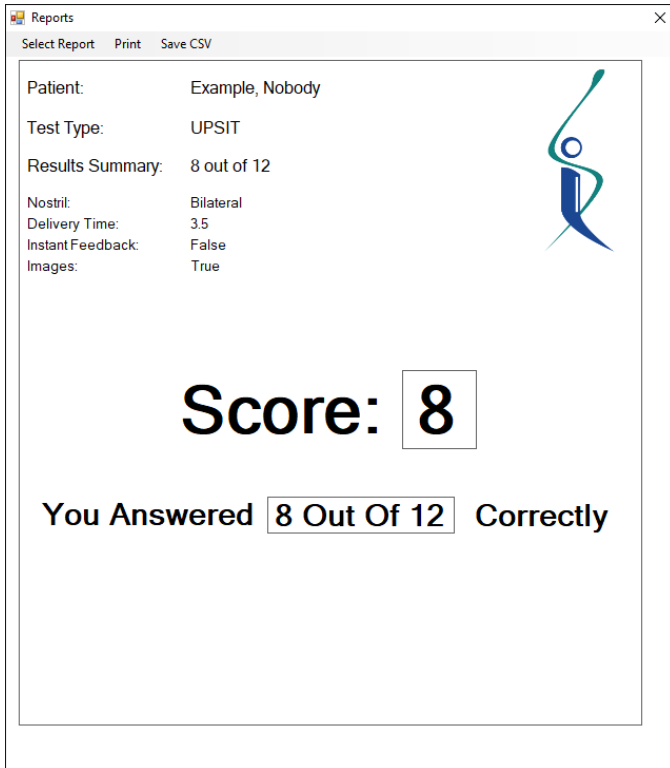
- At the beginning of the test, the patient will be prompted to click a button to begin. Once the test has begun, each question will follow the following procedure:

# **Part 2:**

## **Viewing Test Reports**

# TEST REPORTS

At the conclusion of each test, the system will calculate and save the results. These results can be viewed from the *Test Reports* tab on the menu bar on the main window. Show below are examples results from a *CB-SIT* test (left) and a *Threshold* test (right).



Reports

Select Report Print Save CSV

Patient: Example, Nobody

Test Type: UPSIT

Results Summary: 8 out of 12

Nostril: Bilateral

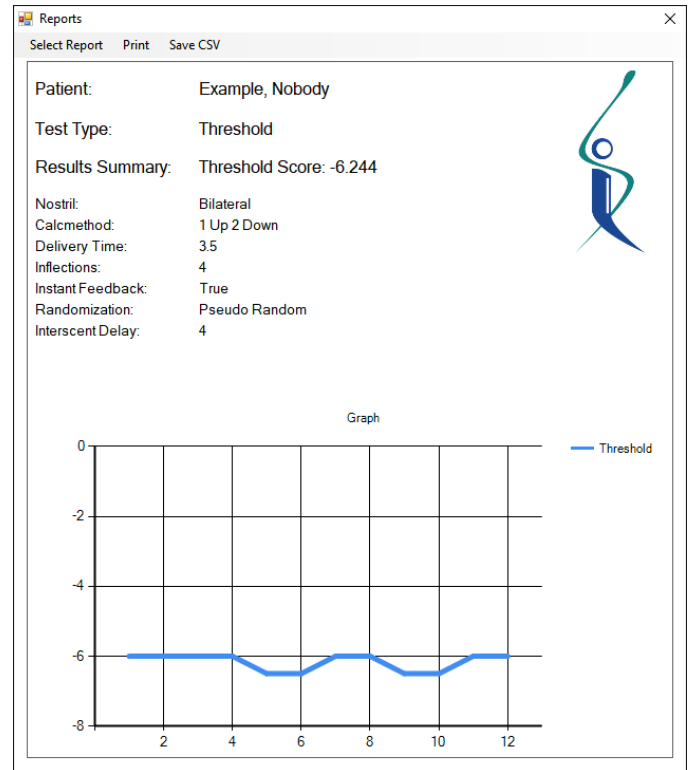
Delivery Time: 3.5

Instant Feedback: False

Images: True

**Score: 8**

You Answered **8 Out Of 12** Correctly



To view the results of a test:

- Select *Test Reports* on the top menu bar on the main screen.
- Select *Reports*.
- Log in with an *Administrative* or *Assistant* account (if required).
  - More information on accounts can be found in the *User/Admin Management* section of this manual.
- Click *Select Report* on the menu bar.
- A window with two lists will appear. Select the name of the patient from the list to the left, and the test in question from the list to the right.
  - You must select both options even if there is only one patient or one list.
- The test results will appear in the form's window.

<TODO>Update BOTH pictures

Test reports can also be printed and exported to CSV via the other options in the menu bar.

# **Part 3:**

## **User/Admin Management**

# USER ROLES

User accounts are used to change configuration settings, view and export results, and perform other maintenance, testing, and administrative actions. The two types of users in the system are *Assistant Users* and *Administrative Users*.

An *Assistant User* has the following privileges:

- Open the *Configuration* window.
- View the kind of patient information that is being collected.
- View the current test settings.
- View the current *DOME* configuration.
- View and export test results.

An *Administrative* user has all of the privileges listed above plus the following:

- View and change the *Database* connection.
- Change what kind of patient information is being collected.
- Change the current test settings.
- View and change the text prompts and instructions shown during tests.
- View the list of users.
- Add *Assistant* and *Administrative* users.
- Remove any *Assistant* user.

The *User Accounts Settings* section of the *Settings and Configuration* section of this manual outlines how to create, modify, and delete user accounts.

# **Part 4:**

## **Settings and Configuration**



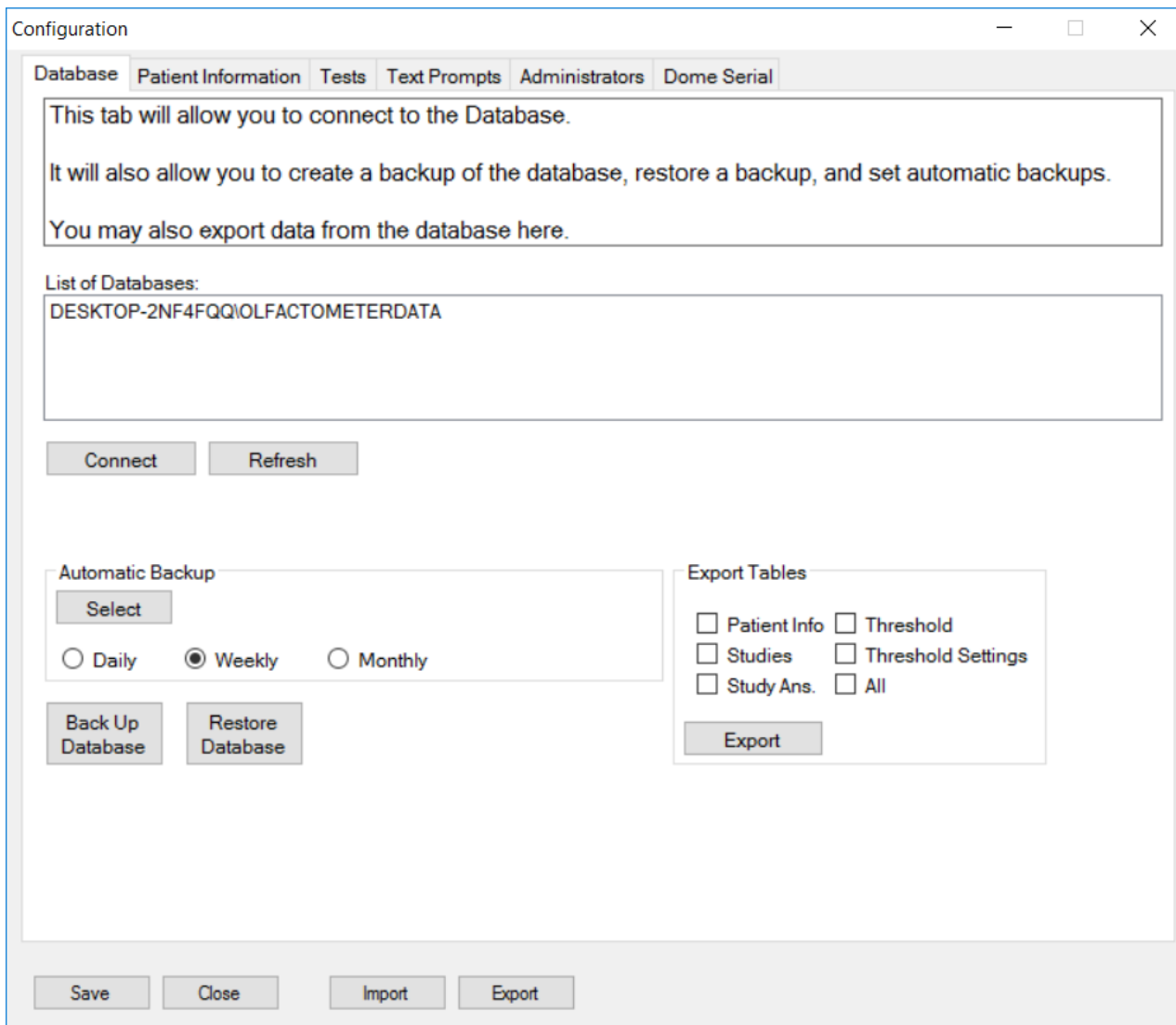
# PROGRAM SETTINGS

The program is designed to give a wide variety of options to customize test features to fit different testing needs, including test durations, types of scents produced, *Threshold* and *CB-SIT* specific settings, and the like.

The following sections will describe the function of each page in the *Configuration* window and outline the value of each setting and it can be customized.

An *Administrative* account is required to view and make changes to settings. The *User/Admin Management* section of this manual describes how *Administrative* and *Assistant* accounts work, and the *User Accounts Settings* section shows how to create and modify user accounts.

# DATABASE SETTINGS



The *Database* tab provides options for database maintenance.

1. The controls on the *Database* tab will allow you to connect to a database, and if applicable, customize the connection properties. In most cases, there will only be one database installed.
  - a. If the list of databases is empty, or is out-of-date, click on *Refresh* and wait for the program to load the list of databases.
  - b. Click on the database you wish to connect to, and ensure that it is highlighted in blue when you click on it.
  - c. Click *Connect* to connect to the database.
    - i. The *Configuration* window will display a status message at the bottom of the window indicating whether the connection was successfully established or not.

1. If the connection was successful, and the admin or assistant has not yet logged in, a login prompt will appear as soon as the connection is established.
2. The *Database* tab will also allow you to export database information to csv files.
  - a. In the *Export Tables* section, click on each table you would like to export, and click the *Export Tables* button. A save dialog will appear for each table you have selected.
3. *Database Backup*:
  - a. The *Back Up Database* button will save a *.bak* file, which contains all of the information that the *Database* currently contains.
  - b. The *Restore Database* button will change/restore the contents of the *Database* to match the contents of a previously saved *.bak* backup file.
  - c. Automatic backups can be set by choosing a path under the *Automatic Backup* section and by choosing a backup interval (daily, weekly, or monthly).

# PATIENT INFORMATION SETTINGS

The screenshot shows a window titled "Configuration" with several tabs: "Database", "Patient Information", "Tests", "Text Prompts", "Administrators", and "Dome Serial". The "Patient Information" tab is selected. Inside the tab, there is a text box stating: "This tab will allow you to change the information that the program will collect from the patient, and will allow you to create your own questions." Below this, there is a section titled "Patient Information" with four checkboxes: "Collect Physician Info" (checked), "Collect Past Medical History" (checked), "Collect Smoking History" (checked), and "Collect Additional Questions" (unchecked). To the right of these checkboxes, there are text boxes for "Protocol" and "Study Name", a "Number to Create" spinner set to 1, and buttons for "Create New" and "Preview". Below these is a dropdown menu labeled "--Select Protocol for Additional Questions--" with "TestS" selected. At the bottom of the window, there are buttons for "Create New", "Update Protocol", "Delete", "Save", "Close", "Import", and "Export".

The *Patient Information* tab provides options for customizing what kind of information you would like to receive from patients. This information is collected before the beginning of each test. The three options which are included by default are listed below. Some or all of these options can be disabled.

1. Collect Physician Info
2. Collect Past Medical History
3. Collect Smoking History

In addition, you can create your own additional questions. To create your own *protocol*:

1. Click on *Create New Protocol*.
2. Enter a *Protocol Name* and *Study Name* in the textboxes to the top right.
3. Specify the number of questions. This can be any number greater than zero.
4. Click *Create New Questions*.
5. Follow the on-screen prompts, and type in each question one-at-a-time.
6. When you are finished, you have the option to preview and change questions. If you would like to do so, click on *Preview Questions* and follow the on-screen prompts.
7. When you are satisfied that everything is complete, click *Submit*, and the *protocol* will be added to the database.

To select and use a protocol:

1. Select the *protocol* you wish to modify from the *Select Protocol for Additional Questions* menu.
2. Check *Collect Additional Questions*.

To modify an existing *protocol*:

1. Select the *protocol* you wish to modify from the *Select Protocol for Additional Questions* menu.
2. Click on *Update Protocol*.
3. You have the option to change the *Study Name* and questions.
  - a. To change the *Study Name*, type the new name in the textbox to the top right of the window.
  - b. To change one or more questions:
    - i. Click *Preview Questions*.
    - ii. Click *Continue* until you reach the desired question.
    - iii. Click *Alter Question*.
    - iv. Type in the new question.
    - v. Click *Submit*.
  - c. To erase the current questions and add more questions:
    - i. Set the number of questions you would like to create.
    - ii. Click *Create New Questions*.
    - iii. Follow the on-screen prompts. This step is similar to the steps taken when creating a *protocol*.
4. When you are satisfied with your changes, click *Submit Changes*.

To delete a *protocol*:

1. Select the *protocol* you wish to modify from the *Select Protocol for Additional Questions* menu.
2. Click on *Delete Protocol* at the bottom right of the window.
3. Confirm that you would like to delete the selected protocol, and ensure you have selected the correct protocol. This action cannot be undone.

## TEST SETTINGS

Configuration

Database

Patient Information

Tests

Text Prompts

Administrators

Dome Serial

This tab will allow you to set and change various test options for the CB-Sit and Threshold tests.

Controls under the 'General Options' box apply for both tests. Other controls are test-specific.

General Options

Delivery Time: 3.5

Instant Feedback: No

Inter-Scent Delay: 4.0

Laterality: Bilateral

Inter-Trial Delay: 5

Malingering Detection: No

Answer Limit: 30

Continuous-Testing Delay: 30

☐ Randomize Laterality

☐ Continuous Testing

Identification Special Options

Show Text / Images: Both

Randomize Sequence: No

Show Choices: No

Threshold Calculation Options

Number Of Inflections: 7

Repeat Limit: 3

Starting PEA: -6.0

Randomization: Pseudo Random

Pseudo Random Order:

1,2,2,1,1,2,1,2,1,1,2,1,2,1,1,2,2,1,1,2,1,2,1,2,1,2,2,2,  
1,1,2,1,2,2,2,1,1,2,1,2,2,1,2,2,1,2,1,1,2,1,2,2,1,2,1,  
2,1,1,1,2,2,1,1,2,1,2,2,1,2,1,1,2,2,1,2,2,1,2,2,1,2,2,  
1,2,2,1,2,2,1,2,1,1,2,2,2,1,2,1,2,2,2,1,1,1,1,2,2,1,2,1,  
2,1,1,2,1,1,2,1,1,2,2,1,2,1,1,1,2,1,1,1,2,1,2,2,1,1,2,  
2,1,1,2,1,1,1,2,1,1,1,2,1,1,1,2,1,2,2,1,1,2,1,2,1,1,2,1,  
2,1,1,2,2,1,1,2,1,2,1,2,1,2,2,2,1,1,2,1,2,2,1,2,2,2,1,2,  
1,2,2,2,1,1,1,1,2,2,1,2,1,2,1,1,2,1,1,2,1,1,2,2,1,2,1,1,  
1,1,2,1,1,1,2,1,2,2,1,1,2,2,1,1,2,1,1,1,2,1,1,1,2,1,1,1,  
2,1,2,2,1,1,2

Identification Tests

BSIT

Test Type: BSIT

Question # 0

Choice A

Choice B

Choice C

Choice D

Set Test

Create Test

Save

Close

Import

Export

The *Threshold / UPSIT* tab will allow you to change settings for each of these tests. The name of the tab will change depending on which test is to be taken, but it will always be the third tab to the left.

Most of the options in the *General Options* section set the options for both *Threshold* and *CB-SIT* tests. The options are as follows:

- *Delivery Time*: the amount of time, in seconds, that the scent will be released.
- *Inter-Scent Delay*: for the *Threshold* test, the amount of time, in seconds, that will elapse between the release of the first and the second scents for each question.
- *Inter-Trial Delay*: the amount of time, in seconds, that will elapse between each question.
- *Answer Time Limit*: the amount of time, in seconds, that the patient has to answer.

- If the patient does not answer within this amount of time, the test will be cancelled, and partial results will be saved and marked as incomplete.

The options in the *Identification Special Options* section apply to the *CB-SIT* test. The options are as follows:

- *Show Text/Images*: specify whether the program should display choices using images only, text only, or both. Both is the default value.
- *Randomize Sequence*: specify whether the program should display the questions in a random order each time the test is taken.
- *Show Choices*: <TODO><discover purpose>

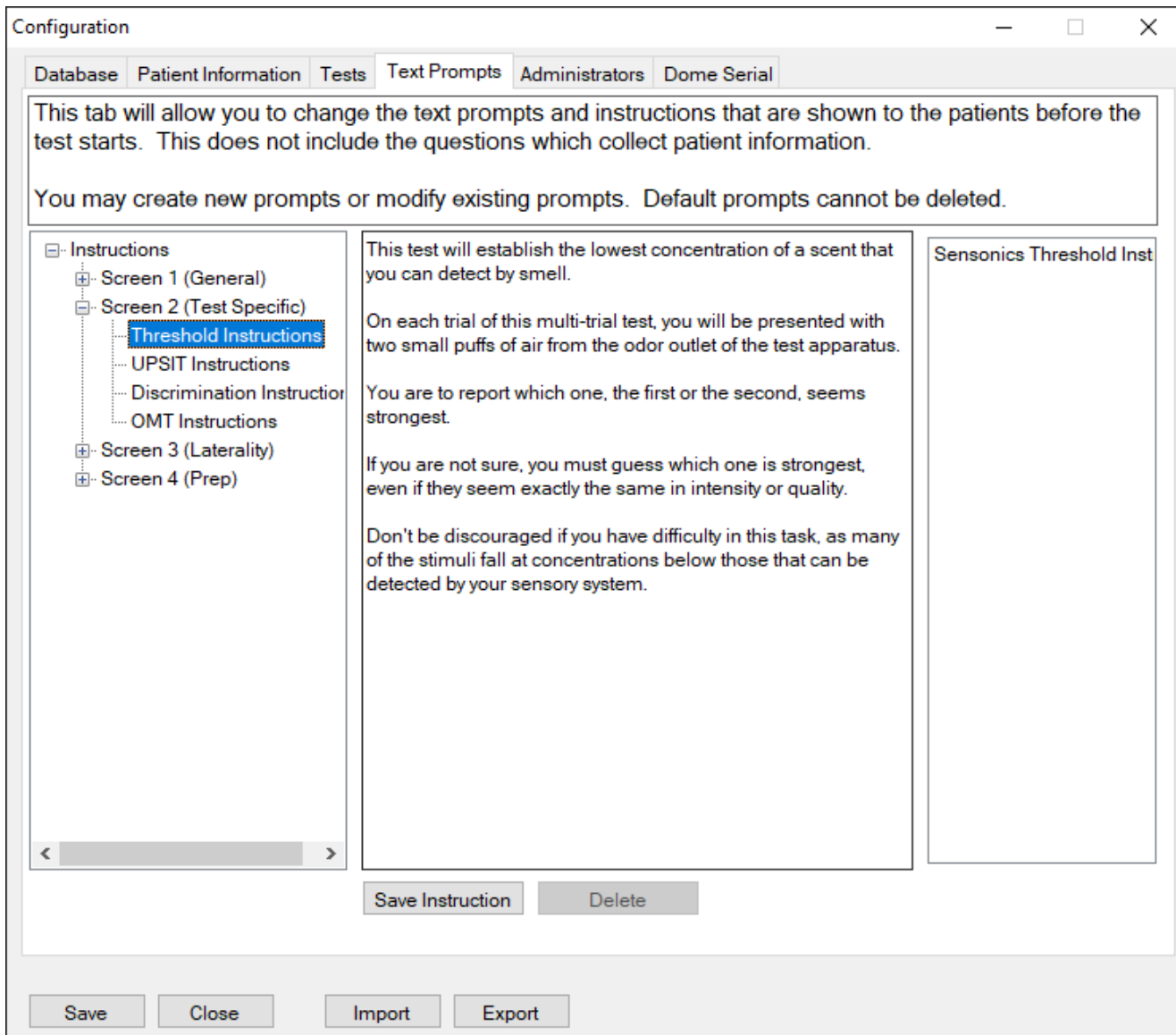
The options in the *Threshold Calculation Options* section apply to the *Threshold* test. The options are as follows:

- *Number of Staircase Reversals*: the computer will track the number of staircase reversals that occur when an individual takes the threshold test. This feature allows you to adjust the length of the test by allowing you to choose the number of reversals that need to occur for the test to end and the results to be calculated. The more reversals, the greater the test reliability (but the longer the test).
- *Randomization*: change the type of randomization used by the software to select which scent will be the correct choice for the subject/patient.
  - *Pseudo Random Order (default)*: this setting allows you to specify the correct answers for each question. The pseudo-random order is specified in the *Pseudo Random Order* textbox. A “1” shows that the first scent is the correct choice. A “2” shows that the second scent is the correct choice. For example, if a “1,2,1” was typed in the textbox, the first scent would be the correct scent for question one, the second scent would be the correct answer for question two, and the first scent would again be the correct answer for question three.
  - *Limited Random*: the correct answers for each question are chosen at random. You specify the amount of times a choice can be correct consecutively by adjusting the *Repeat Limits* value.
- *Repeat Limit*: if the *Randomization* is set to *Limited Random*, this control will be used to specify the maximum number of times a choice can be correct consecutively.
- *Starting PEA*: specifies the concentration of the first scent that is released. The default values is -6.0. The value must fall between -2 and -10, inclusive.

The options in the *Identification Tests* section apply to the *CB-SIT* test.

- The list box (which appears right under the *Identification Test* label, will display the list of all created *CB-SIT* tests.
- The *Set Test* button will set the questions of the *CB-SIT* test to the currently selected test.
- The *Create Test* button will allow you to create a new *CB-SIT* test.

# TEXT PROMPT SETTINGS



The *Text Prompts* tab will allow you to customize the instructions and on-screen prompts that are shown during different parts of each test. Some instructions are always shown, and other instructions are specific to the type of test that is being administered.

To *add* or *modify* an instruction, select which *Screen* you would like to modify. Then, change the text in the middle textbox, and click *Save Instruction*. You cannot override a previously saved instruction, you can only create a new one (to delete an instruction, see below). Enter the name of the new instruction, and click *OK*. The new instruction will appear at the menu to the right.



To *select* which instruction to show (if more than one is available), move to the appropriate *Screen* and click on the instruction you would like to show in the list to the right of the window. Verify that the name of the instruction is highlighted in blue.

To *delete* an instruction, move to the appropriate *Screen*, select the instruction from a list to the right, and click *Delete Instruction*. You cannot delete a default instruction, only ones that have been created using the *Configuration* window.

# USER ACCOUNT SETTINGS

Configuration

Database Patient Information Tests Text Prompts **Administrators** Dome Serial

This tab will allow you to create and edit user accounts.

Accounts can be of type 'Administrator' or of type 'Assistant'. Assistant accounts have less access and control over configuration settings.

Users:

ADMIN, Administrator

Username:

Old Password:

New Password:

Repeat:

Role:

☐ Administrative

☐ Assistant

Create User

Edit User

Delete User

☒ Require Login to View Reports

Save Close Import Export

The *Administrators* tab provides options for creating, modifying, and deleting user accounts.

To create a new account:

1. Type a new username in the *Username* textbox.
2. Type a new password in the *New Password* box.
3. Type that same password in the *Repeat* box.
4. Specify the type of user account, or the *Role*.
5. Click *Create User*.

- a. If there is a user with the same name, you will be prompted to change the username in the *username* box.
- b. If the passwords do not match, you will be prompted to re-type the password and repeat password.

To modify an account:

1. Select the account you wish to modify from the *Users* list to the left.
2. Click *Edit User*.
  - a. This will fill the *Username* text box with the username of the account you have selected.
  - b. This will also change the buttons in the form to reflect that you are editing a user, and not creating a new one.
3. You have the option to:
  - a. Change the username.
  - b. Change the password.
  - c. Change the role to *Administrative*.
4. When you have made the desired changes, click *Edit User*.

**Note:** *Assistant* accounts can be modified by any *Administrative* user, without the need to know the password of the account being modified. However, *Administrative* accounts require the old password to change account information.

To delete an account:

1. Select the account you wish to modify from the *Users* list to the left.
2. Click *Edit User*.
3. Click *Delete User*.
  - a. Use this feature with caution. Once an account is deleted, it cannot be recovered.

An administrator can also enable or disable login security to view patient reports. To do so, login to the *Configuration* window with an administrator account, then under the *Administrators* tab, check or uncheck *Require Login to View Reports*.

# DOME SETTINGS

The screenshot shows a software window titled "Configuration" with several tabs: Database, Patient Information, Tests, Text Prompts, Administrators, and DOME Serial. The "DOME Serial" tab is selected and contains the following text: "This tab will allow you to change the dome serial, and if necessary, update chamber information. This will be useful if the physical dome on the olfactometer has been changed." Below this text is a "Dome Entry" section with the prompt "Please enter dome serial:" followed by five input boxes separated by hyphens. At the bottom of this section are four buttons: "Verify Dome", "Set Dome", "Add New Dome", and "Update Dome", along with a checkbox labeled "Enable Verification". The main window has a footer with four buttons: "Save", "Close", "Import", and "Export".

The *DOME Serial* tab will allow you to change the *DOME* which is registered to the machine. It will also allow you to update the *DOME* layout in the program using an external file.

- *Add DOME*: if you have changed the physical *DOME* on the machine, you will need to update the software with the serial number of the new *DOME*. To do so, enter the *DOME*'s serial number in the *DOME Entry* form, and click *Add New DOME*. If you want to begin using this *DOME* immediately, you will need to use *Set DOME* as shown below.
- *Set DOME*: if you have changed the physical *DOME* and have added the serial number to the program, this will set the software to test based on the *DOME* provided by the serial number entered in the *DOME Entry* form.
- *Verify DOME*: this will verify that the serial number entered in the *DOME Entry* form is valid.
- *Update DOME Layout*: this will update the program to include *DOME* configurations based on the *chamber.txt* file. The software comes with this update pre-installed, so you should not use this feature unless you are otherwise instructed to do so.



# **Part 5:**

## **Threshold Testing**

# DEFINITIONS OF THRESHOLD

The lowest concentration of an odorant that an individual can reliably detect (usually defined as that concentration where detection is midway between chance and perfect detection) is termed his or her **detection or absolute threshold**. At very low concentrations, no odor quality can be discerned, only that something is present that differs from air or the comparison diluent blank or blanks. In modern olfactory detection threshold testing, the subject is asked to report which of two or more stimuli (i.e., an odorant and one or more blanks) smells strongest, rather than to simply report whether an odor is perceived or not. Such “forced-choice” procedures are less susceptible to contamination by response biases (e.g., the conservatism or liberalism in reporting the presence of an odor under uncertain conditions) than non-forced-choice procedures. In addition, they are more reliable and produce lower threshold values **<R13>**. The instructions provided to a subject are critical in measuring a detection threshold, since if the subject is instructed to report which stimulus produces an odor, rather than which stimulus is stronger, a spuriously high threshold value may result (odor quality is present only at higher perithreshold concentrations).

The **recognition threshold** is defined as the lowest concentration where odor quality is reliably discerned. Unfortunately, it is nearly impossible to control criterion biases in recognition threshold measurements. Thus, in a forced-choice situation, guesses are not randomly distributed among alternatives, potentially leading to a spuriously low recognition threshold for the preferred alternative. A classic example of this problem comes from taste psychophysics, where some subjects report “Sour” much more frequently than the other primary qualities in the absence of a clearly discernible stimulus, resulting in a spuriously low sour-taste recognition threshold measurement **<R41>**. **YOUR OLFACTOMETER IS CONFIGURED ONLY TO MEASURE A DETECTION THRESHOLD.**

A third type of threshold is the **differential threshold**, the smallest amount by which a stimulus must be changed to make it perceptibly stronger or weaker. This is also termed a difference threshold or a “just noticeable difference” **<JND>**. The size of the increment in odorant concentration ( $\Delta I$ ) required to produce a JND increases as the comparison concentration ( $I$ ) increases, with the ratio approximating a constant; i.e.,  $\Delta I/I = C$ . This phenomenon was described by Weber in 1834 and was termed “Weber’s Law” by Fechner in 1860 **<18>**. Although differential thresholds have been measured in olfaction, they have received little practical application.

**<TODO><add references (if required)>**

# BILATERAL VS. UNILATERAL TESTING

In most cases, testing both sides of the nose at the same time is adequate for assessing smell function (so-called bilateral or binasal testing). If desired, each side of the nose can be tested separately, which is sometimes needed in clinical case where, for example, lateralized damage to the olfactory pathways occurs (e.g., in some brain operations and in some accident cases). If unilateral testing is desired, the following instructions can be read to the subject before administering the test:

*We will test each side of your nose separately. To do so, we must close the nostril of the side not being tested using a piece of tape comfortably positioned to keep air from entering the non-tested side. The special tape we use does not stick strongly to hair or skin, and is comfortable when applied and when removed. Depending upon your sensitivity to the agents presented, the test session in which both sides of the nose are tested can last anywhere from 20 to 30 minutes. Do you have any questions?*

It should be noted that the sensitivity of the more sensitive side (i.e., that with the lower threshold), rather than the average of the two sides, is usually the best estimate of bilateral threshold sensitivity <2>. If one's goal is to simply determine an individual's overall ability to smell, the bilateral testing minimizes testing time and should be performed. On the other hand, if one is seeking information about each side of the nose, then unilateral testing should be performed. The analogy is with vision; a person blind in one eye may perform well on an eye chart and be capable of discerning visually most objects (although special ability may be compromised). Unilateral testing would be needed, however, to demonstrate that one eye is not adequately functioning.

The examiner should be aware that, in many people, nasal engorgement and, hence, relative airflow, fluctuates across the left and right sides of the nose over time <23;30>. Generally, olfactory test scores are not noticeably influenced by such fluctuations <20;21>, although in cases where considerable nasal occlusion occurs during one phase of this relative airflow shift (e.g., when marked septal deviation is present), such scores may be affected.

It has been suggested that optimal threshold sensitivity occurs when the nose is mildly obstructed <34>. In individuals where marked left:right variation (e.g., > 2 log units) is observed in detection thresholds, repeated testing may help to determine whether the disparity is related to differences in differential engorgement or to intrinsic L:R sensitivity.



# **Part 6:**

## **CB-SIT Testing**

# RELIABILITY OF THE CB-SIT

In general, forced-choice odor identification tests are highly reliable, indeed more so than other tests that can be administered within the same time period. In one study, the CB-SIT was administered on two test occasions separated by at least a week to the same individuals. The test-retest reliability coefficient was 0.71 <4>. This, however, is likely a conservative estimate of its reliability, since the subjects were relatively homogeneous and the reliability of the 40-item UPSIT in this study was only 0.91, a value somewhat lower than the ~0.95 value seen in other investigations.

According to the Spearman-Brown formula (which relates test length to reliability), a test comprised of 12 UPSIT items (i.e., a test 30%/ as long as the UPSIT) would have a reliability of 0.73, compared to the 0.92 test-retest reliability of the whole UPSIT. The aforementioned empirically-determined test-retest reliability coefficient for the CB-SIT ( $r=0.71$ ) is comparable to this value <5>.

**<DATA HERE IS PROBABLY NOT USEABLE IN THIS CASE>**

# STRENGTHS AND WEAKNESSES OF THE CB-SIT

The CB-SIT is the test of choice when < 5 minutes is available for testing. It employs the same sound psychometric principles as the 40-item University of Pennsylvania Smell Identification Test (UPSIT), and incorporates multicultural items, making it useful in numerous cultures. Moreover, the availability of norms allows for a standardized indication of an individual's ability to smell. This test is particularly useful in surveys, where time is at a premium.

The 12-item CB-SIT is admittedly less sensitive in detecting subtle alterations in smell function than the 40-item UPSIT. The decreased sensitivity is due, in part, to its lower reliability. Moreover, the CB-SIT has a smaller range in which abnormal scores can fall. Thus, < 8 categories typically exist below the 5<sup>th</sup> percentile of the CB-SIT normative distribution, compared with ~30 for the UPSIT.

While the CB-SIT is a useful screening test, the limited range of available test scores precludes definitive detection of malingering using statistically improbable responses. Thus, the expected CB-SIT score on the basis of random responding (as would occur in total anosmia) is 3; i.e., since there are 4 choices on each item and responding is forced-choice, 20% of the answers, on average, should be correct ( $0.25 \times 12 = 3$ ). However, since the sampling distribution expected from anosmics falls several points around this value, it is difficult to definitively establish statistically whether a low score on the CB-SIT is due to olfactory dysfunction or to malingering.

<

# COMMON APPLICATIONS OF THE CB-SIT

Like its parent test, 12-item Brief Smell Identification Tests (B-SIT) analogous to the CB-SIT have served as the basis for a number of large surveys undertaken by universities and corporations. For examples, Graves et al (1999) administered the classical B-SIT and a neuropsychological test battery to 1,985 older persons along with the Cognitive Screening Instrument (CASI). Of this group, 1,836 were found not to be demented. Two years later, 1,604 of the subjects were retested on both the B-SIT and the CASI; 69% also were genotyped for apolipoprotein E. The authors found that the B-SIT was the best predictor of subsequent cognitive decline. Relative to normosmics, the odds ratio (OR) for cognitive decline in persons with impaired olfaction (microsmics) was 1.25 (95% CI, 0.83 to 1.89); in anosmics, it was 1.92 (95% CI, 1.06 to 3.47). Persons who were anosmic at baseline and who had at least one APOE-epsilon4 allele had 4.9 times the risk of cognitive decline (95% CI, 1.6 to 14.9) compared with normosmics without the epsilon4 allele.

Graves AB, Bowen JD, Rajaram L et al. 1999. Improved olfaction as a marker for cognitive decline: Interaction with apolipoprotein E epsilon2 status. *Neurology* 53: 1480-1487.

For a listing of peer-reviewed publications employing the B-SIT in clinical settings go to [www.sensonics.com](http://www.sensonics.com), press support tab and academic publications tab.

# **Part 7:**

## **Troubleshooting**

## NO IMAGES AND/OR TEXT IN THE CB-SIT

To turn images and text on or off for the *CB-SIT* test, visit the *Configuration* window, click on the *Tests* tab, and change the options shown in the circle to the desired settings. You will need to exit the test in order to do this.

**Configuration**

Database Patient Information **Tests** Text Prompts Administrators Dome Serial

This tab will allow you to set and change various test options for the CB-Sit and Threshold tests.

Controls under the 'General Options' box apply for both tests. Other controls are test-specific.

**General Options**

Delivery Time: 3.5 Instant Feedback: No

Inter-Scent Delay: 4.0 Laterality: Bilateral

Inter-Trial Delay: 5 Malinger Detection: No

Answer Limit: 30 Continuous-Testing Delay: 30

☐ Randomize Laterality ☐ Continuous Testing

**Identification Special Options**

Show Text / Images: Both

Randomize Sequence: No

Show Choices: No

**Threshold Calculation Options**

Number Of Infections: 7 Repeat Limit: 3 Starting PEA: -6.0

Randomization: Pseudo Random

Pseudo Random Order:

```

1,2,2,1,1,2,1,2,1,1,2,1,2,1,1,2,2,1,1,2,1,2,1,2,1,2,2,2,
1,1,2,1,2,2,2,1,1,2,1,2,2,1,2,2,1,1,2,1,1,2,2,1,2,1,
2,1,1,1,2,2,1,1,1,2,1,2,2,1,2,1,1,2,2,1,2,2,1,2,2,
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1,1,2,1,1,1,2,1,2,2,1,1,2,2,1,1,2,1,1,1,2,1,1,1,2,1,1,1,
2,1,2,2,1,1,2

```

**Identification Tests**

**BSIT**

Test Type: BSIT

Question # 0

Choice A

Choice B

Choice C

Choice D

Set Test

Create Test

Save Close Import Export

## TOO MUCH WAIT TIME DURING TEST TRIALS

The intervals between questions/scents can be changed in the *Configuration* window. To reduce the wait times, open the *Configuration* window, click on the *Tests* tab, and change one or more of the fields in the red circle to the desired values.

[illegible]

# ERROR WINDOW APPEARS

If a strange error window appears, go to the *Configuration* window, and ensure that all settings are properly set, and that none are blank. A blank setting can lead to an unexplained error message.



## ODORS APPEAR TOO WEAK

If odors appear to lose their potency, it is likely that the dome needs to be recharged. Under normal usage, recharging is needed after ~200-250 test administrations. The end user can send the dome back to Sensonics for recharging at a nominal charge. The turn-around time is 48 hours once the dome is received at Sensonics' headquarters. Instructions for removing the dome and returning to Sensonics are provided below.

# Appendix

# ABOUT THIS SECTION

This section describes how to set up the hardware and software of the *Olfactometer*. However, in almost all cases, the initial setup of both the hardware and software is taken care of by *Sensonics International* before shipping the product.

The sections below are useful if you need to replace the *DOME*, totally re-initialize the software, or learn more about the *Olfactometer*.

# OLFACTOMETER PARTS

The main elements of your machine and its parts needed to set up the Olfactometer are described in this section. The setup procedure is described in detail in the next section. Replacement of the dome can be quite tricky, since O-rings at the dome's base can fall out during the procedure. Hence, when dome replacement is needed we encourage you to contact Sensonics directly for further instructions. Sensonics can forward a freshly loaded dome to you for replacement after approximately 200 subjects have been tested. Slight variations in the spatial configuration of the front and back of the olfactometer may occur, depending upon the date of its manufacture, but the basic elements remain the same.

## Olfactometer Diagram



**Figure 1: SCOTT Front Panel Figure 2: SCOTT Back panel**

- A. SCOTT housing
- B. Scent dome
- C. Scent blow holes
- D. Dome fastening screws
- E. Clearing fan
- F. Fan speed adjustment knob
- G. Power switch
- H. Power on light
- I. Power cord inlet
- J. Chassis vent
- K. USB connecting port

## Cables & Tools

1. Power Cord



2. USB Adapter



3. USB 2.0 Cord



4. USB Drive



5. Allen Wrench



6. Nose Tape



7. Bolts



## FIRST TIME OLFACTOMETER SETUP

Attach odorant dome (Figure 3) to the olfactometer manifold (Figure 4) using the 8 dome fastening screws [7] following the test pattern described in Figure 7, using the 3 orientation pegs as a guide (Figures 5 and 6). Note that the O-rings must be situated appropriately in order for the lines to be airtight. When the dome is removed and returned to Sensonics, new O-rings will be provided for re-installation.



**Figure 3: odorant dome**



**Figure 4: Olfactometer manifold**



**Figure 5: orientation pegs**



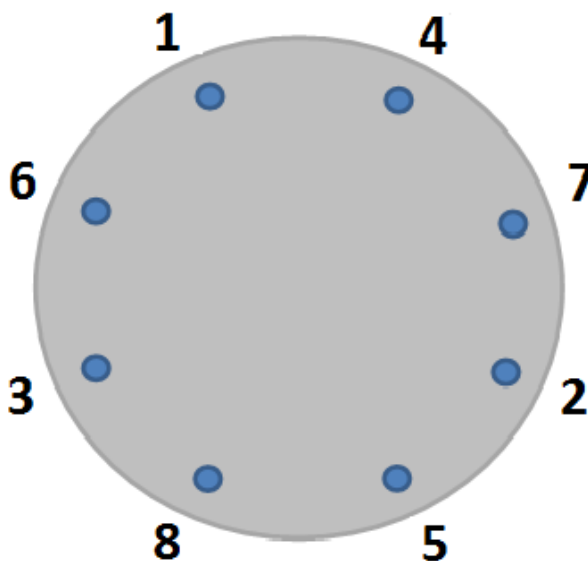
**Figure 6: attach dome to manifold**

Be certain to follow the pattern in Figure 7, while tightening the bolts:

Tighten bolts 1 until it just touches the base. Do not completely tighten this bolt yet.

Skip two bolt positions (clockwise) from the initial bolt and tighten this second bolt until it just touches the base position 2 in Figure 7)

Figure 7: Diagram of star pattern for tightening dome screws.



Repeat steps a and b, following around in the same direction as you started, until all 8 bolts are just touching the base.

Go back to any one of the bolts and tighten **until the base of the odorant dome is snug against the dome manifold (Figure 8).**

Figure 8: Correctly mounted dome and manifold.





Figure 9: NOTE: Your SCOTT will not work correctly if there are any gaps between the dome and manifold.

1. Connect the power cord (1) to the power cord inlet (I)
2. Turn on the SCOTS (G).
3. Connect the USB cord (3) to the olfactometer (K) and then to the computer's USB port.
4. Connect the printer to the computer.
  - a. If the printer is not wireless, plug the printer's USB cord into any available USB port.
  - b. If the printer is wireless, add it via Windows' settings.
5. Plug the computer's power cord into the computer, then into a power inlet.
6. Power on the computer.
7. Power on the olfactometer.
8. When the computer has loaded, open the *Olfactometer* software.
9. Initialize the software as shown on the next page.



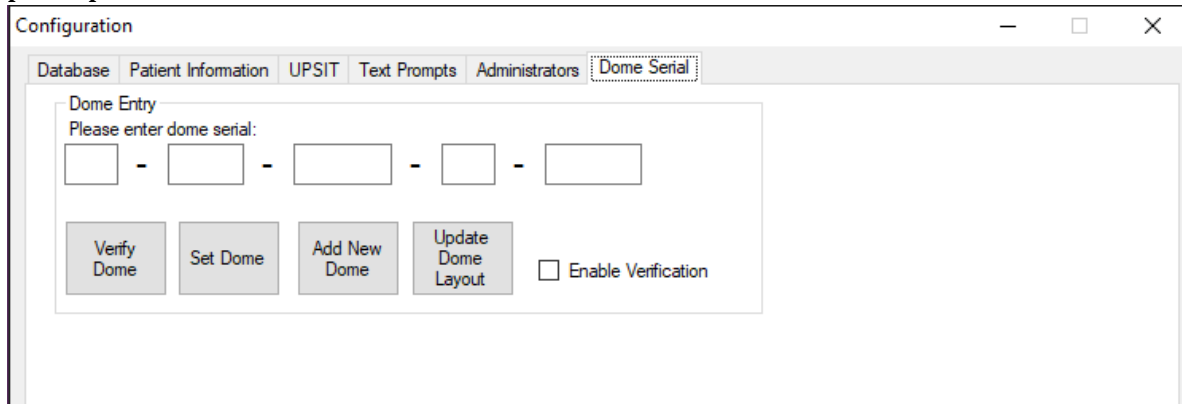
# FIRST TIME SOFTWARE SETUP

When the computer is finished loading for the first time, and the olfactometer is connected, follow the steps below to initialize the software:

1. Click on the *Configuration* tab at the top menu bar.
  - a. The *Configuration* window will open.
2. Check the status bar at the bottom of the screen. If it indicates that the *Database* is disconnected, you will need to connect to the *Database* before using any other part of the program. If it is already connected, you may skip these instructions and proceed to *Step 3*.
  - a. The *Configuration* window will prompt you to connect to a *Database*:

- b. Click on the *Database* you wish to connect to, ensure that the entire item is highlighted in blue, and click *Connect*.
    - c. If the connection is successful, you will be able to view and change *Configuration* settings and begin to test. For more information on *Configuration* visit the *Settings and Configuration* section of this manual.
3. The *Configuration* window will prompt you to login. The default username and password is:
  - a. *Username*: ADMIN
  - b. *Password*: password
  - c. It is highly recommended that you change the password after logging in for the first time. To do so, visit the *User Accounts Settings* section of the *Settings and Configuration* section of this manual.
4. Click on the *Dome Serial* Tab.

5. Find the serial number sticker on the *DOME*, and enter that number into the *DOME Entry* prompt:



- a. If you receive a "*DOME could not be found*" error message, click *Update DOME Layout*, find the *chamber.txt* file, and open it. Then, try to add the *DOME* serial again.
6. Click on *Add New Dome*.
7. Click on *Set Dome*.
8. Click on *Save* at the bottom of the *Configuration* window, and exit the *Configuration* window.
9. Click on the *Maintenance* menu at the top menu bar, and click *Valve Test*.
10. The *Valve Test* will ensure that all of the scents are being produced as expected. The *Test All* feature will produce all scents at a rate of about one per second. The entire test will take about 39 seconds.
11. To begin the test, click on *Test All*. Ensure that each scent is being produced.
- a. If you suspect that a scent is not being produced, record the *valve number* that is displayed at the time.
- b. When the test is completed, select the valve number from the textbox, then click *On*. The scent will be produced until you click *Off*.
- c. If the valve is not producing any odor, **<TODO><reference>or<instruction>**.

