Functional Specification for eTRT system

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eTRT system supports data transactions and data analytics at a hypothetical small/medium clinic specialized in tinnitus retraining therapy (TRT) for management of hearing disorders.

Contents

1 User Interface Specification

1.1 Main Screen

Screen Title: eTRT - Decision Support System for Tinnitus Retraining Therapy.
Screen Icon: Figure 1.

Figure 1: Icon for the Main Screen. Source: tinnitus-pjj.com

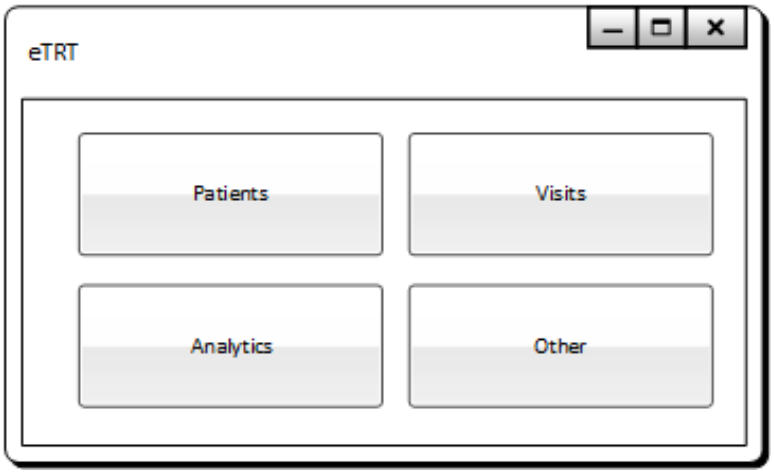

Figure 2: Sample Main screen.

Options to choose from the Main Screen:

- Patients
- Visits
- Analytics
- Other

1.2 Patients Screen

- Add New Patient
- View/Edit Patients

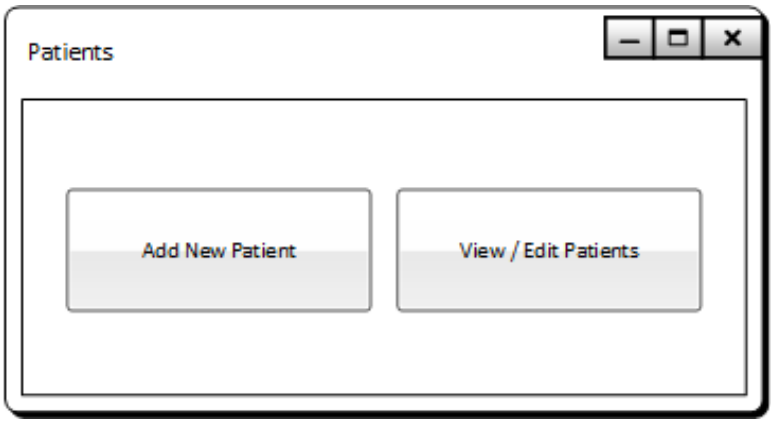

Figure 3: Sample Patients screen.

1.2.1 Add New Patient

- Inactive Fields (generated by the system):
  - THC# - Tinnitus Hyperacusis Center Sequence Number - a unique number assigned to each patient. Generated automatically by the system. It cannot be changed by the user.
  - Current Date
- Active Fields (to be filled out by the user):
  - * First Name
  - o Middle Name
  - * Last Name
  - * Date of Birth (DOB)
  - * Gender (dropdown - F/M)
  - * Phone
  - o E-mail
  - * Street Address
  - * City (dropdown)
  - o State (dropdown)
  - * Zip
  - * Country (dropdown)
  - o Photo
  - o Social Security Number (SSN)
  - o Insurance

* - mandatory, o- optional

- Options:
  - Save - Saves patient data to the system
  - Add Demographics - fill out additional demographics information
  - New Visit - add new visit for the current patient
  - Cancel - Cancel Data Entry

1.2.2 Demographics Screen

- Inactive Fields (auto-filled by the system):
  - THC#
  - Patient Name
  - Current Date
- Active Fields (to be filled out by the user):
  - o Occupation
  - o Work Status
  - o Educational Degree
  - o Tinnitus Onset
  - o Tinnitus Etiology
  - o Hyperacusis Onset
  - o Hyperacusis Etiology
  - o Additional Comments (long text - up to 150 characters)

  * - mandatory, o- optional
- Options
  - Save - Saves demographics data to the system
  - Back - goes back to the Add New Patient screen
  - New Visit - add new visit for the current patient
  - Cancel - Cancel Data Entry

1.2.3 View/Edit Patients Screen

Retrieves patients' records in a table format (by default sorted by THC#):
Operations on the data table:

- Select row in a table
- Unselect row in a table

THC#	Name	Age	Gender	City	State	Date Added
1	John Smith	49	M	Atlanta	GA	2/16/2000
2	Anna Kirkov	55	F	Cleveland	OH	5/3/2000

- Filter table by THC#, Name, City
- Sort table by THC#, Name, City, Date added

Options for the selected record

- View Patient
- Edit Patient
- Delete Patient
- Add New Visit
- Show Current Visit

1.2.4 Patient Lookup Screen

- Search field - search by name, THC#, SSN
- Search results - patients records matched with the search field's value.

Options:

- Edit patient - opens Add New Patient screen
- Add New Visit
- Current Visit - opens the screen of the current visit

1.3 Visits Screen

- Add New Visit
- View/Edit Visists

1.3.1 Add New Visit

- Upper panel: inactive fields (auto-generated by the system):
  - Visit ID - each visit has a unique ID in the system).
  - Visit Date
- Active fields (to be filled out by the user):
  - Patient's THC#

Figure 4: Sample Visits screen.

  - Patient's name. (auto-filled once THC number entered)
  - Visit sequence number for the patient. (auto-filled once THC number entered)
  - Problems in a sequence of ranking, e.i. THL - Tinnitus/Hyperacusis/Hearing Loss; T- Tinnitus; HT - Hearing Loss/Tinnitus.
  - Category: 0/1/2/3/4
  - Protocol - treatment protocol chosen by a patient.
  - Instrument - a type of instrument used for treatment at the visit: V - Viennatone, GS - GSI soft, GH - GHI hard, HA- hearing aid, blank - none.
  - REM - used REM (yes/no).
  - FU - a type of follow-up contact: A - audiology and counseling, C - counseling, T - telephone, E- E-mail, blank - initial visit.
  - Additional Comments - any additional comments for the visit (arbitrary entered by a physician).
  - Next Visit - date of the next scheduled visit.

- Options:
  - THC Lookup - lookup THC number for the patient
  - Add Interview.
  - Add Audiology data.
  - Add Pharmacology info.
  - Diagnose - predicts diagnosis by the system (classifies a patient into a category).
  - Add Instrumentation/REM Details

  - Add Counseling Details.
  - Recommend Treatment - system recommends effective treatment for the current patient/visit.

- Options (lower panel):
  - Save.
  - Cancel.

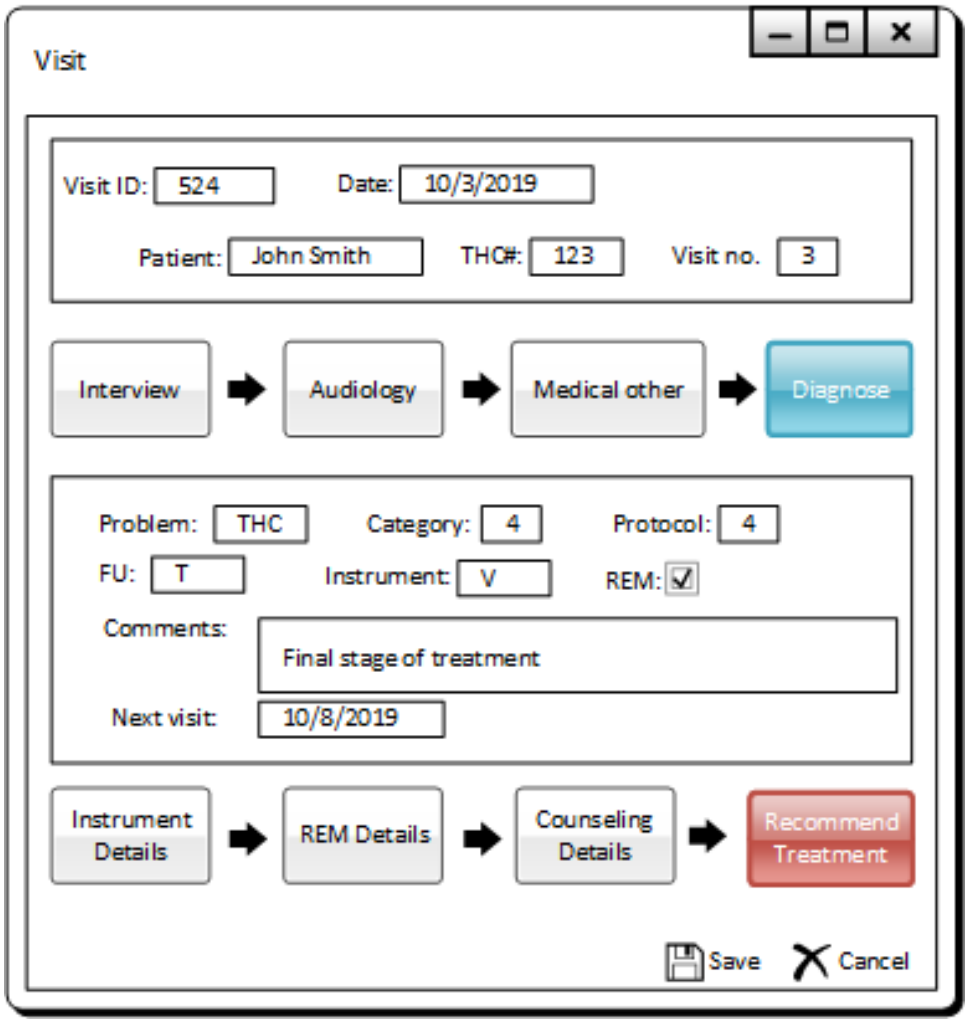

Figure 5: Sample Visit screen.

1.3.2 View/Edit Visits

Retrieves records about all visits in a table format (by default sorted by Visit ID #):

ID	Date	Patient	Visit	Prob	C	CC	Instr	REM	FU	Comments
534	4/10/2001	1-John Smith	3	HT	4	4	V	Y	T	doing well
535	4/10/2001	1-John Smith	4	LHT	4	4	V	N	T	w/SG helps

Operations on the data table:

- Select row in a table
- Unselect row in a table
- Filter table by Patient, Date
- Sort table by Visit ID, Date, C, CC, Instrument.

Options for the selected record

- View/Edit Visit
- Delete Visit
- Analyze

1.4 Interview Screen

- Upper panel: inactive fields (auto-filled by the system):
  - Visit ID - each visit has a unique ID in the system).
  - Visit's Date - auto-filled for the current date.
  - Patient's name.
  - Patient's THC#.
  - Visit's sequence number for the patient.
- Options
  - Initial / Follow-Up Interview Questionnaire
  - Tinnitus Handicap Inventory (THI) Questionnaire
  - Tinnitus Function Index New Questionnaire

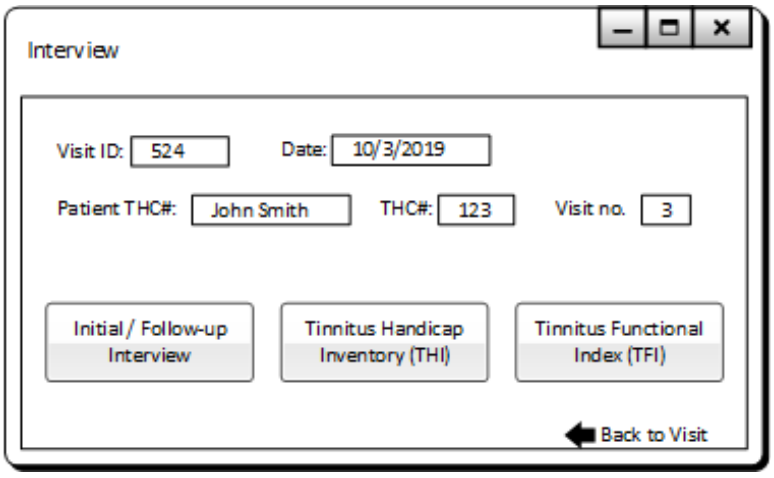

Figure 6: Sample Interviews screen.

1.4.1 Initial / Follow-Up Interview Screen

The Initial Interview is performed at the first visit. The Follow-up Interview is conducted at subsequent visits. The interview screens should follow the template of the paper versions of the questionnaires, provided as an appendix to this document. The upper panel of the screen should be auto-populated with the patient data and the current date. The questionnaire is divided into three sections related to the following hearing disorders: (1) Tinnitus; (2) Sound Tolerance; (3) Hearing Loss (HL).
Options:

- Save
- Cancel
- Help - provides hints to filling out the questionnaires

1.4.2 Tinnitus Handicap Inventory Screen

(THI or Neuman Questionnaire). The screen should replicate the template provided as an appendix to this document. The upper panel of the form should be auto-populated with the patient information and the current date. The main panel consists of 25 questions with three possible answers: Yes / Sometimes / No. The screen should also display the total score for function (F), emotion (E), catastrophic (C), and THI Score (Total Score) computed by the system after answering all questions, and the severity of tinnitus as determined by the scale provided at the bottom of the questionnaire in the appendix.
Questions: scored as 4=yes, 2=sometimes, 0=no. The lower the better.

- F-1 Difficult to concentrate?

- F-2 Difficult to hear people?
- E-3 Tinnitus make you angry?
- F-4 Tinnitus make you confused?
- C-5 Tinnitus make you feel desperate?
- E-6 Do you complain a great deal about your tinnitus?
- F-7 Trouble falling asleep at night?
- C-8 Do you feel like you cannot escape your tinnitus?
- F-9 Does tinnitus interfere with your ability to enjoy social activities?
- E-10 Tinnitus make you feel frustrated?
- C-11 Tinnitus make you feel like you have a terrible disease?
- F-12 Tinnitus make it difficult for you to enjoy life?
- F-13 Tinnitus interfere with your job or household responsibilities?
- E-14 Tinnitus make you often irritable?
- F-15 Tinnitus make it difficult for you to read?
- E-16 Tinnitus make you upset?
- E-17 Tinnitus has caused stress on your relationships with family and friends?
- F-18 Difficult to focus attention away from tinnitus and on to other things?
- C-19 Do you feel you have no control over your tinnitus?
- F-20 Tinnitus make you often feel tired?
- E-21 Tinnitus make you feel depressed?
- E-22 Tinnitus make you feel anxious?
- C-23 Do you feel that you can no longer cope with your tinnitus?
- F-24 Does your tinnitus get worse when you are under stress?
- E-25 Does your tinnitus make you feel insecure?
- Sc F total score function
- Sc E total score emotion
- Sc C total score catestrophic

- Sc T sum of the above
- Handicap severity: 0 to 16 - slight severity, 18 to 36 - mild, 38 to 56 - moderate, 58 to 76 - severe, 78 to 100 - catastrophic

Options:

- Submit - submit answers to the system, calculates total score
- Save - save current responses in the system
- Cancel
- Help - provides hints to filling out the questionnaires

1.4.3 Tinnitus Function Index Questionnaire

The screen should replicate the template provided as an appendix to this document. The questionnaire consists of 25 questions scored from 0 to 10 (10 bad) or in percentage (%).

- Q1 % aware
- Q2 loud
- Q3 in control
- Q4 annoyed
- Q5 cope
- Q6 annoyed
- Q7 concentrate
- Q8 think clearly
- Q9 focus attention
- Q10 fall/stay asleep
- Q11 as much sleep
- Q12 sleeping deeply
- Q13 hear clearly
- Q14 understand people
- Q15 follow conversation
- Q16 quite, resting activities
- Q17 relax

- Q18 peace and quiet
- Q19 social activities
- Q20 enjoyment of life
- Q21 relationships
- Q22 work on other tasks
- Q23 anxious, worried
- Q24 bothered upset
- Q25 depressed

Calculation of overall TFI Score The system should calculate overall TFI Score as follows:

1. Sum all valid answers from both TFI pages (maximum possible score = 250 if the respondent were to rate all 25 TFI items at the maximum value of 10).
2. Divide by the number of questions for which that respondent provided valid answers (yields the respondent's mean item score for all items having valid answers).
3. Multiply by 10 (provides that respondent's overall TFI score within 0-100 range).

Note: Overall TFI score is not valid if respondent omits 7 or more items. To be valid as a measure of tinnitus severity, the respondent must answer at least 19 items (76% of items).

Calculation of subscale scores The system should calculate the 8 subscale scores that adddress 8 important domains of negative tinnitus impact as indicated below. Each subscale has a breif title (in capital letters) and 1- or 2-letter abbreviation (e.g. I for Intrusive, Sc for Sense of Control): Each of the 8 sub-

Subscale Name (and conceptual content)	**Items in Subscale**
I: INTRUSIVE (unpleasantness, intrusiveness, persistence)	#1, #2, #3
SC: SENSE OF CONTROL (reduced sense of control)	#4, #5, #6
C: COGNITIVE (cognitive interference)	#7, #8, #9
SL: SLEEP (sleep disturbance)	#10, #11, #12
A: AUDITORY (auditory difficulties attributed to tinnitus)	#13, #14, #15
R: RELAXATION (interference with relaxation)	#16, #17, #18
Q: QUALITY OF LIFE (QOL) (quality of life reduced)	#19, #20, #21, #22
E: EMOTIONAL (emotional distress)	#23, #24, #25

scales consists of 3 items except for the Quality of life subscale, which consists of 4 items (SEE ITEMS LIST ABOVE). For valid subscale scores, no more than 1 item should be omitted. Computation of subscale scores is as follows:

1. Sum all of that respondent's valid answers for a given subscale.
2. Divide by the number of valid answers that were provided by that respondent for that subscale.
3. Multiply by 10. For the respondent in question, this procedure generates a subscale score in the range 0- 100 for each valid subscale.

Note: Do not compute a respondent's overall TFI score by combining that respondent's valid subscale scores, as the valid subscales may encompass a total number of items that is different from the number of items accepted as valid for the overall TFI score.

1.5 Audiology Screen

This screen is used to enter/edit data related to audiological evaluation of a patient at a medical facility.

- Upper panel: inactive fields (auto-filled by the system):
  - Patient's name.
  - Patient's THC#.
  - Visit's sequence number for the patient.
  - Visit's Date.
- Main panel: active fields (filled by the user):
  - Pure-tone audiogram tests for the right (R) and left (L) ear, in all frequencies in audiogram from 0.25 up to 12 kHz: R25, R50, R1, R2, R3, R4, R6, R8, R10, R12, L25, L50, L1, L2, L3, L4, L6, L8, L10, L12.
  - Right Ear: tinnitus pitch match (T PR), match type (T Rm) - PT/NB/NBN/WN, tinnitus loudness match T LR (in dB), Threshold of Hearing Th R, T RLs.
  - Left Ear: tinnitus pitch match (T PL), match type (T Lm) - PT/NB/NBN/WN, tinnitus loudness match T LL (in dB), Threshold of Hearing Th L, T Ls.
  - WNR / WNL
  - Minimal Masking Level: right ear - MRR, MRB, MBR, left ear - MRL, MLB, MBL
  - R SD / L SD

  - Pure-tone Loudness Discomfort Levels (LDL) tests for the right (R) and left (L) ear, measured in dB for all frequencies from 0.5 up to 12kHz: LR50, LR1, LR2, LR3, LR4, LR6, LR8, LR12, LRTP, LL50, LL1, LL2, LL3, LL4, LL6, LL8, LL12, LLTP
  - Additional Comments, i.e. "unable to do tinnitus matching", "pt had difficulty during tests", "improvement in LDLs".

- Options
  - Save - saves data in the system
  - Cancel - cancels data entry
  - Help - provides hints to audiology evaluation
  - Back - goes back to the Visit screen

1.6 Pharmacology Screen

This screen is used to enter/edit information about patient's additional medical information besides the hearing disorder., such as current diseases, treatment, medications taken.

- Upper panel: inactive fields (auto-filled by the system):
  - Patient's name.
  - Patient's THC#.
  - Visit's sequence number for the patient.
- Main Panel - lists medications currently added to the patient in a table format:

Med #	Medication	Generic	Dose	Duration	Cat chem
1	Paxil	Paroxetine hydrochloride	20 mg		phenylpiperidine
2	Tetracycline	Tetracycline	250 mg		tetracycline

Action	Application	Usual	T side
antidepressant	depression, OCD, social panic, anxiety	20-50 mg daily	Yes
bacteriostatic	infections caused by certain microorganisms	1-2 g in 2-4 equal doses	Yes

- Options
  - Add Medication - adds medication to the current visit - opens a dialog Add Medication
  - Save - saves data in the system
  - Cancel - cancels data entry
  - Back - goes back to the Visit screen

1.6.1 Add Medication Screen

Fields to choose/fill out by user:

- Medication name (from the dropdown)
- Dose
- Duration mo
- Comments

1.7 Instruments screen

The screen is used to add additional information about the sound instruments applied at the visit.

- Upper panel: inactive fields (auto-filled by the system):
  - Patient's name.
  - Patient's THC#.
  - Visit's sequence number for the patient.
  - Visit's Date.
  - Instrument category (based on information entered on the Visit screen)
  - Instrument type (based on information entered on the Visit screen)
- Main panel:
  - Instrument model - dropdown (chosen by the user)
  - Additional comments about the Instrument/sound therapy

1.8 REM Screen

This screen is used to enter detailed information about Real Ear Measurement (REM) performed at the visit.

- Upper panel: inactive fields (auto-filled by the system):
  - Patient's name.
  - Patient's THC#.
  - Patient's Category.
  - Visit's Date.
  - Instrument type (based on information entered on the Visit screen)
- The main panel - the following numeric measurements can be entered:
  - Right ear - Freq RE, Th R SPL, Mix R SPL, Mix R SL, Tol R SPL, Tol R SL, Max R SPL, Max R SL,
  - Left ear - Freq LE, Th L SPL, Mix L SPL, Mix L SL, Tol L SPL, Tol L SL, Max L SPL, Max L SL

1.9 Counseling screen

The screen is used to enter additional information about the counseling provided at the visit.

- Upper panel: inactive fields (auto-filled by the system):
  - Patient's name.
  - Patient's THC#.
  - Visit's sequence number for the patient.
  - Visit's Date.
  - Follow-up (FU) type
- Main panel:
  - Counseling details - long text

1.10 Analytics Screen

- Predict Diagnosis
- Recommend Treatment
- Manage Knowledge Base

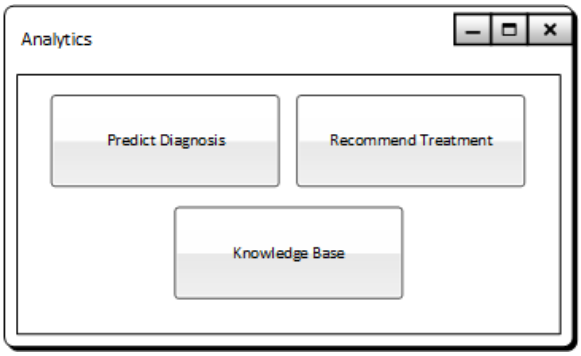

Figure 7: Sample Analytics screen.

1.11 Other Screen

The screen will be used to manage dictionary data in the database, such as geographical/location data, demographics data (occupations, work status), pharmacology data, and details about instruments used in sound therapy of TRT. The dictionary data will be used to populate choices in the dropdown in other

functionalities of the system. Some of the standard data, such as a list of countries, or list of states will be loaded into the system. Users of the system can later add or modify the dictionary data.

- Dictionary Data
  - Location Data
    - City
    - State
    - Country
  - Demographics Data
    - Occupation
    - Work Status
    - Educational Degree
  - Medical Data
    - Problem (i.e. tinnitus, hyperacusis, misophonia)
  - Pharmacology Data
    - Medication
    - Generic
    - Disease
    - Chemical Category
  - Instruments
    - Category
    - Model
    - Type

1.11.1 Location Data Screen

- Add/Edit City - code (auto-generated by the system), name
- Add/Edit State - abbreviation, name
- Add/Edit Country - abbreviation, full name

These data items should be pre-populated with standard location data and their standard abbreviations: US states, US cities, worldwide countries

1.11.2 Demographics Data

- Add/Edit Occupation - occupation id, name.
- Add/Edit Educational Degree - occupation id, name.
- Add/Edit Work Status - status id (auto-generated), full name (i.e. student, working, retired, home), abbreviation (i.e. S, W, R, H).

The dictionaries of occupation and educational degrees should be pre-filled with standard dictionaries for occupations and educational degrees.

1.11.3 Medical Data

- Add/Edit Hearing problem - code (id), full name (i.e. tinnitus, hyperacusis, hearing loss), abbreviation (i.e. T, H, L), description.

1.11.4 Pharmacology Data

- Add/Edit Medication - id, name, description, usual dose, generic, chemical category, application (disease)
- Add/Edit Generic - id, name, and description.
- Add/Edit Disease - id, name, and description.
- Add/Edit Chemical category - id, name, and description.

These dictionaries should be populated with standard data dictionaries for pharmaceuticals.

1.11.5 Sound Instruments Data

- Add/Edit Instrument Category - id, name (i.e. sound generator, combined, hearing aid), abbreviation (SG, CO, HA), and description.
- Add/Edit Instrument Type- id, category, name (i.e. Viennatone, GH-hard, GH-soft, hearing aid) abbreviation (i.e. V, GHH, GHS, HA) and description.
- Add/Edit Instrument Model- id, type, name, abbreviation, and description.

Data Dictionary of instruments, commonly applied within TRT, with their types and models.

- Sound Generators (SG)
  Types:
  - Viennatone (V), models: AmTi, BTE
  - GH-Hard (GHH), models: ITE, ST, TRI-COE
  - GH-Soft (GHS), models: ST, TRI-COE
- Hearing Aid (HA) - types:
  - HA: models: AIR-BTE, BTE, BTE P, CIC, CROS, Interton, ITC, ITE, Jazz-COE, Oticon, Phonak, Vivatone
  - CO: models: TCI-C
- Combined Instruments (CO) - types: CO, models: BTE, TCI-C, TCI-COE

2 Data Storage Specification

The system shall allow storing the data in a persistent, consistent and integral manner. A sample data model is presented in the Figure below as a relational model (storing data in related tables).

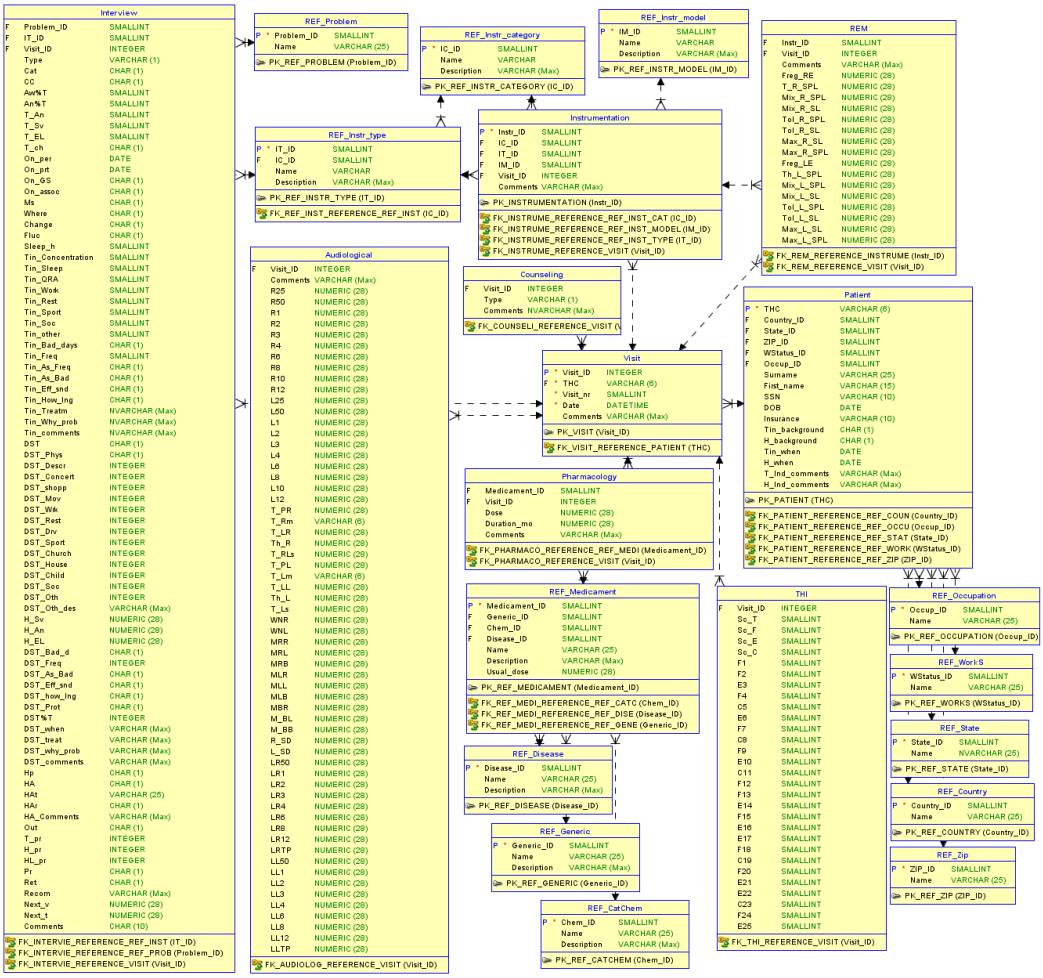

Figure 8: Sample data model (relational) for eTRT system.

3 Use Case Analysis

The actors of the system are: (1) Medical Assistants; (2) Physicians; (3) Patients. The functionalities of the system are divided into transactional functions, such as data entry and modification, and an analytical part. The latter supports physician's decisions in diagnosing and treating patients with data-driven, personalized medical advice. Medical assistants can enter and modify patient and visit data. Patients have access to electronic questionnaires. Physicians can add/modify both patient and visit data, as well as receive suggestions for classifying patients (diagnosis) and recommendations for choosing the treatment method.

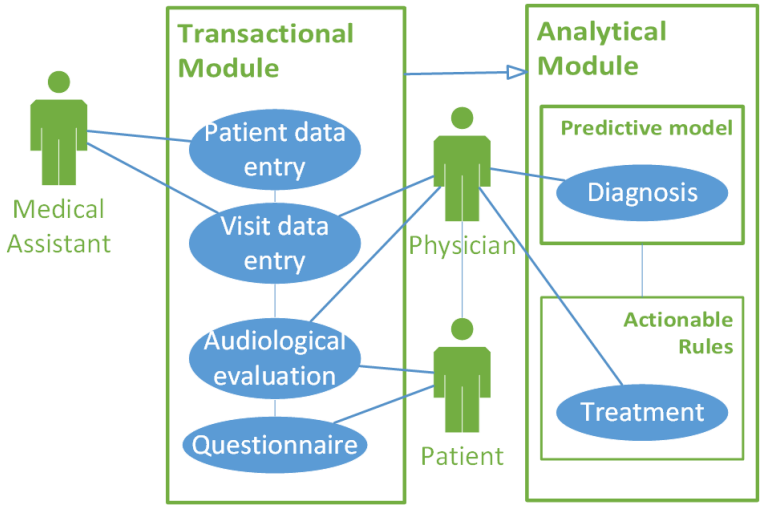

Figure 9: Use Case Diagram for eTRT system.

3.1 Add New Patient

1. The user enters the Main Screen.
2. The user chooses option Patients.
3. The system opens Patients screen
4. The user chooses the option Add New Patient.
5. The system opens the Add New Patient Screen and assigns a new THC# to the patient.
6. The user fills out the information about the new patient.
7. The user chooses the Save option.

8. The user closes the Add New Patient Screen.

Variation # 1: User adds additional Demographics data

1. After step 7, the user chooses Add Demographics option.
2. The system opens the Demographics Screen.
3. The user fills out additional information about the patient.
4. The user clicks the Save option.
5. The user closes the Demographics screen.

3.2 Edit Patient Data

1. The user enters the Main Screen.
2. The user chooses option Patients.
3. The system opens the Patients screen.
4. The user chooses option View/Edit Patients.
5. The system opens View/Edit Patients Screen.
6. The user selects the patient to be modified.
7. The system opens Add New Patient Screen.
8. The user updates data on a patient.
9. The user chooses the Save option.
10. The user closes the Add New Patient Screen.

3.3 Lookup Patient

1. The Lookup dialog appears.
2. The user enters the Patients name, THC# or SSN.
3. The system shows matching patients' records.
4. The user selects the patient record.

3.4 Add New Visit

Variation #1 Adding a new visit from the Patients screen

1. The user performs Add New Patient / Edit Patient
2. The user chooses the New Visit option.
3. The system opens the Visit screen and assigns a unique ID to the visit, adds a sequence number of the visit for the patient, and current date as a date of the visit.

Variation #2 Adding a new visit from the Main screen

1. The user enters the Main Screen.
2. The user chooses the option Visits.
3. The system opens the Visits screen.
4. The user chooses option Add New Visit.
5. The system opens the Visit screen and assigns a unique ID to the visit, and current date as a date of the visit.
6. The user enters the patient's THC #.
   VARIATION #2.1 If THC # not known, the user performs Patients Lookup.
7. The system auto-fills a name of the patient and a sequence number of the visit for the patient.

Next steps:

- The user fills out the information about the new visit.
- The user chooses the Save option.
- The user closes the Visit screen.

3.5 Fill out Interview Form

1. The user performs Add New Visit.
2. The user chooses the option Add Interview.
3. The system opens the Interview screen.
4. The user chooses the option Initial / Follow-Up Interview.
5. The user fills out the required information.
6. The user chooses option Save.

7. The system adds the interview data.

Variation #1 Adding Interview to the current visit

- The user performs Lookup Patient
- The user chooses the Current Visit option.
- Go to step 2.

3.6 Fill out the Tinnitus Handicap Inventory questionnaire

1. The user performs Add New Visit.
2. The user chooses the option Add Interview.
3. The system opens the Interview screen.
4. The user chooses option Tinnitus Handicap Inventory.
5. The user fills out the required information by answering Yes / Sometimes / No to the questions.
6. The user chooses option Submit.
7. The system calculates the THI Score and determines the severity of the problem.

Variation #1 Adding Interview to an existing visit by patient lookup

- The user performs Lookup Patient
- The user chooses the Current Visit option.
- Go to step 2.

Variation #2 Adding Interview to an existing visit by visit edit

- The user performs Edit Visits
- The user selects the record for the visit.
- The user chooses the option Edit Visit
- Go to step 2.

3.7 Fill out Tinnitus Functional Index questionnaire

1. The user performs Add New Visit.
2. The user chooses the option Add Interview.
3. The system opens the Interview screen.
4. The user chooses the option Tinnitus Function Index.
5. The user answers the questions scored 0-10 (10 - bad) or %.
6. The user chooses option Submit.

Variation #1 Adding Interview to an existing visit by patient lookup

- The user performs Lookup Patient
- The user chooses the Current Visit option.
- Go to step 2.

Variation #2 Adding Interview to an existing visit by visit edit

- The user performs Edit Visits
- The user selects the record for the visit.
- The user chooses the option Edit Visit
- Go to step 2.

3.8 Perform Audiology Evaluation

1. The user performs Add New Visit.
2. The user chooses the option Add Audiology.
3. The system opens the Audiology screen.
4. The user fills out the required information.
5. The user chooses option Save.

Variation #1 Adding Audiology to an existing visit by patient lookup

- The user performs Lookup Patient
- The user chooses the Current Visit option.
- Go to step 2.

Variation #2 Adding Audiology to an existing visit by visit edit

- The user performs Edit Visits
- The user selects the record for the visit.
- The user chooses option Edit Visit
- Go to step 2.

3.9 Add Pharmacology data

1. The user performs Add New Visit.
2. The user chooses the option Add Pharmacology.
3. The system opens the Pharmacology screen.
4. The user chooses the Add Medication option.
5. The user fills out the required information.
6. The system fills out additional information, based on the user's choice in the previous step: Generic name, Application (disease), Chemical category, Usual dose
7. The user closes the Add Medication window.
8. The user repeats steps 4-7 for each medication for the patient.
9. The user chooses option Save.

Variation #1 Adding Pharmacology to an existing visit by patient lookup

- The user performs Lookup Patient
- The user chooses Current Visit option.
- Go to step 2.

Variation #2 Adding Pharmacology to an existing visit by visit edit

- The user performs Edit Visits
- The user selects the record for the visit.
- The user chooses option Edit Visit
- Go to step 2.

3.10 Add Instrumentation details

1. The user performs Add New Visit.
2. The user chooses the option Add Instrument Details.
3. The system opens Instrument Details screen with some pre-filled fields.
4. The user fills out/chooses the required information.
5. The user closes the Instrument Details screen.

Variation #1 Adding Instrumentation details to an existing visit by patient lookup

- The user performs Lookup Patient
- The user chooses the Current Visit option.
- Go to step 2.

Variation #2 Adding Instrumentation details to an existing visit by visit edit

- The user performs Edit Visits
- The user selects the record for the visit.
- The user chooses option Edit Visit
- Go to step 2.

3.11 Add REM details

1. The user performs Add New Visit.
2. The user chooses option REM Details.
3. The system opens REM Details screen with some pre-filled fields.
4. The user fills out the required information.
5. The user closes the REM Details screen.

Variation #1 Adding REM details to an existing visit by patient lookup

- The user performs Lookup Patient
- The user chooses the Current Visit option.
- Go to step 2.

Variation #2 Adding REM details to an existing visit by visit edit

- The user performs Edit Visits
- The user selects the record for the visit.
- The user chooses option Edit Visit
- Go to step 2.

3.12 Add Counseling details

1. The user performs Add New Visit.
2. The user chooses option Counseling Details.
3. The system opens Counseling Details screen with some pre-filled fields.
4. The user fills out additional information about the counseling.
5. The user closes the Counseling Details screen.

Variation #1 Adding Counseling details to an existing visit by patient lookup

- The user performs Lookup Patient
- The user chooses the Current Visit option.
- Go to step 2.

Variation #2 Adding Counseling details to an existing visit by visit edit

- The user performs Edit Visits
- The user selects the record for the visit.
- The user chooses option Edit Visit
- Go to step 2.

3.13 Add/edit data dictionary item

3.13.1 Add/edit Location Data

1. The user enters the Main Screen.
2. The user chooses option Other.
3. The system opens Other screen
4. The user chooses option Dictionary data.
5. The system opens the Dictionary data screen.
6. The user chooses option Location data.
7. The system opens the Location data screen.
8. The user chooses the data item to add/edit and fills out/modifies the required information about the location item.
9. The user chooses the Save option.
10. The user closes the screen.

Variation #1: The user adds a new data item from the Patients screen.

1. The user performs Add New Patient
2. Go to step 6.

3.13.2 Add/edit Demographics Data

1. The user enters the Main Screen.
2. The user chooses option Other.
3. The system opens the Other screen.
4. The user chooses option Dictionary data.
5. The system opens the Dictionary data screen.
6. The user chooses the option Demographics data.
7. The system opens the Demographics data screen.
8. The user chooses the data item to add/edit and fills out/modifies the required information about the demographics item.
9. The user chooses the Save option.
10. The user closes the screen.

Variation #1: The user adds a new data item from the demographics screen.

1. The user performs Add New Patient
2. Go to step 6.

3.13.3 Add/edit Medical Data

1. The user enters the Main Screen.
2. The user chooses option Other.
3. The system opens the Other screen.
4. The user chooses option Dictionary data.
5. The system opens the Dictionary data screen.
6. The user chooses the option Medical data.
7. The system opens the Medical data screen.
8. The user chooses the data item to add/edit and fills out/modifies the required information about the medical item.
9. The user chooses the Save option.
10. The user closes the screen.

Variation #1: The user adds a new data item from the Interview screen.

1. The user performs Fill out Interview Form
2. Go to step 6.

3.13.4 Add/edit Pharmacology Data

1. The user enters the Main Screen.
2. The user chooses option Other.
3. The system opens the Other screen.
4. The user chooses option Dictionary data.
5. The system opens the Dictionary data screen.
6. The user chooses option Pharmacology data.
7. The system opens Pharmacology data screen
8. The user chooses the data item to add/edit and fills out/modifies the required information about the pharmacology item.
9. The user chooses the Save option.
10. The user closes the screen.

Variation #1: The user adds a new data item from the Pharmacology screen.

1. The user performs Add Pharmacology data
2. Go to step 6.

3.13.5 Add/edit Instruments Data

1. The user enters the Main Screen.
2. The user chooses option Other.
3. The system opens the Other screen.
4. The user chooses option Dictionary data.
5. The system opens the Dictionary data screen.
6. The user chooses option Instruments data.
7. The system opens Instruments data screen
8. The user chooses the data item to add/edit and fills out/modifies the required information about the instrument item.
9. The user chooses the Save option.
10. The user closes the screen.

Variation #1: The user adds a new data item from the Instruments screen.

1. The user performs Add Instrumentation details.
2. Go to step 6.

4 Non-functional requirements

4.1 Concurrency

The system shall allow multiple users to work with the system at the same time. Concurrency control mechanisms should be provided by the system.

4.2 Consistency

The data stored in the system should be consistent and integral.

4.3 Durability

The data should be stored in the system in a persistent manner.

4.4 Usability

The system should be easy to learn and easy to use.

4.5 Interpretability

The results of the system should be interpretable and understandable by the users.

4.6 Availability

The system should be available to users within standard working hours of a clinic. Functionalities for filling out questionnaires should be available 24/7.

4.7 Scalability

The knowledge base of the system (and its predictive/descriptive models) should be updated every 6 months.

TINNITUS / HYPERACUSIS
INITIAL INTERVIEW FORM

Clinic # :
Name :
DOB :
SSN :
Insurance :
Date :

T&HC#:

tel:
e-mail:

TINNITUS

RE / LE / Both / Head = > Intermittent / Constant
Onset: Gradual / Sudden When
Fluctuations in volume Y / N "Bad days" Y / N Frequency

Description of T sound(s)

Activities prevented or affected:
◯Concentration ◯Sleep ◯QRA ◯Work
◯Restaurants ◯Sports ◯Social ◯Other

Effect of sound: None / Louder / Softer
How long: min / hours / days

Ear overprotection Y / N % of time
in quiet Y / N
Any other T specific treatments

% of time when: Aware Annoyed
Severity: 0 1 2 3 4 5 6 7 8 9 10
Annoyance: 0 1 2 3 4 5 6 7 8 9 10
Effect on Life: 0 1 2 3 4 5 6 7 8 9 10

Why is T a problem

Comments:

SOUND TOLERANCE

Oversensitivity: Y / N Physical discomfort? Y / N "Bad days" Y / N Frequency
Description of troublesome sounds

Activities prevented or affected:
◯Concerts ◯Shopping ◯Movies ◯Work
◯Restaurants ◯Driving ◯Sports ◯Church
◯Housekeeping ◯Childcare ◯Social ◯Other

Effect of sound: None / Stronger / Weaker
How long: min / hours / days

Ear overprotection Y / N % of time
in quiet Y / N
Any other ST specific treatments

Severity: 0 1 2 3 4 5 6 7 8 9 10
Annoyance: 0 1 2 3 4 5 6 7 8 9 10
Effect on Life: 0 1 2 3 4 5 6 7 8 9 10

Why is ST a problem

Comments:

HL

Hearing problem Y / N
Hearing Aid(s) Y / N type:
Ever recommended Y / N

Category:
Recommendation:

Ranking problems: Tinnitus: 0 1 2 3 4 5
Sound tolerance: 0 1 2 3 4 5
Hearing: 0 1 2 3 4 5

Ptn decision:
Next visit:

T - tinnitus **ST** - sound tolerance (hyperacusis + phonophobia)
Is you T preventing or affecting any activities in your life.
QRA - quiet recreational activities: Is your T interfering with QRA such as reading or meditating.
% of time when: **Aware** - What % of time were you aware of your T over last month?
Annoyed - What % of the time over last months T bothered you?
Severity - How strong or loud is your T on average over last month? 0 - no T, 10 - as strong as you can imagine.
Annoyance - How much was T annoying you on average over last month 0 - not at all; 10 - as much as you can imagine.
Effect on life - How much was T affecting your life on average over last month. 0 - no effect; 10 - as much as you can imagine.
Any other T specific treatments - Are you using any other treatments for your T.
Sound tolerance - Is your tolerance to louder sounds the same as people around you?
Hearing - Do you think you have a hearing problem?
Ranking - rank importance of your problems with 0 - no problem, 5 - as large as you can imagine

FU

TINNITUS / HYPERACUSIS FOLLOW-UP INTERVIEW FORM

CATEGORY:
Date of init. couns.
T&HC#: Date of instr. fitt.
SG:
tel: HA:
FUQ #:
Month #:

Clinic # :
Name :
DOB :
SSN :
Insurance :
Date :

TINNITUS

Activities prevented or affected: Changes: Y / N
◯◯Concentration ◯◯Sleep ◯◯QRA ◯◯Work
◯◯Restaurants ◯◯Sports ◯◯Social ◯◯Other

% of time when: Aware (1st) Annoyed (1st)
Has it changed
Severity: 0 1 2 3 4 5 6 7 8 9 10
Annoyance: 0 1 2 3 4 5 6 7 8 9 10
Effect on Life: 0 1 2 3 4 5 6 7 8 9 10

Comments:

"Bad days" Y / N Frequency
Are they: as frequent Y /N as bad Y / N

Effect of sound: None / Louder / Softer
How long: min / hours / days

Ear overprotection Y / N % of time
in quiet Y / N
Any other T specific treatments

SOUND TOLERANCE HL

Description of troublesome sounds

Activities prevented or affected: Changes: Y / N
◯◯Concerts ◯◯Shopping ◯◯Movies ◯◯Work
◯◯Restaurants ◯◯Driving ◯◯Sports ◯◯Church
◯◯Housekeeping ◯◯Childcare ◯◯Social ◯◯Other

Severity: 0 1 2 3 4 5 6 7 8 9 10
Annoyance: 0 1 2 3 4 5 6 7 8 9 10
Effect on Life: 0 1 2 3 4 5 6 7 8 9 10

Comments:

"Bad days" Y / N Frequency
Are they: as frequent Y /N as bad Y / N

Effect of sound: None / Stronger/ Weaker
How long: min / hours / days

Ear overprotection Y / N % of time
in quiet Y / N
Any other ST specific treatments

Hearing problem

Recommendation:

The problem in general: Same / Better / Worse
Ranking problems: Tinnitus: 0 1 2 3 4 5
Sound tolerance: 0 1 2 3 4 5
Hearing: 0 1 2 3 4 5

Next visit:

How would you feel if you had to give back your instruments
Are you glad you started this program? Y / N / NS

Main problems discussed:

T - tinnitus **ST** - sound tolerance (hyperacusis + phonophobia)
Is you T preventing or affecting any activities in your life. ●○ - an activity affected at first visit
QRA - quiet recreational activities: Is your T interfering with QRA such as reading or meditating. ○● - an activity affected as for today
% of time when: Aware - What % of time were you aware of your T over last month?
Annoyed - What % of the time over last months T bothered you?
Severity - How strong or loud is your T on average over last month? 0 - no T, 10 - as strong as you can imagine.
Annoyance - How much was T annoying you on average over last month 0 - not at all; 10 - as much as you can imagine.
Effect on life - How much was T affecting your life on average over last month. 0 - no effect; 10 - as much as you can imagine.
Any other T specific treatments - Are you using any other treatments for your T.
Sound tolerance - Is your tolerance to louder sounds the same as people around you?
Hearing - Do you think you have a hearing problem?
Ranking - rank importance of your problems with 0 - no problem, 5 - as large as you can imagine

Tinnitus Handicap Inventory (THI)

This form is for informational purposes only and should not take the place of consultation and evaluation by a healthcare professional.

Your Name: _____ Date: _____

Instructions: The purpose of this questionnaire is to identify, quantify, and evaluate the difficulties that you may be experiencing because of tinnitus. Please do not skip any questions. When you have answer all the questions, add up your total score, based on the values for each response.

1.	Because of your tinnitus, is it difficult for you to concentrate?	○ Yes (4)	○ Sometimes (2)	○ No (0)
2.	Does the loudness of your tinnitus make it difficult for you to hear people?	○ Yes (4)	○ Sometimes (2)	○ No (0)
3.	Does your tinnitus make you angry?	○ Yes (4)	○ Sometimes (2)	○ No (0)
4.	Does your tinnitus make you feel confused?	○ Yes (4)	○ Sometimes (2)	○ No (0)
5.	Because of your tinnitus, do you feel desperate?	○ Yes (4)	○ Sometimes (2)	○ No (0)
6.	Do you complain a great deal about your tinnitus?	○ Yes (4)	○ Sometimes (2)	○ No (0)
7.	Because of your tinnitus, do you have trouble falling to sleep at night?	○ Yes (4)	○ Sometimes (2)	○ No (0)
8.	Do you feel as though you cannot escape your tinnitus?	○ Yes (4)	○ Sometimes (2)	○ No (0)
9.	Does your tinnitus interfere with your ability to enjoy your social activities (such as going out to dinner, to the movies)?	○ Yes (4)	○ Sometimes (2)	○ No (0)
10.	Because of your tinnitus, do you feel frustrated?	○ Yes (4)	○ Sometimes (2)	○ No (0)
11.	Because of your tinnitus, do you feel that you have a terrible disease?	○ Yes (4)	○ Sometimes (2)	○ No (0)
12.	Does your tinnitus make it difficult for you to enjoy life?	○ Yes (4)	○ Sometimes (2)	○ No (0)
13.	Does your tinnitus interfere with your job or household responsibilities?	○ Yes (4)	○ Sometimes (2)	○ No (0)
14.	Because of your tinnitus, do you find that you are often irritable?	○ Yes (4)	○ Sometimes (2)	○ No (0)
15.	Because of your tinnitus, is it difficult for you to read?	○ Yes (4)	○ Sometimes (2)	○ No (0)
16.	Does your tinnitus make you upset?	○ Yes (4)	○ Sometimes (2)	○ No (0)
17.	Do you feel that your tinnitus problem has placed stress on your relationships with members of your family and friends?	○ Yes (4)	○ Sometimes (2)	○ No (0)
18.	Do you find it difficult to focus your attention away from your tinnitus and on other things?	○ Yes (4)	○ Sometimes (2)	○ No (0)
19.	Do you feel that you have no control over your tinnitus?	○ Yes (4)	○ Sometimes (2)	○ No (0)
20.	Because of your tinnitus, do you often feel tired?	○ Yes (4)	○ Sometimes (2)	○ No (0)
21.	Because of your tinnitus, do you feel depressed?	○ Yes (4)	○ Sometimes (2)	○ No (0)
22.	Does your tinnitus make you feel anxious?	○ Yes (4)	○ Sometimes (2)	○ No (0)
23.	Do you feel that you can no longer cope with your tinnitus?	○ Yes (4)	○ Sometimes (2)	○ No (0)
24.	Does your tinnitus get worse when you are under stress?	○ Yes (4)	○ Sometimes (2)	○ No (0)
25.	Does your tinnitus make you feel insecure?	○ Yes (4)	○ Sometimes (2)	○ No (0)

The sum of all responses is your THI Score >>> 0

0-16: Slight or no handicap (Grade 1)
18-36: Mild handicap (Grade 2)
38-56: Moderate handicap (Grade 3)
58-76: Severe handicap (Grade 4)
78-100: Catastrophic handicap (Grade 5)

Newman CW, Jacobson GP, Spitzer JB. (1996) "Development of the Tinnitus Handicap Inventory." Archives of Otolaryngology - Head and Neck Surgery. 122(2):143-8.
McCombe, A., Baguley, D., Coles, R., McKenna, L., McKinney, C. & Windle-Taylor, P. (2001). "Guidelines for the Grading of Tinnitus Severity: the Results of a Working Group Commissioned by the British Association of Otolaryngologists, Head and Neck Surgeons." Clinical Otolaryngology. 26, 388-393.

TINNITUS FUNCTIONAL INDEX

Today's Date _____ Your Name _____

Month / Day / Year *Please Print*

Please read each question below carefully. To answer a question, select *ONE* of the numbers that is listed for that question, and draw a *CIRCLE* around it like this: (10%) or (1).

I **Over the PAST WEEK...**

1. What percentage of your time awake were you consciously **AWARE OF** your tinnitus?

Never aware ► 0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100% ◄ *Always aware*

2. How **STRONG** or **LOUD** was your tinnitus?

Not at all strong or loud ►0 1 2 3 4 5 6 7 8 9 10 ◄ *Extremely strong or loud*

3. What percentage of your time awake were you **ANNOYED** by your tinnitus?

None of the time ► 0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100% ◄ *All of the time*

SC **Over the PAST WEEK...**

4. Did you feel **IN CONTROL** in regard to your tinnitus?

Very much in control ►0 1 2 3 4 5 6 7 8 9 10 ◄ *Never in control*

5. How easy was it for you to **COPE** with your tinnitus?

Very easy to cope ► 0 1 2 3 4 5 6 7 8 9 10 ◄ *Impossible to cope*

6. How easy was it for you to **IGNORE** your tinnitus?

Very easy to ignore ► 0 1 2 3 4 5 6 7 8 9 10 ◄ *Impossible to ignore*

C **Over the PAST WEEK...**

7. Your ability to **CONCENTRATE**?

Did not interfere ► 0 1 2 3 4 5 6 7 8 9 10 ◄ *Completely interfered*

8. Your ability to **THINK CLEARLY?**

Did not interfere ► 0 1 2 3 4 5 6 7 8 9 10 ◄ *Completely interfered*

9. Your ability to **FOCUS ATTENTION** on other things besides your tinnitus?

Did not interfere ► 0 1 2 3 4 5 6 7 8 9 10 ◄ *Completely interfered*

SL **Over the PAST WEEK...**

10. How often did your tinnitus make it difficult to **FALL ASLEEP or STAY ASLEEP**?

Never had difficulty ► 0 1 2 3 4 5 6 7 8 9 10 ◄ *Always had difficulty*

11. How often did your tinnitus cause you difficulty in getting **AS MUCH SLEEP** as you needed?

Never had difficulty ► 0 1 2 3 4 5 6 7 8 9 10 ◄ *Always had difficulty*

12. How much of the time did your tinnitus keep you from **SLEEPING** as **DEEPLY** or as **PEACEFULLY** as you would have liked?

None of the time ► 0 1 2 3 4 5 6 7 8 9 10 ◄ *All of the time*

08.15.08

Please read each question below carefully. To answer a question, select *ONE* of the numbers that is listed for that question, and draw a *CIRCLE* around it like this: (10%) or (1).

A	**Over the PAST WEEK, how much has your tinnitus interfered with...**	*Did not interfere*										*Completely interfered*
	13. Your ability to **HEAR CLEARLY**?	0	1	2	3	4	5	6	7	8	9	10
	14. Your ability to **UNDERSTAND PEOPLE** who are talking?	0	1	2	3	4	5	6	7	8	9	10
	15. Your ability to **FOLLOW CONVERSATIONS** in a group or at meetings?	0	1	2	3	4	5	6	7	8	9	10

R	**Over the PAST WEEK, how much has your tinnitus interfered with...**	*Did not interfere*										*Completely interfered*
	16. Your **QUIET RESTING ACTIVITIES**?	0	1	2	3	4	5	6	7	8	9	10
	17. Your ability to **RELAX**?	0	1	2	3	4	5	6	7	8	9	10
	18. Your ability to enjoy "**PEACE AND QUIET**"?	0	1	2	3	4	5	6	7	8	9	10

Q	**Over the PAST WEEK, how much has your tinnitus interfered with...**	*Did not interfere*										*Completely interfered*
	19. Your enjoyment of **SOCIAL ACTIVITIES**?	0	1	2	3	4	5	6	7	8	9	10
	20. Your **ENJOYMENT OF LIFE**?	0	1	2	3	4	5	6	7	8	9	10
	21. Your **RELATIONSHIPS** with family, friends and other people?	0	1	2	3	4	5	6	7	8	9	10

22. How often did your tinnitus cause you to have difficulty performing your **WORK OR OTHER TASKS**, such as home maintenance, school work, or caring for children or others?

Never had difficulty ► 0 1 2 3 4 5 6 7 8 9 10 ◄ *Always had difficulty*

E	**Over the PAST WEEK...**

23. How **ANXIOUS** or **WORRIED** has your tinnitus made you feel?

Not at all anxious or worried ► 0 1 2 3 4 5 6 7 8 9 10 ◄ *Extremely anxious or worried*

24. How **BOTHERED** or **UPSET** have you been because of your tinnitus?

Not at all bothered or upset ► 0 1 2 3 4 5 6 7 8 9 10 ◄ *Extremely bothered or upset*

25. How **DEPRESSED** were you because of your tinnitus?

Not at all depressed ► 0 1 2 3 4 5 6 7 8 9 10 ◄ *Extremely depressed*

 08.15.08