GPD

User Manual

11. NOVEMBER 2022

VERSION 2

Content

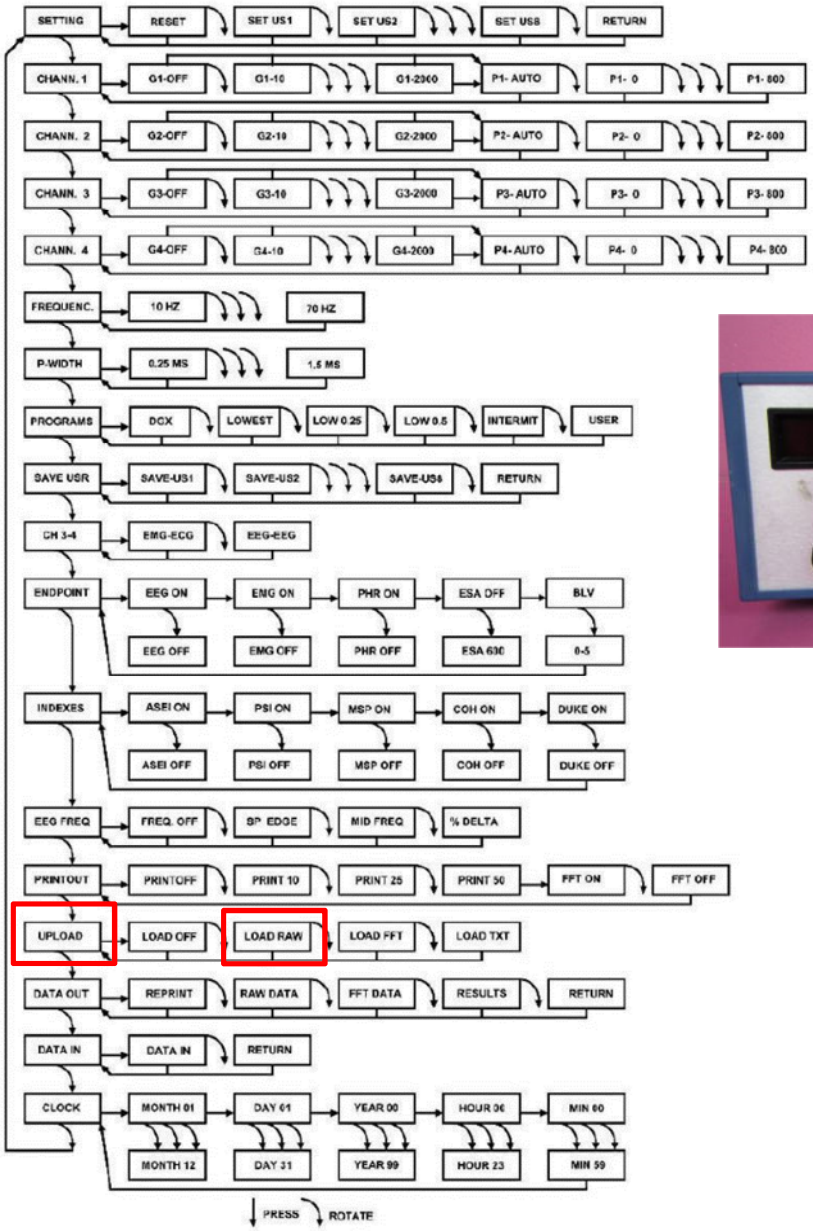
!ONLY CONNECT THYMATRON TO A LAPTOP IN BATTERY MODE! IT MUST NOT BE PLUGGED INTO A POWER SOCKET WHILE ATTACHED TO THE THYMATRON!

ATTENTION: GPD is a program for documentation purposes only, no therapeutic decisions may be based on its data. Data security is in the responsibility of the individual user.

!ONLY CONNECT THYMATRON TO A LAPTOP IN BATTERY MODE! IT MUST NOT BE PLUGGED INTO A POWER SOCKET WHILE ATTACHED TO THE THYMATRON!

1. Setting up THYMATRON 4 to automatically transfer data to GPD

Press the FLEXDIAL button (red), turn right until «--- UPLOAD» appears. Press FLEXDIAL and turn right again until « --- LOAD RAW» appears, press FLEXDAIL. Then, the data should be automatically transferred after each stimulation.



Flexdial Flowchart & Thymatron Flexdial (right side image; red circle)

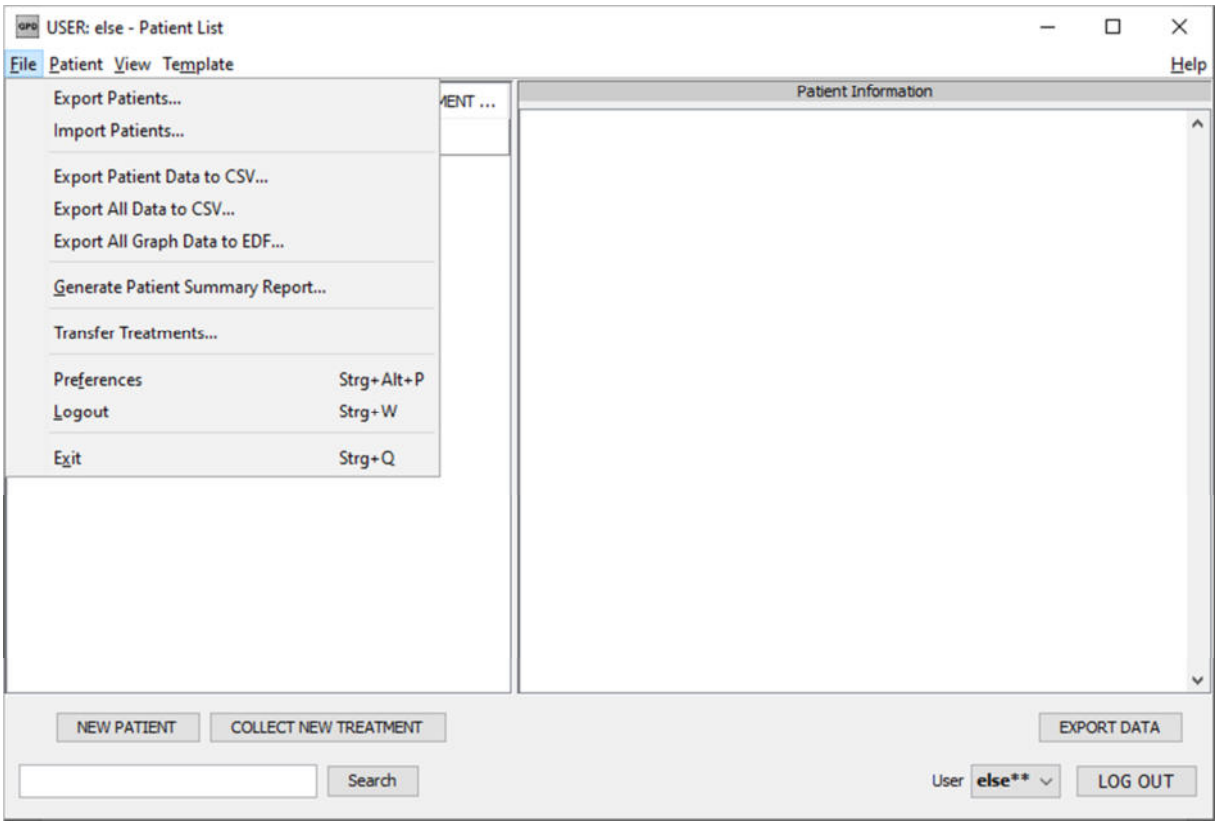
2. Installing GPD

a) If no previous GPD version exists:

- Download the portable and configured GPD version *GPD_Genet* from our website (use the link we sent).
- Discuss with local IT service solutions so that all people performing ECT have access to the same database. Possible solutions:
  - GPD stored locally on laptop (e.g. C:-drive)
  - Set up one user for all persons performing ECT
  - Install GPD on a protected hard disk or USB (be aware of data loss!)

b) If a previous GPD version already exists:

- Export all patients and treatment data of the current patient list by clicking *File→Export Patients...*. This will create a ZIP file containing all the data.
- Download the portable and configured GPD version *GPD_Genet* from our website (use the link that was sent along).
- Re-import previous patient data by clicking *File→Import Patients...* and selecting the corresponding ZIP file (see above).

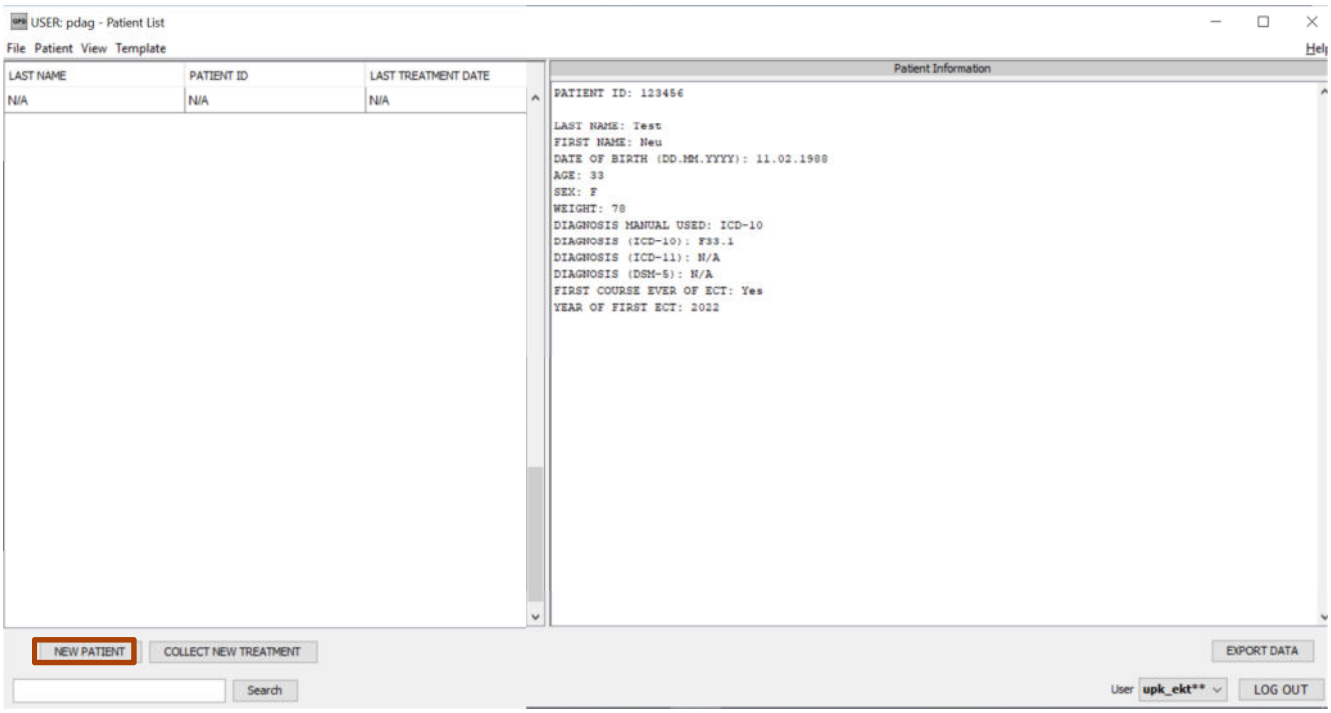


-

In both cases, be sure to have the current

3. Create new patients:

- **Please only add *new* patients to GPD, i.e. patients who are receiving an index treatment of the ECT series.**
- Click on «**NEW PATIENT**» and fill in the corresponding fields.
- If his/her diagnosis is not listed, please select «**Other (please specify here)**» and overwrite it.
- In case of typing errors: After filling in all fields, entries in the Patient Information window can be overwritten. E.g., if the wrong diagnosis manual was selected, please also adjust the diagnosis accordingly. For example, if ICD-11 was selected by mistake (DIAGNOSIS MANUAL USED) --> correct it there and also change the next field (DIAGNOSIS (ICD-10)) accordingly (i.e. DIAGNOSIS (ICD-11) instead of DIAGNOSIS (ICD-10)).
- If a patient returns for another index series update the fields
    - **PATIENT ECT SERIES NUMBER** must be incremented by one
    - **DIAGNOSIS** if the patient is treated for a different diagnosis. Previous diagnoses will still show up in the exported treatment data.
    - **AGE**

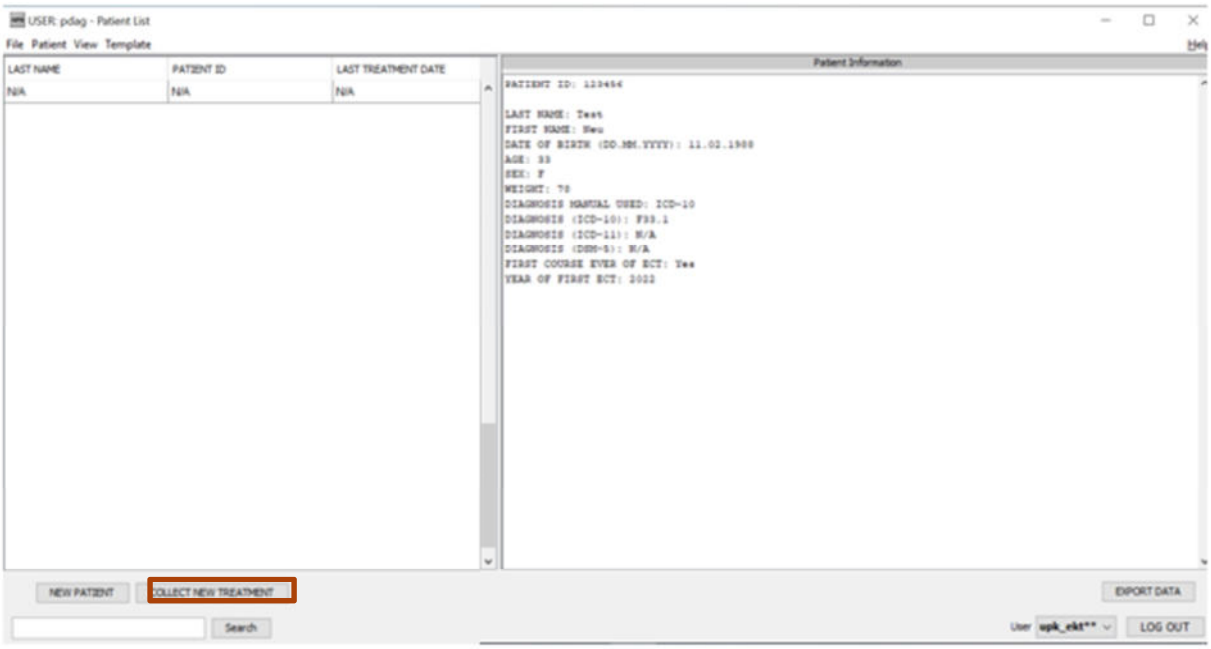


NOTE: If fields in patient information are not filled in completely, they will pop up again with every treatment. It does not help if they are filled in during the treatment, but they must be entered in the Patient Information window itself so that they do not pop up again.

EXCEPTION: Weight is queried every sixth treatment in order to document the course of it during treatment. In addition, Patient Status is asked every fourth treatment to document any changes during treatment.

4. Enter a new ECT treatment:

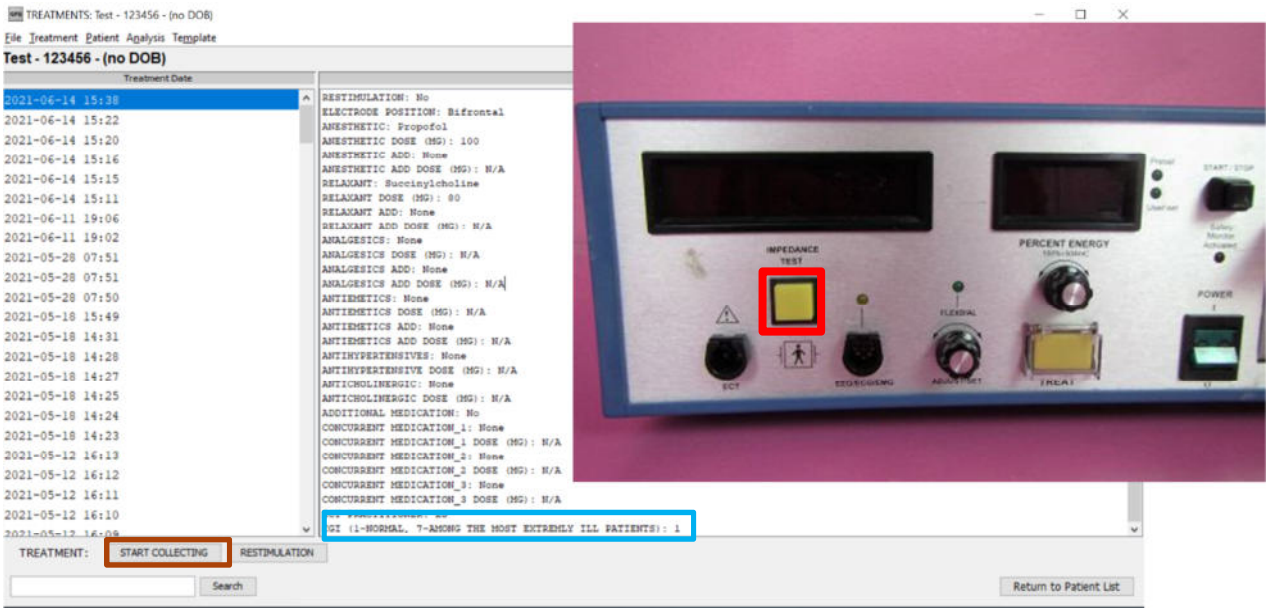
- Select patient by clicking on him/her once and then click on «**COLLECT NEW TREATMENT**»



- Fill in corresponding fields up to CGI-S-rating (last question, in blue below). If a drug is not listed, please select «**Other (Please specify here**)» and overwrite it directly. The ECT physician will assess the CGI score.

- Prepare patient in parallel (including the connection of EEG, (EMG) and stimulation electrodes).

- Then click on «**START COLLECTING**» and press the yellow button «**IMPEDANCE TEST**» at the Thymatron. The EEG recording appears on the screen (ATTENTION: before stimulation, Thymatron needs approx. a 5 sec rest to establish the baseline).



- During treatment (before stimulation, while EEG and ECG recording is running) each time after a medication is administered set the according **marker** (just press the corresponding number on keyboard):

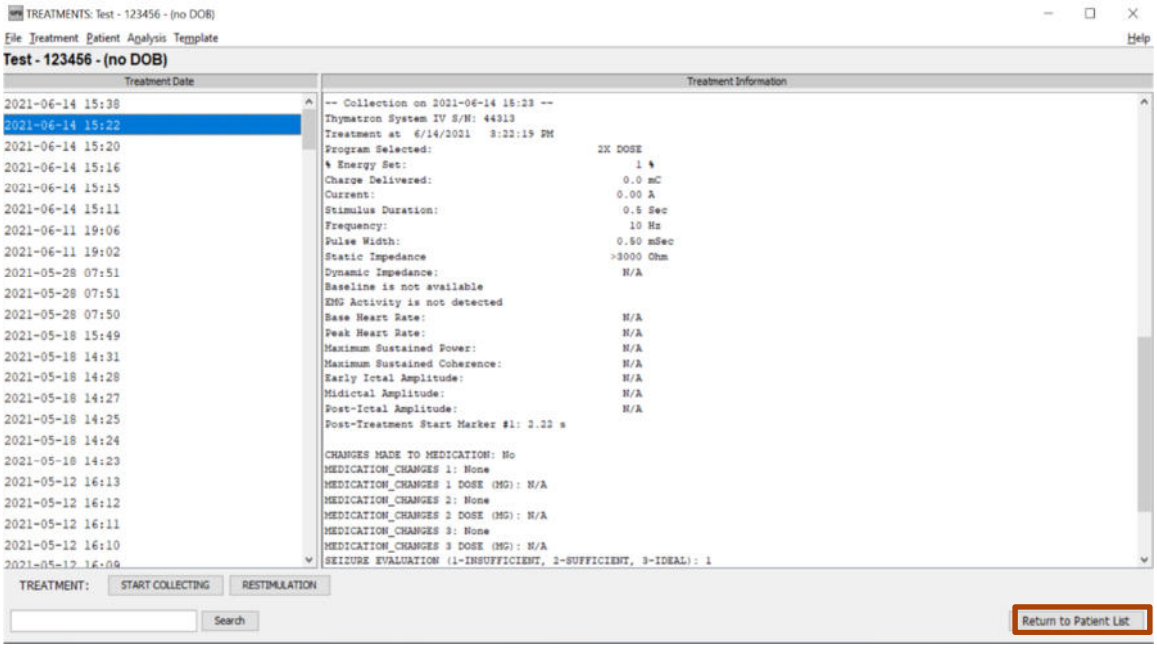
  Marker **1**: Anesthetics Administered
  (End of injection)

  Marker **2**: Relaxant Administered
  (End of injection)

  If possible, press **3** at end of seizure:
  Marker **3**: Seizure End (optional)

- After the treatment and after all data have been transferred (Thymatron flashes "OUT->->->" during data transfer), continue to fill in the corresponding fields:

  Changes to medication: refers to changes in previously entered medication. Please insert here only the additional amount you administered and not the total amount. For instance, if a patient was administered 80 mg of Propofol in the beginning and then a restimulation was needed where the patients was administered additional 20 mg of Propofol, please write then only 20 mg Propofol in "Changes to medication" and not 100 (i.e. 80 + 20).
  Recommendation: Recommendations for the next treatment (e.g. next time + 10%, change to Etomidate, add Caffeine, wait longer before stimulation, etc.).
  Comments: relevant medical information not directly related to ECT (e.g. add Ebrantil next time, add Güdel, ...)

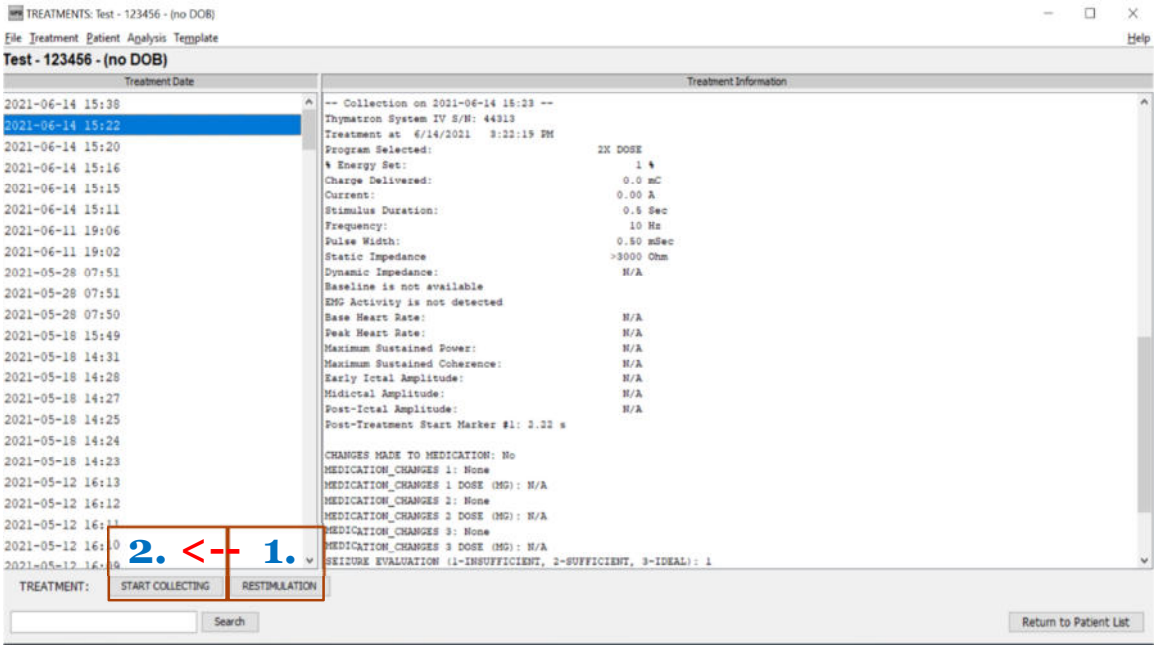


- Finally click on «**RETURN TO PATIENT LIST»**

- **If a treatment is missed (i.e. not entered in GPD), it should be entered manually using the THYMATRONS paper print-out. Even in the case that no information is obtainable for this specific treatment, a treatment should be added manually to ensure correct number of treatments for this patient**

5. Restimulation:

- In case of **restimulation** wait until the Thymatron has transferred all data and fill in the requested post treatment information.
- Then, click on «**RESTIMULATION**» → GPD prepares a new treatment for restimulation, e.g. takes over data from the previous treatment etc.
- After GPD has taken over medication etc. from the previous session, click on !!«**START COLLECTING**»!! and press «**IMPEDANCE TEST**» on the Thymatron. Afterwards, proceed as described under 2.



6. Possible Errors:

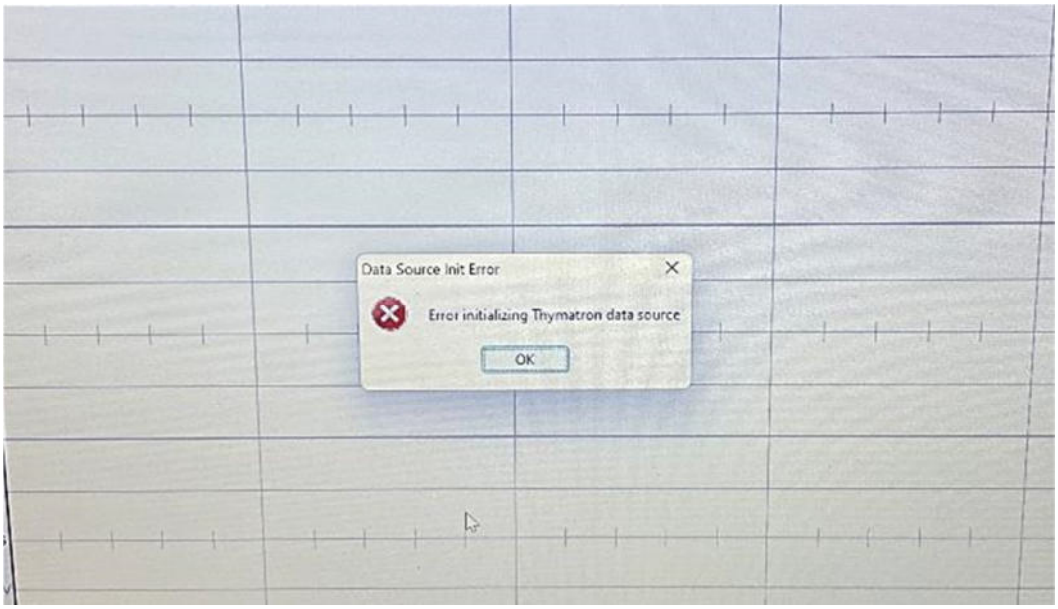
I. Data transfer from Thymatron to GPD does not work after successful stimulation

The current treatment data is stored on the Thymatron until

a) it is switched off or
b) the impedance key is pressed or
c) Start/Stop is pressed.

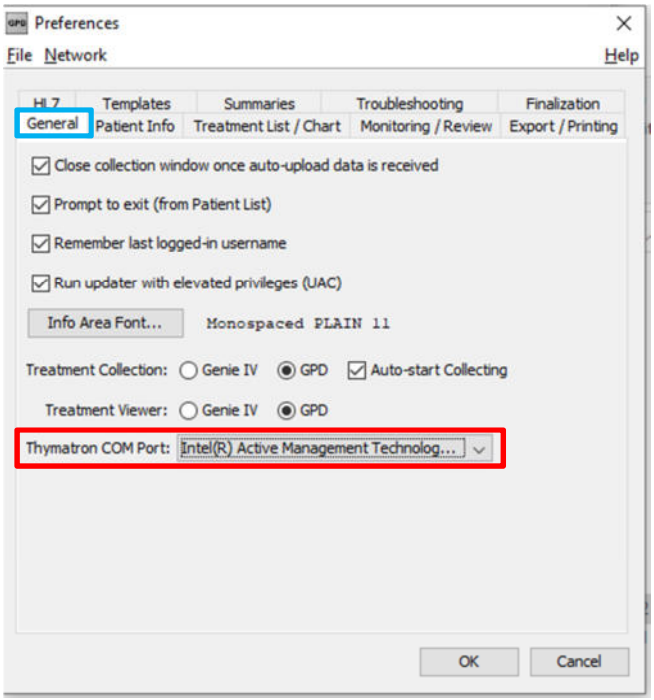
Please check if

1) Cable is connected correctly?
   2) COM-Port is detected?
2) In case of doubt, close GPD and open again or even shut down the laptop and start again.
3) Then open the corresponding treatment again (double click on patient -> select and click on the particular treatment) and click on START COLLECTING. The window displaying the EEG graph should appear.
4) Press the FLEXDAIL button (red), turn right until «--- DATA OUT» appears. Press FLEXDAIL and turn right again until « --- RAW DATA» appears, press FLEXDAIL. Data of the last session should then be transferred.



II. Error initiating Thymatron data source

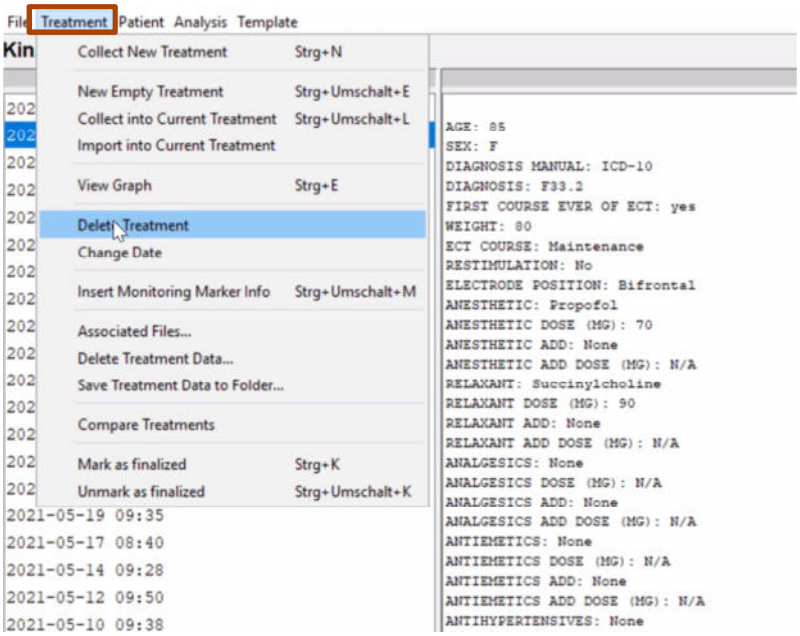
Find the correct port name for the cable you use by right-clicking on *This Computer* in the windows menu -> Manage -> Device Manager look for the cable name and memorize the COM Port otherwise just type in the search bar *device manager* and then proceed as just described. As soon as you have memorized the COM Port, open GPD and go to File -> Preferences, then a window will pop up (see picture below). Here go to the tap *General* (blue) and select the correct COM Port, you memorized before, for the Thymatron COM Port (red). Then, the error should be solved.



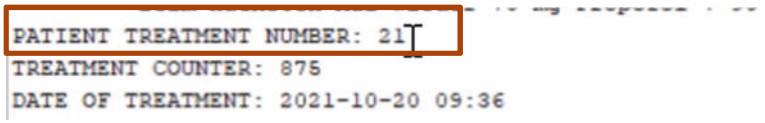
III. Treatment abortion

If a treatment is cancelled before stimulation (i.e. if no stimulation and seizure parameters were recorded), the treatment should be deleted in the GPD immediately:

click/mark treatment--> Treatment in the task menu--> Delete Treatment



However, if another treatment including a stimulation was performed and collect before the previous treatment (without a stimulation) was deleted , the Patient Treatment Number of the current treatment must be corrected after the previous treatment was deleted. This means that the patient treatment number must be subtracted by one in the current treatment (e.g. 21 -> 20).



IV. Further support

In case you need any further support, visit this website

https://github.com/elektrika-inc/GPD-wiki/wiki

https://genet-ect.org

or contact us via email:

contact@genet-ect.org

genet.steeringcommitee@gmail.com

7. Templates and Exporting Data

This part of the manual offers information on how to correctly place the GENET template files for the patient information and the treatment data entry in the GPD installation folder tree, and a step-by-step guide for data export.

Of important note: the settings file and template files that are described here are plain text files and can be edited with caution in a **plain text editor program**. In Microsoft Windows this is, e.g., the "notepad" or "editor" program, which is readily available on all Windows installations. **The plain text files cannot (should not) be edited with a text processing program such as Microsoft Word or alike! Also, editing on macOS can change the internal file structure and cause unforeseeable effects, even when edited with a plain text editor.**

V. GENET-GPD Configuration Pack

The template files are released by GENET as configuration packs to ensure a standard for data collection and compatibility for data sharing via the GENET Database (GENET-DB). As such, they reflect the idea of stability and sustainability and updates will only be released if absolutely necessary.

A current copy of the template files can be found in the download section of the GENET website, either as single package or bundled with the current release of the GPD software:

https://www.genet-ect.net/downloads/index.php

The single configuration package file is a zip-archive named like this:
"GENET GPD Templates vXYZ_yyyy_mm_dd.zip"

The zip-archive contains templates for data entry and export:

ChangeLog.txt	Information on changes to previous versions
GENET_DB_Export.vXYZ-2-tables.ftl	Export template
patient-template.txt	Template for the patient information page
treatment-template.txt	Template for the treatment data page

To make the templates available to your GPD installation, place all **template files** (**GENET_DB_Export.vXYZ-2-tables.ftl, patient-template.txt, treatment-template.txt**) into the **user** folder of your GPD installation and overwrite the existing ones.

When replacing the template files in the user folder, GPD must not be running!

Depending on the GPD installation type (regular vs. portable) you can find the user folder either here for the **regular installation**

C:\[some path]\GPD**user**

or here for the **portable installation**

C:\ [some path]\GPD\portable\appdata\GPD**user**

If unsure, just copy the files to both folders.

It is highly encouraged to install **GPD as portable application**! This ensures that all ECT practitioners (users) can access all patients that are listed in GPD, independent of the Windows account they are currently logged in with. A requirement for this is that the read/write permissions to the GPD installation folder and subfolders are unrestricted for the GPD users. This can be arranged for by your IT department.

VI. Data Entry Templates

The two template files patient-template.txt and treatment-template.txt determine the structure and the data fields of the patient information page and the treatment data collection page. They represent the minimum standard that it is required by the GENET-DB as published in Freundlieb, N., Schneider, E. et al. (2023)[1]. Some extensions have been introduced since, they are described here.

Patient Information Page

The fields of the patient information page are filled for each patient before the first ECT treatment recording. Some fields are copied to the treatment data page for each subsequent treatment. Most of the fields are self-explanatory, they are defined in Freundlieb, N., Schneider, E. et al. (2023); some are new and may need a comment, see Box 1. Especially the new field PATIENT ECT SERIES NUMBER needs some explanation. This index documents how many ECT series, i.e., index treatment blocks or active phases have been started with the same patient. This index is copied to the treatment data field CURRENT ECT SERIES NUMBER and allows the association/matching of an ECT series cycle with the accompanying clinical and cognitive data that was collected alongside the treatment series on the six time points T0-T5.

PATIENT ID: 123456	
LAST NAME: Devereaux	
FIRST NAME: Sophia	
DATE OF BIRTH (DD.MM.YYYY): 11.05.1960	
AGE: 65	
SEX: F	Biological sex at birth
GENDER: F	Gender; may differ from sex
WEIGHT: 73	
INITIAL STIMULATION HEURISTICS: Age	How the first energy setting is determined
DIAGNOSIS MANUAL USED: ICD-10	
DIAGNOSIS (ICD-10): F33.2	
DIAGNOSIS (ICD-11): N/A	
DIAGNOSIS (DSM-5): N/A	
PATIENT ECT SERIES NUMBER: 1	The current counter of ECT treatment series (= index + maintenance). Is copied to each treatment page. **Must be incremented, when patient starts a new treatment series!**
YEAR OF FIRST ECT: 2022	

Box 1. The patient information fields in template version v094:

[1] Freundlieb, N., Schneider, E., Brühl, A., & Kiebs, M. (2023). GENET-GPD: A documentation tool to digitally collect longitudinal ECT treatment data and associated biosignals. *Brain stimulation*, *16*(4), 1173–1175. https://doi.org/10.1016/j.brs.2023.07.053.

The patient information pages and the treatment data pages are represented in GPD as editable plain text after they were generated by the initial step-through process (text entry and drop-down boxes). In this way, patient information can easily be updated and entry mistakes can be fixed, but it is also a possible source of errors:

- It is extremely important to leave a colon (**:**) and a blank space ( ) between each field descriptor the field contents!
  For example:
  `LAST NAME: Devereaux`

- The guided step-through process with drop-down boxes ensures that the names of medication compounds used when entering the treatment data are free of spelling errors. When editing/typing substance names freely, mind the correct spelling!

Note: There is <u>no</u> undo or reversal of last entry (ctrl + z) in the patient information and treatment data editor! Also, any change on these text pages is immediately stored in GPD, no need for a "save button".

Treatment Data Page

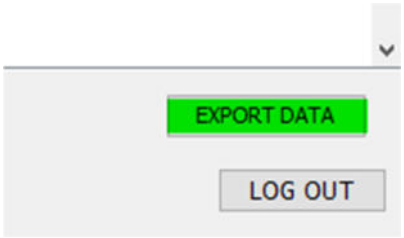
The fields in the treatment data page are also listed in Freundlieb, N., Schneider, E. et al. (2023).

The new patient information fields GENDER and CURRENT ECT SERIES NUMBER are also copied to the treatment data page when recording a new treatment. The patient information field CURRENT ECT SERIES NUMBER appears there as field PATIENT ECT SERIES NUMBER.

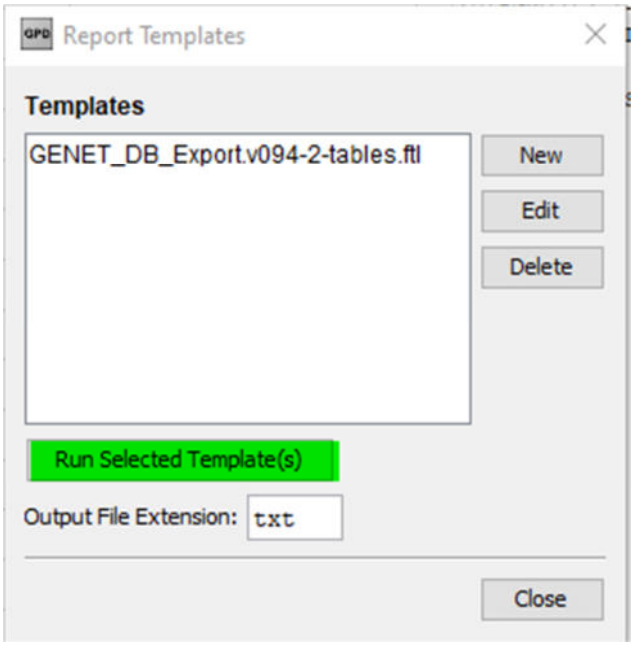
VII. GENET GPD Data Export Template

The GPD data can be uploaded to the GENET-DB via intermediary comma separated values text files (CSV). When running the special GENET-GPD export template (GENET_DB_Export.vXYZ-2-tables.ftl), two CSV files are generated; one for the patient information and one for the treatment data.

To initiate the data export, open GPD in the Patient List view and klick the EXPORT DATA button.



In the next dialog window, select the export template you want
to run (GENET_DB_Export.vXYZ-2-tables.ftl)
and click the Run Selected Template(s) button.

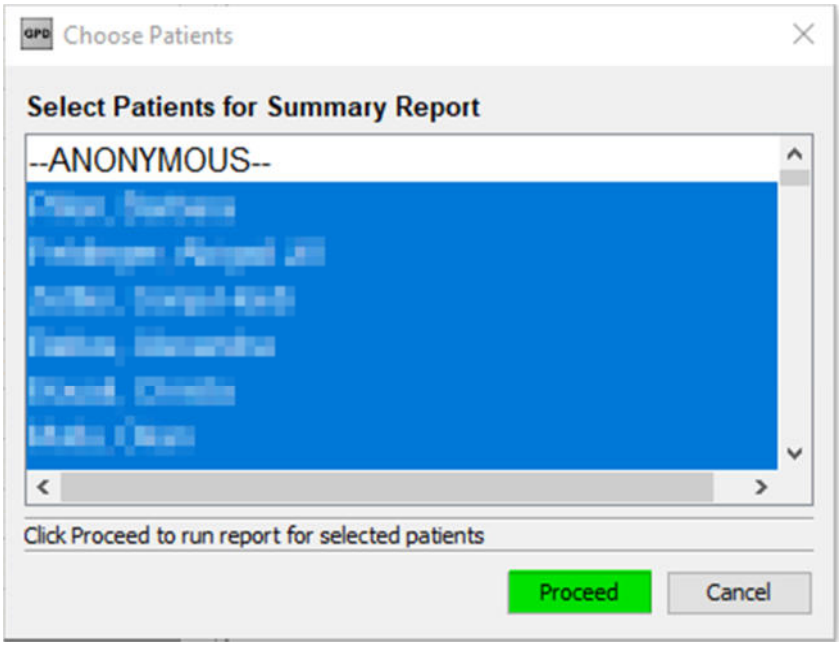


In the next dialog window, select all patients that you want to export,
the Windows standard selecting short cuts work here:

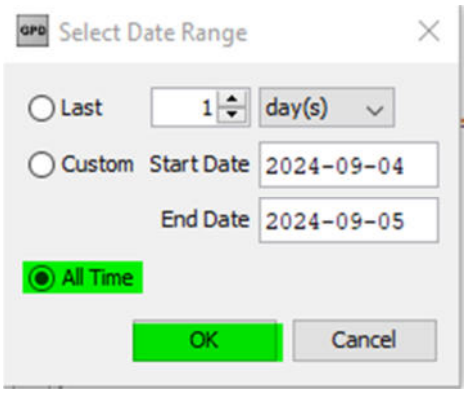
- CTRL + A → select all
- hold CTRL + klick → select/deselect single patients
- select one + hold SHIFT + klick another → select range between the two

Always deselect the --ANONYMOUS-- patient (this is just a technically necessary pseudo-patient).

Then Proceed.



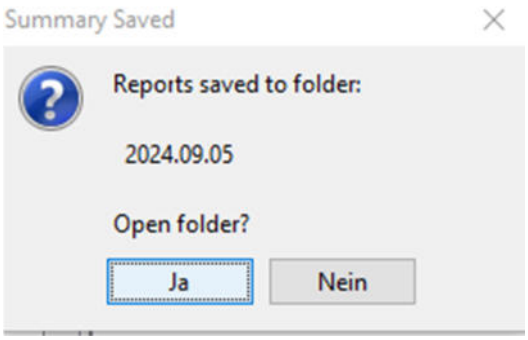
The next dialog window offers to select a time frame for the exported treatments.
For example, to export of **all treatments** select All Time and continue with Ok.
Alternatively, define a time frame of your interest by the time window selector or by date.



Then a standard Windows save dialog opens and you can choose a destination for the two export files.

After choosing the folder and acknowledging with Ok, GPD will start the export; this may take a while depending on the number of exported treatments, there is no progress indicator.

When the export is completed, GPD notifies that with a little window offering to open the destination folder.



And the export is done.

The column structure of the two resulting CSV files (one for the patient information, one containing the treatment data) is such that the files are ready to be uploaded into the GENET-DB. The decimal separator is the dot (.) and the columns are separated by comma (,)! Decimal separator and column separator can be adjusted on the upload page, but be aware that it needs to match how it is in the CSV files.

Before attempting the upload, please be sure that the fields that should contain numeric values indeed do contain numeric values. Invalid field contents will be listed when uploading, so you can check back with the data source.

It is a question of personal preference, whether the data is corrected in GPD or in the exported table.

It is, however, important to note that if you are usually using Excel to work with data tables, please be aware that Excel changes the “date_of_treatment” column from ISO format YYYY-MM-DD to the local format, i.e., for Austria/Germany/Switzerland to DD.MM.YYYY! For that reason I highly recommend the freeware LibreOffice Calc to work with the data table, because it does not change the date format and the edited table is by default saved back to the comma separated format. Excel also is uneasy with this aspect, since it changes the decimal sign to the local one (comma) and writes back to file a semicolon separated format, which cannot be readily uploaded to the database. As mentioned above, the decimal separator and column separator can be adjusted on the upload page, but it must be done explicitly to match the CSV file structure.

If you are working in a very restricted IT environment and would like to try LibreOffice Calc, there exists a portable version that would run directly out of its folder from any location in your filesystem, without installation.

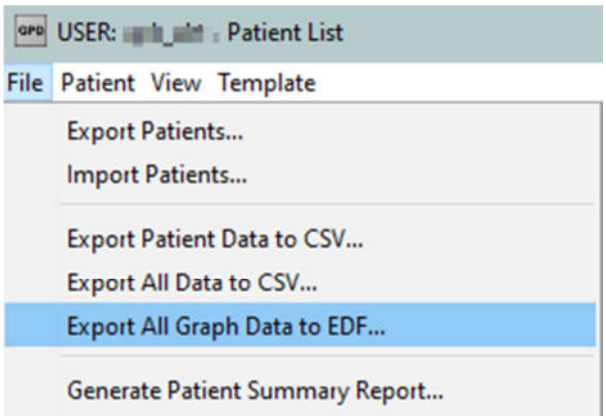
For data importing to the GENET-DB refer to the dedicated Manual.

VIII. EEG Data Export to EDF

The EEG and ECG recordings of the ECT treatments can be exported as EDF files (European Data Format) for analysis with EEG processing software.

Export all EDF files to a folder:

GPT Patient List view → Menu "File" → "Export All Graph Data to EDF..."



Then pick a folder in the upcoming dialogue and export.

For each treatment, two EDF files are exported. One holds the entire recording with all the preparation time before the stimulation (larger file) and the other (smaller file) contains only a cut-out of the post-stimulation part, i.e., the seizure until the recording is stopped.

The two files share the same file name, which is composed of the GENET ID and a **timestamp** that corresponds to the "DATE OF TREATMENT" field on the treatment data page. They are distinguished by an added index 1 or 2. The **indexing** is done so that the #1 in most cases is the seizure cut-out and #2 the whole, but not consistently. If there were more than two EDF files for a treatment, something is wrong, e.g., a second treatment was recorded into the first, which should not happen.

Example for a pair of EDF files:

1. 42431_123456_20240816073909-**1**.edf – size 67 kb → smaller → seizure only
2. 42431_123456_20240816073909-**2**.edf – size 611 kb → larger → whole recording

To match the EDF files with the exported treatments, the identifying portion of the filenames are present in the treatments data table in the column 'edf_file_name'. However, the timestamp part in the data table column is actually two digits shorter, because the information on seconds is missing there:

EDF filename: **42431_123456_20240816073909**-1.edf
Entry in column 'edf_file_name': **42431_123456_202408160739**

The two resulting, correctly named EDF files are ready for uploading to the GENET database. EDF upload is done on a different system than the REDCap web application.