

# Automated report generation

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## Instructions for use

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# 1 Introduction

This program automatically generates usability testing reports for medical devices. The design of the generated reports has been developed in such a way that they satisfy the guidelines established in the medical device standards. The generated reports best describe usability testing that has been performed using eye tracking methods, but they can also be used for other types of medical device testing. To generate these documents, the inputs that can be provided are simple parts of text, eye tracking data obtained through programs such as *cGOM* or *Tobii Pro Lab*, or pictures. The program will then take care of the formatting and the layout and will create graphs and tables to visualize the data.

Please follow these instructions to generate a usability testing report automatically.

You should be able to run the program by following **only the instructions written on the images**. However, you can always **read the accompanying text if you need more details**.

## 2 Installation

### 2.1 Download Git repository

#### Download project repository

In order to have the repository that contains the program and the files on your computer, you have to **download it from GitHub**. You can find it using this link:

[https://github.com/how2know/Usability\\_Testing\\_Report\\_Generator](https://github.com/how2know/Usability_Testing_Report_Generator)

Once you are on the GitHub repository webpage, you can click on the **green “Code” button**, and then on the **“Download ZIP” button** to download the repository on your computer.

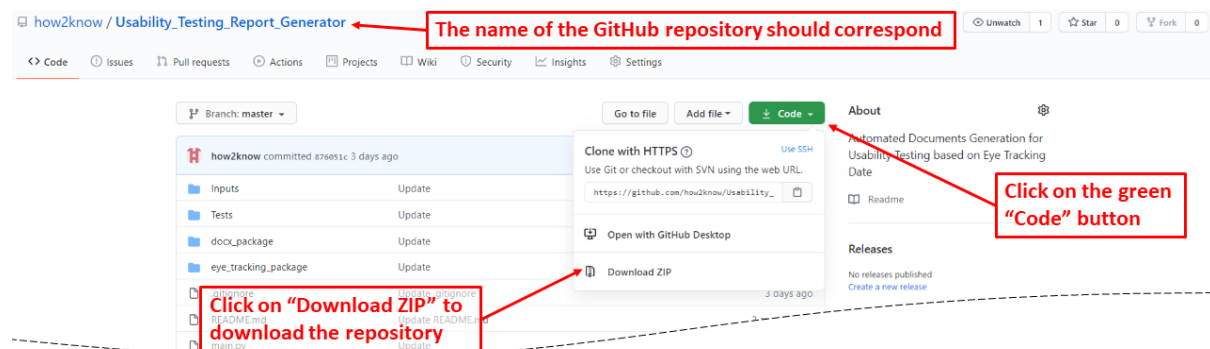


Figure 1: Click on the green “Code” button, and then on the “Download ZIP” button to download the repository on your computer.

Once you have downloaded the repository, you can **open the .zip file** that you have just downloaded and copy-paste the directory *Usability\_Testing\_Report\_Generator-master* at the location you want. It is also possible to rename the directory if you want to.

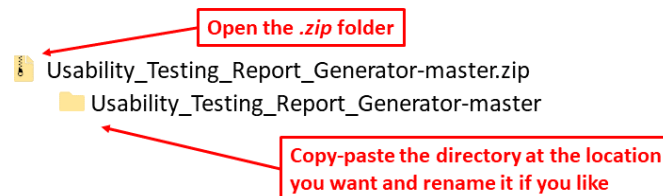


Figure 2: Open the .zip folder and copy-paste the directory at the location you want and rename it if you like.

## 2.2 Python installation

### Install Python

If you already have Python 3 installed on your computer, you can **skip this step**.

It is necessary to have Python 3 installed on your computer to run the program. If you do not have it, you can download it from the official Python website:

<https://www.python.org/downloads/>

You can click on the **“Download Python 3.X.X”** button to download the latest version of Python. Then, you can **run the downloaded *python-3.X.X.exe* file** and follow the instructions on your screen for the installation. You only have to make sure to check **“Add Python 3.X to PATH”** during the installation.

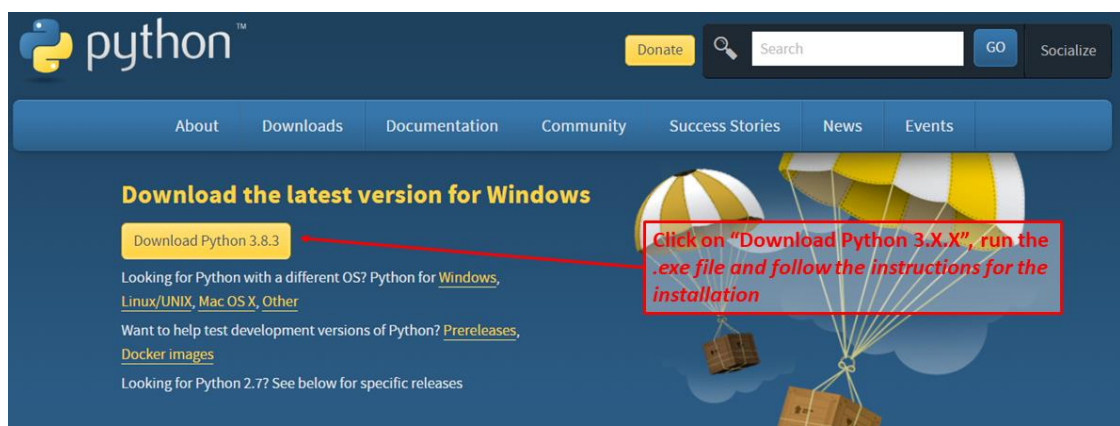


Figure 3: Click on “Download Python 3.X.X” to download the latest version of Python, run the downloaded .exe file and follow the instructions on your screen for the installation.

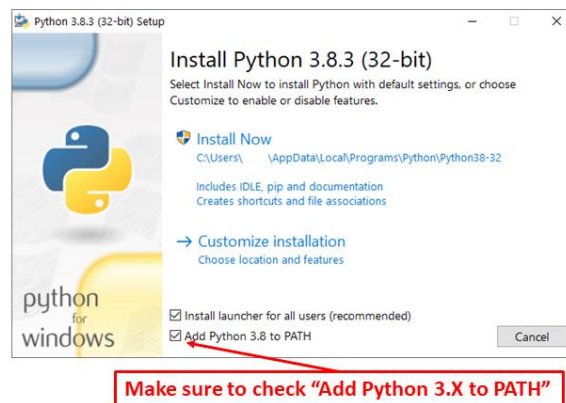


Figure 4: Make sure to check “Add Python 3.X to PATH” during the installation.

## 3 Inputs

### 3.1 Text input form

The text input form is a *.docx* file that can be opened with *Microsoft Word* and is located in the *Inputs* directory. It is a restricted document, which means that it is only possible to write the **inputs in the white boxes** and the rest of the document (grey boxes and titles) cannot be edited. The chapters of the text input form follow the same order as in the report. **Every input is optional**, which means that the report will be generated even if some boxes are left blank.

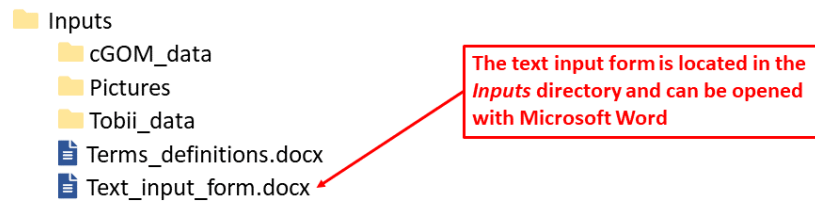


Figure 5: The text input form is located in the *Inputs* directory and can be opened with *Microsoft Word*.

The restriction of the document can be stopped in *Microsoft Word* using the password “stop”.

#### 3.1.1 General information, cover page and header

##### Give information about the study, the cover page and the header

On the first page of the text input form, you can give general information about the study, the cover page, and the header. You can fill the white boxes with text or number in order to give the different inputs. **All text should be written in small letters**, except the proper nouns which can have a capital letter at the beginning. This is relevant if you are then using parameters in your paragraphs (see *Add paragraphs*).

Title and subtitle	
Title	medical device usability testing
Subtitle	formative study 3

Information about document approval	
Author's name	Charlie Chaplin
Author's function	actor
Reviewer's name	Nelson Mandela
Reviewer's function	political leader
Approver's name	Albert Einstein
Approver's function	physicist

Write text or number in the white boxes

Write proper nouns with a capital letter

But keep the rest in lowercase

Figure 6: Write the inputs in the white boxes of the first. All text should in lowercase, except the beginning of the proper nouns.

A **summary of the inputs and their meaning** is presented below:

- Type of study: ----- Type of the study, e.g. “formative study”, “summative study”
- Study number: ----- Number of the study, e.g. “3” if this is the third formative study
- Identification number: ---- Identification number of the report
- Number of participants: --- Number of participants that took part in the study
- Number of critical tasks: -- Number of critical tasks that were performed during the study
- Title: ----- Title of the report
- Subtitle: ----- Subtitle of the report
- Author’s name: ----- Name of the author of the report
- Author’s function: ----- Function of the author of the report
- Reviewer’s name: ----- Name of the person that reviewed the report
- Reviewer’s function: ----- Function of the person that reviewed the report
- Approver’s name: ----- Name of the person that approved the report
- Approver’s function: ----- Function of the person that approved the report
- Firm name:----- Name of the firm that will appear in the header
- Header title: ----- Title of the report that will appear in the header
- Version / ID: ----- Version or ID number that will appear in the header

Refer to *Add picture captions* to see how to **insert a caption for the picture of the cover page**.

### 3.1.2 Classical chapters

The classical chapters represent all chapters and subchapters of the report except “Definitions” and all subchapters of “Results”. They all have the same structure and are defined in the same way through the text input form.

#### Add paragraphs

For every chapter, you can **write the paragraphs in the white boxes under the chapter heading**. As the form is restricted, you are not allowed to add special features such as bullet lists, numbered lists, etc. If you want to add such features in your text, you will have to do it later manually (see *Add last features*).

It is also possible to insert up to three parameters in your paragraphs. A parameter works like a variable. To add a parameter, you have to write {0}, {1} or {2}, which refer to the corresponding parameter, at the place of your paragraph where you want the parameter (see example in *Figure 7*). You must then add a value to the corresponding parameter by choosing one of the options proposed in the drop-down list. These options correspond to other inputs that you can give on the first page of the text input form.

**Input**

**Purpose**

Please write the chapter text below:

This is the first paragraph of the chapter "Purpose". Everything you write here will be added to the report.

This is the second paragraph of the chapter. You can write anything you want, but you should not change the style of these paragraphs.

You can also use parameters in your text if you like: this is the {0} number {1}.

Parameter	Reference	Value
Parameter 0	{0}	Type of study
Parameter 1	{1}	Study number
Parameter 2	{2}	-

**Output**

**Purpose**

This is the first paragraph of the chapter "Purpose". Everything you write here will be added to the report.

This is the second paragraph of the chapter. You can write anything you want, but you should not change the style of these paragraphs.

You can also use parameters in your text if you like: this is the formative study number 3.

**Figure 7 annotations:**

- Write the chapter text in the white box
- Include reference to parameters
- Select parameters values
- Your text will be written in the report including the parameters

Figure 7: Write the chapter paragraphs in the white box and include parameters if you like. For example, if you write “This is the {0} number {1}.” in the paragraph box and you choose “Type of study” as Parameter 0 and “Study number” as Parameter 1, the output text in the report will be “This is the formative study number 3.” given that your inputs for “Type of study” and “Study number” were “formative study” and “3” respectively.

Parameters are interesting in the case where you reuse the same structure for a chapter across different studies. For example, except for a few exceptions such as study number, type of study or number of participants, a chapter will often not change much between two studies of the same device. Therefore, it is possible to simply reuse the same text by only changing the input given for the parameter value.



## Add picture captions

For each chapter, you also have the possibility to **add up to three pictures and their caption** in the report (see *Add pictures* for adding pictures in the report). To add a caption, you can write text in the white box next to the name of the added pictures. The caption will then be added below the corresponding picture.

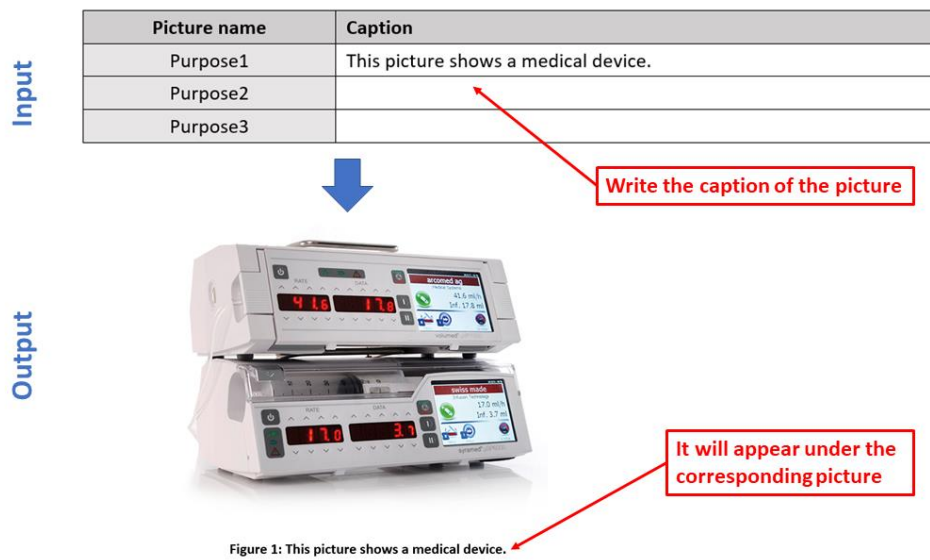


Figure 8: Write the caption next to the name of the picture and it will be added to the report.

### 3.1.3 Definition chapter

#### Add definitions

You can add the definition of some terms in the report. To add the definition of a term, you simply have to **select “Yes” in the drop-down list located next to the term you want to define**. All selected definitions will then be added to the report in alphabetical order. Each added definition will be followed by a reference to the standard from which it is taken.

IEC 62366-1

Abnormal use	No
Accompanying documentation	No
Correct use	No
Formative evaluation	Yes
Hazard-related use scenario	No
Normal use	No
Patient	Yes
Primary operating function	No
Summative evaluation	Yes
Task	No

Usability	No
Usability engineering	Yes
Use environment	No
Use error	No
Use scenario	Yes
Use specification	No
User	No
User group	No
User interface	Yes
User interface specification	No

Choose “Yes ” or “No” to specify which terms you want to define in the report

Figure 9: Choose the terms you want to define in your report by selecting “Yes” or “No”.

The **standards from which the definitions are taken** are the EU Regulation 2017/745 [1], the IEC 62366-1 [2] and the FDA Guidance: Applying Human Factors and Usability Engineering to Medical Devices [3]. You can **find all definitions in the file *Terms\_definitions.docx*** located in the Inputs directory. This document is also restricted and cannot be edited, but the restriction can be stopped using the password “stop”.

### 3.1.4 Result chapters

#### Give information about critical tasks

In order to perform the effectiveness analysis and time on tasks analysis properly, the critical tasks must be defined beforehand. You can **define up to 15 critical tasks by writing their name and a small description** in the corresponding white boxes.

Information about critical tasks

Critical task	Name	Description
Critical task 1	Opening	The user opens the box.
Critical task 2	Disinfection	The user disinfects the material.
Critical task 3	Collecting samples	The user collects the samples of blood.
Critical task 4	Storing	The user stores the samples in the cold room.
Critical task 5	Cleaning	The user cleans the workplace.
Critical task 6		
Critical task 7		
Critical task 8		

Write the name of the critical task

Give a small description of the task

Figure 10: Write the name and a small definition of the critical tasks in the corresponding white boxes.

#### Perform an analysis

At the beginning of each subchapter of the “Results” chapter, you are asked if you want to perform the analysis. Choose “Yes” or “No” to answer the question. If you choose “Yes”, a subchapter that shows the result of the analysis and its discussion will be added to the report. If you choose “No”, the analysis will not be performed and the subchapter will not appear in the report.

Effectiveness analysis

Do you want to perform this analysis?

Choose if you want to perform the analysis or not

Figure 11: Choose if you want to perform an analysis or not.

## Add the effectiveness analysis

In an effectiveness analysis, you can specify if a participant had a problem while completing a critical task and determine the importance of the problem. To indicate that a problem occurred, you can **write the number of the problem** in the first table in the row of the critical task during which the problem occurred and the column of the participant that completed the task. In the second table, you can then **choose the importance of the problem in the drop-down list** next to the problem number and **give a small description** in the corresponding white box. It is possible to specify up to 15 problems.

Information about effectiveness analysis

Task that caused a problem

Participant who completed the task

Critical task	P1	P2	P3	P4	P5	P6	P7	P8	P9	P10	P11	P12	P13	P14	P15
Critical task 1		1				1		1							
Critical task 2	2			2						2					
Critical task 3				3											
Critical task 4	4	4													
Critical task 5		5					5			5					
Critical task 6															
Critical task 7															

Write the number of the problem

Choose the importance of the problem

Write a small description of the problem

Problem	Problem type	Problem description
Problem 1	Important problem	Participants forgot to disinfect.
Problem 2	Critical problem	Participants did not manage to open the box.
Problem 3	Marginal problem	The participant did an error in the number.
Problem 4	Marginal problem	Participants forgot to use soap.
Problem 5	Critical problem	Participants did not clean the device at all.
Problem 6	-	
Problem 7	-	

Figure 12: Indicate if a problem occurred by writing its number in the first table and give the importance of the problem and a small description in the second table.

In the report, a table where the problems are highlighted by color depending on their importance will then be created and the problem descriptions will be written under the table. The table also contains name of the critical tasks.

Effectiveness analysis

Problems are highlighted by color depending on their importance

	P1	P2	P3	P4	P5	P6	P7	P8	P9	P10
Disinfection		1				1		1		
Opening	2			2						2
Collect sampling				3						
Storing	4	4								
Cleaning		5					5			5

No problem found

Marginal problem found

Important problem found

Critical problem found

Problems description

1. Participants forgot to disinfect.
2. Participants did not manage to open the box.
3. The participant did an error in the number.
4. Participants forgot to use soap.
5. Participants did not clean the device at all.

Problems are also described

Figure 13: In the report, a table is created and the problems are described. In the table, the problems are highlighted by color depending on their importance.

## Add a discussion

At the beginning of each subchapter of the “Results” chapter, you can **add discussion of the results of the analysis**. To add a discussion, you can follow the same process as described in *Add paragraphs*.

## Choose plot type

At the beginning of “Time on tasks” and “Average fixation” subchapter, you have the possibility to choose the **type of plot** that will be generated in the report to visualize the data. You have the choice between “**Bar plot**” and “**Box plot**”. You can see the difference between a bar plot (Figure 15) and a box plot (Figure 16) in the figures below.

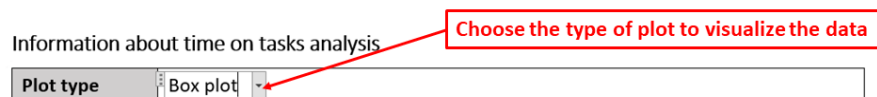


Figure 14: Choose what type of plot you prefer to visualize the data.

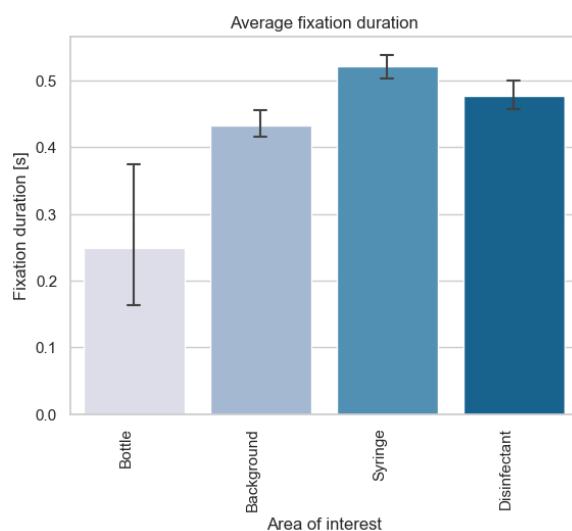


Figure 15: Bar plot showing average fixations.

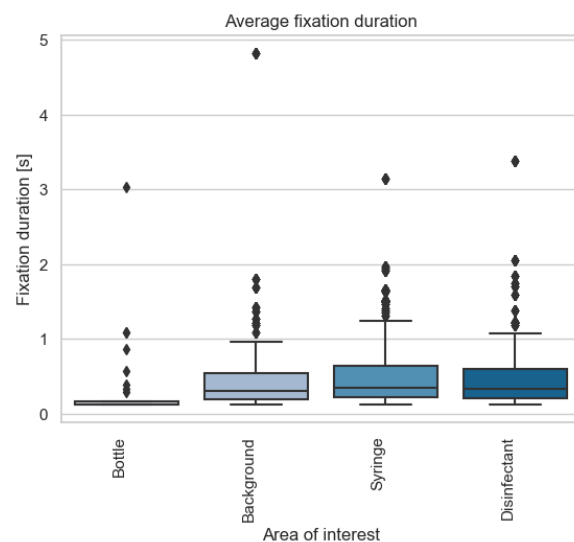


Figure 16: Box plot showing average fixations.

## Add a time on tasks analysis

In a time on tasks analysis, you can indicate the amount of time a participant spent to complete a critical task. To specify this, you can **write the time in seconds** in the row of the critical task that was completed and the column of the participant that completed the task.

Critical task	P1	P2	P3	P4	P5	P6	P7	P8	P9	P10	P11	P12	P13	P14	P15
Critical task 1	9	11	10	7	4	21	13	15	19	9					
Critical task 2	6	3	7	2	6	2	5	4	3	2					
Critical task 3	34	38	29	43	55	34	61	25	46	53					
Critical task 4	14	24	17	23	27	19	29	17	15	20					
Critical task 5	13	25	19	14	26	23	19	18	21	25					
Critical task 6															
Critical task 7															

Figure 17: Indicate the amount of time in seconds that a participant took to complete a critical task.

It is also possible to indicate the times directly in the videos of the eye tracking glasses using Tobii Pro Lab. You can either choose to import the recordings of all participants at the same time, analyze them all and then export the data of **all participants in the same file**, or to do it **for each participant separately**. If you choose to work with the recordings of all participants at the same time, it is important that you **rename all the participants** “Participant1”, “Participant2”, “Participant3”, etc. after having imported the recordings of the glasses in Tobii Pro Lab (see instructions of the Tobii Pro Lab User’s Manual [4]). You can do it by clicking on the name of the participant in the “Participants” panel.

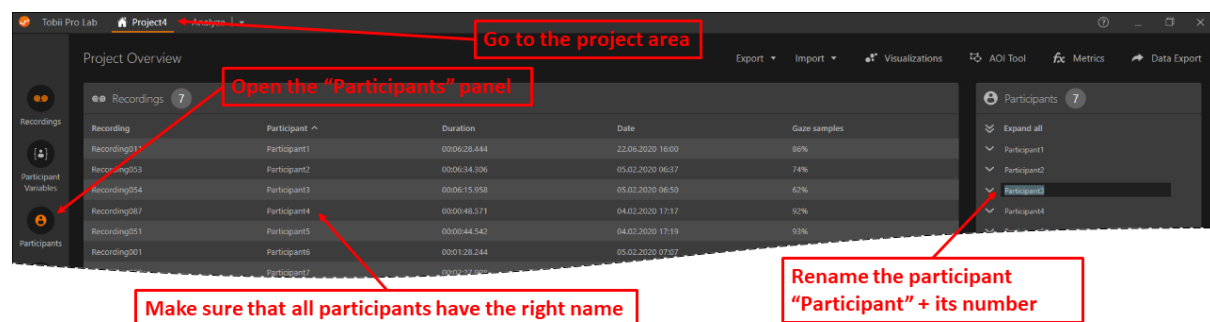


Figure 18: If you decide to work with the recording of all participants at the same time, you have to make sure to rename all participants to “Participant1”, “Participant2”, “Participant3”, etc. in the “Participants” panel.

Then, you can choose to analyze a recording in the “Analyze” area. To indicate the start and end time of a task, you can **add a new event** that you must name “Task” and add the task number at the end, e.g. “Task2”. The task number corresponds to the number of the critical task in the critical tasks table (see Give information about critical tasks). Then, you must **choose the start or end time in the timeline** of the recording by using the red cursor and once the red cursor is placed in the right time, you can add a “bookmark” of the event to the timeline that will correspond to the start or end time of a critical task. Thus, two bookmarks must be placed on the timeline for each task corresponding to its start and end time.

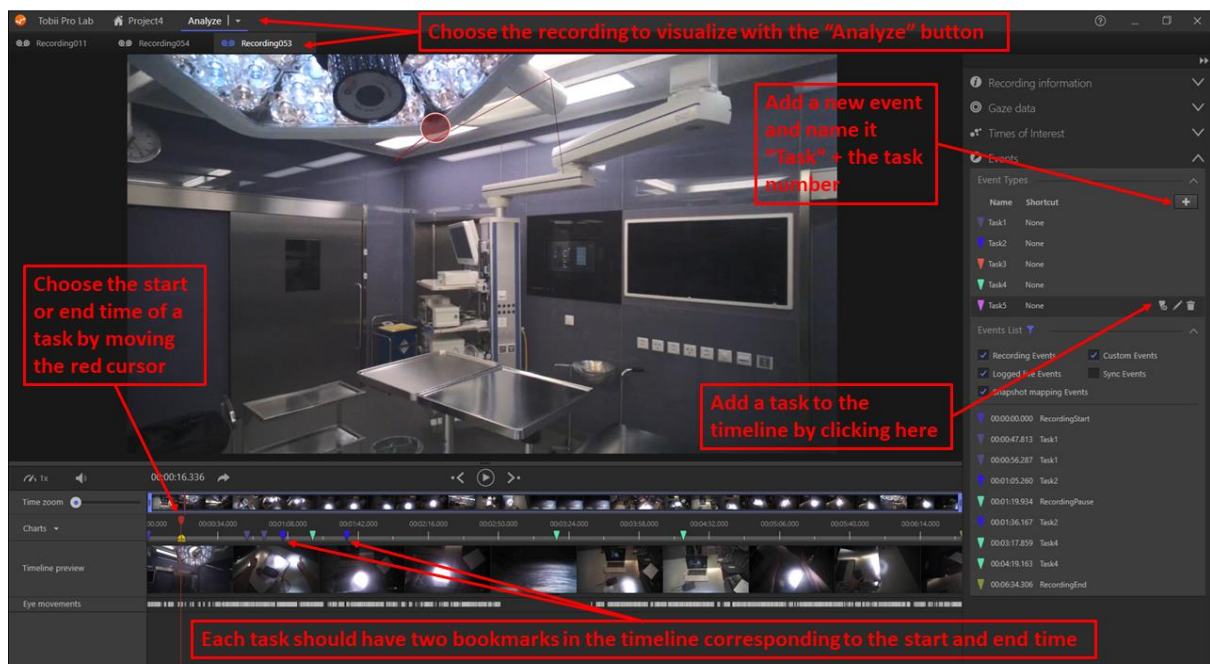


Figure 19: In the "Analyze" area of a recording, you can create events and name them "Task1", "Task2", "Task3", etc. in reference to the critical task number. Then, you can add two "bookmarks" for each task in the timeline of the recording that corresponds to its start and end time.

Once you are finished indicating the times on the recording, you can choose the **"Data Export"** option in the "Analyze" area in order to export the data. To make it work, you have to make sure to select to **export the "General" data**, to use **microseconds** as **"Timestamp precision"**, and to **export the file as .tsv**. You can choose if you want to export the data of all participants in the same file or to create a separate file for each participant. At the end, press on the **"Export 1 file"** button to create the file (refer to *Save Tobii data* to see how you have to save the file(s)).

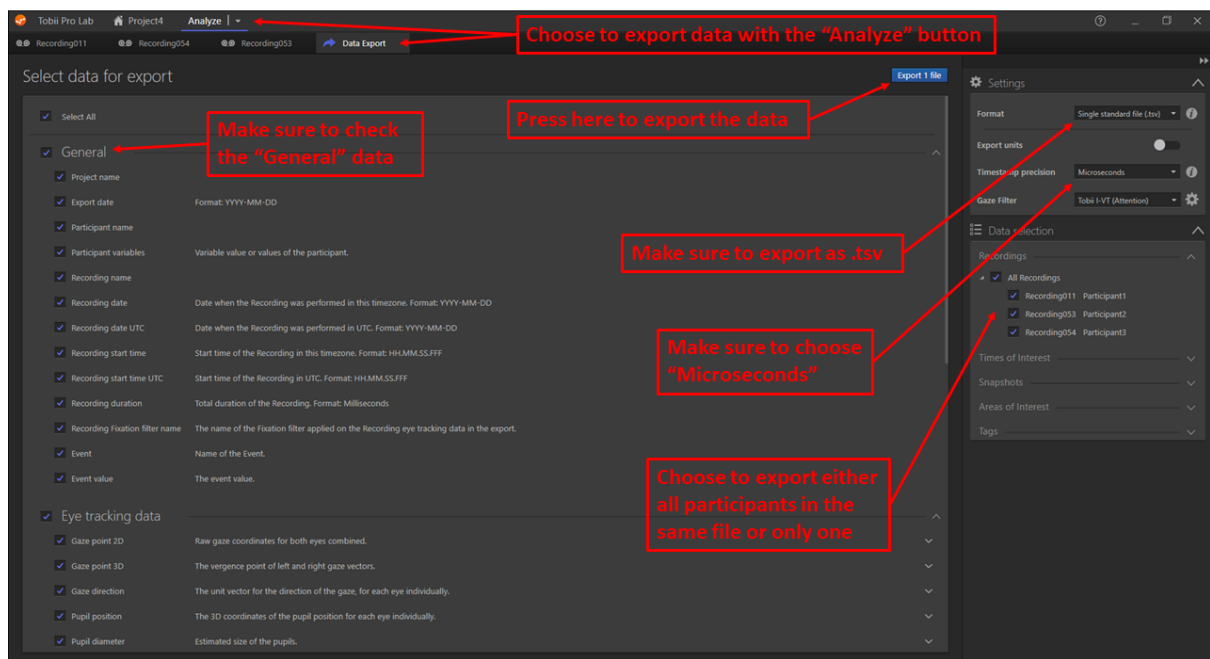


Figure 20: Choose the "Data Export" option in the "Analyze" area to export the data. Before the export, make sure to select all "General" data, to export as a .tsv file and to choose "Microseconds" as "Timestamp precision". You can also either choose to export the data of all participants in one file or to export the data of only one participant.

### **Add a dwell times and revisits analysis**

You do not need to give any special input in the text input form in order to perform the dwell times and revisits analysis. The plots and table for this analysis are created with the cGOM data only. Refer to *Save cGOM data* to see how you should load the cGOM files.

### **Add an average fixation analysis**

You do not need to give any special input in the text input form in order to perform the average fixation analysis. The plots for this analysis are created with the cGOM data only. Refer to *Save cGOM data* to see how you should load the cGOM files.

### **Add a transitions analysis**

You do not need to give any special input in the text input form in order to perform the transitions analysis. The plots for this analysis are created with the cGOM data only. Refer to *Save cGOM data* to see how you should load the cGOM files.



### 3.1.5 Appendix

#### Add participants characteristics

In the appendix, you have the possibility to fill a table with the participants characteristics. For each participant, you can add his characteristics by writing them in the corresponding white boxes. A table containing the participants characteristics will then be added in the appendix of the report.

Participants characteristics

Participant	Gender	Age	Function	Disease / Handicap	Experience	Known similar devices
Participant 1	Male	42	Patient	Blind	Little experience	ETH pump
Participant 2	Female	33	Nurse		Experienced	EPFL pump
Participant 3	Male	27	Nurse		Little experience	ETH pump
Participant 4	Male	25	Nurse		No experience	
Participant 5	Female	23	Patient	Deaf	No experience	
Participant 6	Female	36	Patient	Paraplegic	Experienced	ETH pump
Participant 7	Male	37	Physician			
Participant 8	Female	31	Physician			

Write the participants characteristics in the corresponding white boxes

Figure 21: Write participants characteristics in the corresponding white boxes

## 3.2 Pictures

### Add pictures

It is possible to add up to three pictures in each chapter and subchapter of the report. To add a picture, you have to **save the image file in the *Pictures* directory** located itself in the *Inputs* directory. The name of the image file must correspond to the name of the chapter or subchapter where spaces are replaced by underscores and end with a number between 1 and 3, e.g. *Device\_specification2.jpg*. To be sure, you can **check the image file name in the caption table** at the end of each chapter and subchapter of the text input form. All pictures will then be added at the end of the corresponding chapter or subchapter.

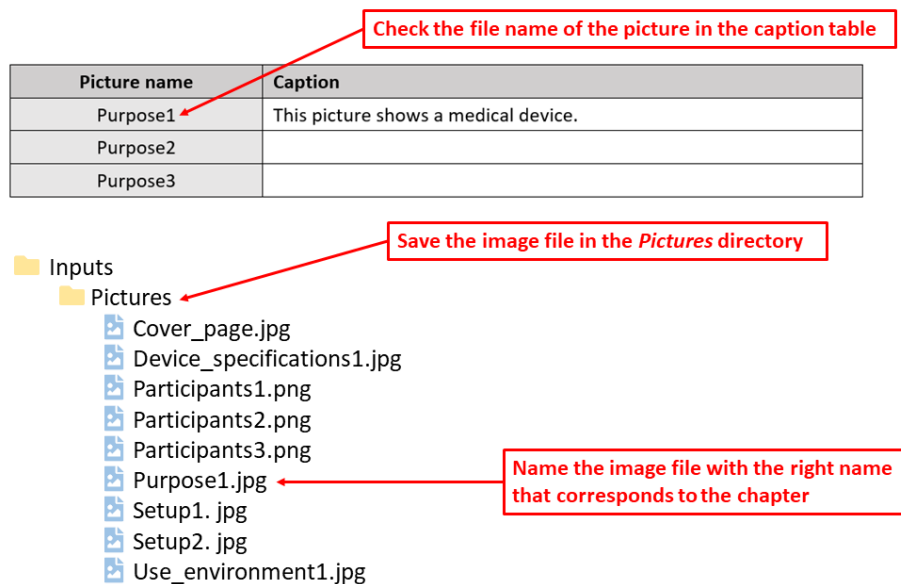


Figure 22: To add a picture in the report, save its image file in the *Pictures* directory and name it with the right name that corresponds to the one that you find in the caption table in the text input form.

## 3.3 Data

### 3.3.1 cGOM data

#### Save cGOM data

To perform the dwell times and revisits, average fixations and transitions analyses, you must give cGOM data as input. To do it, you must save the *.txt* files that you got from cGOM in the **cGOM\_data directory** located itself in the *Inputs* directory. The files must be named “Participant” and end with the participant number, e.g. *Participant3.txt*. In a normal case, you should save up to 15 files, which corresponds to the maximal number of participant that you can give in the text input form. However, if more than 15 participants took part in your study, it is still possible to save more than 15 *.txt* files in the *cGOM\_data* directory and they will all be used to create the different plots.

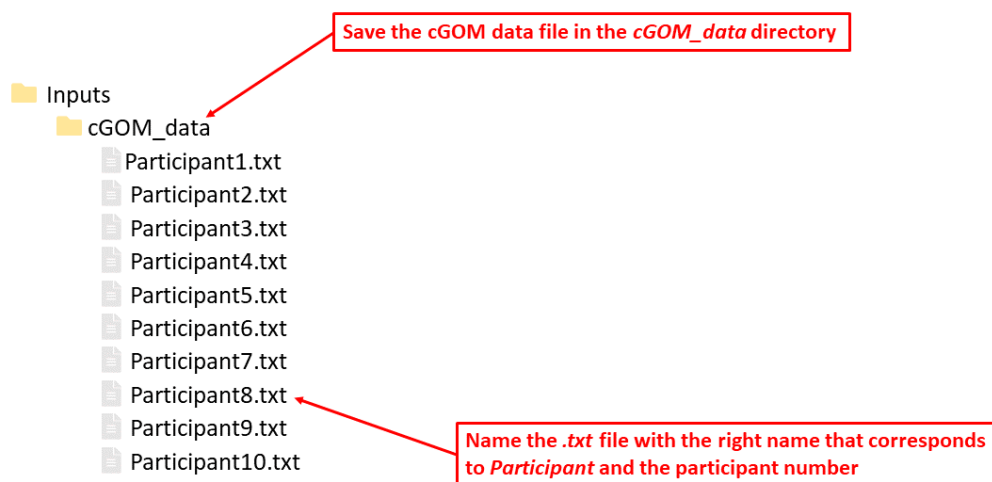


Figure 23: Save the *.txt* files that you got from cGOM in the *cGOM\_data* directory and name them “Participant” with the participant number at the end.

### 3.3.2 Tobii data

#### Save Tobii data

If you decide to use *Tobii Pro Lab* to indicate the times for the time on tasks analysis, you have to save the exported *.tsv* file in the ***Tobii\_data*** directory located itself in the *Inputs* directory. If you exported **one file for each participant**, the files must be named “Participant” and end with the participant number, e.g. *Participant4.tsv*. If you decided to export **only one file that contains the data off all participants**, name it *All\_participants.tsv*.

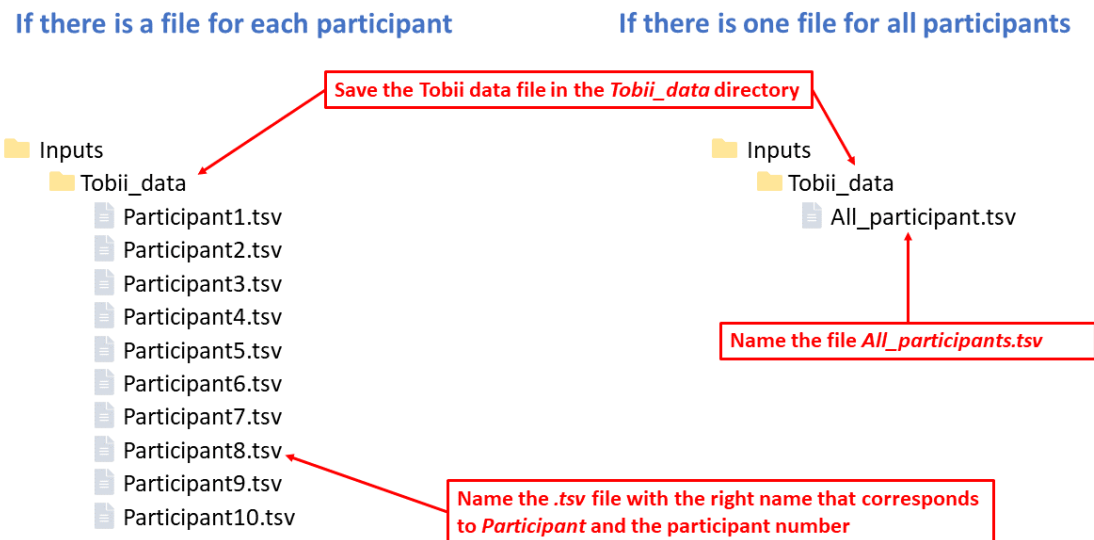


Figure 24: Save the *.tsv* files that you got from cGOM in the *Tobii\_data* directory. If you exported one file for each participant, name it “Participant” with the participant number at the end, and if you decided to export only one file that contains the data off all participants, name it *All\_participants.tsv*.

## 4 Program execution

When you are finished giving all the inputs, you can execute the program via the command prompt. First, you have to make sure to **close every files that will be used for the generation of the report**, i.e. *Terms\_definitions.docx* and *Text\_input\_form.docx* (and *Report.docx* if you have already generated it once) you can open the command prompt by typing “command prompt” in the Windows Search Bar. Before writing in the command prompt, you can copy the path of the folder that contains the program by right-clicking on address bar of the File Explorer and selecting “Copy address”.

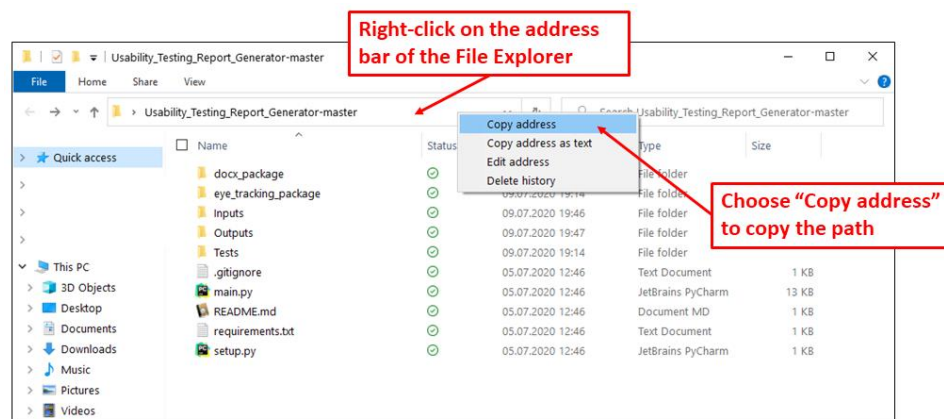


Figure 25: Right-click on the address bar of the File Explorer and choose “Copy address” to copy the path of the directory.

You can then **go in the directory of your program via the command prompt** by typing “cd” and a space, and pasting the path of your directory.



Figure 26: Type “cd” and a space in the command prompt and then paste the path of the program directory.

Before executing the program, you have to **install the required libraries** by typing “pip install -r requirements.txt” in the command prompt.

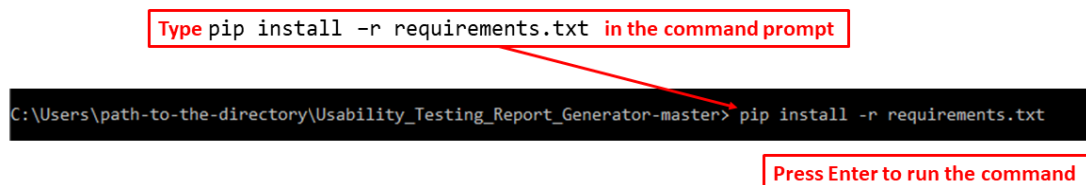


Figure 27: Type “pip install -r requirements.txt” in the command prompt to install the required libraries.

Finally, you are able to **run the program** by typing “python main.py” in the command prompt.

**!** Before the execution, **close all .docx files** used for the report generation, i.e. *Terms\_definitions.docx* and *Text\_input\_form.docx* (and *Report.docx* if you have already generated it once)

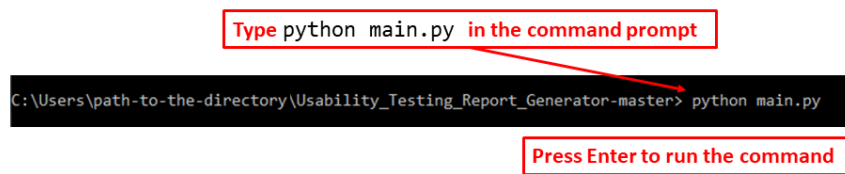


Figure 28: Type “python main.py” in the command prompt to execute the program with Python.

# 5 Output

## 5.1 Report

After executing the program, the report will be created based on the inputs you gave. It will be saved in the main directory with the name **Report.docx**. You can open it with Microsoft Word and edit it if you like to.



Figure 29: The report is automatically saved in the main directory and can be opened with Microsoft Word.

### Add last features

Unfortunately, it is not possible to automate every aspects and features of a report. So, to make your report perfect, you will have to **add the last features yourself** using *Microsoft Word*. For example, you may want to add some bullet lists or numbered lists, to bold or italicize a word, or change some others layout and formatting aspects. **References must also be added manually**, for example using Citavi.

## 5.2 Plots

For each analysis that you decided to perform, different plots and/or tables will be created to visualize the data. **A plot will be created for each participant** and saved in the *Outputs* directory. It will allow you to compare the plots of the different participants. **Another plot will also be created based on the data of all participants** and be automatically added in the report and saved in the *Outputs* directory too.

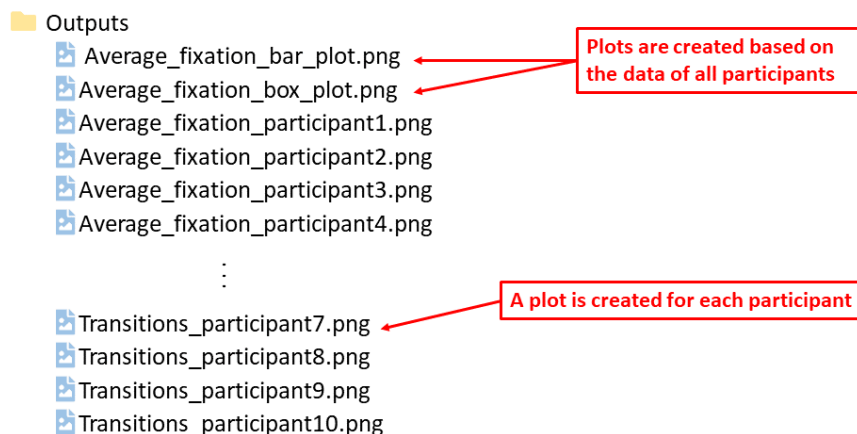


Figure 30: One plot for each participant and plots based on the data of all participants are created.

## 6 References

1. Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC.
2. IEC 62366-1 Medical devices - Part 1: Application of usability engineering to medical devices. Edition 1.0. Geneva: International Electrotechnical Commission; 2015. ISBN:978-2-8322-2281-2.
3. FDA (2016) Applying Human Factors and Usability Engineering to Medical Devices: Guidance for Industry and Food and Drug Administration Staff.
4. Tobii Pro Lab User's Manual: <https://www.tobii.com/siteassets/tobii-pro/user-manuals/Tobii-Pro-Lab-User-Manual/?v=1.142>.