Guidance Sheet 12:

Lung Function Sub Study

Centre for Trials Research
Canolfan Ymchwil Treialon

For Sites Taking Part in the Lung Function Sub Studies

Introduction

The Tremoflo N-100 Airwave Oscillometry System is a portable medical device intended to monitor lung function in newborns and infants. The device measures airway resistance, reactance and other lung function parameters.

Although the device is portable, please only use it in the hospital and is not intended for home use. The device can be used for research purposes only and is not to be used for diagnostics.

Equipment

You will be provided with the following equipment:

- Tremoflo N-100 Airwave Oscillometry System
- Laptop with the Tremoflo software installed
- Masks (3 different sizes) (single use)
- Filters (single use)

Set Up

The laptop will arrive with the necessary software installed and activated to use the Tremflo. The following equipment will be provided:

In addition, a power supply and an ethernet cable will be supplied. A calibration test load and test load adapter will also be supplied.

The Tremflo will need calibrating, to calibrate the machine please contact the BALLOON Trial Manager (kotechasj@cardiff.ac.uk) to set up a Team's call at a convenient time with Thorasys, the Tremflo manufacturer. This call needs to take place in the afternoon (as they are based in Canada) and please allow 2 hours for the calibration, although it may not take that long.

Taking a Measurement

To power up the Tremoflo system, briefly press the power button on the Tremoflo cradle. The power button will light up, briefly alternating between green, yellow and red before settling to a steady yellow colour.

The Tremoflo has two power indicator lights. On the cradle, a power and status indicator light around the power button can light up in green, yellow or red, each colour has a significance as shown in the below table. The second power indicator, located on the top of the handheld unit, lights up in blue when power is supplied to the handheld unit and does not change colour with the system status.

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Colour	Status	Details
Unlit/Gray	Off	The tremoflo is powered down.
Flashing	Starting	The tremoflo firmware is booting.
Green	Ready	The tremoflo is powered up, communicating with the software, fully initialized and ready for use.
Yellow	Standby	The tremoflo is powered up and either waiting to connect to the software or being initialized.
Red	Error	The tremoflo is powered up, but a critical error has occurred and the system is not ready for use. Refer to Appendix A for possible causes and solutions.

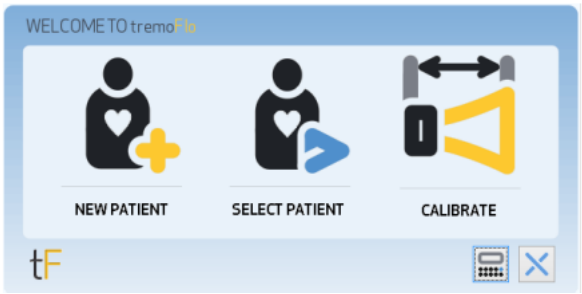
With the computer running start the Tremoflo software by either clicking the Tremoflo icon in the task bar or by double clicking the Tremoflo icon of the desktop.

Enter your username and password and then click login.

Next the software shows a Welcome dialog.

New Patient: Click to add and test a new patient.

Select patient: To select an existing patient from the database to retest or review collected data. Please see note below *

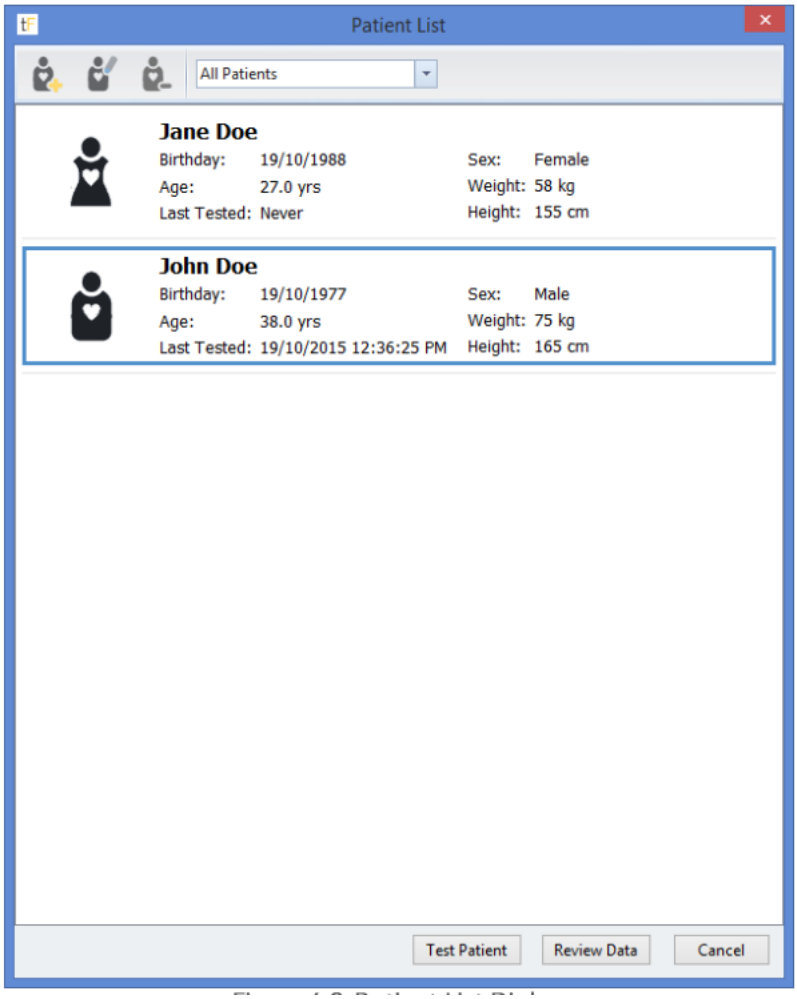


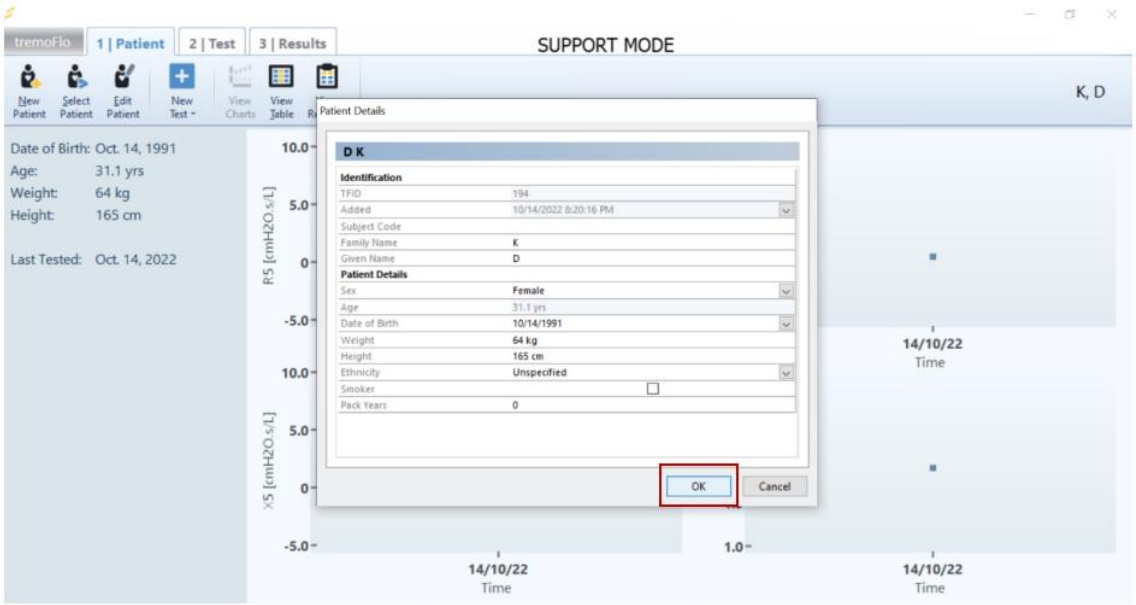
To add a new patient select **New Patient** from the **Welcome** dialog or from the Tremoflo toolbar on the **Patient** tab to display the **New Patient** dialog. Enter the patient information.

Field	Information Entered	Format
First Name	Patient's first name	Alphanumeric Text
Last Name	Patient's last name	Alphanumeric Text
Subject Code	Custom Code	Alphanumeric Text
Sex	Male/Female	From drop-down list
Date of Birth	Date Of Birth	As per regional settings
Weight	Body Weight	See Table 4.3
Height	Body Height	See Table 4.3
Ethnicity	Patient's Ethnicity	From drop-down list

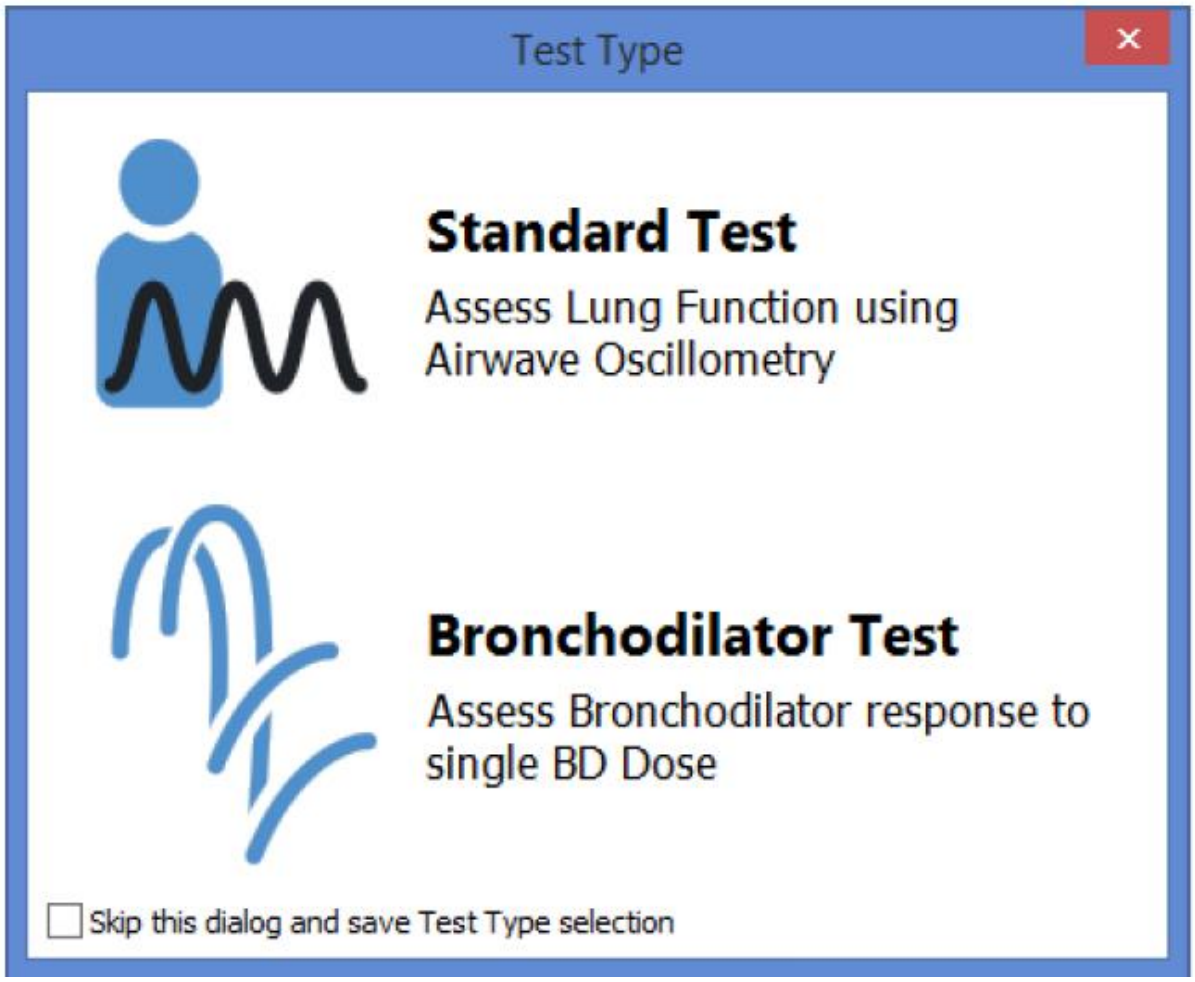
Please use centimetres for length/height and kilograms for weight.

If you wish to choose a patient who is already in the database please choose select **Patient**. *Please enter a participant as new patient when you see them at baseline, and another new patient at 6 months corrected age and another new patient at 12 months corrected age. When you see the participant at baseline please use the PID with a 0 at the end . When you see the participant at 6 months of age please use the PID with a 6 at the end. When you see the participant at 12 months of age please use the PID with a 12 at the end.


Patient List
All Patients
Jane Doe
Birthday: 19/10/1988
Age: 27.0 yrs
Last Tested: Never
Sex: Female
Weight: 58 kg
Height: 155 cm
John Doe
Birthday: 19/10/1977
Age: 38.0 yrs
Last Tested: 19/10/2015 12:36:25 PM
Sex: Male
Weight: 75 kg
Height: 165 cm
Test Patient
Review Data
Cancel

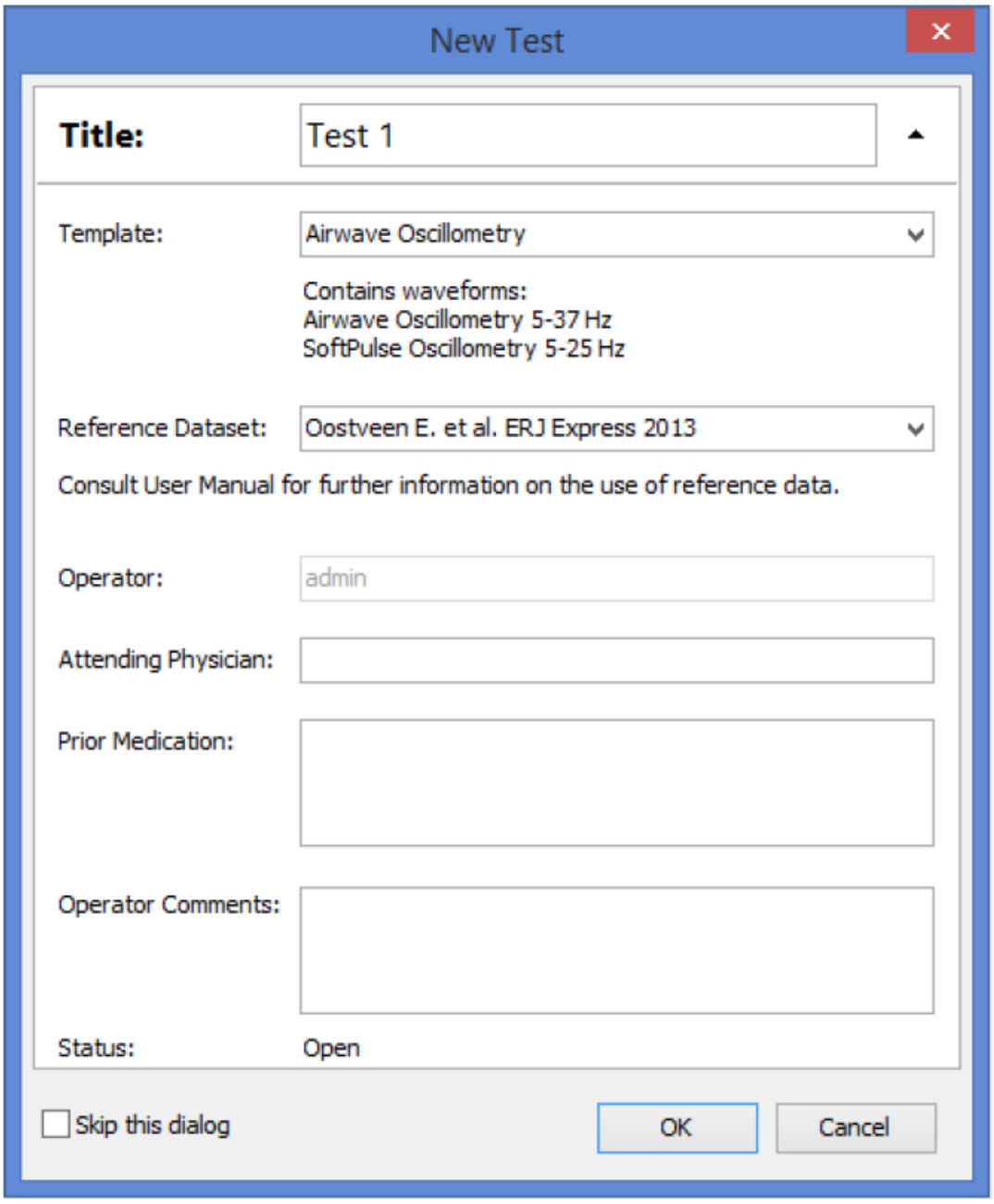


When choosing "**Test a patient**" the test type dialog will appear with a choice of two test types:



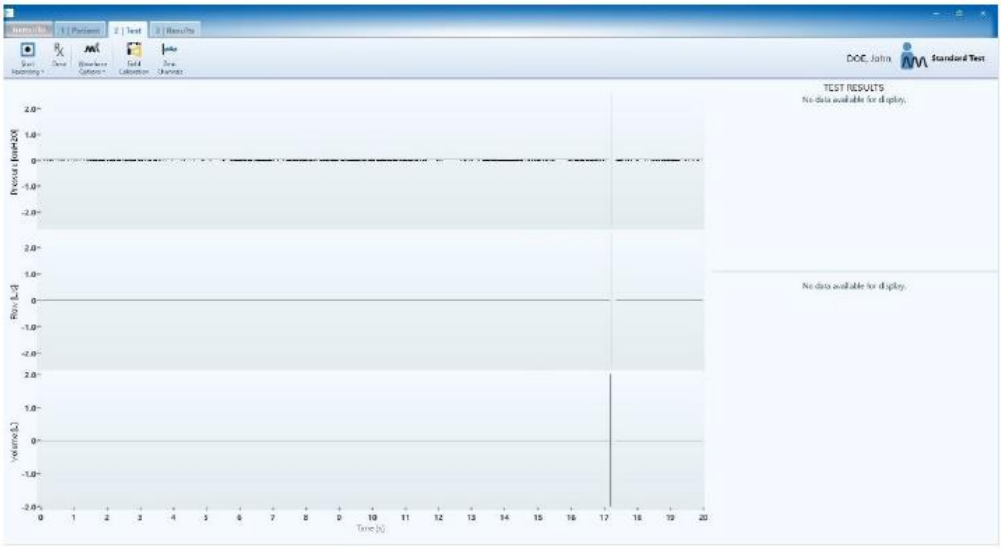
Please select **Standard test**.

Once you select **Standard test** type the **Test properties** dialog is displayed. Chose the **Reference data set** (You will choose N-100 template) and fill in the other fields as required.



Closing the **Test properties** dialog completes the start-up sequence of the Tremoflo software. At this point, the device will connect to the software and be initialised. Once the system initialisation is complete the screen will display the main window of the Tremoflo software in the **Test Tab**. At this point, you are ready to take your first

measurement. The machine may ask you to calibrate it, please use the 90 load to do this and attach it to the end of the tubing using the load adapter.



Please now prepare the baby for testing. The baby should be asleep and if possible swaddled to prevent movement.

1. Make sure the Tremoflo is showing the test screen.
2. Use gloves when handling the Tremoflo
3. Remove a new and packaged filter and mask from its wrapping and insert into the machine as show in the diagram below.
4. Position the baby as shown below

(link to video on website)

The video at https://www.youtube.com/watch?v=umMhsT-6ke4 shows the machine in action in a child.

Once the baby is breathing quietly, please complete at least **three** satisfactory measurements of 25-30 seconds each by pushing the button on the handheld unit to start the measurement. The device will vibrate and you will hear a quiet noise. The Tremoflo automatically ceases measuring when the measurement is complete. Measurement data are automatically stored without the need for user intervention.

When the test is complete, the test should be marked as closed in the Tremoflo software.

Please dispose of the mask and filter following your Trust/Health Board guidance. It is important to clean the exterior of the machine using a mild detergent of a neutral pH with warm water and a soft cloth. Take care not to press against or otherwise damage the mesh screen inside.

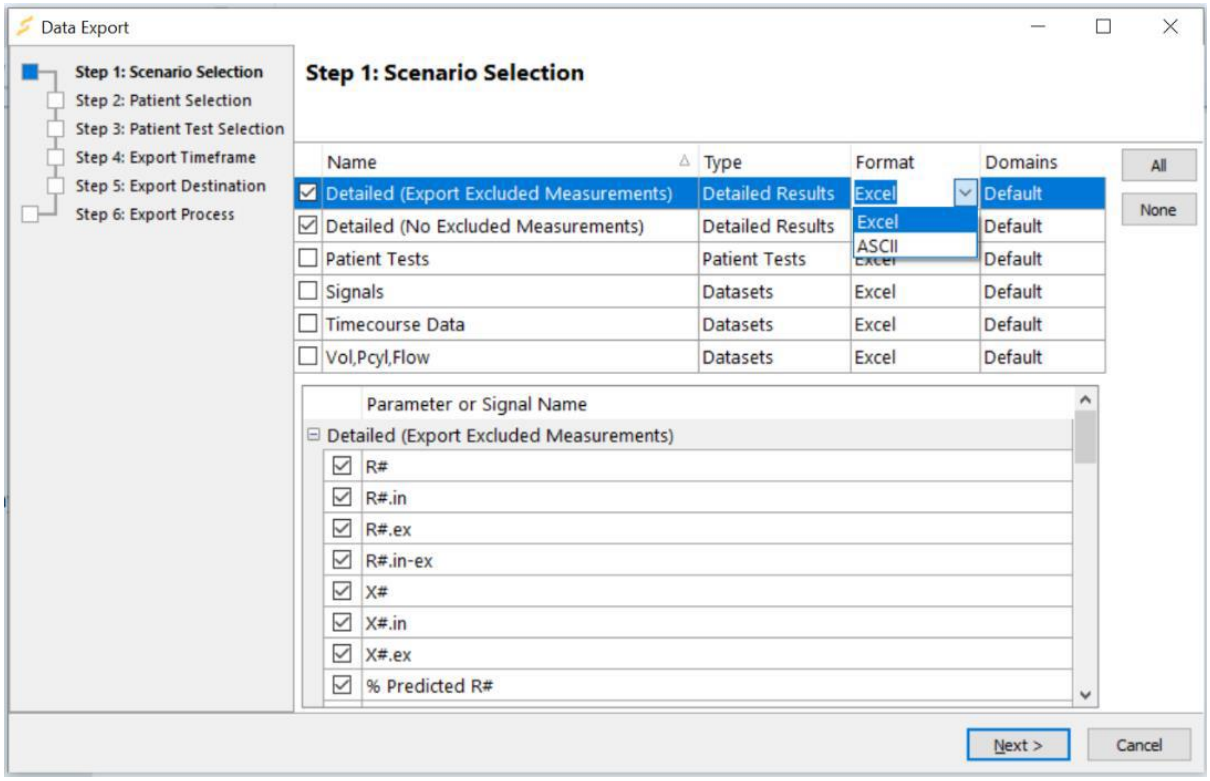
Downloading the data

Please download the data after each patient by following theses steps and transfer securely to the BALLOON team.

Go to the Tremoflo menu in the software (top left corner).

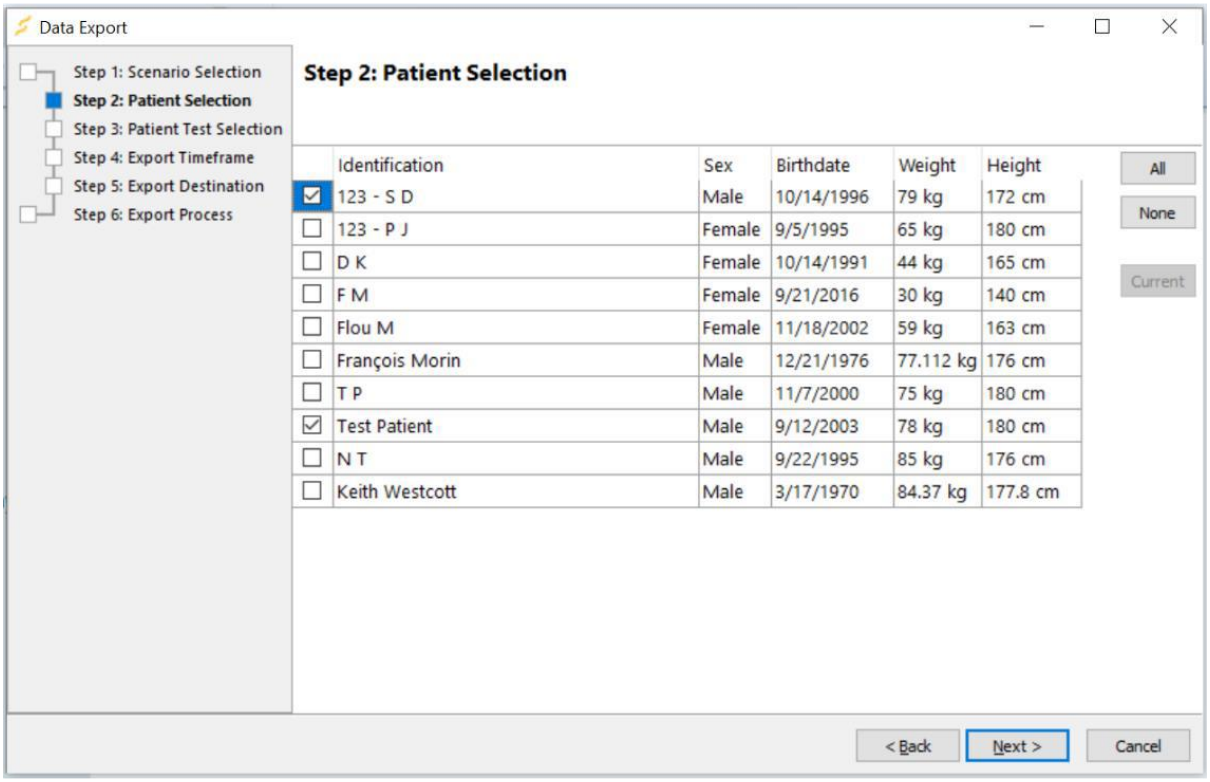
Select the "**Export Data**" option.

On the **Data Export Wizard**, select the needed export scenarios and the export format.

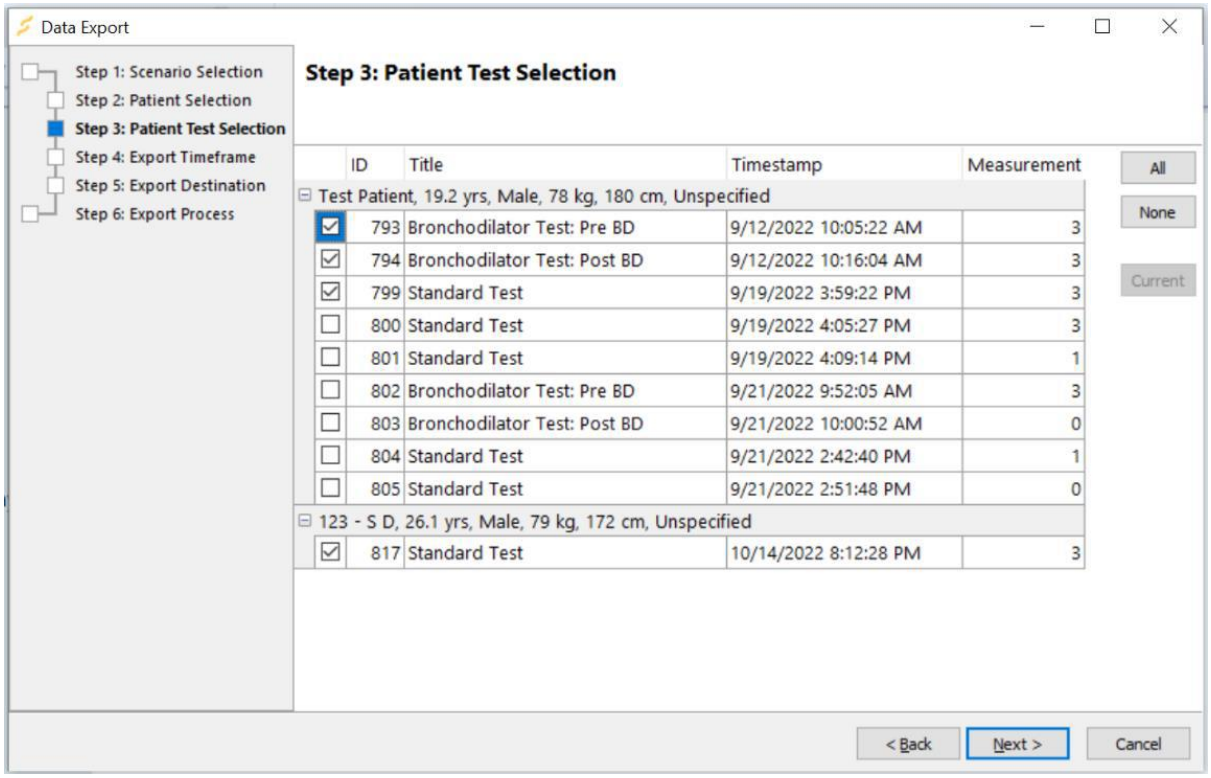


Click on the "**Next**" button.

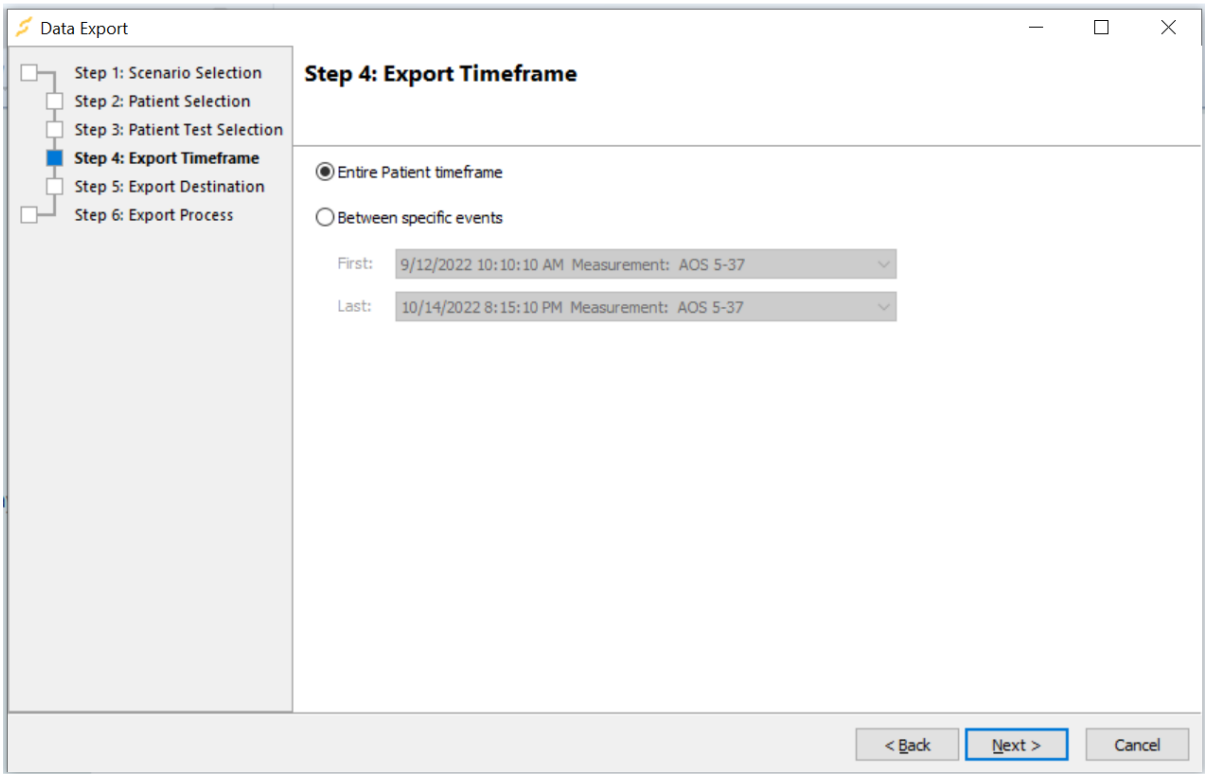
Select the patients containing the data that need to be exported. Click "**Next**".



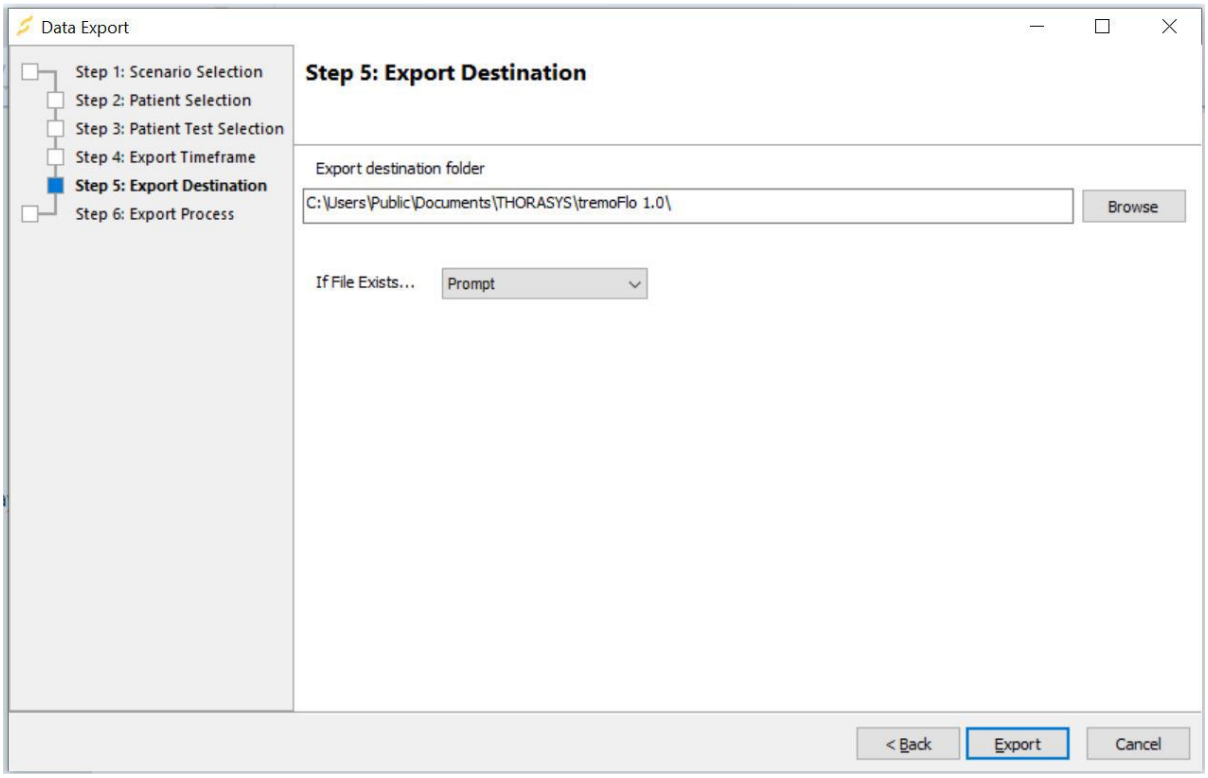
For each Patient, select the tests containing the data that need to be exported. Click "**Next**".



Select the timeframe. Click "**Next**".



Choose the default exportation path or switch it with your own one. Click "**Export**".



If the participant is for training only, please also send the following demographics.

- BALLOON ID
- Birthweight
- Current Length
- Current Weight
- Gestation at birth
- CGA
- Date of measurement
- DOB Gender
- On supplementary oxygen

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To transfer securely

Save the document as a PDF

Visit https://fastfile.cardiff.ac.uk/

Fig 1.

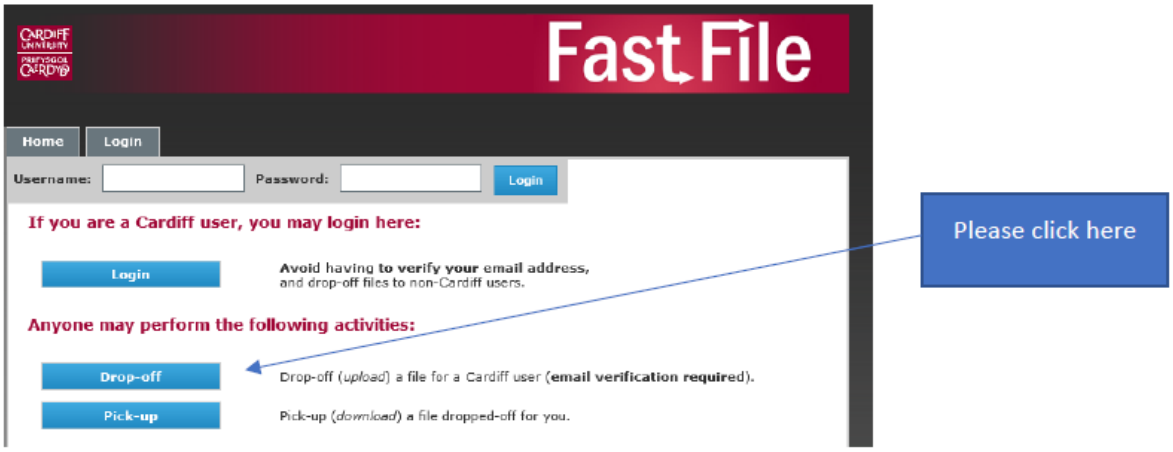


Fig 2.

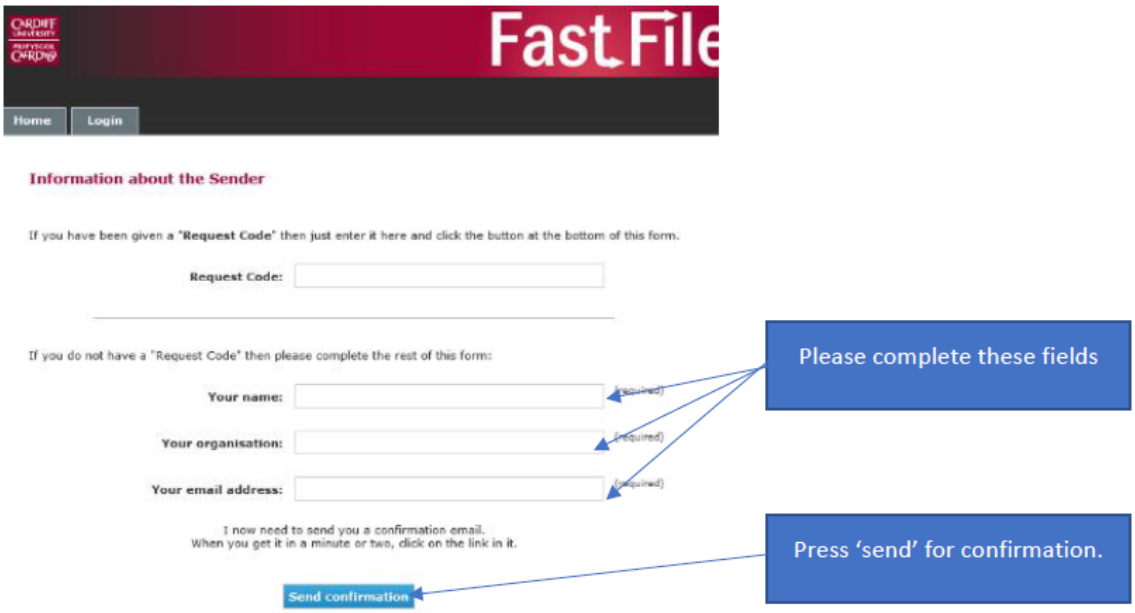
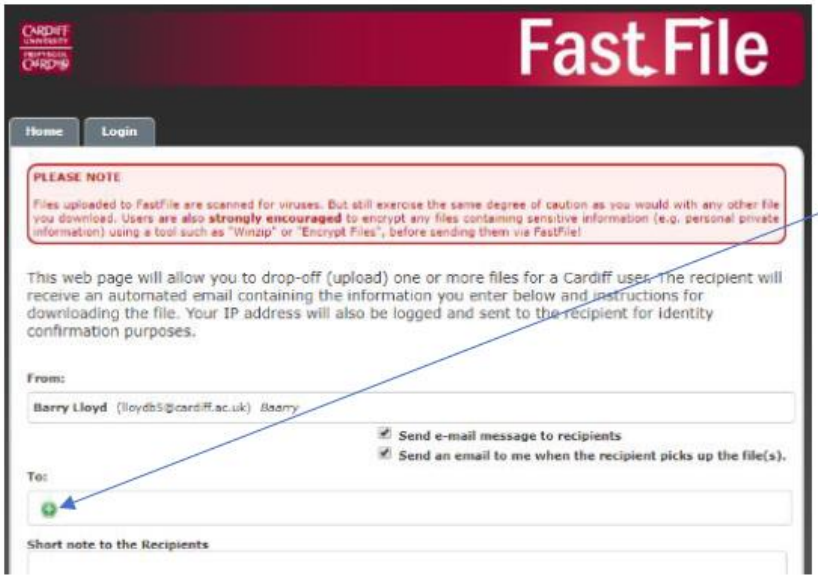

Fast File
Home
Login
Information about the Sender
If you have been given a "Request Code" then just enter it here and click the button at the bottom of this form.
Request Code:
If you do not have a "Request Code" then please complete the rest of this form:
Your name:
Your organisation:
Your email address:
I now need to send you a confirmation email.
When you get it in a minute or two, click on the link in it.
Send confirmation
Please complete these fields
Press 'send' for confirmation.

Fig3.


Fast File
Home
Login
Now wait for the email message from the FastFile to arrive and click on the link in it.
You may close this window.
You will be directed to the main menu in a moment.
Please check your mailbox and follow the link

Fig 4.


Fast File
Home
Login
PLEASE NOTE
Files uploaded to FastFile are scanned for viruses. But still exercise the same degree of caution as you would with any other file you download. Users are also strongly encouraged to encrypt any files containing sensitive information (e.g. personal private information) using a tool such as "Winzip" or "Encrypt Files", before sending them via FastFile!
This web page will allow you to drop-off (upload) one or more files for a Cardiff user. The recipient will receive an automated email containing the information you enter below and instructions for downloading the file. Your IP address will also be logged and sent to the recipient for identity confirmation purposes.
From:
Barry Lloyd (lloydb5@cardiff.ac.uk) Baarry
Send e-mail message to recipients
Send an email to me when the recipient picks up the file(s).
To:
Short note to the Recipients
Please click on this symbol


Fast File
Add Recipients
Add Many
Name: OASIS
Email: CTR-OASIS@cardiff.ac.uk
Add Recipient
This web page will allow you to drop-off (upload) one or more files for a Cardiff user. The recipient will receive an automated email containing the information you enter below and instructions for downloading the file. Your IP address will also be logged and sent to the recipient for identity confirmation purposes.
From:
Barry Lloyd (lloydb5@cardiff.ac.uk) Baarry
Enter BALLOON
Enter BALLOON@cardiff.ac.uk

Troubleshooting

If you have any problems using the Tremoflo system please contact the BALLOON Trial team (BALLOON@cardiff.ac.uk). We will be able to put you in touch with Thorasys' technical support if we are unable to help you.