MRC National Survey of Health and Development

UCL

CLOSER calibration study 2015

MANUAL OF PROCEDURES

TNS

TNS BMRB

closer
Cohort & Longitudinal Studies Enhancement Resources

Contents

Introduction

Continuous and normally distributed measures of physical and cognitive capability and physiological function, such as lung function and blood pressure, repeated over time, provide dynamic tools for investigating health and ageing processes across the life course. Ideally, within a study, the same measurement instruments and protocol would be used at each time point of assessment in order to study within person changes with age. It is also of interest to carry out cross-cohort comparisons of such measures and investigations of secular trends. These comparisons are more easily interpreted if studies use comparable measurement protocols and instruments. However, changes in methods of measurement over time are inevitable as technology develops and better and more convenient methods and equipment become available, and old equipment become obsolete. For example, many cohort studies have recently had to change the type of spirometers used to measure lung function as it is has become impossible to calibrate the old ones.

The challenge with such changes is that machines may systematically measure the function differently, as has been shown with a comparison between blood pressure measured using old random zero sphygmomanometers and newer automated devices (Stang A, et al. Algorithms for Converting Random-Zero to Automated Oscillometric Blood Pressure Values, and Vice Versa. Am J Epidemiol 2006; 164(1):85-94). Similarly, an adjustment was required in a cross-cohort comparison of lung function to harmonise measures recorded using two different types of spirometer (Orfei L et al. Early influences on adult lung function in two national British cohorts. Arch Dis Child 2008; 93(7): 570-4). In order to facilitate both comparisons between cohorts and longitudinal comparisons within cohorts knowledge about the difference between the measurements of different machines is needed.

We therefore plan to carry out a machine calibration study in order to estimate mean differences in measurements of different machines and to derive correction factors which could be used in future analyses to harmonise measurements across different machines. We will do this by comparing measurements from different machines in the same individuals. We reviewed the measurements and equipment used in the Cohorts and Longitudinal Enhancement Resource (CLOSER) studies and other large cohorts in order to prioritise the most important and useful comparisons for this national resource. We propose to 1) compare two types of spirometers - micromedical Plus and NDD Easy-on - for measurement of lung function; 2) compare four types of dynamometer - Nottingham electronic, Jamar manual, Jamar electronic, Smedley - used to measure grip strength; 3) compare two models of sphygmomanometer - Omron 705-CP and Omron 907 - used to measure blood pressure.

Study design

The sample will be selected from the TNS Omnibus survey. The TNS Omnibus involves a multi-phase sampling design whereby the geography of Great Britain is stratified using 2011 Census small area statistics and the Postcode Address File (PAF) to define sample points.

TNS BMRB/MDG will send a letter to the selected sample, reminding them of their participation in the TNS Omnibus and inviting them to take part in the study.

Participants who respond positively to the letter will be recruited to the study and an appointment will be booked by TNS BMRB/MDG.

Healthy participants will be invited to take part in the calibration study in order to investigate the systematic differences in measurement of blood pressure, lung function and grip strength across different machines. These are simple non-invasive measurements using standard equipment and protocols.

Each participant will have their blood pressure recorded using 2 different machines, will perform spirometry on 2 different machines and will perform a grip strength test on 4 different machines; the ordering of machines for each type of function will be by random allocation. The visit is designed to ensure that blood pressure is measured after adequate rest, and that there is rest between the two spirometry measurements.

Blood pressure will be measured twice on each machine with the participant in a seated position after 5 minutes of rest. Grip strength will be measured twice in each hand on each machine. Lung function will be assessed following ATS/ERS criteria. Participants will have their height and weight measured and will also complete a short questionnaire to obtain basic demographic, health and lifestyle information.

At the end of the visit, participants will receive a copy of their results and a £50 incentive.

Contacting participants and arranging a visit

Each participant will have been sent an advance letter and information sheet. Hayley Cheshire, TNS BMRB, will telephone all the volunteers and book an appointment, provided they do not fulfil any exclusion criteria.

A confirmation letter will sent out with direction to the MRC Unit for Lifelong Health and Ageing, London. A reminder text/call will be sent prior to the visit.

Google calendar

A Google calendar has been set up to record the visits, it is anticipated that each visit will take under one and a half hours throughout the day:

8:45 – 10:15

10:30 – 12:00

12:45 – 14:15

14:30 – 16:00

16:45 – 18:15

Please contact Hayley Cheshire (Hayley.Cheshire@tns-bmrb.co.uk) if you have any problems accessing the calendar.

When appointments have been booked in, please enter your name in the space provided to indicate the booking confirmation.

Before the visit

Make sure you have the correct details for the participant.

Check that you have the correct materials and equipment (including spares) to conduct the assessment (see checklist below).

Checklist of materials

- Consent form
- Measurement card
- Pen
- Questionnaire ?
- Stopwatch

- Handgrip dynamometer
  - Jamar electronic
  - Jamar hydraulic
  - Nottingham MKIII
  - Smedley
- Blood pressure monitor
  - Omron 907-HEM
  - Omron 709CP

- Laptop
- Spirometer
  - NDD Easy-on PC spirometer and plastic mouth pieces
  - Micromedical Plus and cardboard mouth pieces
- Scales

Introducing the assessment

The general rule is to keep your initial introduction short, simple, clear and to the point:

- Say who you are: "I am one of the Researchers called..."
- Say who you work for: "I work for UCL and am carrying out the data collection for the CLOSER calibration study".

The assessment

The assessment consists of a short questionnaire and taking a number of health measurements: blood pressure, hand grip strength, lung capacity and height/weight.

Informed consent:

This is an essential part of the interview.

Use a pen when completing the booklet and ensure that signatures are always in pen, not pencil. Use capital letters and write clearly. Do not erase any of the personal information. If necessary, cross out errors with a single line, initial and date, and re-write so that any corrections can be seen.

Remind the participant that their participation is entirely voluntary and they can withdraw at any time.

The visit will take the following format:

Blood pressure - machine 1

Blood pressure - machine 2

Grip strength - machine 1

Lung function - machine 1

Rest and completion of short questionnaire

Height and weight measurement

Grip strength - machine 2

Lung function - machine 2

Grip strength - machine 3

Grip strength - machine 4

Following in the consent process, please follow the machine order on the measurement card. This will indicate the order in which you should conduct the measurements.

Blood pressure protocol

Introduction:
Two different models of sphygmomanometer will be used to measure blood pressure. If possible, three BP measurements will be taken with each machine with a 1 minute gap between each measurement.

To ensure comparability of measures across devices a standard protocol will be used. This standard protocol is described below and is followed by information specific to each device.

Equipment:
Omron HEM-907 automated digital oscillometric sphygmomanometer
Omron 705-CP automated digital oscillometric sphygmomanometer
Normal and large cuff
Thermometer
Measurement card
Stopwatch

EXPLAIN THE TEST:

READ OUT
"We would like to measure your blood pressure. This test will be done using 2 different machines and each time I would like to take 3 measurements. I am going to leave you to sit for a few minutes. During that time you must not read or do anything and your legs are to remain uncrossed. When the time is up, I will carry out three recordings with a minute in between them. During this time I will not speak to you and you must not speak to me. Once I have completed all six recordings I will tell you what they are."

GENERAL PROTOCOL:

1. Ask the participant to sit with legs uncrossed at the end of a table near the front right-hand corner with the right arm resting comfortably, palm up, on the table.
2. Position the Omron so that the readings cannot be seen by the participant.
3. Sit at the front of the table close to the right-hand end, facing the machine.
4. Ask the participant to remove any watch and expose the upper right arm
5. Make sure that the rolled up sleeve does not constrict the arm.
6. Select the appropriate cuff
7. Locate the brachial pulse just medial to the biceps tendon
8. Wrap the cuff round the arm like a tape measure and position the cuff so that the centre of the inflation bag (marked on the pocket) lies over the brachial artery. The lower edge should be 2 to 3 finger-breadths (about 1 inch) above the cubital fossa.
9. Connect the cuff to the sphygmomanometer.

10. Explain that the machine will take blood pressure three times and that the participant can request to stop at any time.
11. Ask the participant not to move his/her arm while the measurement is being taken. The instrument is sensitive to movement while deflating, and may fail to take a reading.
12. Explain to the participant that before you measure their blood pressure, it is necessary to sit quietly for at least **THREE** more minutes with legs uncrossed to rest.
13. Keep conversation to a minimum until after blood pressure measurements.
14. Following the first three measurements. Swap the instruments and repeat steps 6-11.
15. Allow the participant to sit for a further **TWO** minutes before taking further measurements

INFORMATION ABOUT EACH DEVICE:
705-CP (Omron 1 – old style machine)

1. When first set up the display is likely to be showing the time.
2. Press the GREY 'sphyg/clock' button to prepare the machine to take a reading.
3. The display will show a zero and a heart symbol.
4. Preset should be set to 170. In a few cases, with the pressure valve set to 170, the sphyg will fail to inflate sufficiently. In these cases, repeat the measurement with the pressure valve set higher.
5. Press the white Start button. The cuff will automatically inflate and slowly deflate. When the reading is complete the machine will alternate between showing systolic and diastolic BP and showing pulse.
6. Record value of the pulse, systolic, and diastolic measurements in the relevant boxes.
7. Set a stopwatch for 1 minute and repeat at 1 minute intervals.
8. Record value of the pulse, systolic, and diastolic measurements in the relevant boxes.

HEM-907 (Omron 2 – new machine)

1. When first set up the display should be blank.
2. Press the GREEN 'On/Off' button to prepare the machine to take a reading.
3. Set the MODE Selector to "AVG."
4. The display will show a zero and a heart symbol.
5. Preset should be set to 180.
6. Press the blue start button. The cuff will automatically inflate and slowly deflate. When the reading is complete the machine will alternate between showing systolic and diastolic BP and showing pulse.
7. The Omron will automatically perform the next two reading, at 1 minute intervals.
8. At the end of the measurements, average values are displayed. DO NOT enter this reading. Press the grey deflation button to cycle through the 1st, 2nd and 3rd readings.

Record value of the pulse, systolic, and diastolic measurements in the relevant boxes.

NOTE:
Occasionally participants become faint during blood pressure measurement: this is usually evident from the very low pressure readings and slow pulse. If this is happening disconnect the cuff and give the participant a chance to recover before repeating the measurements, as long as the participant is willing. If you are concerned, please contact Nik, Dan, Marcus or Andy

Answering queries about the participant's blood pressure
Three blood pressure measurements are taken. The first reading can be high because people are nervous about having their pressure taken. Base the feedback on the lowest measure.

If systolic blood pressure is under 140 mmHg **and** diastolic blood pressure is under 85 mmHg please say:
"Your blood pressure is normal"

If the blood pressure is mildly raised (systolic 140-159 or diastolic 85-99 mmHg) please say:
"Your blood pressure is a bit high today. Blood pressure can vary from day to day and throughout the day so that one high reading does not necessarily mean that you suffer from high blood pressure. You are advised to visit your GP within 3 months to have a further blood pressure reading to see if this is a once-off finding or not."

If the blood pressure is moderately raised (systolic 160-179 or diastolic 100-114mmHg) please say:
"Your blood pressure is a bit high today. Blood pressure can vary from day to day and throughout the day so that one high reading does not necessarily mean that you suffer from high blood pressure. You are advised to visit your GP within 2-3 weeks to have a further blood pressure reading to see if this is a once-off finding or not."

If the blood pressure is severely raised (systolic >/= 180 or diastolic >/= 115mmHg) please say:
"Your blood pressure is high today. Blood pressure can vary from day to day and throughout the day so that one high reading does not necessarily mean that you suffer from high blood pressure. You are strongly advised to visit your GP within 5 days to have a further blood pressure reading to see if this is a once-off finding or not."

The participant might wish to make a note of their blood pressure for their own notes. Inform them know that you will photocopy the measurement card at the end of the visit,

Grip strength protocol

Introduction:
Four different types of dynamometer will be used during the calibration study: the Nottingham electronic; Jamar hydraulic; Jamar digital; Smedley. Wherever possible, four measures will be ascertained using each device (2 measures in each hand (in the order: Left 1, Right 1, Left 2, Right 2)).

To ensure comparability of measures across devices a standard protocol will be used when performing each set of grip strength tests (see Roberts et al, Age and Ageing 2011;40(4):423-9). This standard protocol is described below and is followed by information specific to each device.

Equipment:
Dynamometer
A standard straight backed chair with solid arms

Checks before performing the first set of grip strength measurements:

Exclusion criteria.
swelling or inflammation, severe pain or recent injury in their hands
surgery to the hand in the last 6 months (if there is a problem with one hand only use just take measurements on the other hand)
blood pressure over ≥200mmHg for systolic or ≥120mmHg for diastolic.

If the participant has any of these, explain to the participant that they cannot do the grip strength tests as it would not be safe

EXPLAIN THE TEST:

READ OUT:
"We would like to assess the strength of your hand in a gripping action. This test will be done using 4 different machines and each time I would like to take 2 measurements in each hand."

NOTE:
The participant should have use of both hands as a screening question will have been asked before recruitment. However, if the participant only has use of one hand please record this and perform the two measurements in that hand.

READ OUT:
"Which is your dominant hand?"

Proceed with the tests (if participant has use of both hands the order of the tests for each device will be: Left hand, Right hand, Left hand, Right hand)

GENERAL PROTOCOL:

1. Sit the participant comfortably in a standard chair with legs, back support and fixed arms. Use the same chair for every measurement.

2. Ask the participant to rest their left forearm on the arm of the chair in the mid-prone position (i.e. with the thumb facing upwards) and their wrist just over the end of the arm of the chair in a neutral but slightly extended position.

3. Place the dynamometer handle in their left hand (and when using either of the Jamar devices carefully place the wrist strap around the participant's left wrist)

4. Position the hand so that the thumb is round one side of the handle and the four fingers are around the other side. The instrument should feel comfortable in the hand. Alter the position of the handle if necessary. Large rings may need to be removed.

5. Tell the participant: '**after I say 'And Go' I will need you to squeeze the handle of the device as hard as you can, just for a couple of seconds until I tell you to stop and then let go.'** Make it clear that gripping very tightly registers the best score.

6. Once you are happy that the participant's arm is positioned correctly and that the device is ready to record (see details for each device below) you are then ready to take the measure.

7. Say '**And Go!'** at which point, the participant should squeeze as hard as they can for a couple of seconds and then release quickly. You should provide verbal encouragement by telling the participant to **'Squeeze, squeeze, squeeze'** and then you should tell them after a few seconds to stop.

8. During the test please make sure that the participant's arm remains in position resting on the arm of the chair.

9. Record the value on the display to the nearest 0.1kg (for the Jamar digital and Nottingham Electronic devices), 1kg (for the Jamar hydraulic device) or 0.5kg (for the Smedley device).

10. Once the value for the left hand is recorded carefully take the dynamometer from the participant and repeat the test in the participant's right hand.

11. NOW REPEAT THE INSTRUCTIONS ABOVE AND TAKE A SECOND MEASUREMENT IN THE LEFT HAND, FOLLOWED BY A SECOND MEASUREMENT IN THE RIGHT HAND

INFORMATION ABOUT EACH DEVICE

NOTTINGHAM ELECTRONIC

1. The machine needs to be connected to the mains and requires at least 20 minutes to warm up.

2. Connect the handset lead to the input socket on the front and set range knob to zero. Connect the power cable to the back, and plug into the mains. Do not hold the leads or allow the transducer (the handle) to dangle as this may damage the connection.

3. Switch on:
   a. at the wall,
   b. at the back of the dynamometer (a green light should come on),
   c. at the front of the dynamometer (the display should light up).
   d. if either does not light up, check that all the cables are pressed fully into their sockets.

4. Before taking the first measure use the 'set zero' knob to adjust the display so that the black dot is in the centre of the display panel (i.e. reads 0.00).

5. Turn the range switch anti-clockwise and set to 'hold 100kg'.

6. After positioning the participant's left arm (as described above) place the transducer in their left hand (wire up). Check that the handle is the correct size; if the participant's hands are very large you may need to use the larger handles on the transducer.

7. After taking the measure, record the value on the display as soon as possible. It will remain displayed for 10 seconds and then reset automatically.

8. Once the handle has been transferred to the other hand, ensure the display has reset itself to 00.0 before taking the next measurement.

9. If the display does not reset itself to 00.0 after a measurement has been taken, turn the range switch back to zero, wait a few seconds and then turn it back to 'hold 100'

10. If the range switch is set to 'hold 100', the dynamometer has been properly charged and a participant's first attempt does not register on the display, turn the range switch to 'hold 20' and ask the participant to start again

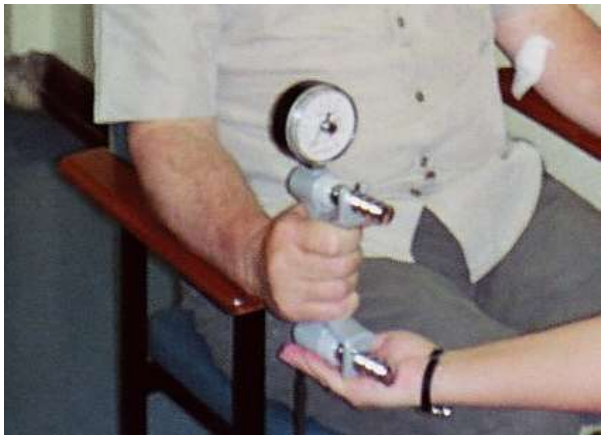
11. Once the tests are complete, turn off the dynamometer and disconnect the handle and power supply.

JAMAR HYDRAULIC

1. Adjust the grip position so that it is the correct size for the participant's hands. The grip handle may be placed in any of five positions to accommodate the size of the participant's hand. This is done as follows:
    a. Unhook the clasp from the lower end of the handle.
    b. Push the lower end of the handle so that the slotted portion rotates away from the lower shaft.
    c. Making sure not to drop the handle allow it to separate from the top shaft.
    d. Determine the appropriate grip position and replace the top part of the handle on the top shaft.
    e. Rotate the lower part of the handle onto the lower shaft until it clicks into place.
    f. Hook the clasp back around the lower end of the handle
    g. Once you are happy that the participant's left arm is positioned correctly check that the red needle is pointing to 0. The needle can be reset by turning the knob in the centre of the dial. Place the dynamometer in the participant's hand with the dial facing away from the participant. You are then ready to take the measure.

2. After performing the test in the left hand, read grip strength in kilograms from the outside dial and record the result to the nearest 1kg. Reset the dial to 0 and repeat the test in the right hand.

3. At the end of testing, replace the handle in the neutral position and place the dynamometer back in the box.



JAMAR ELECTRONIC

1. Take the dynamometer out of the box and turn it on by pressing the [On / Off] button

2. Check that the dynamometer settings are correct – the display panel should show KG on the right hand side and LR 5 in the top left hand corner (if the settings are not correct, follow instruction 4 for resetting the dynamometer)

3. Setting the dynamometer display to "LR 5"
   - Press [SELECT TEST] until it reads "LR1" in the top left hand corner of the display panel
   - Then press [# OF TRIALS] until the number "5" is displayed on the panel

4. Adjust the grip position so that it is the correct size for the participant's hands. The grip handle may be placed in any of five positions to accommodate the size of the participant's hand. This is done as follows:
   a. Push the lower end of the handle so that the slotted portion rotates away from the lower shaft.
   b. Making sure not to drop the handle allow it to separate from the top shaft.
   c. Determine the appropriate grip position and replace the top part of the handle on the top shaft.
   d. Rotate the lower part of the handle onto the lower shaft until it clicks into place.

5. Once you are happy that the participant's left arm is positioned correctly and **just before you start the test press the [TEST] key** (and check that a number in the left hand corner of the display is flashing and that the display reads 0.0). You are then ready to take the measure.

6. After performing the test in the left hand, note down the reading then position the device in the participant's right hand before pressing any of the buttons on the front of the device.

7. Once you are happy that the participant's right arm is positioned correctly and **just before you start the test press the [TEST] key** (and check that a number in the left hand corner of the display is flashing and that the display reads 0.0). You are then ready to take the measure.

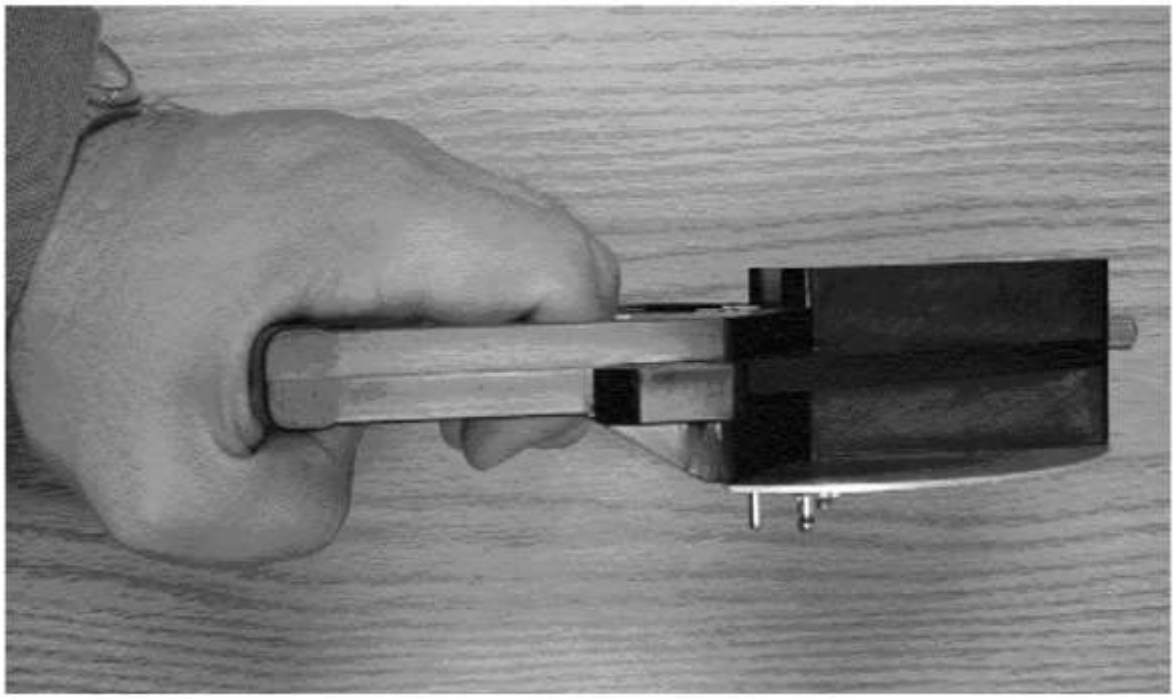
8. Once all four measures (or two measures if the participant only has use of one hand) are recorded turn the dynamometer off by pressing the [On / Off] button

9. Adjust the grip position and place the dynamometer back in the box.

SMEDLEY
(Amended from details in: NatCen Nurse protocol https://www.understandingsociety.ac.uk/files/data/documentation/wave2/Nurse-Protocols.pdf)

1. Adjust the lever of the dynamometer to suit the participant's hand. To do this:
    a. Put the bar of the dynamometer on the pads at the top of the participant's palm (see Figure).

    b. Check to see if it is a good fit by asking the participant to grip the dynamometer - the middle section of their fingers should be flat across the top of the metal bar (see Figure). If they are not you will need to adjust it.



c. To adjust it, you need to lift the metal lever on the side of the dynamometer and rotate the grip until it is in a more suitable position then repeat step b.
d. When you have a good fit, replace the lever on the side of the dynamometer.

2. Before performing the first test ensure the arrow is pointing to 0.

3. Once the left arm is positioned correctly place the device in the participant's hand with the dial facing outwards (the other way around from the above pictures).

4. The most accurate reading is achieved if you look directly down on the scale.

5. After each measurement has been recorded reset the device to 0 (by manually moving the arrow back to 0) before performing the next test.

Lung capacity protocol

Introduction:
Two different types of spirometer will be used during the calibration study: the ndd Easy on-PC and the Micromedical plus. If possible 3 good measures will be obtained from each device and participants can have up to 5 attempts on each device.

To ensure comparability of measures across devices a standard protocol will be used.

Equipment:
Laptop with Easy on-PC software
Easy on-PC sensor
Micromedical Plus
Spirettes
Water for participants

Before the lung capacity measurement explain to the participant that this is a test to assess their lung capacity and that this test will be done using 2 different machines. Explain that each time you would like to take 3 valid measurements.

Exclusion criteria:
Abdominal or chest surgery in the past three weeks
Admission into hospital for a heart complaint or stroke in the past six weeks

Explaining the test:

Explain:
"You will need to stand up for this test. First you will need to take as full and as deep a breath as you can so as to fill your lungs to capacity. Then make a tight seal, with your lips, around the tube, place your tongue under the mouthpiece, and blow out as hard, as fast and as long as you can, until no more air can come out and you are instructed to stop. You will be doing this at least three times 3 times in order to make sure that we obtain similar results. You may feel slightly lightheaded whilst doing this. Remember you need to blow as hard as you can, as fast as you can and for as long as you can. I will also be encouraging you to blow for as long as possible."

While providing this verbal demonstration, it is helpful for you to demonstrate the procedure to the participant, using your own spirette.

The participant needs to be standing to perform this test in order to get the best result. However, should they be unable to stand then perform the test seated.

INFORMATION ABOUT EACH DEVICE

NDD EASY ON-PC

Opening the participant's spirette:

1. To open the spirette, tear along the dotted line of the plastic cover until the black mark.
2. Insert the spirette into the sensor by lining up the triangle on the spirette with the triangle of the sensor.
3. Remember to hold the plastic cover over the mouthpiece until the spirette is inserted completely.

Performing a practice blow:

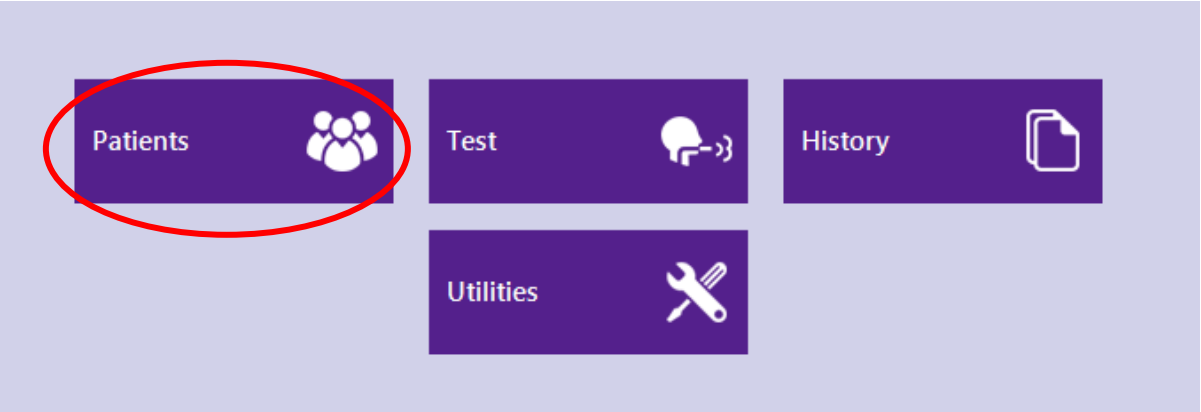
Explain to the participant that they are going to do a practice blow first to ensure that they perform the test correctly. This will not count towards the number of blows they do.
Allow the participant to do a practice but do not let them blow for the full time, stop them mid blow.
The practice is done to make sure they have understood the technique. If they have not understood, explain again. If necessary you may need to perform another practice blow.

Preparation

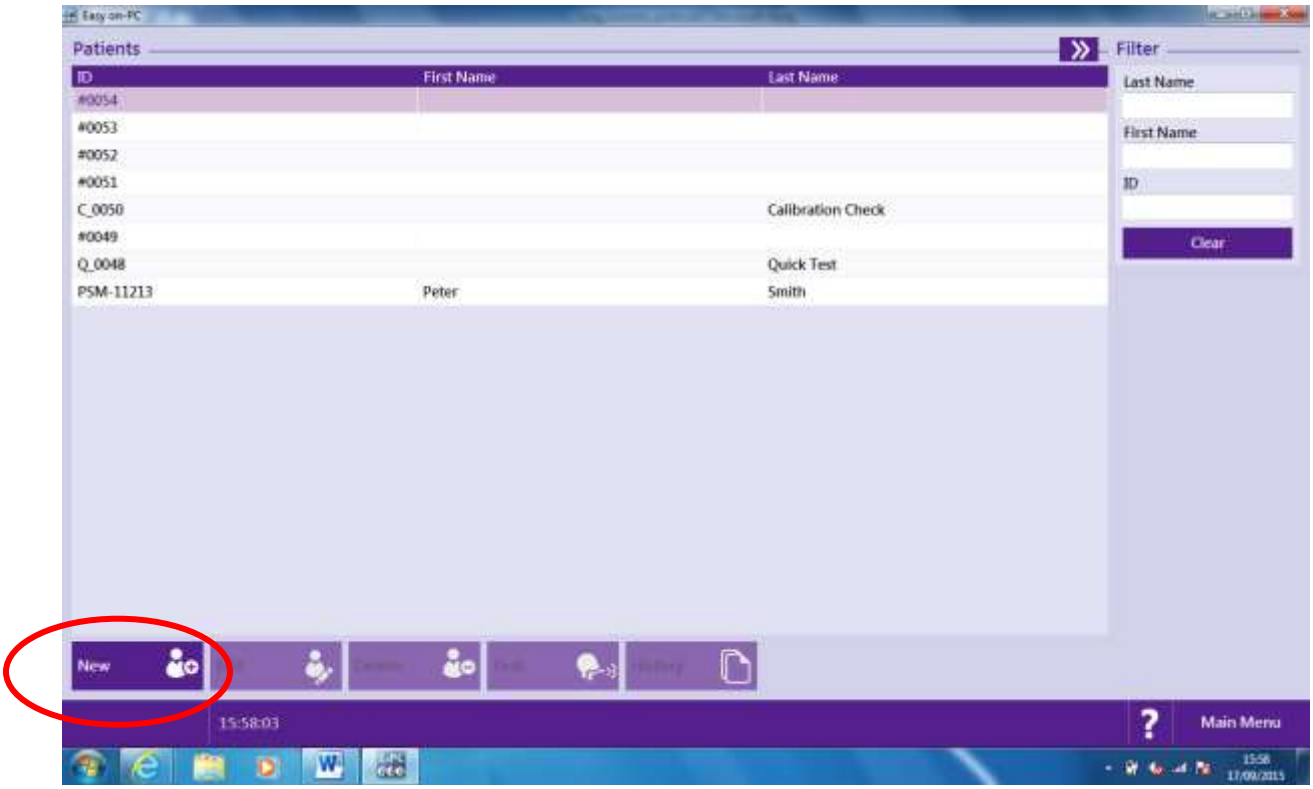
- Plug the spirometer into the USB port before launching the software.
- Click on **"Easy –on-PC".**

Selecting a participant:

1. When you are happy they have the technique correct, click on the icon **'Patients'**

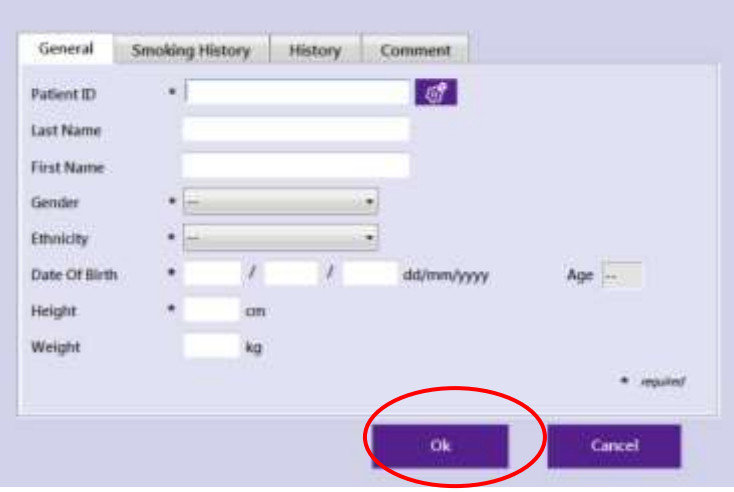


2. You will need to add your participant, click on **"New".** This is at the bottom on the left, circled in red

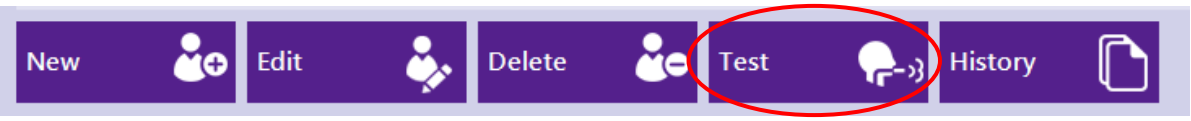


3. Complete the following fields:
Patient ID
Last Name – Initial of surname
First Name – Initial of first name
Gender
Ethnicity
Date of Birth
Height – in cm

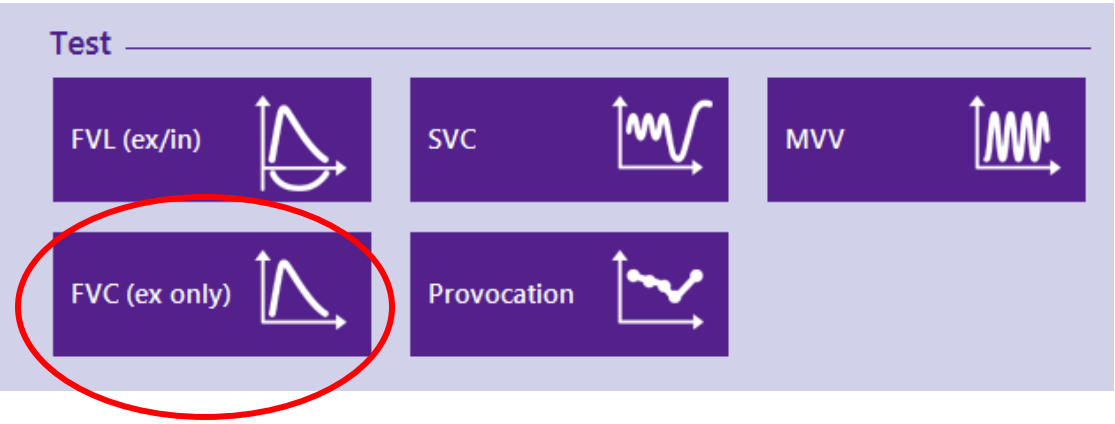
Once all complete, click OK



4. Then click on **TEST** at the bottom of the screen, circled in red.



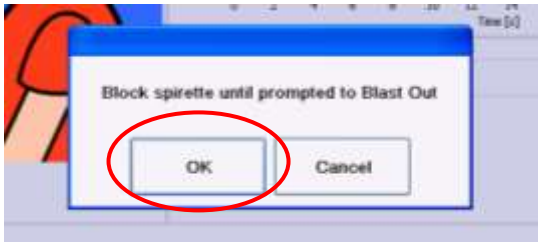
5. Now click on **FVC (ex only)** as circled in red below.



6. Once you have clicked on **FVC (ex only)** you will be able to perform the test.

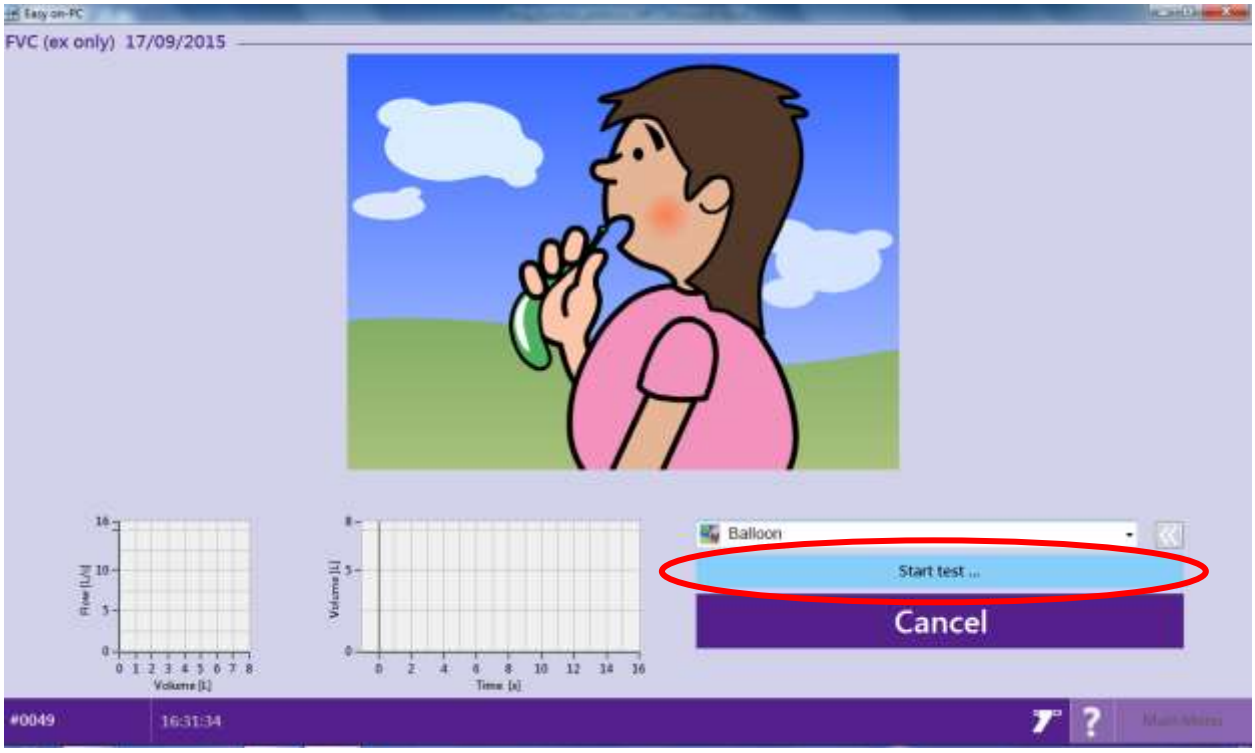
<u>Performing the test:</u>

7. A screen will appear and a pop up will ask you to **Block spirette until prompted to Blast Out.**



8. Cover the BACK of the spirette the participant used for the practice, with the palm of your hand and **click on OK.**

9. The programme will set the baseline and when it has done this you will see the programme say **START TEST**



10. Ensure that when this screen appears you see the boy or girl with the balloon. This is the incentive to encourage the participant to blow for as long as they can.

11. Ask the participant to stand up and hand them the spirometer. When they are ready say:
"Ready, Begin"

It is important to visibly observe the participant perform the maneuverer, making sure that he/she appears to have taken a deep breath, correctly placed the mouthpiece and they are tolerating the test. Do not stand in front of the participant when they are blowing, keep observing aside.

12. Give the participant enthusiastic verbal encouragement whilst they are blowing by saying:

"Keep blowing, keep blowing"

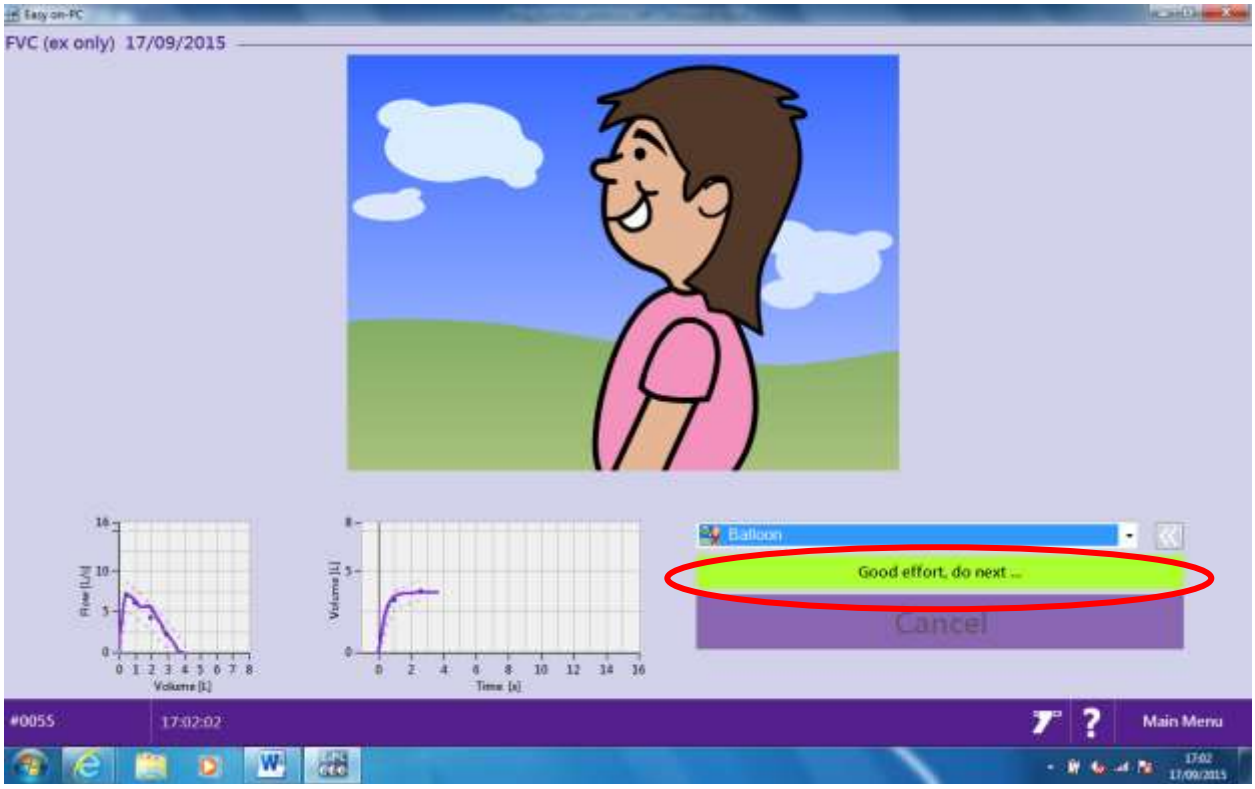
13. Encourage the participant to keep blowing until they feel that there is no more air in their lungs. If the participant is facing the screen they will be able to see the boy or girl blowing the balloon up and the participant needs to keep blowing until the balloon pops and the program says **'Analyzing data'**.

14. If the participant feels they cannot continue blowing or feels dizzy etc, stop the test. Check if they are happy to continue and if you feel they are able to continue, complete the rest of the test.

15. If after having performed the test standing, the participant feels that they are able to continue but would feel safer performing the test seated, indicate this in the measurement card.

16. If the participant or you feel they should not continue, stop the test. You will then need to enter discontinued and continue to the next test.

17. After each blow the programme will provide you with a result. If the participant has been able to blow well and performs a satisfactory blow it will appear with the wording **'Good Effort, do next...'**



18. If the participant is happy to continue with the next blow, click on ADD TRIAL, wait for **Start test** and say:

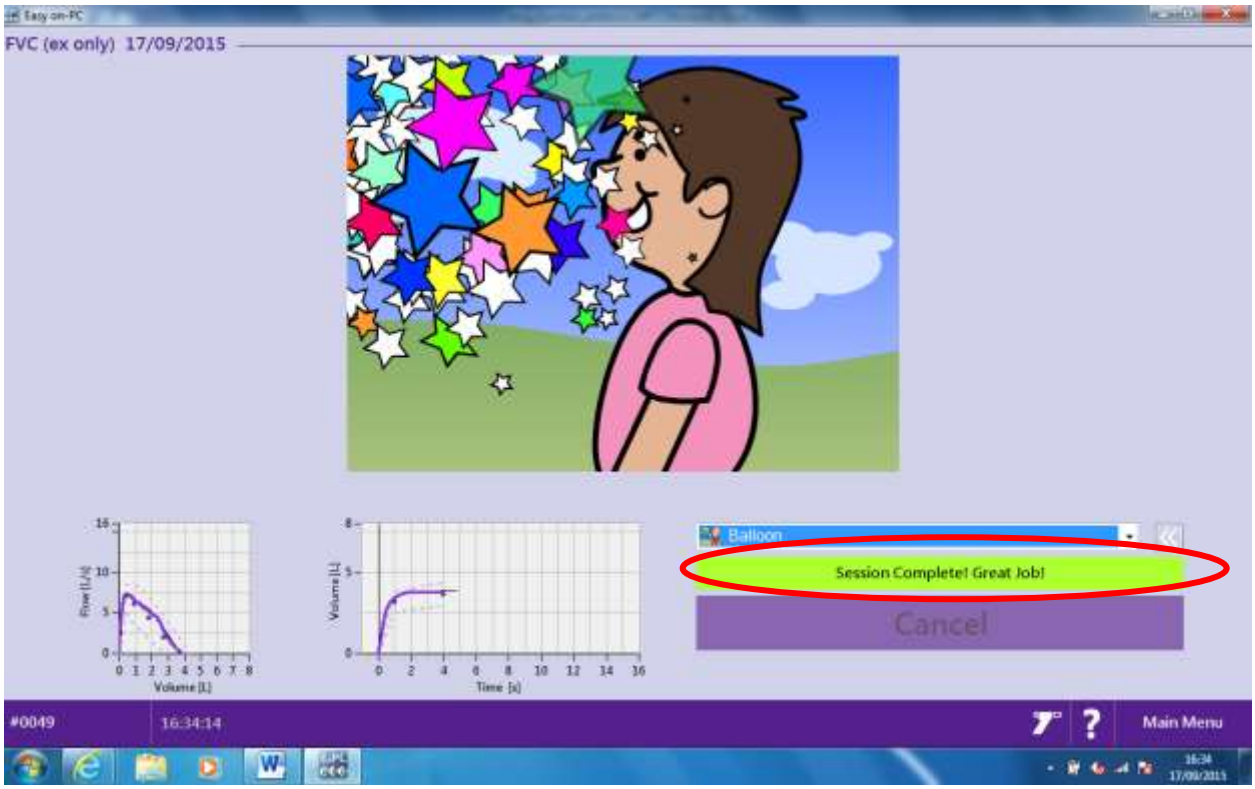
"Ready, Begin"

19. Repeat points 10 - 17 for all subsequent readings. You will not need to set the baseline for the subsequent tests.

20. You need to achieve 3 readings of similar values. The programme will advise you when you have these by displaying the wording:

    'Session Complete! Great Job!'

    This is circled in red in the screen shot below.

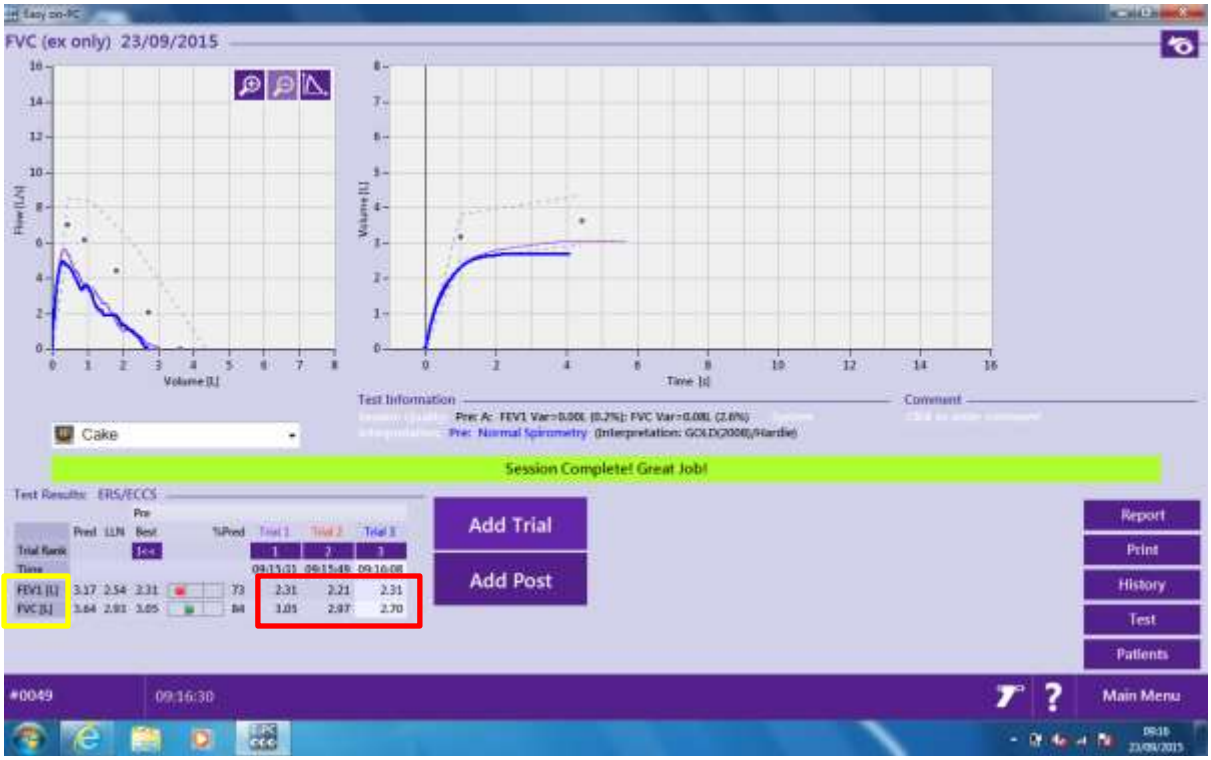


21. You will now not need to perform any further readings.

22. If however you have not achieved 3 readings of similar values, the programme will give you information as to where the problem was, e.g. 'Deeper breath'. Please see the list below of instructions given by the program following an unsatisfactory manoeuvre (blow) and how these should be interpreted.

23. You must only ever perform a **maximum of 5 blows.**

24. If the participant reaches the 5th blow without achieving 3 readings of similar values, do not do any more. Explain to the participant that is the end of the test



25. Please note down the FEV1 and FEC (yellow box), for all of the completed trials (red box). The maximum number of trials is 5.

26. Once complete, the mouthpiece can be thrown in the bin and the software can be closed down.

Technically unsatisfactory blows and program advice

A technically unsatisfactory blow can occur for many reasons. Below is a list of the instructions given by the program following an unsatisfactory manoeuvre (blow) and how these should be interpreted.

Messages following unsatisfactory blows

Message	Reason	Advice
Don't hesitate…	The participant exhaled air in short bursts	Participant must breathe out (blast out) all the air at once, not in short bursts
Blast out faster…	The participant did not blast the air out fast enough	The participant must breathe out the air as fast as hard and as fast as possible
Blow out longer…	The participant did not breathe out for long enough OR stopped when they still had air in their lungs	The participant needs to breathe out for longer OR they need to force out as much air from their lungs as possible
Test abrupt end!	The blow stopped sooner than was expected	The participant needs to breathe out for longer OR they need to force out as much air from their lungs as possible
Good effort, do next…	The blow was acceptable	This is an acceptable blow. They need a two more of these for the overall session to be complete
Do not start too early!	The participant was breathing through the spirette before the program was ready	The participant needs to wait until the screen reads 'Start manoeuvre' until they breathe through the spirette
Cough detected. Try again…	The participant coughed while blowing	The participant needs to avoid coughing if possible.

DISCONTINUED PROTOCOL

Lung function can be discontinued for various reasons and at any point during the testing.

Please refer to the table below for further information.

Scenario/Software interpretation	**Action**
1st attempt – Good effort (Green) 2nd attempt – Good effort (Green) 3rd attempt – Good effort (Green) **SESSION COMPLETED**	No further attempts required.
1st attempt – Good effort (Green) 2nd attempt – Deeper breathe (Orange) 3rd attempt – Don't hesitate (Orange) **SESSION COMPLETED**	No further attempts required.
1st attempt – Good effort (Green) 2nd attempt – Deeper breathe (Orange) 3rd attempt – Don't hesitate (Orange) **OR** 1st attempt – Deeper breathe (Orange) 2nd attempt – Deeper breathe (Orange) 3rd attempt – Don't hesitate (Orange)	If the **you** or **the participant** feel it is okay to continue – continue to do a further one or two attempts to achieve the 5 attempts. **OR** If **you or the participant** do not want to or feel able to continue – DO NOT do any further attempts.
1st attempt – Deeper breathe (Orange) 2nd attempt – Deeper breathe (Orange) 3rd attempt – Don't hesitate (Orange)	If after 3 attempts you feel that the participant is not able to understand the technique required to obtain a satisfactory blow, DO NOT do any further attempts.

MICROMEDICAL

Protocol:

1. Attach an unused cardboard tube and guard to the spirometer.

2. Move the switch from the 'off' to the 'blow' position.

3. Ask the participant to stand up and to take as deep a breath as possible, place their lips around the mouthpiece to make an airtight seal, and then blow out the air into the mouthpiece **as fast, as hard and for as long as they can**. Warn the participant that they may feel slightly light-headed doing this. Try to encourage them to improve their performance at each go. The results are strongly affected by how the respondent blows. Emphasise they must blow **as hard as possible** and for **as long as possible**. A shallow extended blow will give a false reading, although participants suffering from respiratory problems may only be able to blow like this.

4. Give verbal encouragement.

5. Give the participant a practice go, then three recorded attempts. If the participant is distressed or has bad problems after any of the attempts, and does not want to continue, DO NOT INSIST.

6. The machine will initially show a value for FEV_1. Record this in the appropriate place on the schedule and then move the switch to the 'view' position. The machine will cycle through four measurements, **FEV_1**, **FVC, FER** (%) and **PEF** displaying each in turn. Record the first two measurements - **FEV_1**, and **FVC**

   N.B. You can 'freeze' one of the measures by moving the switch back to blow. When you return it to display it will carry on cycling through the measures. However, be careful: if you inadvertently move it to 'off' you will lose any remaining information.

7. Switch the machine off and on again after each blow. Remember to record the measurements before you switch off.

8. Give adequate time in between attempts for the participant to get their breath back.

9. Reassure the participant that a degree of 'wheeze' is normal if the test is done properly, with maximum effort.

10. For each blow indicate whether you think they blew correctly.

11. Now repeat this procedure at least twice more.

12. If the participant provided 3 measurements with the correct technique then you do not need to take any more.

13. If however you have not achieved 3 readings with correct technique, carry out up to 2 more attempts until you have achieved 3 measures with correct technique.

14. You must only ever perform a **maximum of 5 blows.**

15. After the final recorded attempt, hold onto the machine firmly, and ask the participant to remove the cardboard tube and guard. Ask the participant to throw them away for you. (The inside of the turbine casing may get clogged up after use with respondents who have chest trouble, etc. If this happens, ask for a replacement.)

After the assessment

Once all of the measurements have been taken you need to:

1. Photocopy the measurement card and give the photocopied measurement card to the participant. Do not photocopy the 'Office use only' page.

2. Give the participant the £50 high street voucher. Jane Johnson, UCL LHA, will have these. The participant will need to sign that they have received the voucher and you will need to counter sign.

3. Thank the participant for their time and make sure they sign out.

4. Check the room is clean and tidy for the next participant. If you have the last appointment of the day, please make sure all of the machines are switched off.

Data entry

The data from the measurement card will need to entered into an excel file.

Appendix 1: TNS participant invitation letter

TNS headed paper

<Participant address>

<Date>

REF: 260132366 / <SERIAL NO.>

Dear <Title> <Surname>

The CLOSER Calibration Study

You may remember participating in the TNS Omnibus survey in <Month Year >. Your help with the survey was very much appreciated and you said that we could get back in touch with you in the future regarding further research studies.

We are writing now to ask for your help with a health study which is being conducted by researchers from the MRC Unit for Lifelong Health and Ageing at University College London (UCL) and is led by Professor Rebecca Hardy. It is called the CLOSER Calibration Study.

We are inviting **men and women aged 45 and over to undertake three health measures** (blood pressure, lung capacity and hand grip) using different models of medical equipment. This will help researchers draw accurate conclusions when they compare studies that have recorded these health measures in different ways. None of the measurements are invasive and we are looking for people of all levels of fitness to take part. Further details of the measures can be found in the information sheet enclosed. All the information you give us and the results from the measurements will be treated in the **strictest confidence**.

My colleague Hayley Cheshire will call you in the next few weeks to check whether you are willing to take part and to set up an appointment at a convenient time. If you participate you will receive a **£50 high street shopping voucher** as a token of our appreciation. The appointments will take approximately 90 minutes and are being held at the University in Central London.

If you have any questions about the study please do not hesitate to call the UCL team directly on 0800 952 0249. If you do not want to be contacted about the study please let us know by calling the TNS BMRB Freephone number 0800 051 0889 and provide your name and reference number printed at the top of this letter.
We look forward to speaking to you shortly,

Best wishes

Gillian Prior
Head of Longitudinal Research
TNS BMRB

Appendix 2: Participant information sheet

Harmonisation of physiological measures in cohort studies:
CLOSER Calibration Study

We would like to invite you to participate in this research project called the CLOSER Calibration Study. It is up to you to decide whether to take part or not; choosing not to take part will not disadvantage you in any way. If you do decide to take part you are still free to withdraw at any time and without giving a reason. Before you decide whether you wish to take part, it is important for you to understand why the research is being done and what your participation will involve. Please take the time to read the following information carefully and discuss it with others if you wish.

Background
The UK has a number of long-running cohort studies. These follow the same group of people across their lifetime. Measurements of biological function are measured repeatedly in order to look at health across life and to compare the health of different generations. Ideally, exactly the same equipment would be used for every measurement in order to ensure that changes observed represent real changes and are not just due to changes in the methods used. However, methods of measurement will change over time as technology develops and becomes more accurate and convenient.

To be able to make valid comparisons across studies and within-individuals across age, we need to be able to make allowances for the differences in methods of measurement over time and between studies. An equipment calibration study is therefore needed which compares measures of function taken on the same individuals using different machines.

Why have I been chosen for the study?
You have been identified as someone who has taken part in the TNS Omnibus and has said they would be willing to be approached to take part in further research. UCL is working with TNS BMRB (the part of TNS that carries out social research).

To protect your privacy, the invitation letter and this information sheet have been sent by TNS BMRB in complete confidence – your personal details have not been given to anyone else. TNS BMRB is compliant with the 1998 Data Protection Act and abides by professional codes of conduct established by the Market Research Society and Social Research Association, to ensure that all data is kept strictly confidential. The CLOSER Calibration Study research team has no information about you. If you do decide to take part in the study, only the CLOSER Calibration Study appointments team and researchers will have access to your contact details.

Unfortunately you will not be able to participate if you:

- have had a chest infection (such as influenza, pneumonia, bronchitis, severe cold) or been coughing up blood of unknown origin in the last 4 weeks
- have had a heart attack, other heart complaint or stroke in the last 6 weeks
- have had a detached retina, ear or eye surgery in the last 3 months
- have had abdominal or chest surgery or a blood clot in the lung in the last 3 months
- have had surgery to either hand in the last 6 months
- have had a collapsed or punctured lung in the last 12 months
- have ever been diagnosed with an aneurysm in chest, brain or stomach

- are currently on medication for tuberculosis
- have swelling or inflammation, severe pain or recent injury in your hands

What will the study involve?
The study will compare machines for three different non-invasive, simple functional measures: blood pressure, lung capacity and hand grip strength. You will be asked to complete these measurements several times using different equipment.

Many of you will be familiar with blood pressure measurements as these are taken regularly by doctors – we will ask you to have your blood pressure measured using two different sets of equipment.

Grip strength, which is a good marker of overall muscle strength, is measured using a dynamometer. This test involves squeezing a handle as hard as possible for just a few seconds. We will ask you to do this test using four different dynamometers.

Lung capacity is measured using a spirometer. This test involves taking a deep breath and then blowing the air out of your lungs into a tube. We will ask you to do this test using two different spirometers.

Finally, your height and weight will be measured and you will be asked to complete a two page questionnaire providing basic health and lifestyle information. This will take about 5 minutes to complete and will help us to interpret our findings.

You will be asked not to smoke, drink a caffeinated beverage (e.g. tea, coffee, cola) or use an inhaler for the hour before the test as these may influence the spirometry measurements.

Where will the study take place?
The study will take place at MRC Unit for Lifelong Health and Ageing at UCL, 33 Bedford Place, London, WC1B 5JU, at a time that is convenient to you.

How long will the Study last?
A trained researcher will carry out all of the assessments. The whole study visit will take no more than one and a half hours. The measures will be spread out during the hour and a half with time to rest between measures.

Will you compensate me for my time?
You will receive a £50 high street shopping voucher for participating in the study and to cover any travel costs that you may incur.

What are the benefits and risks of taking part?
You will receive a sheet summarising your results, and you will be advised to see your GP if your blood pressure is found to be high or if you have particularly low lung capacity. All tests are straightforward and non-invasive and there are no side effects from any of the tests.

How will my test results and information be stored?
All the information you give us and the results from the measurements will be treated in the strictest confidence. They will be stored securely and will be the responsibility of the MRC Unit for Lifelong Health and Ageing at UCL. The data will be stored on password protected UCL computers and will be coded and kept in an anonymous form.

No link will be made between your personal data (such as your name and contact details) and the results of your tests and the information you provide on the questionnaire.

What will happen to the results of the research?
We shall publish the results of the calibration study in scientific journals and present them at academic meetings. Your results will be anonymised and treated in the strictest confidence and no participant will be identifiable in any report or publication.

Who is funding and organising the research?
The study is funded by the Cohorts and Longitudinal Studies Enhancement Resource (CLOSER) which is itself funded by the UK Economic and Social Research Council (ESRC) and the Medical Research Council (MRC). The study research team is based at the MRC Unit for Lifelong Health and Ageing at UCL.

Who has reviewed the study?
This research project has been given a favourable ethical review by the UCL Research Ethics Committee (6338/001).

If you have any queries about the study please contact:

Jane Johnson
MRC Unit for Lifelong Health and Ageing at UCL
33 Bedford Place
London
WC1B 5JU

Freephone: 0800 952 0249
Telephone: 020 7670 5700
Email: jane.johnson@ucl.ac.uk

Appendix 3: Telephone recruitment questionnaire

Serial =

CLOSER Calibration Study – Telephone recruitment

Hello – Can I just check that I have got through to <NAME>?

I'm calling about a research project called the CLOSER calibration study. I'm Hayley Cheshire, a Research Associate, calling from TNS BMRB, who is working with University College London.

Q1 We recently wrote to you to ask for your help in our study. Please may I check that you received the letter?

Yes 1
No 2

IF NO:

I'm sorry that you didn't receive it. The letter invited you to take part in this health study. Would you like me to explain over the phone and send another letter and information leaflet to you?

Yes 1
No 2

Q2 Is this something that might be of interest to you?

Yes 1
No 2

INFORMATION ABOUT THE STUDY:

Looking to recruit people aged 45 to 74 to take part in our study.
Study is being run between October and December this year
Offering £50 high street voucher as token of our appreciation (https://www.highstreetvouchers.com/gift/where-to-spend-love2shop-vouchers)
As part of study – you will be asked to have different health measurements taken – **BP, lung capacity, grip strength** using different models of machine.
Analysts will look at possible variation in health measures as a result of using different equipment.
You will get the results of the tests

Q3 Before we go any further, can I just check the following health exclusions that might prevent you from taking part? Have you had:

	Yes	**No**
A chest infection (such as influenza, pneumonia, bronchitis, severe cold) in the last 4 weeks?	1	2
Have been coughing up blood of unknown origin in the last 4 weeks	1	2
A heart attack or other heart complaint in the last 6 weeks?	1	2
A stroke in the last 6 weeks?	1	2
Abdominal or chest surgery in the last 3 months?	1	2
Have you ever been diagnosed with an aneurysm in chest, brain or stomach?	1	2
A detached retina or eye surgery in the last 3 months?	1	2
Ear surgery in the last 3 months?	1	2

A collapsed or punctured lung in the last 12 months?	1	2
A blood clot in the lung in the last 3 months?	1	2
Are you currently on medication for tuberculosis?	1	2
Surgery to either hand in the last 6 months?	1	2
Have you had swelling or inflammation, severe pain or recent injury in your hands?	1	2

Q4 Can I arrange an appointment for you to go along to UCL offices to take part (by researchers)? MRC Unit for Lifelong Health and Ageing at UCL, 33 Bedford Place, London, WC1B 5JU.
Yes 1
No 2

Appointments Monday to Friday
Have 5 possible time slots per day (8.45, 10.30, 12.45, 2.30, 4.45)
Should take no more than 1.5 hours.
No smoking or caffeinated drink (tea/coffee) or inhaler, an hour before.
We will send confirmation letter and map in post.

Q5 What date/time suits you best?

APPOINTMENT INFORMATION

Appt Day/Date	
Appt Time	
Other information:	

Q6 Can I just check your contact information?

Full name	
Age	
Address	
Postcode	
Home Tel	
Mobile Tel	
Work Tel	

Q7 Would you be happy for me pass your contact information to University College London in case they need to contact you in relation to your booked appointment?
Yes 1
No 2

That's the end of the call. Thank you for your time and help. I would just like to confirm that I am Hayley Cheshire calling from TNS BMRB. This is a genuine research study, conducted within the Market Research Society's Code of Conduct and all your replies will be treated in the strictest confidence. Should you wish to check any details of the call or our organisation I can provide you with relevant numbers to call. Would you like to take these down?

IF NECESSARY:

To verify that we are registered as a Market Research organisation, with a professional code of conduct, please call the Market Research Society on their verification service. The number is 0500 39 69 99 - you will be connected free of charge from a landline.

To find out further information about our organisation or the nature of this particular study, you can contact Gillian Prior (Head of Longitudinal Research) on 020 7656 5656.

Appendix 4: Participant confirmation letter

REF: 260132366 /
Dear

The CLOSER Calibration Study

Thank you for agreeing to take part in the CLOSER Calibration Study. All the information you give us and the results from the measurements will be treated in the strictest confidence.

Your appointment details are listed below. We have also enclosed a map of the venue.

Date:

Time:

Venue: MRC Unit for Lifelong Health and Ageing at UCL
33 Bedford Place
London
WC1B 5JU

On the reverse of this letter we have listed conditions that would exclude you from taking part in the study, please double check that none of these apply to you before attending your appointment.

Please arrive 5 minutes before your appointment time. Upon arrival press the entry buzzer, wait for a reply and then give your name stating you are a participant in the CLOSER Calibration Study. We recommend you wear loose clothing, and please do not smoke, drink a caffeinated beverage (e.g. tea, coffee, cola) or use an inhaler for the hour before your appointment.

As a token of our appreciation, a £50 high street shopping voucher will be given to you at the end of the appointment.

If for any reason you cannot make this appointment, or would like to reschedule, please call the UCL team directly on 0800 952 0249.

We look forward to seeing you then,

Best wishes

Gillian Prior
Head of Longitudinal Research
TNS BMRB

Exclusion criteria for CLOSER Calibration Study

Unfortunately you will be unable to participate in the study if you:

have had a chest infection (such as influenza, pneumonia, bronchitis, severe cold) or been coughing up blood of unknown origin in the last 4 weeks

have had a heart attack, other heart complaint or stroke in the last 6 weeks

have had a detached retina, ear or eye surgery in the last 3 months

have had abdominal or chest surgery or a blood clot in the lung in the last 3 months

have had surgery to either hand in the last 6 months

have had a collapsed or punctured lung in the last 12 months

have ever been diagnosed with an aneurysm in chest, brain or stomach

are currently on medication for tuberculosis

have swelling or inflammation, severe pain or recent injury in your hands

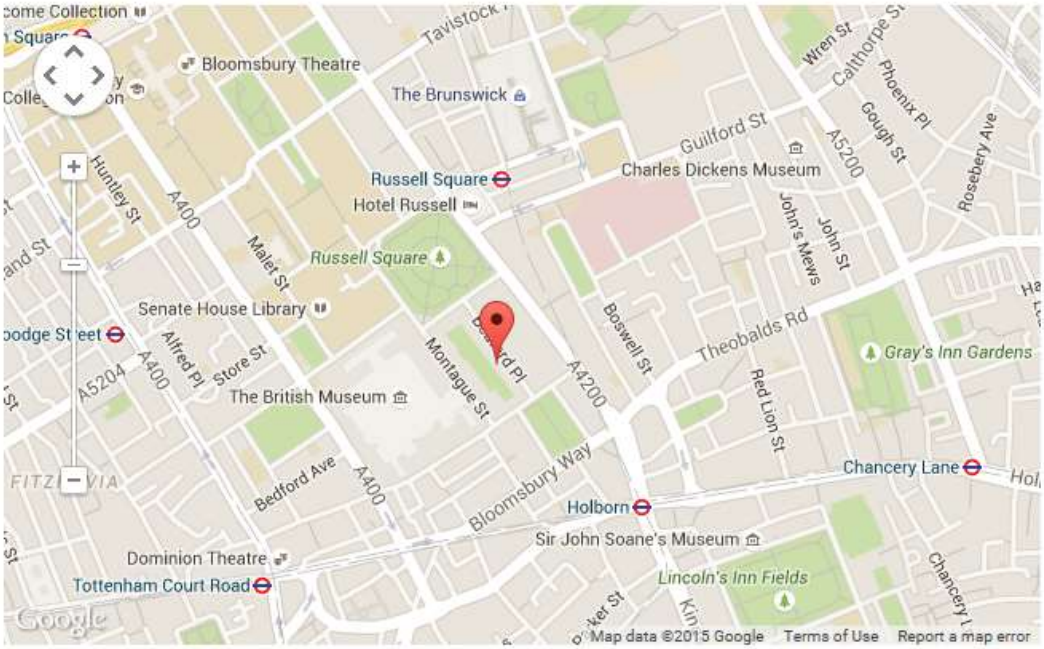
Registered in England & Wales No. 3073845
TNS UK Limited Registered Office: Westgate, London W5 1UA

CLOSER Calibration Study

How to Find Us

Address:
MRC Unit for Lifelong Health and Ageing at UCL (LHA)
33 Bedford Place
London WC1B 5JU
UK

Map:



Getting to LHA by public transport:

Tube
The nearest underground stations are Russell Square (Piccadilly line) and Holborn (Piccadilly and Central line).
Also close by is from Tottenham Court Road (Central and Northern line).

Mainline train
The nearest overground railway station is Euston.

Telephone:

You can telephone us on: 0800 952 0249.

Appendix 5: Participant consent form

C1. General consent v1 06/01/15

STRICTLY CONFIDENTIAL

Place label here

MRC Unit for Lifelong Health and Ageing

UCL

Harmonisation of physiological measures in cohort studies: CLOSER calibration study
Researcher: Prof Rebecca Hardy

This study has been approved by the UCL Research Ethics Committee (Project ID number): 6338/001

Thank you for your interest in taking part in this research. Before you agree to take part, the person organising the research must explain the project to you.

If you have any questions arising from the Information Sheet or explanation already given to you, please ask the researcher before you decide whether to join in. You will be given a copy of this consent form to keep and refer to at any time.

Thank you for reading the information sheet about the measure we should like to make today

	Please initial box
1. I confirm that I have read and understand the information sheet for study (version 1 dated January 2015) I have had the opportunity to consider the information, ask questions about the study and have had these answered satisfactorily.	☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.	☐
3. I agree to take part in the above study.	☐

Name of Participant	Date	Signature
Name of Nurse	Date	Signature

MRC Unit for Lifelong Health and Ageing at UCL, 33 Bedford Place London WC1B 5JU
Tel: 0044 20 7670 5700 website: www.nshd.mrc.ac.uk

Appendix 6: Participant questionnaire

ID: ☐☐☐

MRC Unit for Lifelong Health and Ageing

UCL

CLOSER Calibration Study Questionnaire

This questionnaire provides us with information that we need in order to be able to interpret the results of your tests correctly. Please tick the appropriate box or give further details in the space provided. Please ask the nurse if you are unsure about anything.

All information you give us will be treated in the strictest confidence.

Age: _____ years Male/female

1. At what age did you finish your continuous full-time education at school or college?
   - Never went to school ☐
   - 14 or under ☐
   - 15 ☐
   - 16 ☐
   - 17 ☐
   - 18 ☐
   - 19 or over ☐

2. How is your health in general?
   - Excellent ☐
   - Very good ☐
   - Good ☐
   - Fair ☐
   - Poor ☐

3. Have you ever been told by a doctor that you have had:

a) a heart attack (myocardial infarction)?
   - No ☐
   - Yes ☐

b) angina?
   - No ☐
   - Yes ☐

c) other type of heart disease?
   - No ☐
   - Yes ☐

4. Have you ever been told by a doctor that you have hypertension or high blood pressure?
   - No ☐
   - Yes ☐

If **yes**, are you on any medication for hypertension/high blood pressure?
   - No ☐
   - Yes ☐

5. Do you have arthritis or other musculoskeletal conditions that affects your hands?
   - No ☐
   - Yes ☐