



MULTI-ETHNIC STUDY OF ATHEROSCLEROSIS

EXAM 7 Home Visit

Field Center Manual of Operations

**January 20, 2023
Version 1**

MOP Version Change Log

Version Date	Summary of Changes

Multi-Ethnic Study of Atherosclerosis Exam 7 Field Center Manual of Operations for Home Visits

Contents

1	OVERVIEW	4
1.1	Purpose and Objectives	4
1.2	How to use this manual	4
2	EQUIPMENT AND SUPPLIES	4
3	EXAM 7 HOME VISIT PROCEDURES	7
3.1	Summary of Exam 7 Home Visit Components	7
3.2	Data Collection Forms.....	8
3.3	Order of Exam Components.....	9
3.4	Exam Component Selection Requirements and Prioritization	9
4	PREPARING FOR THE EXAM 7 HOME VISIT	10
4.1	Prior to the Home Visit.....	10
4.2	Optional verbal consent for Exam 7 Questionnaires.....	10
4.3	COVID-19 screening policy.....	10
4.4	Pre-visit Reports and Forms	10
4.5	Completion of Forms at the Home Visit	10
4.6	Set up Participant Supplies.....	10
4.7	Staffing	10
4.8	Guidelines for Examination of Diabetic Participants.....	11
5	EXAMINATION PROCEDURES	11
5.1	Participant Reception and Consent.....	11
5.2	Anthropometry	11
	Standing Body Height	12
	Body Weight.....	13
	Girth and Neck Circumference Measurements	13
5.3	Seated Blood Pressure	13
5.4	Pulse Oximetry	17
5.5	Biosample Collection	17
5.6	Cognitive Assessment	23
5.7	Questionnaires	23
5.8	Spirometry	23
5.9	ABPM.....	34
5.10	Hip activity monitor	34
5.11	Wrist activity monitor.....	34
5.12	Continuous glucose monitor.....	34
5.13	Heart Monitor Patch	34
5.14	Home Sleep Study	34
5.15	Post Exam Activities and Exit Interview.....	35

1 OVERVIEW

The MESA Exam 7 Protocol includes a home visit option to allow participation for those who are unable or unwilling to come to the clinic. Home visits improve retention rates and provide an additional way to help keep participants connected to MESA.

As we continue, keep the above in mind when you perform the procedures on those gracious and willing participants. The ultimate value of this study depends on you and on the quality of the data that you collect.

1.1 Purpose and Objectives

The purpose and objectives of the MESA Exam 7 are described in detail in the main Exam 7 Manual of Operations.

1.2 How to use this manual

This manual contains step-by-step instructions for completing all the components in MESA Exam 7 during a home visit. Many of the steps and procedures are the same as in the clinic visit; thus, where appropriate, the main manual of operation should be consulted.

You should carefully study all sections that relate to procedures that you will be performing, and you should keep this manual handy as a reference. If you have questions about anything in the manual, please direct them to your Study Coordinator or the MESA Coordinating Center.

2 EQUIPMENT AND SUPPLIES

Most supplies and equipment needed for the Exam 7 home visit are the same as those used in the clinic visit. The following supplies and equipment should be transported to the home:

Exam equipment & supplies

Item	Procedure
Tablet PC computer and power cord	General
T-Mobile Wi-Fi Hotspot	General
Disposable face masks	General
Paper (PDF) copies of questionnaires and forms (backup)	General
Reading glasses or magnifying glass	General
Participant retention blanket	General
Participant retention tote bag	General
Consent forms in the appropriate language (and participant folders/files)	Consent
UBACC Questions	Consent
Portable scale for home visits (SECA)	Anthropometry
Gulick II 150 cm anthropometric tapes	Anthropometry
Germicidal cleanser and wipes	Anthropometry
Current version of Prescriber's Digital Reference (pdr.net)	Medications
OMRON 10 Series Wireless Bluetooth Upper Arm blood pressure monitor (model BP7450)	Seated Blood Pressure
Storage case for OMRON blood pressure Monitor	Seated Blood Pressure
Watch or stop watches (to time five-minute rest and resting heart rate)	Seated Blood Pressure

Item	Procedure
Devon Medical Handheld Pulse Oximeter PC-66	Oximetry
Questionnaire response option flip book	Questionnaires

Core exam phlebotomy and laboratory supplies and equipment

Item	Procedure
Lab coats and gloves	Blood Collection
Phlebotomy / Processing Form	Blood Collection
Washcloths/Towels	Blood Collection
Emesis Basin	Blood Collection
Smelling salts	Blood Collection
Lab mats and wipes	Blood Collection
Approved biohazard disinfectant (bleach solution alternative)	Blood Collection
Plastic tray with compartments for phlebotomy supplies	Blood Collection
Winged Push Button Retractable Butterfly needles (21 G) with luer adapter (B-D # 367344)	Blood Collection
Vacutainer barrels	Blood Collection
Tourniquets	Blood Collection
Alcohol prep pads	Blood Collection
Sterile Gauze (2x2)	Blood Collection
Surgical tape - paper tape (easier on participants)	Blood Collection
Band-Aids	Blood Collection
Pre-labeled Blood collection tubes (take extras)	Blood Collection
Blood tube rack	Blood Collection
Insulated receptacle with cold packs	Blood Collection
Stopwatches or timers	Blood Collection
Scissors	Blood Collection
Pens	Blood Collection
Small portable sharps container (LSS product #: 55520)	Blood Collection
Biohazard waste bag for soiled gauze/etc. (LSS Product #: 37944)	Blood Collection
IATA Packing Instruction 650 compliant leak-proof container for storage of filled blood tubes (ThermoSafe product #: VIAL650)	Blood Collection
IATA Packing Instruction 650 compliant packaging material including: pressure vessel with stop lock lid, and corrugated outer carton with required markings (ThermoSafe product #: INF2000)	Blood Collection
Refrigerant material (cold pack) to keep blood tubes cool (ThermoSafe product #: 405)	Blood Collection
Appropriate label for Category B Diagnostic Sample transport (ThermoSafe Product #: L3900)	Blood Collection
Biospecimen barcode labels	Blood Collection

Ancillary Study Equipment and Supplies

Item	Procedure
Stopwatch (for cog testing and SPPB)	Cognitive Assessment
CASI “kit” (pen, soft-lead pencil with eraser, five objects for naming and recall)	Cognitive Assessment
Blank sheets of paper; piece of blank cardboard (for covering five objects during recall)	Cognitive Assessment
Cognitive assessment paper forms	Cognitive Assessment
Two No. 2 graphite pencils without erasers	Cognitive Assessment
Drawing of complex figure (UDS: Benson Complex Figure Test)	Cognitive Assessment
Audio recorder	Cognitive Assessment
N95 masks	Spirometry
Disposable gloves	Spirometry
Disposable gowns	Spirometry
Eye protection (Face shield)	Spirometry
EasyOne spirometer and cable	Spirometry
Disposable spirettes	Spirometry
Tablet PC with NDD EasyWare spirometry software	Spirometry
Calibration syringe, 3.00 liters, Han Rudolph model # 5530 (you should have from Exam 3/4/5/6)	Spirometry
Nose clips	Spirometry
Disposable filters	Spirometry
Connector	Spirometry
Participant Daily Diary	Home Monitors
GENEActiv Wrist Actigraphy Monitor	Wrist Actigraphy
PDI Sani-Cloth Disinfecting Wipes	Wrist Actigraphy
Participant Materials	Wrist Actigraphy
OnTrak ABPM Monitor	ABPM
PDI Sani-Cloth Disinfecting Wipes	ABPM
Participant Materials	ABPM
ActiGraph wGT3X-BT [30 monitors/FC]	Hip Monitor
ActiGraph belts or belt clips [1/participant]*	Hip Monitor
ActiLife 6 Lite License [1/FC] download	Hip Monitor
Neo Hub w/ 7 USB-NEO Cables [1/FC]	Hip Monitor
PDI Sani-Cloth Disinfecting Wipes	Hip Monitor
Prepaid mailers for returning monitors (e.g., Amazon Basics Poly Bubble Mailer, 8.5" x 12")	Hip Monitor
Participant Materials	Hip Monitor
Cardiac monitors (Cardea SOLO patch)	Heart Monitor Patch
Prepaid mailers for returning monitors	Heart Monitor Patch
Participant Materials	Heart Monitor Patch
Disposable razors to be used as needed	Heart Monitor Patch
Extra gauze pads to be used as needed	Heart Monitor Patch
Extra alcohol wipes to be used as needed	Heart Monitor Patch

Item	Procedure
Latex free gloves (small, medium, large sizes)	Heart Monitor Patch
Continuous glucose monitor sensors	Glucose Monitor
Continuous glucose monitor readers	Glucose Monitor
Adhesive patches	Glucose Monitor
Prepaid mailers for returning sensors	Glucose Monitor
Alcohol wipes	Glucose Monitor
Participant Materials	Glucose Monitor
RIP belts, Nox cannula w/filter, Snap on electrodes (small size), Blue snap sensors, lead with attached electrode, NuPrep skin prepping gel, Ten20 Conductive EEG paste, Tensive Adhesive Gel	Polysomnography
Tape Measure, 60"	Polysomnography
Marking pencil for skin (marking electrode placement)	Polysomnography
Nylon hair comb/hair clips	Polysomnography
Medicine cups 1 oz.	Polysomnography
Latex free gloves (small, medium, large sizes)	Polysomnography
Cotton-tipped applicators 6"	Polysomnography
Prep N' Stay skin preparation solution	Polysomnography
Gauze squares, 1"x1", 4"x4", Single-ply 1" non-stretch gauze rolls	Polysomnography
Tongue depressors, non-sterile 6"	Polysomnography
PDI Sani-Cloth Disinfecting Wipes	Polysomnography
Toothbrushes (for cleaning electrodes)	Polysomnography
Bandage scissors	Polysomnography
Under pads (blue chux for surface protection)	Polysomnography
Transpore/Micropore tape, Cover Roll Stretch Adhesive Tape	Polysomnography
Powerex MH-C801D battery chargers and NiMH rechargeable batteries	Polysomnography
AAA alkaline batteries	Polysomnography
Ziploc plastic bags	Polysomnography

3 EXAM 7 HOME VISIT PROCEDURES

3.1 Summary of Exam 7 Home Visit Components

The components below can be conducted at a home visit. If feasible, the participant can also be invited to come to the clinic after the home visit for scanning and/or other procedures that are not possible during a home visit.

- Consent
- Anthropometry
- Oximetry
- Seated Blood Pressure
- Blood Collection
- Cognitive Assessment
- Questionnaires
- Spirometry
- Monitor device placement and instructions

- ABPM
- Hip activity monitor
- Wrist activity monitor
- Continuous glucose monitor
- Heart Monitor Patch
- Overnight Sleep Study (polysmnography)

Exam 7 components excluded from the home visit include:

- Urine collection
- Hair follicle and nasal brushing sample collection
- Arterial stiffness
- Clinician Physical Exam
- Short Physical Performance Battery
- Lung CT
- Brain MRI
- Brain PET

3.2 Data Collection Forms

All forms will be administered using the REDCap Data Collection system using a tablet PC, unless otherwise noted below.

Study Tracking Forms:

- Call Log
- Clinic Reception
- Participant Tracking
- Exit Report

Exam Component Forms:

- Anthropometry
- Seated BP & Pulse Oximetry
- Biosample Collection
- Medications
- Cognitive Function Testing Completion
- Neighborhood Questionnaire Completion

Participant Questionnaires:

Questionnaires can be completed on paper, by phone, web survey, or during an interview

- Medical History
- Personal History
- Neighborhood Questionnaire
- Health & Life
- COVID-19 History
- Sleep Questionnaire
- Family History
- Sleep Study PSG Questionnaire
- Environmental Exposures
- Daily Stress Survey (completed by phone survey)
- Participant Diary (completed on paper)

Reading Center and Monitoring Exclusion & Completion Forms:

- Spirometry Completion
- CGM Completion
- Hip and Wrist Activity Monitors Completion
- Stress Reactivity Completion
- 24H ABPM Home Tracking
- Sleep PSG Tracking

3.3 Order of Exam Components

The complete home visit will require about 3 hours. Every effort should be made to perform all the components of the examination within during the home visit. Field Centers may vary the exam sequence if needed.

Guidelines for the visit order are listed below. Many elements are left to the discretion of the individual field center.

1. Consent and participant questionnaires may be completed prior to the home visit by phone, video visit, or using web surveys or mailed paper forms.
2. Anthropometry and blood pressure are completed while the participant is fasting when possible, immediately following the greeting and informed consent, and before the blood draw.
3. Resting blood pressures should be collected before the blood draw and after the participant has been in the seated position for at least five minutes.
4. When possible, the blood draw should be done after an 8-hour fast and before 12:00 noon.
5. Questionnaires and other exam procedures may be administered at any time during the visit. During the interviews, make every effort to avoid distractions, ensure privacy, and maintain confidentiality for the participant.

3.4 Exam Component Selection Requirements and Prioritization

Participants will be scheduled with the expectation that they will undergo ALL procedures and complete ALL questionnaires for which they are selected. However, for those few participants who are unable to participate fully, the following guidelines should be followed.

Core Exam procedures (blood pressure, anthropometry, medications, phlebotomy) are prioritized above all ancillary study procedures.

MESA Lung components: All participants are selected for spirometry.

MESA MIND components: Participants with a MESA MIND Visit A diagnosis of dementia are not selected cognitive function testing.

MESA Sleep components: Participants are encouraged to complete the home sleep study, activity monitors, and 24-hour blood pressure monitor. None are requirements for completing other MESA Sleep components. The overnight sleep study and 24-hour blood pressure monitors should not overlap.

MESA 24H-ACT components: The hip and wrist activity monitors must be worn together over the same time period.

MESA Stress Reactivity: Participants must agree to complete both the heart monitor patch and the daily stress questionnaire.

4 PREPARING FOR THE EXAM 7 HOME VISIT

4.1 Prior to the Home Visit

Participants due to have an Exam 7 home visit should be contacted at minimum one week prior to the planned appointment date.

4.2 Optional verbal consent for Exam 7 Questionnaires

Participants may choose to complete questionnaires prior to consent. Document verbal consent using the procedure described in the Exam 7 MOP.

4.3 COVID-19 screening policy

All participants should be screened for flu-like symptoms and a positive COVID test at:

- the time of scheduling
- the reminder phone call on the day before the visit
- the beginning of the visit.

If they screen positive, visits should be delayed until 14 days after a positive test or the beginning of symptoms, whichever is later, and until they are feeling in their normal health.

This screening is not a substitute for institutionally mandated screenings.

4.4 Pre-visit Reports and Forms

Follow details described in the Exam 7 MOP

4.5 Completion of Forms at the Home Visit

Complete all forms using direct data entry into REDCap when at all possible. If unable to use participant's WIFI, set up mobile Hot-Spot and ensure that your computer is linked. Have recently printed paper copies of all forms as back up if needed and be sure to enter data into REDCap as soon as possible.

4.6 Set up Participant Supplies

Set up vacutainer and aliquoting tubes for the basic Exam 7 on the racks and attach the pre-printed labels to the tubes. Pack all phlebotomy supplies, including labeled blood collection tubes, in the biosample collection container for transportation to home visits. Leave the labeled cryovials at the clinic where they will be ready for processing when the blood samples arrive.

Prepare information packets and return mailers for home monitors. Ensure that monitors are charged and ready for deployment.

4.7 Staffing

At least two clinic staff should go to the participant homes to perform the home visit. If staffing permits, a third person could go to the home in a separate vehicle and return to the clinic with the blood samples as soon as they are collected.

4.8 Guidelines for Examination of Diabetic Participants

Diet-controlled diabetics must fast overnight and are treated the same as non-diabetics.

Diabetics taking oral hypoglycemic medications or insulin must fast after midnight (unless a bedtime snack was prescribed by their physician) and be ready at the home visit without taking their hypoglycemic medication. They should have their morning medication dose with them. Schedule all known diabetics taking oral hypoglycemic medications or insulin for examination as early as possible (before 9 a.m.). Draw fasting blood samples promptly on arrival at the home (after measuring blood pressure). Immediately following venipuncture, allow the participant to have breakfast and instruct them to take hypoglycemic medication as prescribed.

5 EXAMINATION PROCEDURES

5.1 Participant Reception and Consent

The Check-In and Reception process is the first thing the participant experiences upon arrival and sets the tone for the entire visit. The home reception process is important in setting the participant's frame of mind for the rest of the exam day. Greet each participant warmly as soon as you arrive at the home.

If you arrive at the home and the participant is acutely ill (e.g., COVID-19, "flu" or bronchitis), do not continue with the clinic examination. Plan to contact them to reschedule the appointment after they have recovered.

Refer to the Exam 7 Clinic Exam MOP for specific details about the reception and consent processes and entering the information into the REDCap database.

If non-participants are present during the visit, address the participant directly and do not encourage conversation with other persons. If necessary, ask that the participant be left alone for visit.

5.2 Anthropometry

PURPOSE

Overall, the purpose of the anthropometry procedures are the same as for clinic exams 1-6 (to acquire general measures of body size, shape and obesity) and the resulting data will be useful in virtually every analysis and manuscript produced that makes use of the Exam 7 data.

MATERIALS AND EQUIPMENT

- 12" 30°/60°/90° triangle
- Adhesive tape (easy removal)
- Metal measuring tape
- Pencil (No. 1 or No. 2 preferred)
- SECA 815 Elegancia digital floor scale or similar model
- Omron portable blood pressure device
- Gulick II 150 cm anthropometric tape

METHODS

Methods for completing the height and weight will need to be modified according to the equipment appropriate for the home visit.

General Instructions:

For all measurements, participants should wear light clothing but no shoes (thin socks or “pillow slippers” OK). Have participants completely empty their pockets and remove excessive amounts of jewelry that could affect the weight measurement.

Take a single measurement at each body site and record on the anthropometry form using specific rounding rules for each procedure. Record any modifications in measurement techniques (e.g. height decreased from a hunched posture or weight that exceeds the capacity of the scale).

Specific Instructions:

Standing Body Height

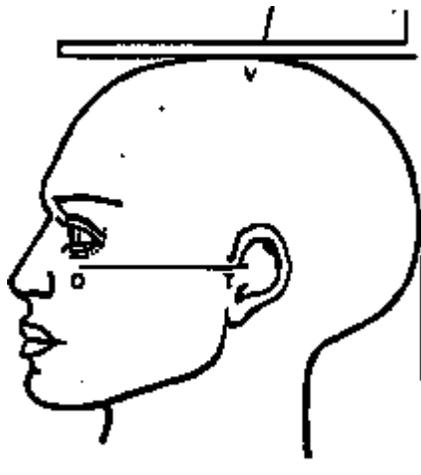
Equipment

- 12” 30°/60°/90° triangle
- Adhesive tape (easy removal)
- Metal measuring tape
- Pencil (No. 1 or No. 2 preferred)

Use a hard, flat floor which is even and without carpet. Measurement may be inside a doorway, against a closed door, or in a hallway. Use an area that does not have a baseboard, threshold, or other protrusion.

Ask the participant to tilt the head forward so you can place a piece of adhesive tape vertically on the wall in the area where the height will be measured. Place the tape loosely, with one end folded over so that it will be easy to remove without damaging the wall.

For accurate measurement of height, the participant must be standing in a vertical plane. To achieve this position, have the participant stand erect on the floor or horizontal platform, with back against the vertical Stadiometer, heels against the wall, and feet or knees together—whichever come together first. Have the participant look straight ahead, with head in the Frankfort horizontal plane (Figure 1, below).



The Frankfort Plane includes the lower margin of the bony orbit (the bony socket containing the eye) and the most forward point in the supratragal notch (the notch just above the anterior cartilaginous projections of the external ear)—also referred to as the upper margin of the external auditory meatus (the hole in the ear).

Figure 1. Frankfort Plane for Measuring Body Height

Place the triangle over the crown of the head, with the long edge against the wall and the right angle toward the floor. The triangle should touch the scalp lightly, carefully centered with the nose. Make sure the long edge of the

triangle is flat and held steadily against the wall. Mark the tape exactly where the corner of the right angle touches the tape. Be sure to mark the tape from underneath the triangle with the pencil angled upward.

Ask the participant to step out from under the triangle. Open the metal measuring tape and make sure it is straight. Secure it against the wall by pressing it with your foot at the “0” end, or by taping it. Keeping the tape vertical and flat against the wall, read the measurement closest to the mark on the tape and record to the nearest 0.1 cm.

If you are unable to measure the actual height of the participant because the triangle does not rest directly over the scalp, estimate height to the nearest 0.1 cm, record in the Anthropometry Form and answer “yes” to the question, “Was there a modification in protocol?”

If any modification was made to obtain height, enter “yes” to the question, “Was there a modification in protocol?”

Body Weight

Equipment

- SECA 815 Elegancia digital floor scale

Check the scale prior to the visit to verify that the batteries are operational.

Instruct the participant to stand in the middle of the platform of the scale, with head erect and eyes looking straight ahead. Wait until the display is constant. Record the results, to the nearest 0.5lbs, in REDCap.

If a participant has a prosthetic limb or breast prosthesis, measure weight with the prosthesis *on*.

If a participant is frail or unsteady, measure weight while participant is lightly steadied by you or an assistant.

If a participant is unable to stand on the scale for a weight measurement, do not attempt a weight measurement.

If any modification were made to obtain weight, record “yes” to the question, “Was there a modification in protocol?”

Girth and Neck Circumference Measurements

Girth and neck circumference measurements are performed the same way in the home as in the clinic. Refer to the Exam 7 MOP for specific instructions.

5.3 Seated Blood Pressure

PURPOSE

The purpose is fully described in the Exam 7 MOP.

Pulse oximetry will also be measured at this time

MATERIALS AND EQUIPMENT

- Measuring tape (for arm circumference)
- Watch or stopwatch (to time five-minute rest and resting heart rate)
- OMRON Series 10 Blood Pressure Device

Preparation

Record the date of the procedure, blood pressure device type and device number on the Seated Blood Pressure Form during the five-minute rest period.

Before the BP measurement procedure, explain to the participant what to expect and how long the procedure will take. The following script is suggested:

This part of the exam involves taking your resting blood pressure. It will take about 10 minutes. We would like you to sit with both feet on the floor and your arm supported on the table. We will have you sit quietly for five minutes. Then we will take your blood pressure three times, two minutes apart using an automated device. We will give you your blood pressure readings and some material to help you interpret them at the end.

Measure the right arm circumference as follows:

- Ask the participant to bare the upper arm.
- Ask the participant to sit or stand holding forearm horizontal, i.e., parallel to the floor.
- Measure arm length from the acromion (bony extremity of the shoulder girdle) to the olecranon (tip of the elbow) using a metric tape.
- Mark the midpoint on the dorsal (back) surface of the arm.
- Ask participant to relax arm alongside of the body.
- Draw the measuring tape snugly around the arm at the midpoint mark, keeping the tape horizontal. Only pull the tape snug enough so that the first red-bead marker can be seen. Tape should not indent the skin. If you can see both beads, the tape is too tight. Record the arm circumference measured to the closest (0.1) cm in the Seated Blood Pressure Form.

Rest Period

The participant should rest for five minutes (timed using a watch or stopwatch) prior to the heart rate and blood pressure measurement.

When the five-minute rest period is over, but before the first blood pressure measurement is started, record the time of day in the Seated Blood Pressure Form in military time.

Positioning the Participant

The workstation should be free of excessive noise or distractions.

The participant should be seated and relaxed in a comfortable chair, to ensure that:

- They are sitting up (not slouched).
- Both feet are on the floor (legs/ankles not crossed).
- Right forearm is supported resting on the table.

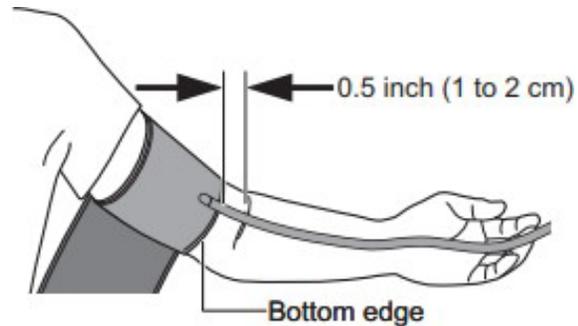
The participant should not talk, eat, or drink during the procedure.

Ideally, the blood pressure device output will not be visible to the participant during the measurement, as this may cause anxiety.

Application of the Blood Pressure Cuff

Plug the arm cuff into the monitor by inserting the air plug into the air jack securely until it clicks.

Place the cuff around the upper left arm so that the mid-height of the cuff is at heart level, with the arm resting comfortably on a table. The bottom edge of the cuff should be 0.5 inch (or 1 – 2 cm) above the inside elbow and the air tube should be on the inside of the arm, aligned with the middle finger.



Wrap the cuff securely around the arm.

If applying the cuff to the right arm, place the cuff around the upper right arm. The air tube should instead run along the side of the elbow, along the bottom of the arm. Avoid having the arm rest on the air tube.

Blood Pressure Measurement

To begin the blood pressure procedure, press the “Start/Stop” button on the lower right of the monitor. All symbols on the screen display will appear before starting a measurement.

Use the guest mode to take a single measurement by pressing and holding the “Start/Stop” button for more than 3 seconds. No readings will be stored in memory in this mode.

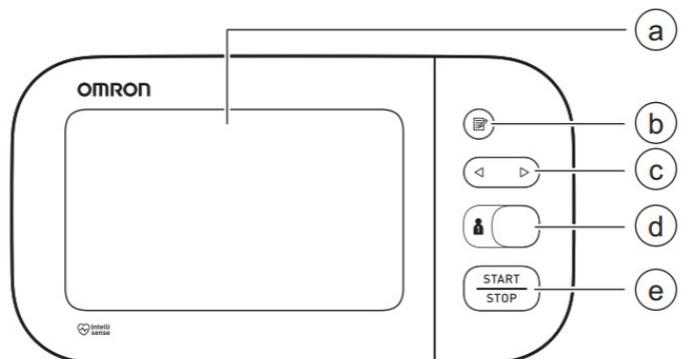
Release the “Start/Stop” button when the user ID and date/time display on the top right corner of the screen turn off. The arm cuff will automatically start to inflate.

To stop the measurement at any point, press the [START/STOP] button once to deflate the arm cuff.

Once the monitor detects the participant’s blood pressure and pulse rate, the cuff automatically deflates. *Record the first blood pressure reading in the Seated Blood Pressure Form.*

Wait 2-3 minutes before pressing and holding the “Start/Stop” button for more than 3 seconds again, entering into guest mode. Releasing the “Start/Stop” button after the user ID and date/time display turn off will initiate another reading. *Record the second blood pressure reading in the Seated Blood Pressure Form.*

Front of the monitor



- (a) Display
- (b) [Memory] button
- (c) [Forward/Backward] buttons
- (d) [User ID selection] switch
- (e) [START/STOP] button

Repeat waiting 2-3 minutes and pressing, holding, then releasing the “Start/Stop” button to take a third measurement. *Record the third blood pressure reading in the Seated Blood Pressure Form.*

The monitor will automatically turn off after 3 minutes.

Optionally, the OMRON 10 monitor can take and automatically record measurements for 2 people using the “User ID selection” switch above the “Start/Stop” button. The monitor can store up to 100 readings per user. User 1 is designated by moving the switch to the right-most position. User 2 is designated by moving the switch to the left-most position.

After selecting a User ID, press the “Start/Stop” button once. Once the monitor detects the participant’s blood pressure and pulse rate, the cuff automatically deflates. The blood pressure and pulse rate are displayed with the previous reading.

Wait 2-3 minutes before proceeding with a second reading using the same User ID, pressing the “Start/Stop” button only once.

Wait another 2-3 minutes before finishing with a third reading using the same User ID.

To view the three consecutive readings stored in memory on the device, press the circular “Memory” button on the top right corner of the device, above the left and right arrow buttons, with the User ID selected.

A memory number will appear on the bottom left corner of the screen. After the memory number appears, the latest reading will appear on the right side of the screen, along with a past reading on the left for comparison.

Press the left or right arrow buttons to scroll through the previous readings stored in memory. The left directional arrow indicates older readings. The right directional arrow indicates more recent readings.

To view the average reading based on the 3 readings taken in the most recent 10-minute timeframe, start with the monitor turned off and the User ID selected. Press and hold the circular “Memory” button for more than 3 seconds. An “AVG” symbol will flash on the top of the screen, above a calculated average reading on the right side of the screen.

Once the three consecutive blood readings are recorded in the Seated Blood Pressure Form, click on the “Memory” button again just once with the User ID selected. Wait until the latest reading along with a past reading appears on the display. While holding the “Memory” button down, press and hold the “Start/Stop” button for more than 3 seconds. The display should start flashing.

When the display stops flashing, all readings for the designated User ID are deleted. Turn off the monitor by pressing the “Start/Stop” button once or waiting 3 minutes.

New readings for the selected User ID can be taken the next time the monitor is turned on.

Storing and Cleaning the OMRON 10 Series Monitor

After using the monitor, unplug the air plug by pulling on the plastic air plug at the base of the tube, not the tube itself.

Gently fold the air tube into the arm cuff, avoiding bending or creasing the tube

excessively. Avoid storing the monitor and its components:

- If wet.
- In locations exposed to extreme temperatures, humidity, direct sunlight, dust or corrosive vapors such as bleach.
- In locations exposed to vibrations or shocks.

To clean the monitor, use a soft dry cloth or a soft cloth moistened with mild (neutral) detergent only. Then wipe with a dry cloth. Do not use any abrasive or volatile cleaners, including gasoline, thinners, or similar solvents. Do not immerse the monitor and its components in water.

BP Measurement Instructions for Participants with Short, Thick Arms

Occasionally there will be a participant whose upper arm is too thick and short for the cuff or on whom the cuff pops open on inflation. The alternative procedure in this case is to obtain the resting blood pressure in the right *forearm*.

Measure the forearm circumference at the midpoint between the olecranon (elbow) and the ulnar styloid (wrist bone on pinkie side). Select the proper size cuff based on the forearm measurement. The blood pressure procedure is otherwise the same.

Document on the Seated Blood Pressure Form that you have measured the *forearm blood pressure*.

Reporting Blood Pressure Results to Participants

The technician may verbally provide the participant with the blood pressure reading (the average of the last two pressures), *if asked*, after the procedure has been completed.

Alternatively, if the blood pressure is normal (<140/90), the technician may say that it is normal, particularly if asked.

If the blood pressure is not normal (>140/90) but not at an alert level (>210 mm Hg), the technician should exercise the standard option of not discussing the interpretation or stating that it does appear to be high (or “somewhat elevated”) but that, again, it will be discussed later.

If an alert level is identified, follow your local clinic procedures for address alerts. (If symptoms of severe hypertension are present, notify a MESA clinician immediately). See alert reporting procedures in the Exam 7 MOP.

5.4 Pulse Oximetry

The procedure for measuring oxygen saturation in the home is the same as in the clinic. Refer to the Exam 7 MOP for specific instructions.

MATERIALS AND EQUIPMENT

- Pulse Oximeter: Devon Medical Handheld Pulse Oximeter PC-66

5.5 Biosample Collection

Overview

Blood collection in the home poses unique challenges. Of utmost importance is safety for both the

participant and the technician, while maintaining sample quality in order for the home visit data integrity to be comparable with previous data collected in a clinical setting. Blood collected off site must be kept at the proper temperature during transport and processed **within 3 hours of collection**. All biohazardous, and potentially biohazardous, material is to be handled and transported in accordance with OSHA, IATA & DOT safety regulations. Filled blood tubes should be packaged in compliance with IATA Diagnostic Specimens Packaging Instructions 650 and comply with DOT regulations whenever they are being transported from the home visit back to the laboratory.

Specific regulations mandated by individual institutions must also be complied with when appropriate. Check with your own institution's guidelines and Risk Management department for any specific policies they may have in place.

Supplies and Equipment

The following is a list of supplies and equipment needed to facilitate in-home sample collection.

- Clean Lab coat and gloves (take several gloves)
- Phlebotomy / Processing Form
- Washcloths/Towels
- Emesis Basin
- Smelling salts
- Lab mats and wipes
- Approved biohazard disinfectant (bleach solution alternative)
- Plastic tray with compartments for phlebotomy supplies
- Winged Push Button Retractable Butterfly needles (21 G) with luer adapter (B-D # 367344)
- Vacutainer barrels
- Tourniquets
- Alcohol prep pads
- Sterile gauze (2x2)
- Surgical tape - paper tape (easier on participants)
- Band-Aids
- Pre-labeled blood collection tubes (take extras)
- Blood tube rack
- Insulated receptacle with cold packs.
- Stopwatch or timer
- Scissors
- Pens
- Small portable sharps container (LSS product #: 55520) –
- Biohazard waste bag for soiled gauze/etc (LSS Product #: 37944).
- IATA Packing Instruction 650 compliant leak-proof container for storage of filled blood tubes (ThermoSafe product #: VIAL650)
- IATA Packing Instruction 650 compliant packaging material including: pressure vessel with stop lock lid, and corrugated outer carton with required markings (ThermoSafe product #: INF2000)
- Refrigerant material (cold pack) to keep blood tubes cool (ThermoSafe product #: 405)
- Appropriate label for Category B Diagnostic Sample transport (ThermoSafe Product #: L3900)
- Large tote or duffel type bag for equipment storage and transport

Please note that this list of Supplies and Equipment are suggestions based on IATA regulations. The lab can work with individual sites to assist in compliance for safe transport of blood samples as needed.

For all Mesa Exam 7 Home Visits, the blood collection will follow the Mesa Classic collection. Nine tubes

containing a total of 69.5 mL of blood will be drawn.

MESA Classic Venipuncture

Initial preparation for specimen collection prior to the arrival of participants is similar to that of previous MESA Exams.

Venipuncture Procedure:

Informed consent must be obtained before blood is drawn. Complete the questions on the Phlebotomy Form with the participant prior to the start of venipuncture.

There are usually two options for setting up for venipuncture in the home depending on whether the participant is mobile or confined to bed. The ideal area for the blood draw is wherever there is adequate space for the participant to be comfortably seated (or reclined) and there is available table or counter space with a surface that can be easily cleaned (possibly the kitchen). Be sure to cover the surfaces with absorbent lab mat to contain potential contamination.

Follow the detailed procedure in the Exam 7 MOP section 5.6.

For the EDTA and PAXgene tubes, in absence of a tube rocker, gently invert the tubes for 30 seconds to ensure adequate mixing. These tubes should be placed in their transport containers with cold packs as soon as phlebotomy is completed.

Complete the Phlebotomy form - recording venipuncture start time and tourniquet elapsed time.

Priority of Tubes & Preparation of Phlebotomy Draw-tubes and Aliquot Racks

For the MESA collection, a maximum of approximately 69.5 mL of blood will be collected from each participant into 9 draw tubes. There are no additional tubes collected specifically for quality control purposes.

The order in which the tubes are collected is important and is done as follows:

MESA 7 Draw Tubes:

- | | | |
|----|--------------------|------------|
| 1. | 10 mL EDTA | purple top |
| 2. | 10 mL EDTA | purple top |
| 3. | 10 mL EDTA | purple top |
| 4. | 10 mL EDTA | purple top |
| 5. | 10 mL Serum | red top |
| 6. | 5 mL Serum | red top |
| 7. | 2 mL EDTA | purple top |
| 8. | 10 mL EDTA | purple top |
| 9. | 2.5 mL PAXgene RNA | red top |

Note: For MESA 7 home visit, draw tubes collected and the priority of tubes has changed from previous MESA Exams.

MESA 7 Draw Tube Collection and Processing

1. 10 mL EDTA Tubes (#1-4 & 8) are purple-topped EDTA tubes (BD# 366643). After filling, these tubes are mixed for ~30 seconds on the tube rocker, or inverted 8 times then placed on cold packs. The draw tubes are centrifuged and the plasma pooled and aliquoted into 54 cryovials (#01-54)

color-coded with blue caps. Participants selected for EDTA QC will have 0.5 mL plasma aliquoted, from the same pooled plasma as the repository cryovials, into a 0.5 mL cryovial labeled with the participant's EDTA blind duplicate label. (Participants selected for EDTA QC are also selected for urine QC.)

2. 10 mL & 5 mL Serum Tubes (#5 & #6) are red-topped Serum tubes (BD# 367820 & 367814). These tubes are silicone coated with a clot activator. Immediately after filling, gently invert tube 5 times to ensure proper mixing of the clot activator with the blood. After collection and initial mixing, these tubes remain upright at room temperature for a minimum of 60 minutes, but no longer than 90 minutes, to allow the blood to clot. Serum from the 10 mL and 5 mL centrifuged draw tubes is pooled then aliquoted into 14 cryovials (#55 – 68) color-coded with red caps. Participants selected for serum QC will have 0.5 mL serum aliquoted, from the same pooled serum as the repository cryovials, into a 0.5 mL cryovial labeled with the participant's serum blind duplicate label.
3. 2 mL EDTA Tubes (#7) is a purple-topped EDTA tube (BD# 367841). After filling, these tubes are mixed for ~30 seconds on the tube rocker, or inverted 8 times then placed on cold packs before placing upright in a -80°C freezer. Do NOT centrifuge the EDTA whole blood tube.
4. PAXgene RNA Tube (#9) is a red-topped PAXgene Blood RNA tube (BD# 762165) containing 6.9 mL of proprietary RNA stabilization additive. Even though these tubes are tall, similar to a 10 mL tube, the sample collection is only 2.5 mL. Prior to collection, ensure the PAXgene RNA tube is at room temperature and correctly labeled with the provided MESA barcode draw tube label. After filling, these tubes are gently inverted 8-10 times, and can be kept at room temperature until placing upright in a -80°C freezer. Do NOT centrifuge the PAXgene RNA tubes.

Safety Issues / Precautions for Handling Blood Specimens

Safety issues and precautions for handling blood specimens at home visits are the same as stated in the Exam 7 MOP.

Awareness of safety concerns and precautions in handling biohazardous material is of the utmost importance at home visits, and Standard Precautions should be used by personnel involved in phlebotomy.

Package and Transport of Samples From the Home To the Lab for Processing

Safety, temperature control, and timing are the critical concerns in transporting the filled blood tubes to the Lab for processing.

Human blood is considered a biohazardous material, therefore handling and transporting it must be done in compliance with DOT and IATA regulations.

All biohazardous material is to be transported in spill / leak proof primary and secondary containers (see Supplies and Equipment) conforming to the DOT/IATA regulations for clinical specimens.

1. Care should be taken to keep all tubes in an upright position during transport.
2. For EDTA blood tubes, a DOT/IATA approved over-pack containing adequate cold packs should be used to facilitate and maintain tube temperatures between 4°- 8°C during transportation. Care should be taken to avoid accidental freezing of these tubes.

3. Serum and PAXgene tubes should remain at room temperature during transport. If using the same secondary container for all tube types, ensure the serum and PAXgene tubes are adequately insulated from the cooling effects of the cold packs.
4. Package filled draw tubes following IATA Packing Instructions 650 which specify placing the tubes in both primary and secondary sealed containers. Adequate absorbent material need to be placed in the primary container to absorb all liquid in case a tube breakage during transport. Be sure to label the outside of the secondary container as “Diagnostic Specimens Category B” and “UN3373”.
5. Ideally, EDTA tubes should be centrifuged in < 30 minutes from the draw. Serum tubes should be centrifuged in > 40 and < 90 minutes from the draw. However, for home visits, the elapsed time between venipuncture and processing has been extended to a maximum of 3 hours.
6. Keep extra clean gloves, absorbent material, biohazard wipes, and empty biohazard bags easily accessible during transporting in case of an accident.

Conclusion of Home Visit

It is critical that the participant’s home be left in the same or better condition as when the technician first arrived.

1. Biohazard materials (anything that may have come in contact with blood products) are placed into properly marked biohazard bags and transported back to the clinic for proper disposal.
2. Cleaning surfaces: Ideally surfaces where phlebotomy was set up should be lightly wiped with disinfectant. The goal is to disinfect without damaging any surfaces. Obtain participant permission before applying any surface disinfectants. Since this is the participant’s blood in their own home, they may object to the use of bleach. In case of spillage or tube breakage, clean up the area immediately, if necessary, soap and water may be obtained from the participant. In unusual cases notify the supervisor for additional instructions.
3. BE SURE NOTHING IS LEFT BEHIND

Processing

Once back at the laboratory, these samples should be centrifuged as soon as possible. The centrifuge start time must be recorded on the Processing form. Standard processing procedure for Mesa 7 Collection (MOP section 6) is followed:

- Description of aliquots – MESA 7 Aliquots

MESA 7 Blood Aliquots:

Collection Tube	Sample Type	Number of Aliquot vials	Color Code	Volume per Aliquot Vial
5 x 10 mL EDTA draw tubes (#1-4 & 8)	Plasma (pooled)	42 (Cryos# 01-10 & 23-54)	Blue	0.5 mL plasma in 0.5 mL cryovials
		12 (Cryos# 11-22)	Blue	0.25 mL plasma in 0.5 mL cryovials
	pRBC	5 (Tube#75-79)	White	~5 mL pRBC in 10 mL transfer tubes
10 mL & 5 mL Serum draw tubes (#5 & #6)	Serum (pooled)	14 (Cryos# 55-56)	Red	0.5 mL serum in 0.5 mL cryovial
2 mL EDTA WB (#7)	(do NOT centrifuge)	(do NOT aliquot)		Remains in draw tube.
1 x PAXgene RNA (#9)	(do NOT centrifuge)	(do NOT aliquot)		Remains in draw tube.

- EDTA plasma → Cryovials# 01-54. Keep draw tubes, pooling tube, and cryovials on wet ice or cold packs during processing. After centrifuging, pool plasma from the five 10 mL EDTA tubes in a labeled 50 mL tube (or other suitable pooling tube). After the plasma is removed from the draw tubes, pour remaining packed cells into each of appropriately labeled 10 mL transfer tubes. Gently invert the pooling tube containing the plasma several times to ensure it is thoroughly mixed. Aliquot, by the volumes specified in the table above, into cryovials# 01-54 and color-code with blue caps. Double check the specified sample volume is being aliquoted into the correctly labeled cryovial. Freeze cryovials in an upright position at -80°C or colder within 10 minutes of aliquoting. After aliquoting is complete, discard the empty pooling tube in the biohazard waste container.
- Serum → Cryovials# 55-68. Keep draw tubes, pooling tube, and cryovials cool on wet ice or cold packs during processing. After centrifuging, pool serum from the 10 mL and 5 mL draw tubes in a 15 mL tube (or other suitable pooling tube). After the serum is removed from the draw tubes, the draw tubes with the remaining coagulated cells can be discarded in the appropriate biohazard waste container. Gently invert the pooling tube containing the serum several times to ensure thoroughly mixed. Aliquot 0.5 mL into cryovials# 55-68 and color-code with red caps. Double check the specified sample volume is being aliquoted into the correctly labeled cryovial. Freeze cryovials in an upright position at -80°C or colder within 10 minutes of aliquoting. After aliquoting is complete, discard the empty pooling tube in the biohazard waste container.
- EDTA pRBC → # 75-79. The packed red blood cells from the EDTA draw tubes are poured over into labeled transfer tubes with cryovial labels #s 75-79. Freeze transfer tubes in an upright position at -80°C or colder within 10 minutes of aliquoting. After pour over is complete, discard the empty draw tubes in the biohazard waste container.
- EDTA 2 mL WB → # 80. The EDTA whole blood tube is NOT aliquoted (and NOT centrifuged). Double check the draw tube is labeled with its correct MESA barcode label – the 5-digit Biospecimen ID + 1-digit visit year ‘7’ + the 2-digit repository identifier ‘80’. The sample remains in the draw tube and is frozen upright in a -80°C freezer.
- PAXgene RNA → # 81. The PAXgene RNA tube is NOT aliquoted (and NOT centrifuged). Double check the draw tube is labeled with its correct MESA barcode label – the barcode label includes the 5-digit Biospecimen ID + 1-digit visit year ‘7’ + the 2-digit repository identifier ‘81’. The sample remains in the draw tube and is frozen upright in a -80°C freezer.

Freeze all cryovials within 10 minutes of aliquoting at -80C

Special Circumstances

Low sample volume

If there is insufficient sample volume within a sample type to make the full set of aliquots, fill the lowest numbered cryovials for that sample type first. Any partially filled (less than the specified volume) cryovial should be marked with a “P” on the cryovial label and a “P” in the comment field of the Processing Form next to that cryovial number. Note: Do not have multiple partially filled cryovials for a sample type. It is more important to have aliquots filled to their specified volume with a reduced number of total aliquots, then to have multiple partially filled aliquots.

Aliquots cannot be frozen within 10 minutes.

Every effort should be made to freeze cryovials at -70°C or below as soon as possible after aliquoting. If specimens cannot be placed immediately at -70°C or below, they may be temporarily (< 2 hours) stored at -20°C or placed on dry ice until transfer to -70°C or below. Dry ice is the preferred solution.

Shipping Blood Samples

Home Visit samples are included in the regular weekly shipments.

Other

Repack home visit kit with supplies at the end of the day. Refreeze all ice packs. Wipe down all materials to make sure they are biohazard free.

5.6 Cognitive Assessment

Cognitive assessment is performed the same way in the home as in the clinic. Refer to the MESA MIND Cognitive Testing MOP for specific instructions.

5.7 Questionnaires

The questionnaires are performed the same way in the home as in the clinic. Refer to the Exam 7 MOP for specific instructions.

5.8 Spirometry

EQUIPMENT AND SUPPLIES

- EasyOne Pro spirometer and charging cable
- NDD EasyWare spirometry software installed on a notebook computer with Windows.
- Calibration syringe, 3.00 liters, Han Rudolph model # 5530 (you should have from Exam 3/4/5/6).
- Disposable spirettes, disposable filters, and connector
- Nose clips
- Personal protective gear: n95, disposable gown, face shields, gloves

Initial Configuration of the EasyOne

Configuration

It is critical that all spirometers used for MESA-Lung be configured identically. The factory-set default configuration will not store the numeric results and the curves from the three 3 best maneuvers. Initial configuration will be done by the Spirometry Reading Center (SRC) before the spirometer is sent to the site, though **three of the configured settings (Interpretation, Time Format, and Weight Units) must be changed before beginning data collection**, as noted below. Once configured for MESA-Lung please don't change the configurations. The custom configuration is retained by the spirometer even if the batteries are removed or become dead.

Accessing and Checking the Configuration using EasyWare Software

Open the EasyWare software program on the clinic tablet. Connect the spirometer to the tablet with the cable and turn the spirometer on by pressing and holding the On/Off button. Check that the status bar in the lower right corner of the EasyWare software window changes from "Not connected" to "Device connected" to ensure that the software recognizes the connection. Click the "View" menu and then "Device Configuration" to open the EasyOne Device Configuration. The window that opens will have three tabs: Test Settings, General Settings, and Report Settings. Click on each tab and compare them to the above configuration settings to ensure that the Test Settings, General Settings, and Report Settings match those listed below.

Accessing and Checking the Configuration using EasyOne Spirometer

On the main menu of the spirometer, use the arrow keys to navigate down to "Configuration" and select it by pressing "Enter". Select "Test Settings" and check that the settings listed there match those listed below. When you reach the end of the Test Settings, press "Enter" to return to the Configuration menu and repeat the process with "General Settings" and "Report Settings" to ensure that the General Settings and Report settings match those listed below.

• Test Settings

- Predicted source: choose "NHANES III"
- Additional Pediatric: choose "None"
- Value Selection: Choose "Best Value"
- Interpretation: choose "NHLEP"

CHANGE THIS THE FIRST TIME

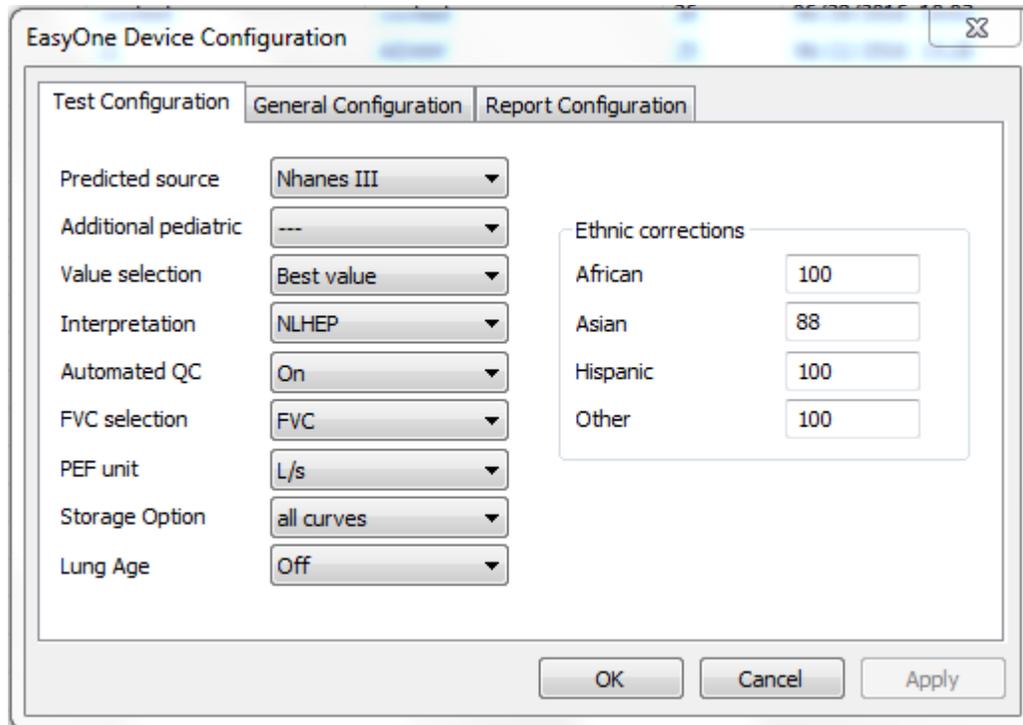
- Automated QC: Choose "On"
- FVC Selection: Choose "FVC"

VERY IMPORTANT

- PEF Unit: Choose "L/s"
- Storage Option: Choose "All Curves"

VERY IMPORTANT

- Lung Age: choose "Off"
- African Ethnic Correction: Choose "100%"
- Asian: Choose "88%"
- Hispanic Ethnic Correction: Choose "100%"
- Other Ethnic Correction: Choose "100%"



- **General Settings**

- Time Format: Choose "24 hours"

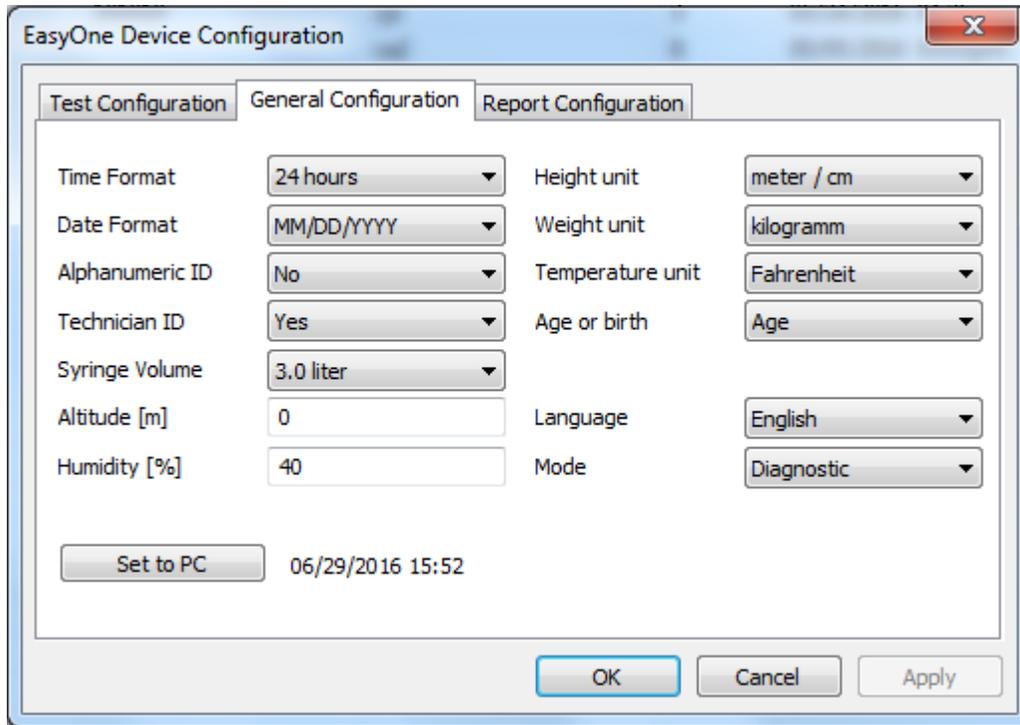
CHANGE THIS THE FIRST TIME

- Date Format: Choose "mm/dd/yy"
- Alpha-numeric ID: Choose "No"
- Technician ID: Choose "Yes"
- Calibration Syringe Volume: Choose "3.0 L"
- Altitude: Enter altitude (0 is ok if approximately at sea level)
- Humidity: Choose "40%"
- Height Units: Choose "meter / cm"
- Weight Units: Choose "kilogram"

CHANGE THIS THE FIRST TIME

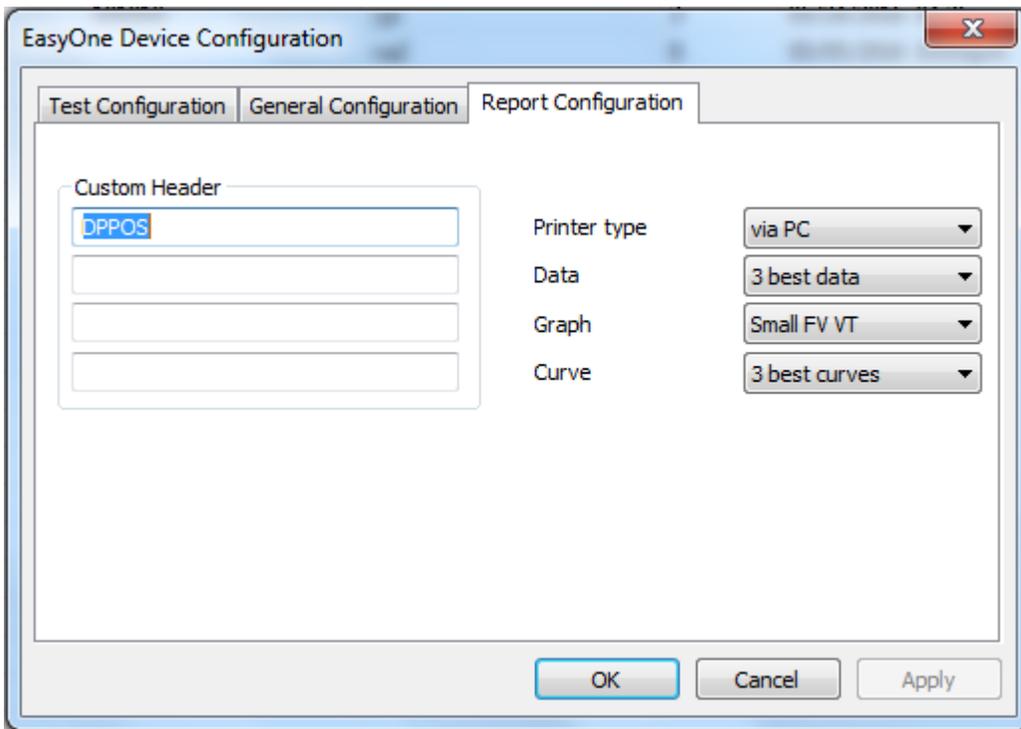
- Temperature Units: Choose "°F"
- Age Entry: Choose "Age"
- Language: Choose "English"
- Mode: Choose "Diagnostic"

VERY IMPORTANT



- **Report Settings (it is not expected that you will need to print results)**
 - Report Headers: Enter "MESA Lung"
 - Printer Type: Select "via PC" (or select the type of printer you are using)
 - Data Option: Choose "3 Best Data"
 - Graph Options: Choose "Small FV VT"
 - Curve Option: Choose "3 Best Curves"

The entries for humidity, altitude, and temperature only affect the accuracy of measured inspired flows. Even if they are entered incorrectly or change over time, the accuracy of the FEV1 and FVC will not be affected. It is very important to configure the spirometer by selecting "All Curves" under the curve options, so that all the data is saved.



Using the EasyOne™ keys to Navigate the Menu

- ON/OFF: Press and hold this key for about 2 seconds to turn the unit ON. It turns itself off after 3 minutes of inactivity. No data is lost.
- Enter Key: Selects highlighted menu items and enters highlighted or typed-in data items.
- Keys 1 to 9: Allows entry of numbers and letters. In fields in which both numbers and letters appear, enter letters by pressing the appropriate key in rapid succession. This causes the corresponding number and letter sequence to scroll through the highlighted position in the data field. Simply stop when the desired number or letter is displayed (numbers appear after pressing a button 4 times). Both upper case letters, numbers, and lower case letters are available (in that order). It is not necessary to use lower case letters.
- Esc (0) Key: Serves as both the numeric zero and the escape key. Press briefly to enter a zero. Press and hold the key to activate the escape function. The Escape function moves the cursor sequentially to previous menus, menu items, or data fields, depending on the cursor position. To enter a blank space, press the Esc key rapidly to toggle between the number zero and a blank space.
- Arrow Keys <>: Move the cursor. In menus, the arrow keys allow scrolling up or down through menu items. In data fields, the left arrow key either erases previously entered numbers or letters (like a backspace key), or scrolls left through a data list. The right arrow key acts either like an Enter key or scrolls right through a data list.

Spirometry Calibration

Weekly Calibration Checks

Use a 3.00 liter calibration syringe with a spirette **once each week** of testing to verify the volume accuracy of each spirometer that you use for this program.

Choose "Check Calibration" from the Main menu.

1. Choose "Calibration Check" from the Calibration menu.
2. Firmly insert the CAL Spirette into the spirometer, matching the arrows. Firmly attach the Spirette to the calibration syringe using the grey plastic NDD adapter.
3. Press Enter.
4. Fill the syringe with room air (listen for a click).
5. Inject the full 3-liters from the syringe smoothly into the spirometer (taking about one second), and then pull back fully on the syringe (until you hear it click again). To avoid damage, don't "slam" the syringe at the end of the injection by pushing the air out too vigorously as this may cause erroneous calibrations.
6. The goal of the calibration check is to verify that the spirometer measures FVC with better than 3% accuracy. Since a 3.00 liter syringe is used, the FVC should fall between 2.90 and 3.10 liters.
7. If the calibration check fails, check for correct insertion of the Spirette into the spirometer (triangular arrows aligned), ensure that you are using an NDD calibration syringe adaptor, and check for air leaks inside the syringe and at the connections. Repeat the calibration check. If it fails again, try a new Spirette. If it fails again, call the SRC (see contact information at the back of this manual). We cannot change the factory preset calibration factors, so the spirometer must be returned to the factory for repair. Do not continue to use an inaccurate spirometer. In the event that this occurs, ask the SRC to ship a loaner spirometer.
8. Document the test and its result in the calibration log.

During weekly calibration checks, please also check the configuration of the spirometer.

Monthly 3-Speed Flow Linearity Check

A calibration check utilizing multiple different injection flow rates should be performed **each month** as follows:

1. Choose "Check Calibration" from the Main menu.
2. Choose "Multi-flow Check" from the Calibration menu.
3. Firmly insert the CAL Spirette into the spirometer, matching the arrows. Firmly attach the Spirette to the calibration syringe using the grey plastic NDD adapter.
4. Press Enter.
5. Fill the syringe with room air.
6. Repeat the injection 3 times. The first time, take at least six seconds to empty the syringe very slowly. The second time, empty the syringe in about 3 seconds. The third time, quickly empty the syringe in less than a second. After each injection, the machine will prompt you that the flow rate is acceptable.
7. Document the test and its result in the calibration log.

Preparation and Testing

Spirometry Instructions and Preparation

1. Chat with the patient to achieve rapport. Wash your hands and don PPE including disposable gown, face shield, and n95 mask.
2. Suggest that the participant use the bathroom if they have not done so recently. The hard blowing involved with spirometry may result in some participants losing some urine and recent urination will minimize this.

3. Complete the spirometry completion form on RedCap.
4. If you are using **both the laptop and the spirometer** to collect data (**preferred**):
 - a. Open the EasyWare software program on the clinic laptop.
 - b. Connect the spirometer to the laptop with the cable and turn the spirometer on by pressing and holding the On/Off button. Check that the status bar in the lower right corner of the EasyWare software window changes from “Not connected” to “Device connected” to ensure that the software recognizes the connection.
 - c. In the EasyWare program, select “Edit” -> “New Patient” and enter the participant’s data into the window that opens, based on the table below and your conversation with the participant. If you are performing spirometry for technician training, please enter “999999” for the ID (ID Number).

EasyWare Field	Participant’s Data Entry
Name	Enter the participant’s ACROSTIC
ID	Enter the participant’s ID Number (or “999999” for training).
Birth date	Enter the participant’s birth date.
Height	Enter the participant’s height in centimeters , as measured during the visit.
Gender	Enter the participant’s gender.
Ethnic	Enter the participant’s race/ethnicity as stamped on the Spirometry Completion Form. Please note that, for the purpose of calculating predicted spirometry results, Pacific Islanders are grouped with Caucasians, and Native Americans are listed as “Other”.
Tech ID	Enter your MESA Tech ID.
Weight	Enter the participant’s weight in kilograms , as measured during the visit.
Asthma	Enter whether the participant currently has asthma (Yes/No).
Smoker	Enter whether the participant currently smokes (Yes/No).

5. If you are using **only the spirometer** to collect data:
 - a. Select “Perform Test” on the main menu by pressing “Enter” and select a “New” test by pressing “Enter” again.
 - b. Enter the participant’s data into the next screen, based on the table below and your conversation with the participant. If you are performing spirometry for technician training, please enter “999999” for the ID and for the Nickname use your 2-digit clinic number followed by sequentially increasing numbers (e.g., 010001, 010002... for clinic 1, and 020001, 020002 for clinic 02, etc.). This will alert the SRC that these are training tests.
 - c. b. If you need to edit the TechID on the spirometer, use the back arrow (<-) to delete the existing TechID, and then enter the new TechID.

EasyOne Plus Field	Participant’s Data Entry
ID	Enter the participant’s ID Number (or “999999” for training).
Name	Enter the participant’s ACROSTIC

EasyOne Plus Field	Participant's Data Entry
Birth date	Enter the participant's birth date.
Height	Enter the participant's height in centimeters , as measured during the visit.
Weight	Enter the participant's weight in kilograms , as measured during the visit.
Ethnic	Enter the participant's race/ethnicity as stamped on the Spirometry Completion Form. Please note that, for the purpose of calculating predicted spirometry results, Pacific Islanders are grouped with Caucasians, and Native Americans are listed as "Other".
Gender	Enter the participant's gender.
Smoker	Enter whether the participant currently smokes (Yes/No).
Asthma	Enter whether the participant currently has asthma (Yes/No).
Tech ID	Enter your MESA Tech ID.

6. Explain the purpose of the examination and the need for extra effort from the patient to get maximal results. Say "I want to measure how much and fast you can breathe out."
7. Ask the patient to loosen any tight clothing. If they have dentures that are not secure, ask them to remove the dentures for the test. (Provide clean denture cups for such patients.)
8. Take your personal Spirette (with your name written on the mouthpiece). Demonstrate a DEEP inspiration, exaggerate body language, eyes wide, shoulder, back, on your tiptoes. Demonstrate proper placement of the mouthpiece (stick out your tongue and place the mouthpiece on top of it). BLAST out the air using exaggerated body language. Note to technician: Be sure to demonstrate this procedure by placing the mouthpiece inside your mouth BEFORE blasting out.
9. Ask the patient to sit up straight during the examination and not to bend over very much while exhaling. Please note, if after one maneuver you feel that the patient would give much better results while standing, it is alright to ask the participant if they would like to stand but be sure to place a solid chair directly behind them and don't encourage them to squeeze the air out towards the end of the exhalation maneuvers.
10. Get a new Spirette for the patient's use. Allow them to see the package being opened so that they know that it's clean.
11. Have the patient practice getting their mouth sealed around the Spirette. They can do this by placing their Spirette into their mouth before it is attached to the spirometer. You can tell them "place the Spirette on top of your tongue, seal it with your lips, but don't bite down on it." You should observe the lip seal during practice and the test to be sure the patient has obtained a good lip seal
12. Carefully watch their body language and correct any problems.

Start the Actual Maneuvers

1. Insert and twist the patient's Spirette so that the arrow on the Spirette lines up with the arrow on the spirometer. Push the Spirette in firmly.
2. Connect the adapter and disposable filter to the spirette. Be sure to push the adaptor in firmly so that there is a seal between the adapter, the connector, and the spirette.
3. If you are using **both the laptop and the spirometer** to collect data (**preferred**):
 - a. On the EasyWare screen, click on the top left icon for "On-Line Test"

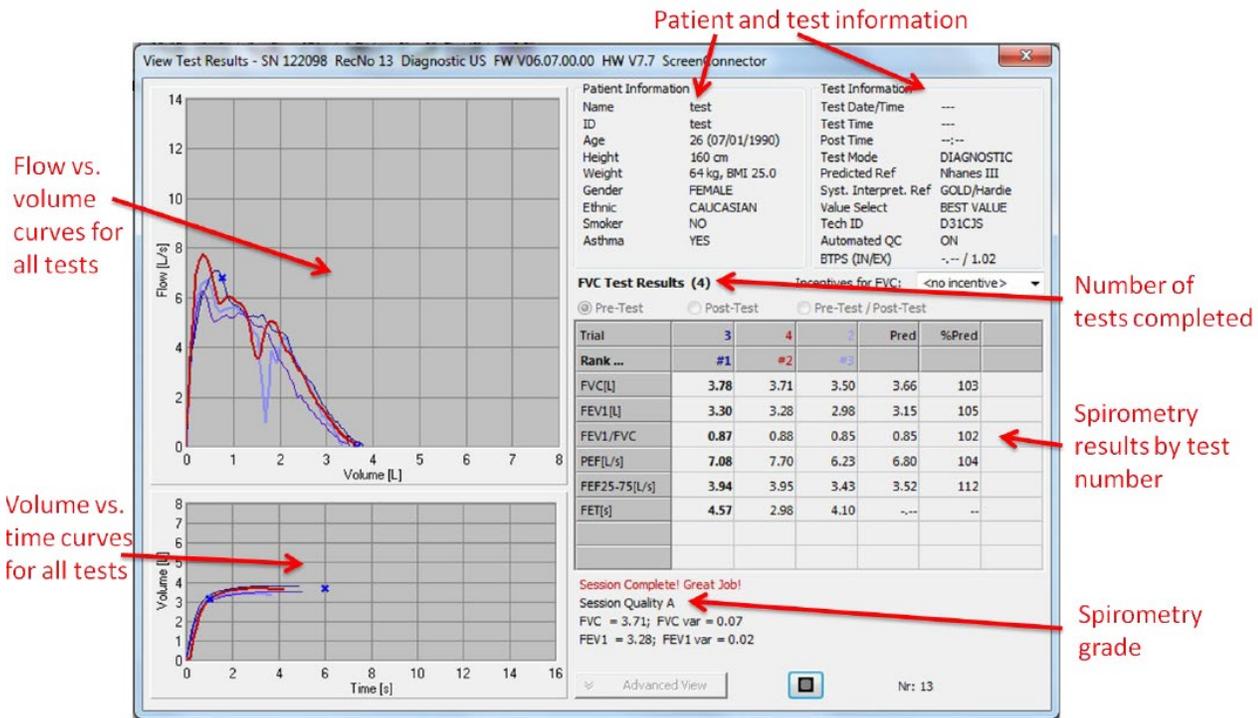
- b. On the spirometer, press “Enter” to select “Perform Test”. Then, use the arrows to choose “Recall” and “Enter” to select it.
 - c. Press “Enter” again to select the information you just entered into the EasyWare program. The patient’s information will appear on the spirometer – if it is correct, press enter again to confirm.
4. If you are using **only the spirometer** to collect data:
 - a. No additional steps are needed, proceed to #4.
5. Select "FVC" to begin the testing sequence.
6. Place a nose clip on their nose. The nose clip may be removed between the breathing maneuvers. If the nose clip falls off or is uncomfortable, try a different model of nose clip or the patient may hold his nose during the maneuver.
7. Before the first trial for each patient, you must set a no-flow baseline. The display will prompt you to "Block Spirette until prompted to Blast out." This is accomplished by leaving the Spirette partially bagged or covering the bottom of the Spirette with your thumb. It is critical that no air flows through and the sensor is still during the zeroing procedure.
8. Select "Next." You will hear a buzzing sound -- wait until it stops.
9. The display will indicate that the baseline is being set, which takes only 1-2 seconds.
10. The spirometer will then read "Blast out."
11. Hand the spirometer to the patient and coach them to take a maximal inhalation. Watch their body language. Don't hold the spirometer while they blow into it (since this would restrict their deep breaths).
12. Coach the patient loudly to BLAST out as hard and fast as possible immediately after taking a maximal inhalation (i.e., Tell the patient not to hold his/her breath after the maximal inhalation). After a second, quietly tell them to continue blowing out for at least six seconds. Watch their body language. The spirometer will beep throughout and will give a longer beep to let you know that expiratory airflow has decreased to the point where you can stop the test.
13. Tell the patient it is now okay to come off the mouthpiece.
14. Use the laptop to observe the flow-volume curves displayed or, if you are performing spirometry without the laptop, take the spirometer from the patient and observe the small flow-volume curve displayed on the LCD. Learn to recognize the patterns of unacceptable maneuvers.
15. Press "Enter" to see the quality of the curve. After 1 maneuver, the best quality grade possible is “D” (i.e. one acceptable maneuver). If the quality grade is unacceptable, the patient will need additional coaching. If the patient looks like they're not taking a big enough breath or is not blasting out quickly enough, they will also need additional coaching.
16. Repeat the maneuvers until a quality grade of “A” or “B” is obtained. (An “A” is not possible until you have completed 3 maneuvers, see section 7.3 for a complete explanation of the spirometry grades). If you feel that the inspiration was inadequate, try another test regardless of the quality grade.
17. For another maneuver, press “Next.”
18. It is important to perform up to 8 maneuvers if needed to achieve good quality results (a test session with a grade of “A” or “B”); however, use your judgment if the participant is becoming overly fatigued. If

good quality results do not occur after 5 trials, considering asking another technician to help by coaching the patient for the final maneuvers.

19. The spirometer will display the message "Session Complete!" when quality results are achieved.

View the Results

If you are using the laptop and the spirometer to collect data, the EasyWare program will open a window for you to view the results during the test as the test is being completed, including the following elements: Once the test is complete, the summary of the results can be viewed on the spirometer by choosing "Data". Then, use the arrow keys to navigate between the screens and see the actual and predicted values, best test curves, and test session quality information (including variability in parameters and quality grade).



The spirometer uses regression equations from NHANES III to calculate predicted normal (reference) values for the measured parameters. These equations use the age, gender, race, and height that you enter for a particular patient to complete the calculation. This is the reason participants have been grouped into the following ethnic categories, which are pre-set on the spirometer:

- Caucasian – all participants of Caucasian or Pacific Islander heritage, both of which have the same predictive equations.
- Hispanic – all participants of Hispanic or Latino heritage.
- Asian – all participants of Asian heritage.
- Other – all participants of Native American heritage.
- African – all participants of African, black, or African American heritage.

The predicted values represent the expected values that a healthy person of that age, gender, race, and height would produce during a maximal spirometry effort. On the display, the predicted normal values (PRED) are compared to the patient's values to calculate the percent of predicted values (%PRED). Use

the "Best" values for reports. Please note, all of the testing done for DPPOS will be labeled as "Pre" in the Spirometer, because the default is to record results pre- and post-bronchodilators (inhaler medications).

On occasion, you may not get a FEV1% or FVC% predicted from the spirometer (if the participant is particularly old and/or short). If that occurs, still record the other values.

Saving PDF of Results

1. Connect the spirometer to the computer.
2. Select "Print Results" from the Main Menu. Make sure the printer is set to "Print to PDF".
3. Choose "Single Test" and scroll using the arrows until the desired record is found, and press Enter to save the test as a pdf.
4. Upload test to RedCap.

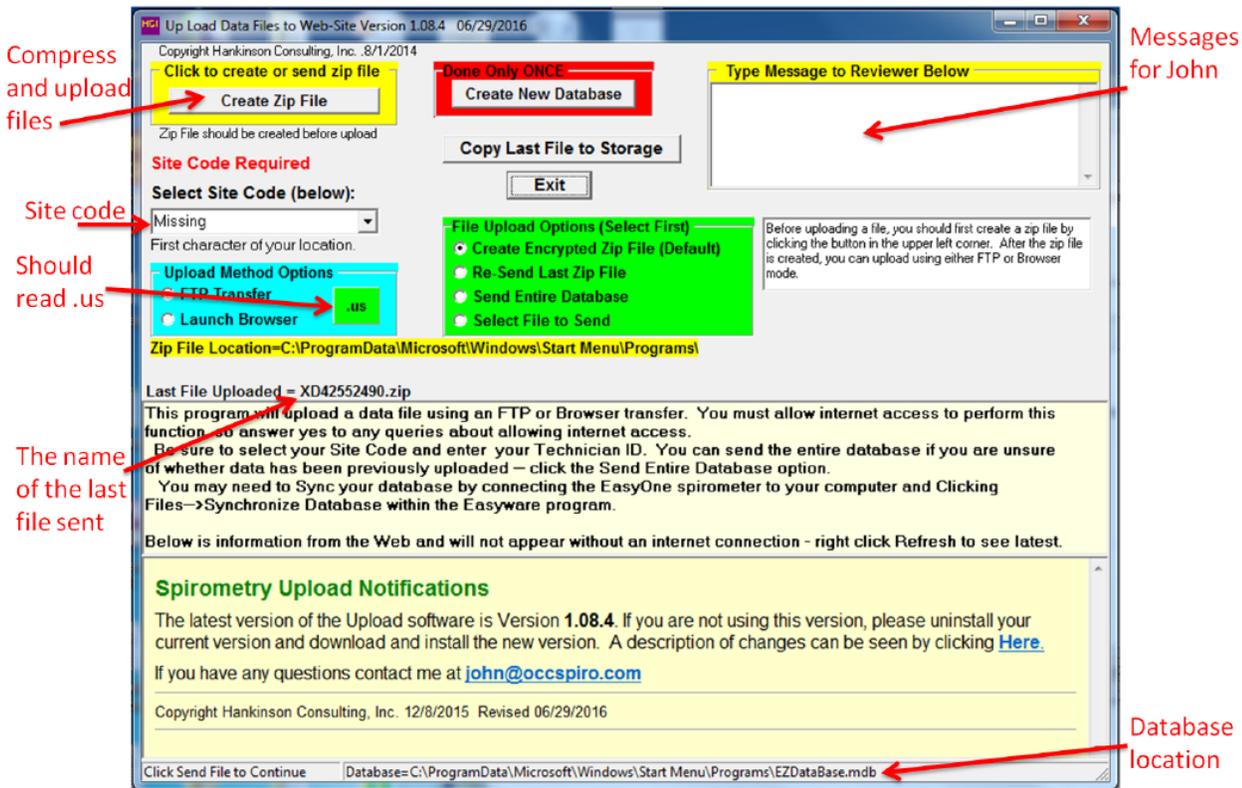
Back Up and Transmit the Data

Please ensure that the "EasyWare" and "EZUpload" software are downloaded on the computer you will use. Instructions for installation of software can be found on the Manuals page.

The spirometer automatically stores the results of patients in its internal memory (about 200). Every time the spirometer is connected to the computer, the data stored in the spirometer will be sent to the computer automatically. Make sure that ALL spirometers have been connected to the computer EVERY DAY BEFORE copying all data for transfer to the SRC.

1. If you are using **both the laptop and the spirometer** to collect data (**preferred**):
 - a. No additional steps are needed, proceed to #3.
2. If you used **only the spirometer** to collect data:
 - a. Open the EasyWare software program on the clinic laptop.
 - b. Connect the spirometer to the laptop with the cable and turn the spirometer on by pressing and holding the On/Off button. Check that the status bar in the lower right corner of the EasyWare software window changes from "Not connected" to "Device connected" to ensure that the software recognizes the connection.
 - c. Once the spirometer syncs, the individual data will be displayed by name in the order in which the tests were performed. Click on an individual entry to view the flow-volume and volume-time plots as well as the numerical data in column form.
3. Open the EZUpload program.
4. Select your clinic name from the Site Code drop-down message and enter a message to the Reviewer into the text box if you would like to.
5. Click the "Create Zip File" button.
6. A dialogue box will appear giving you the file name and asking if you want to upload it – write down the file name and click "Yes". Another dialogue box will appear – click "OK" to begin file transfer. Wait until the text at the top changes from "Click OK to begin file transfer" to "Transfer complete, Click Exit", and then click "Exit". Your file has been transferred.

You can now close the EZUpload program.



5.9 ABPM

The ABPM is applied the same way in the home as in the clinic. Refer to the Exam 7 MOP for specific instructions.

5.10 Hip activity monitor

The hip activity monitor is applied the same way in the home as in the clinic. Refer to the Exam 7 MOP for specific instructions.

5.11 Wrist activity monitor

The wrist activity monitor is applied the same way in the home as in the clinic. Refer to the Exam 7 MOP for specific instructions.

5.12 Continuous glucose monitor

The CGM is applied the same way in the home as in the clinic. Refer to the Exam 7 MOP for specific instructions.

5.13 Heart Monitor Patch

The heart patch monitor is applied the same way in the home as in the clinic. Refer to the Exam 7 MOP for specific instructions.

5.14 Home Sleep Study

The sleep study equipment is applied the same as described in the Exam 7 MOP.

5.15 Post Exam Activities and Exit Interview

At the end of the exam, check the list of forms to be sure all are complete. If there are forms or procedures remaining, schedule a second visit either to the home, or if the participant is willing, to the clinic to complete the exam. Questionnaires and cognitive function test can also be completed remotely.

During the exit interview, show a PDF of the Exit Report to the participant and discuss the content. The report can be emailed to the participant or printed and mailed once back at the clinic.

Ask the participant if they have any questions at exam exit time. After you have answered any questions, thank the participant.