



INITIAL CALIBRATION GUIDE



GOAL OF INITIAL CALIBRATION

The MAIN goal of the initial calibration procedure is to determine if your patient is stimuable to the Lombard Effect. You will basically answer yes/no at the end of calibrating the device.

If your patient is stimuable by increasing their sound pressure level (SPL) with the SpeechVive in place, they will most likely be a good candidate for the SpeechVive device. 90% of patients in clinical trials continued to see improvement with SpeechVive over time.

You will answer this question at the end of the calibration by comparing their “baseline SPL” to their “final SPL.”

Session Summary

Below are the session values for your records.

| | | | | | |
|----|--------|--------------|-------|-------------|----|
| F0 | 201 Hz | Baseline SPL | 79 dB | Sensitivity | 23 |
| | | Target SPL | 82 dB | Output | 11 |
| | | Final SPL | 85 dB | | |

CANCEL

FINISH

BEFORE YOUR PATIENT ARRIVES:

1. Gather Materials
2. Assemble Microphone
3. Assemble SpeechVive
4. Connect Microphone and SpeechVive to computer
5. Confirm Connections on Software
6. Navigate to “Device Programming”

GATHER MATERIALS



SpeechVive Clinical Kit



Computer with SpeechVive Software

**Turn on your computer and load the SpeechVive software*

ASSEMBLE THE MICROPHONE

Headworn Microphone



Beta SHURE pre-amplifier



Mic Mate condenser



USB typ B cable



ASSEMBLE SPEECHVIVE

SpeechVive device



Rubber Ear Piece



**It is recommended to start with size "medium"
adjust to large/small as needed*

Micro USB

**Plugs into the SpeechVive under
the rubber flap located at the bottom of
the device*

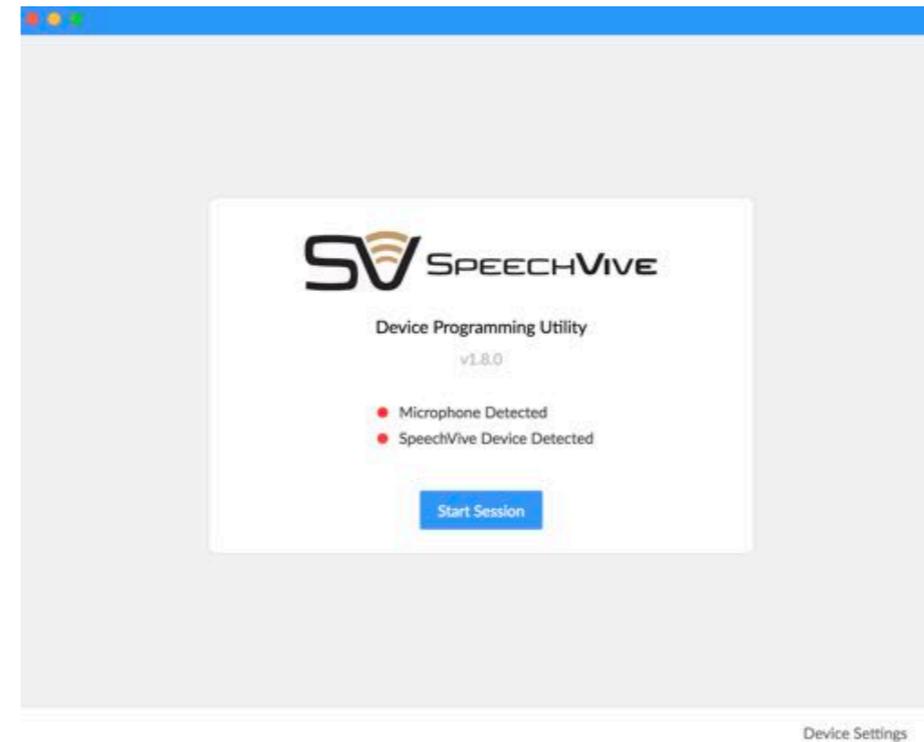


CONNECT SPEECHVIVE AND MICROPHONE TO THE COMPUTER



CONFIRM CONNECTIONS ON COMPUTER

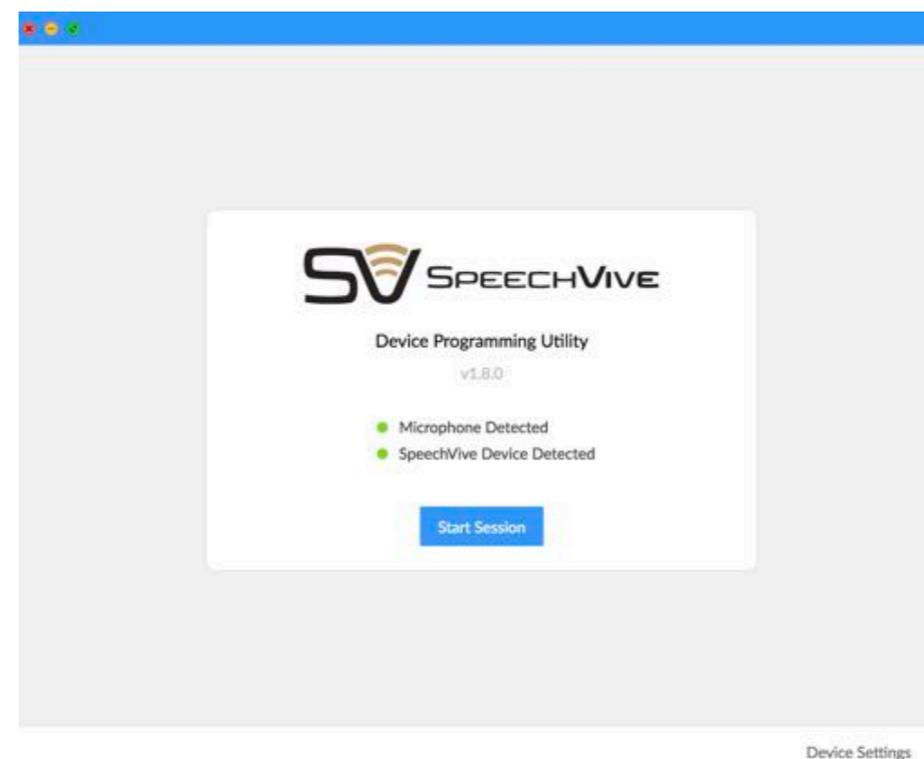
Before connecting the SpeechVive and Microphone, red lights will be present on the Device Programming Utility screen



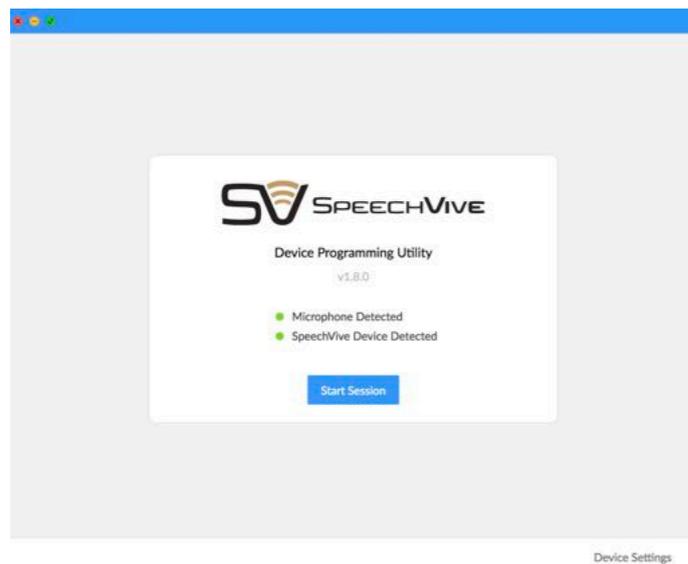
Once connected, green lights will appear indicating connectivity.

**Be advised, it may take up to 60 seconds for the SpeechVive device to be detected*

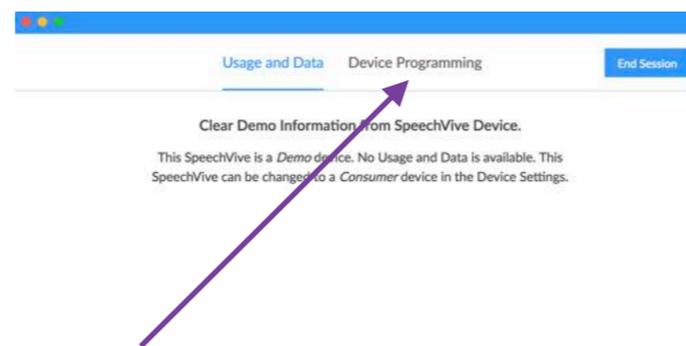
***Do not continue if you do not have green lights for both the microphone SpeechVive. Go to TROUBLESHOOTING*



NAVIGATE TO “DEVICE PROGRAMMING”

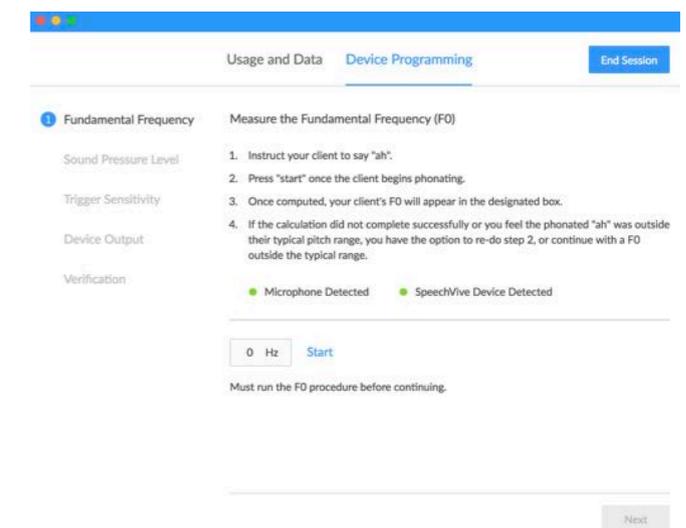


Select “Start Session”



For your “Demonstration Unit” in the clinic,
data is not synthesized.

Select “Device Programming”



You are now on the 1st Step for
“Device Programming”

ONCE YOUR PATIENT ARRIVES:

1. Provide education for SpeechVive trial
2. Place Headworn Microphone on patient
3. Execute Steps 1 and 2 of Calibration Software
4. Place SpeechVive on patient (keep mic in place)
5. Execute remaining steps of Calibration Software
6. Determine if patient is stimulable to the Lombard Effect
7. Educate patient for results of SpeechVive trial
8. Determine if patient is a good candidate for SpeechVive

PROVIDE EDUCATION FOR SPEECHVIVE TRIAL

Suggested Script:

“In our time today I’d like to try out a device called the SpeechVive. I’m not going to tell you too much about what the device does right now, but we’ll discuss it at the end.

You will wear this microphone (show patient microphone) that will allow me to take some measurements of your voice.

Later, you will also wear the SpeechVive (show patient SpeechVive.) When you have the SpeechVive on, you can expect to hear sounds in your ear. It sounds similar to a group of people all talking at once. Sometimes the sounds will be soft and at other times, the sounds will be louder.

While we try this, I will be asking you to talk. It’s important that you choose a topic that you can discuss for at least 60 seconds. Some topic ideas could be: your favorite vacation, your family, your favorite hobby, or anything else you want.

Do you have any questions about what we’re going to do today?”

**If your patient is wearing hearing aides, request that they remove the aid on the ear the SpeechVive will be on.*

PLACE THE HEAD-WORN MICROPHONE ON YOUR PATIENT



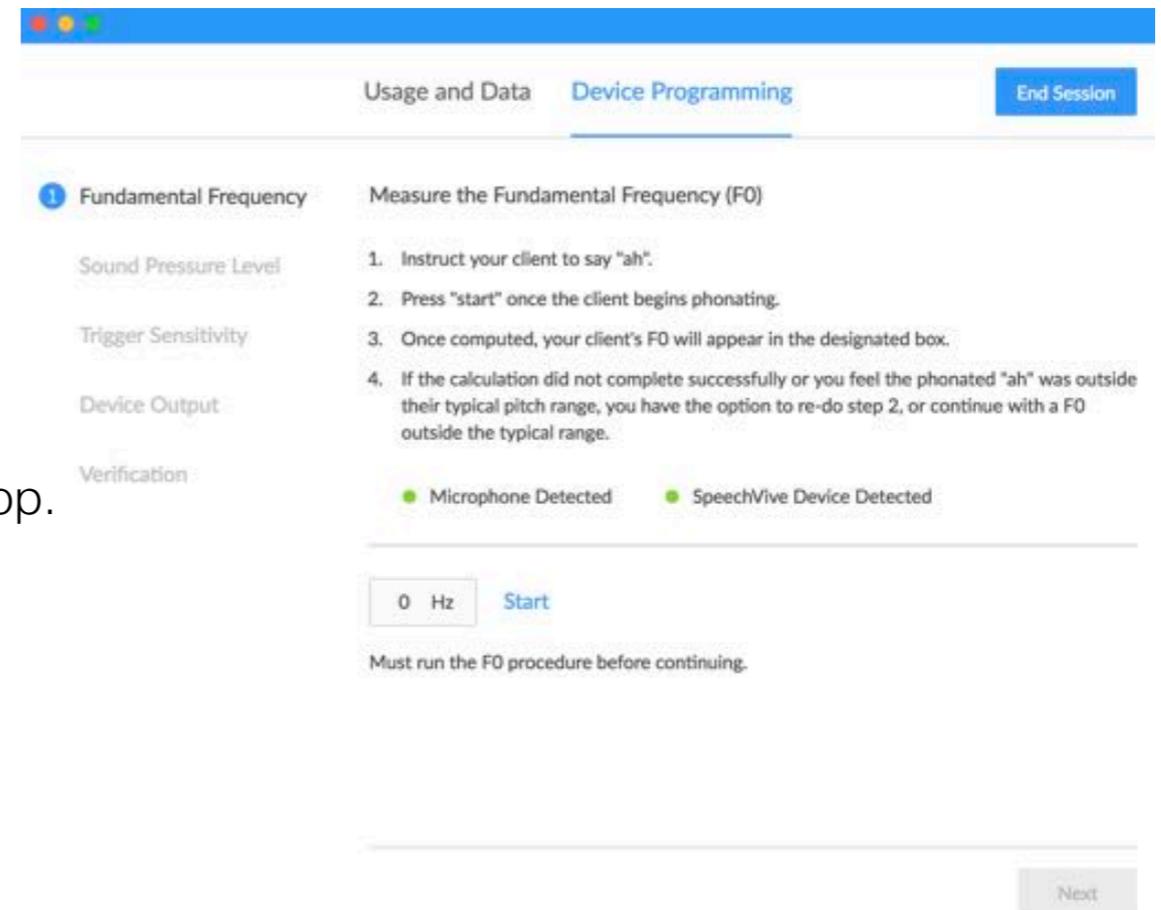
Ensure the microphone is a distance of 6 cm (approximately 2.5 inches) from your patient's mouth in parallel.

EXECUTE STEP 1

Measure the Fundamental Frequency (F0)

Suggested Script:

“I want you to say “ah” and hold it. I’ll tell you when to stop. Like this (demonstrate sustained phonation.)”



The voiced speech of a typical adult male will have a fundamental frequency from 85 to 180 Hz, and that of a typical adult female from 165 to 255 Hz.

Troubleshooting tip: Some users tend to SING their “ah” To ensure the best outcome, make sure your user produces “ah” with their natural spoken pitch.

EXECUTE STEP 2

Measure Baseline SPL (*sound pressure level*)

Suggested Script:

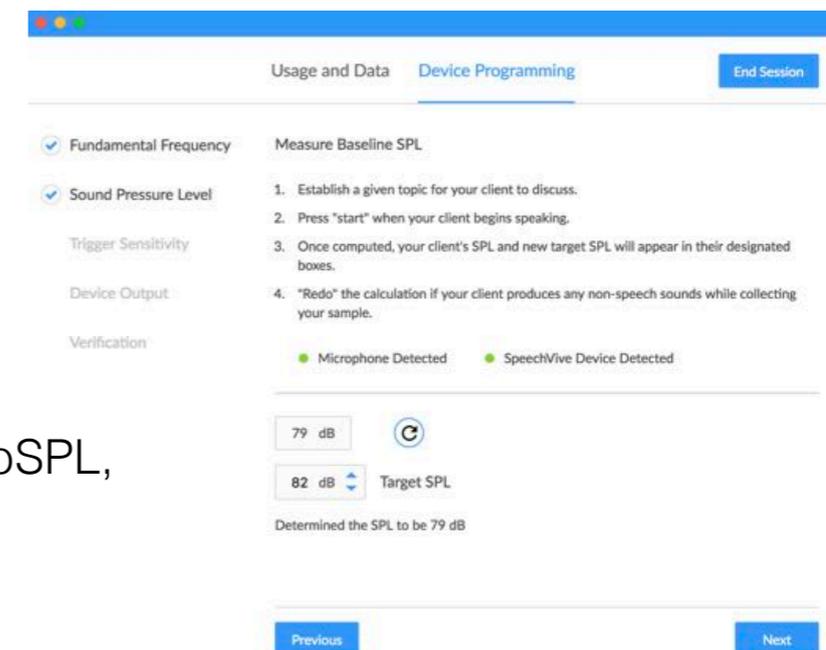
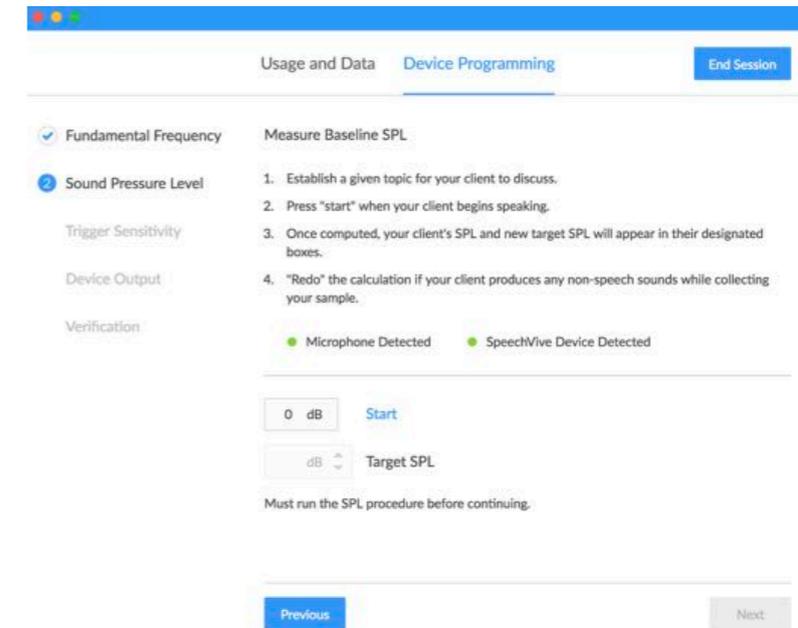
“As we discussed before we started, I want you to talk about a topic of your choice for at least 60 seconds.”

Troubleshooting Tip: The user should only wear the head-worn microphone.

DO NOT fit SpeechVive for this baseline measurement

Therapeutic target range: +3 to +5 dbSPL from baseline, you can adjust the target as you deem appropriate based on your clinical judgement.

For the INITIAL CALIBRATION, do not worry too much about the target dbSPL, the goal is to determine stimulability, not therapeutic ranges.



PLACE THE SPEECHVIVE ON YOUR CLIENT

**keep the microphone in place*



Troubleshooting Tip: The SpeechVive cannot be switched from a right to a left ear device. DO NOT TWIST the earpiece. This is similar to a spinal cord.

If you have a patient that requires a different device, contact SpeechVive.

Ensure the rubber earpiece is snugly in the auditory meatus (you may need to change sizes). The rubber earpiece should rest just behind the tragus to ensure the accelerometer in the earpiece will feel the F0 vibrations during speech

EXECUTE STEP 4

Configuring Device Sensitivity

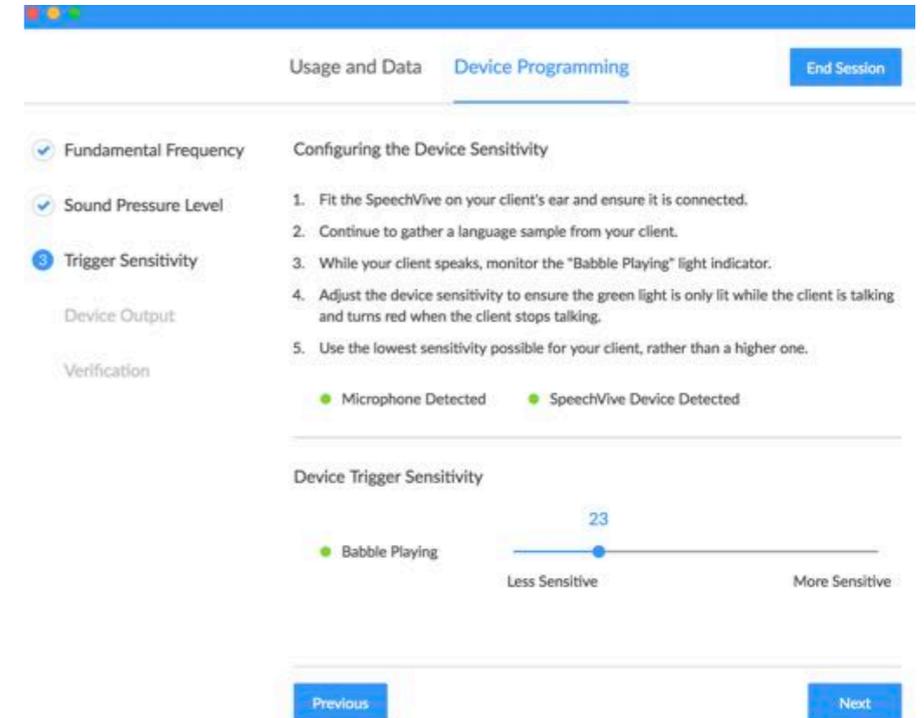
Suggested Script:

“I would like you to read this paragraph aloud. You will hear sounds turn off and on while you speak.”

The objective is to ensure that the device only triggers the “babble” cue when your patient speaks and turns off when they are not speaking.

Watch the “babble playing” indicator while your patient continues to speak. You want the light to turn green IMMEDIATELY when your patient speaks and red IMMEDIATELY when they cease. *Go for 95% accuracy on this one, less resonant phonemes may not trigger the cue.

**Feel free to use a phonemically balanced reading passage (included) during this phase.



Troubleshooting Tip: For an INITIAL CALIBRATION, there is no need to spend a lot of time/effort on this screen. Simply ensure that the setting triggers accurately.

When the babble does not start immediately: INCREASE the sensitivity

When the babble does not stop immediately: DECREASE the sensitivity

EXECUTE STEP 5

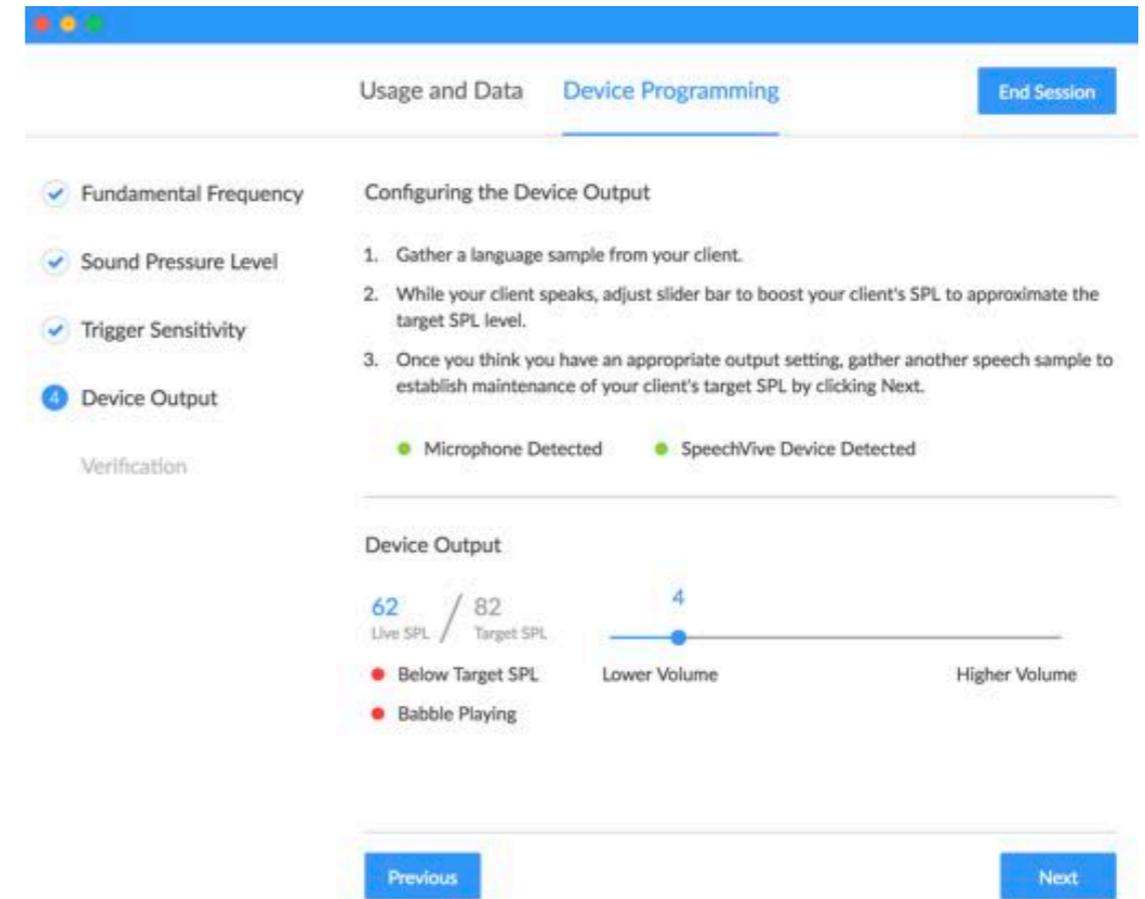
Configuring the Device Output

Suggested Script:

“Please keep talking about a topic that you can speak about for at least 2 minutes. While you speak, you may hear the sounds in your ear get louder or softer.”

The “Device Output” sets the volume of the sound cue in your patient’s ear. The objective is to increase the volume to a level that your patient speaks at their “Target SPL.”

Watch the “Live SPL” while you move the volume gauge to match it to the “Target SPL.”



Troubleshooting Tip: For an INITIAL CALIBRATION, you may choose to increase the volume near the top threshold level. This will give you an idea of their stimulability. While it may be above the therapeutic range for your patient, it will most likely give a larger perceptual change for the trial. This can be helpful for a caregiver/spouse to hear the different in the patient’s speech with/without the Lombard Effect as a cue.

For a personal device fitting, care would be taken to set the device within the therapeutic range that was previously determined.

EXECUTE STEP 6

Verify Sound Pressure Level

Once you set the “Device Output” from the previous step, keep your patient talking and take an average sound pressure level.

At times, this can be difficult to get from your patient, as they fatigue or run out of ideas to talk about. Encourage them to speak without long pauses as that will decrease the average, artificially.

If you are unable to obtain this measure with a spontaneous speech sample, you may use a reading passage or serial speech activity. Keep in mind that this may artificially inflate the reading.

Troubleshooting Tip: If your patient is outside the target SPL range (+/-1dBSPL), use the “previous” button to go back to the Device Output screen and adjust the volume of the cue as needed. When you return to the Verification screen, simply restart the average by clicking the circled arrow.

The screenshot shows a software window with a blue header bar. On the right side of the header, there are two tabs: "Usage and Data" and "Device Programming", with "Device Programming" selected. To the right of the tabs is a blue button labeled "End Session". Below the header, there is a vertical list of steps on the left, each with a checkmark and a number. The steps are: "Fundamental Frequency", "Sound Pressure Level", "Trigger Sensitivity", "Device Output", and "5 Verification". The "Verification" step is highlighted with a blue circle around the number 5. To the right of the list, the title "Verify Sound Pressure Level" is displayed. Below the title, there are two numbered instructions: "1. Ask the patient to discuss a topic and verify that the SPL is within 1dB of the target." and "2. You may choose to end the session with a value outside of the range or re-adjust the Device Output in the previous step." Below the instructions, there are two green status indicators: "Microphone Detected" and "SpeechVive Device Detected". In the center, there is a display showing "85 dB" in a box, a circled arrow icon, and "82 Target SPL". Below this display, there is a text box that reads: "The client's SPL is above the target SPL level. You may choose to end the session or re-adjust the Device Output setting in the previous step until the SPL is approximate to the target SPL level." At the bottom of the window, there are two blue buttons: "Previous" on the left and "Finish" on the right.

DETERMINE IF YOUR PATIENT IS STIMULABLE TO THE LOMBARD EFFECT

Session Summary

Below are the session values for your records.

| | | | | | |
|----|--------|--------------|-------|-------------|----|
| F0 | 201 Hz | Baseline SPL | 79 dB | Sensitivity | 23 |
| | | Target SPL | 82 dB | Output | 11 |
| | | Final SPL | 85 dB | | |

CANCEL

FINISH

Compare Baseline SPL to Final SPL. If there is an increase, your patient IS stimuable to the Lombard Effect (approximately 80% of the population).

EDUCATE YOUR PATIENT FOR THE RESULTS OF THE SPEECHVIVE TRIAL

Suggested Script:

(Show patient “session summary”) “Thank you for trying out the SpeechVive today. The SpeechVive is a device that has been proven to help people with hypokinetic dysarthria/Parkinson’s disease (whichever you prefer) have more understandable speech.

It uses a response that most of us have called the Lombard Effect. This is our natural response to speak louder, slower, and to over-enunciate when we’re in a loud environment. This is the same phenomenon that occurs when someone speaks to you while listening to music with their headphones on—they end up speaking louder than is necessary in for a quiet setting. In clinical research, the SpeechVive improved the speech volume and quality for 90% of the test subjects over 8 weeks of use.

We know that increasing speech volume is a successful intervention for speech changes like you’re experiencing. There’s over 30 years worth of research behind that. The Lombard Effect was identified 150 years ago and has been used in speech therapy for over 50. However, the SpeechVive is the first device to put this type of intervention into a small, wearable product.

Let’s take a look at your results (show “session summary”). When you spoke without the SpeechVive, your sound pressure level was _____. To put this number into perspective, if I was to speak in my office without any background noise using my “indoor voice,” my sound pressure level would be around 80 dBSPL. Now, take a look at what your sound pressure level was with the SpeechVive. It was _____. It looks like you *are/are not* stimulative to the Lombard Effect.

In research comparing people with Parkinson’s Disease to their peer group, people with PD were about 3 dB below their peers in conversation.”

DETERMINE IF YOUR PATIENT IS A GOOD CANDIDATE FOR SPEECHVIVE

Suggested Script:

“Now that we’ve seen that you are stimuable to the Lombard Effect, let’s discuss if the SpeechVive device is going to be a good option for you. One reason people are seeing such great success with the SpeechVive is that they don’t have to remember to be loud when speaking. The device automatically triggers loud speech for you, every time you talk.

Because you won’t have to remember your loud speech, we won’t have to practice it in therapy. That means we won’t have to see each other as often as we would if we use a speech volume “coaching” approach.

Also, when you’re having a conversation, you only need to focus on your ideas and listening to your conversation partner. You won’t have to think about your speech or do any extra practice.

For the best results with the SpeechVive, it’s recommended that you wear it during the day. Especially when you know you will be talking. It’s also a good idea to read aloud or have a long phone conversation at least 5 days each week while wearing the SpeechVive. This will ensure that you’re using your louder voice often.

You can kind of think of SpeechVive the same way you might think about ankle weights. If you were to wear ankle weights while doing your normal walking activities, over time you’d be stronger without doing any special exercises. The same thing can be said for SpeechVive. By wearing the SpeechVive while speaking, over time the physiology of your respiratory and laryngeal (voice box) systems start to work more efficiently for speech and begins to look more like what we expect from someone without voice changes.

With Parkinson’s disease, we expect people to experience a decline over time. This decline effects your voice, too. Even if you have been practicing strategies, typically we see people needing more therapy within a year or two. If you choose to use SpeechVive, we expect the decline to be more gradual due to the continued loud voice you’re using. Also, if you do experience a decline, we can simply reprogram your SpeechVive for your new levels.

If you’d like to try SpeechVive, they offer a 60 day full refund. We can try the device for 2 months while you’re in therapy.”

***It is also appropriate to explain additional/other therapy options available based on your clients severity and cognitive levels.*

HOW TO ORDER A SPEECHVIVE THROUGH THE VA

SpeechVive is in the SAMS and VISTA system and available throughout the VA System

Submit your purchase request following the guidelines established by your prosthetics department

DUNS # 07-940-2885

Phone # 1-800-392-3309

Fax # is 215-326-2943

Address: 603 Wexford Drive Lafayette, IN 47905

Item #:

SV1001R (right sided device and charger, only) \$2495

SV1002L (left sided device and charger, only) \$2495

SV1003R (right sided, bundle*) \$2950

SV1004L (left sided, bundle*) \$2950

*the “bundle” is a new product package. It includes a 1-year replacement warranty, small carrying case for the device and Velcro strips that can be used to affix the device to a patient’s eye glasses.

**If you would like to have the SpeechVive device shipped directly to your patient, it can be calibrated at the factory before being shipped. Simply email alambert@speechvive.com with the “Session Summary” information and it will be done.

ADDITIONAL RESOURCES

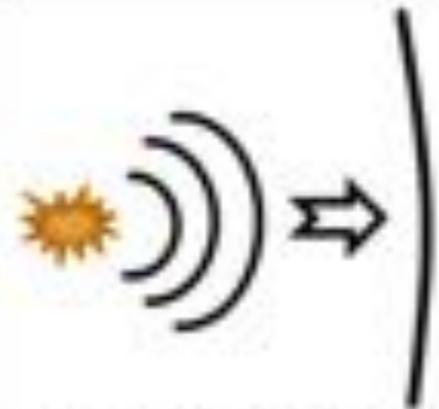
REMEMBER:

You're not alone! If you would like one of SpeechVive's SLPs to assist you with a calibration, they are happy to help.

Email: alambert@speechvive.com

Call/Text: 303-578-8103

A CHART EXPLAINING CHANGES IN SPL RELATIVE TO LOUDNESS PERCEPTION

| Change of Level | Loudness Perception | Sound Pressure Effect | Sound Intensity Cause |
|-----------------|--------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------|
| |  |  |  |
| Decibels | Loudness Gain Factor | Voltage Gain Factor | Power Gain Factor |
| + 20 dB | 4.000 | 10.000 | 100.000 |
| + 10 dB | 2.000 • | 3.160 | 10.000 |
| + 6 dB | 1.516 | 2.000 • | 4.000 |
| + 3 dB | 1.232 | 1.414 | 2.000 • |
| ± 0 dB | 1.000 | 1.000 | 1.000 |
| - 3 dB | 0.812 | 0.707 | 0.500 • |
| - 6 dB | 0.660 | 0.500 • | 0.250 |
| - 10 dB | 0.500 • | 0.316 | 0.100 |
| - 20 dB | 0.250 | 0.100 | 0.010 |

Grandfather Passage

You wish to know all about my grandfather. Well, he is nearly 93 years old, yet he still thinks as swiftly as ever. He dresses himself in an old black frock coat, usually several buttons missing. A long beard clings to his chin, giving those who observe him a pronounced feeling of the utmost respect. When he speaks, his voice is just a bit cracked and quivers a bit. Twice each day he plays skillfully and with zest upon a small organ. Except in the winter when the snow or ice prevents, he slowly takes a short walk in the open air each day. We have often urged him to walk more and smoke less, but he always answers, “Banana oil!” Grandfather likes to be modern in his language.

The Rainbow Passage

When the sunlight strikes raindrops in the air, they act as a prism and form a rainbow. The rainbow is a division of white light into many beautiful colors. These take the shape of a long round arch, with its path high above, and its two ends apparently beyond the horizon. There is, according to legend, a boiling pot of gold at one end. People look, but no one ever finds it. When a man looks for something beyond his reach, his friends say he is looking for the pot of gold at the end of the rainbow. Throughout the centuries people have explained the rainbow in various ways. Some have accepted it as a miracle without physical explanation. To the Hebrews it was a token that there would be no more universal floods. The Greeks used to imagine that it was a sign from the gods to foretell war or heavy rain. The Norsemen considered the rainbow as a bridge over which the gods passed from earth to their home in the sky. Others have tried to explain the phenomenon physically. Aristotle thought that the rainbow was caused by reflection of the sun's rays by the rain. Since then physicists have found that it is not reflection, but refraction by the raindrops which causes the rainbows. Many complicated ideas about the rainbow have been formed. The difference in the rainbow depends considerably upon the size of the drops, and the width of the colored band increases as the size of the drops increases. The actual primary rainbow observed is said to be the effect of super-imposition of a number of bows. If the red of the second bow falls upon the green of the first, the result is to give a bow with an abnormally wide yellow band, since red and green light when mixed form yellow. This is a very common type of bow, one showing mainly red and yellow, with little or no green or blue.

DOCUMENTATION SAMPLE

SPEECH FUNCTION: SLP donned microphone at a distance of 5 cm from the veteran's mouth for baseline measurements.

BASELINE: Mr. VETERAN participated in a monologue speaking task for 60 seconds with sound pressure level of 80 dB and f0 of 193 Hz [The f0 of the adult human voice ranges from 100-300 Hz]with estimated 75% of utterances were intelligible during monologue task of known topic. Sensitivity was 15.

STIMULABILITY TESTING: The Speech Vive [right sided device] was donned with medium size ear piece fitting. During 60 second monologue speaking task with Output [multi-talker babble to induce Lombard effect] set to 18, Mr. VETERAN achieved 88 dB SPL with estimated intelligibility of 90%. Output was adjusted to 14 and Target SPL was 83 dB with estimated 80% of utterances were intelligible. Mr. VETERAN demonstrated the ability to achieve the target SPL during three subsequent trials of monologue speaking task [60 seconds per trial].Videoconferencing with Speech Vive consultant terminated upon completion of the equipment trial. SLP proceeded with education.

SLP provided the veteran and his caregiver/spouse with EDUCATION on SpeechVive including:

- ___Funding Sources
- ___Indicated technology
- ___Advantages and Disadvantages
- ___Patient financial responsibilities
- ___Safety
- ___Repairs and Maintenance
- ___Delivery location for requested items
- ___Expected wait times for requested items
- ___Expected timeframe for plan of care
- ___Reassessment and follow-up procedures
- ___Contact information

Veteran and his caregiver verbalized understanding of the information. Mr. VETERAN requested to proceed with ordering the Speech Vive and the plan of care using the equipment.

IMPRESSIONS:

1. Mild to moderate hypokinetic dysarthria likely due to xxxx characterized by reduced vocal intensity, fluctuating rate of speech, and stuttering with improved vocal intensity and speech intelligibility with the use of a non-speech generating augmentative and alternative communication device [Speech Vive].

ST frequency:

HBPC ST to provide treatment 1x/month for 6 months for speech-language therapy to improve overall communication function.

PROGNOSIS is good based on the patient's motivation, family support, access to equipment and ST services, and stimulability for improvement.

Plan:

1. HBPC ST to initiate POC, 1x/month.
2. ST to order 1. SpeechVive Item #SV1001R (right sided device and charger, only) (\$2495) Vendor: SpeechVive
3. ST will explore other modalities for the veteran to achieve optimal communication function. Veteran will most likely benefit from a comprehensive augmentative and alternative communication assessment to identify which speech generating device(s) are most appropriate for Mr. VETERAN to meet his communication needs.

LONG TERM GOAL [6 VISITS]

1. Patient will increase intelligibility from 75% to 90% of the time in order to convey information over the telephone in an emergency.

SHORT TERM GOALS [6 VISITS]

1. Patient will increase vocal loudness to reach a target sound pressure level of 85 dB with SpeechVive donned to communicate effectively during simple structured conversational speech for 30 minutes.
2. Patient will increase vocal loudness to reach a target sound pressure level of 85 dB with SpeechVive donned to communicate effectively during phone conversation for 15 minutes.

Troubleshooting

Coming Soon