



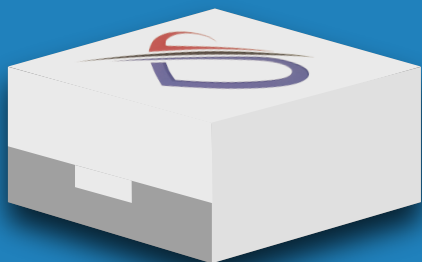
# AffeX-CT User Guide

The AffeX-CT device is an investigational device for the treatment of high blood pressure by non-invasive transcutaneous nerve stimulation.

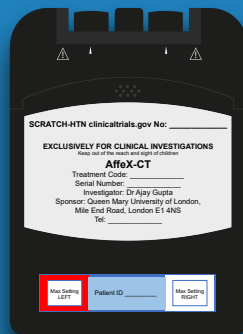
The user guide is for participants recruited into this study and is to be used in conjunction with the training provided.

# YOUR TRIAL KIT

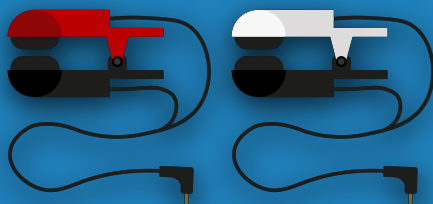
## 1 Box



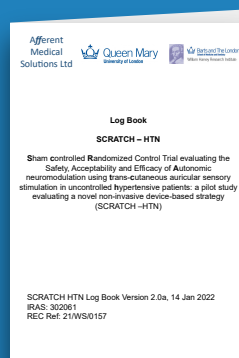
## 1 AffeX-CT Device



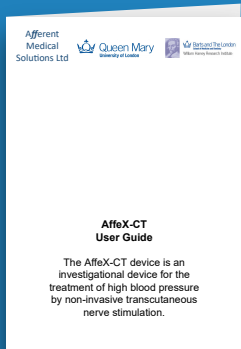
## 2 sets of leads with attached ear clips (1 spare in case of damage or loss)



## 1 Log Book



## 1 User Guide



## 1 IFU



# DAY 0 - TRAINING SESSION

**You will be shown this device, and what is expected of you on your screening visits, and prior to the randomization (inclusion) in the study. Thereafter, your training session will be carried out at your randomisation visit (which is likely to be your second clinic visit) and for the purpose of this study, this will be day 0 of your trial. At this visit the research nurse will:**

- Carry out a first assessment, using the study assessment device. This will inform us what levels of stimulation may be required for each ear. We will make note of those levels.
- The nurse will then train you to use the device - which will be performed using a training device.
- You will be handed your own study-device, labelled with a unique anonymised patient identifier, and where we will record the level of your stimulation determined during the training session. This will be your prescribed level of stimulation.
- You will be asked to use your own device under supervision of the research nurse. You will use the settings that were assessed for you, or lower.  
In addition, whilst you can lower the stimulation level setting below the prescribed level if you feel uncomfortable, you should NOT set the stimulation level above the level that has been prescribed to you.
- Please note that when you use your 'own' device at prescribed settings, you may or may not experience the sensation you felt during the assessment with the study device.

- This supervised stimulation will be done for a few minutes in the presence of the nurse, and then you will complete a full 30 minutes stimulation whilst in the research facility. We will monitor you for a further half an hour.
- We will also agree with you the best time and place to carry out the treatment. The best time is when you are relaxed in the evening between 6pm and 10pm, preferably after 8 pm. Each treatment session lasts 30 min.
- We recommend that you should be in a relaxed state, either sitting or lying, whilst applying the stimulation. It doesn't matter if you are watching television, talking, reading or listening to music (but not whilst using any headphones, airpods or Bluetooth ear devices) or just lying on the bed. (NB. You can do this stimulation whilst working or walking too, but that is not a recommended option.)
- During the training session, whilst you are undergoing stimulation, we will also go through your log book with you and fill in the first page.

## DAY 1 - USING THE DEVICE

**When you carry out the treatment on your own you will need to take the following steps:**

### Step 1 - Preparation

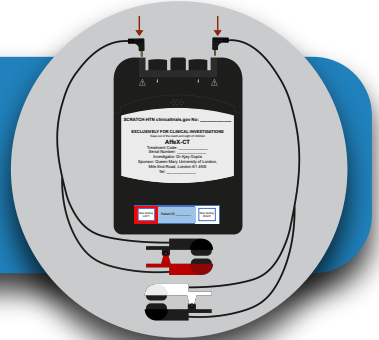
**You will need to:**

- Set yourself at least half an hour in the evening when you have some calm time.
- Choose a time when you are not carrying out any other physical activity. The best time is when you are watching TV, listening to music (but not whilst using any headphones or airpods or Bluetooth ear devices. NB. It is contra-indicated to use any other ear device when self-stimulation using the study device), reading, or working on the computer.
- Have your kit with you.
- Have a wetwipe or cleaning material to clean your outer ear.
- Have a tissue moistened with water handy to moisten the clips.
- Have your log book and pen handy.

# Step 2 - Using the Device

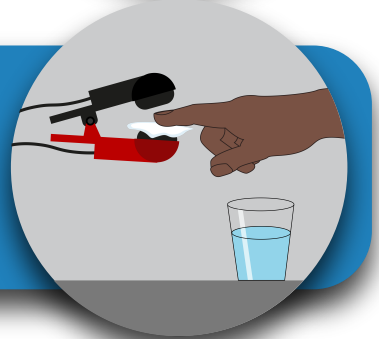
# 1

Attach the leads to the machine.



# 2

Moisturise the part of the clip in contact with your ear, by wiping it with a wet tissue (e.g dipped in water).



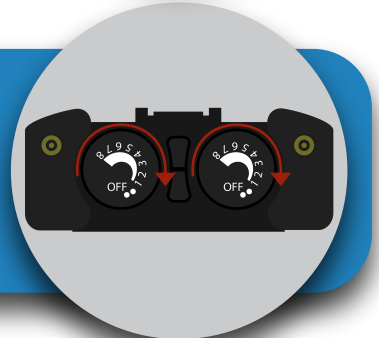
# 3

Attach the ear clips to the tragus on both sides, ensuring the red clip is attached to the outer side of the left ear and the white clip is attached to the outer side of the right ear.



# 4

The device is turned on by turning both the left and right dials towards the right (clockwise). A green light will be on when the stimulation is applied.



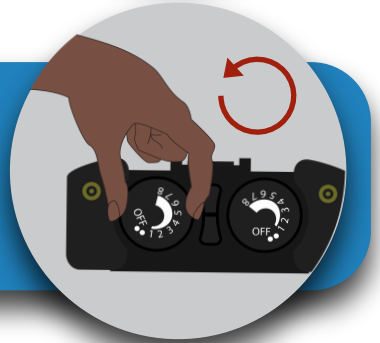
# 5

For each ear:

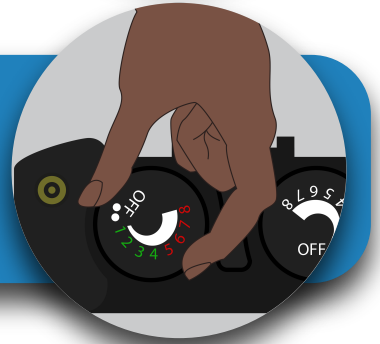
- Turn the device on by turning the dial slowly towards the right (clockwise) until you reach the correct stimulation level prescribed at your training session. You may or may not feel a tingling sensation.



- If you feel a tingling sensation and it is uncomfortable, turn the dial down one number lower. You may need to dial it one number further down during the treatment session if the sensation is uncomfortable.



- Do not turn the dial above the level prescribed, as that may cause you some tingling sensation and unease.



- Your sensation might change from day-to-day, even when stimulation is applied at the prescribed levels. If that happens, please go down by one unit to the level prescribed/used.



# 6

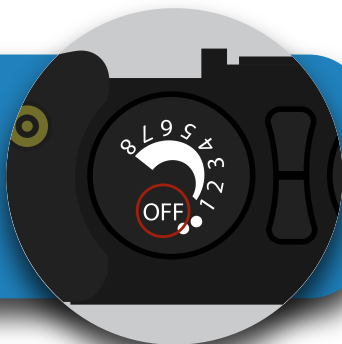
You should use this device, as prescribed, for 30 minutes only. We recommend you use external timers, or a watch or whatever is convenient to time this stimulation. The device itself may also provide information about the session, as green lights will go off after 30 minutes.

However, this is not a reliable method, and we recommend using an external timer.



# 7

Make sure you turn the dial off when your session has ended.



# 8

Write down your notes on this sessions results in your log book with details about duration, and whether there were any interruptions or not.



# QUESTIONS

Is it painful?

No. The treatment at the prescribed level is not painful, you should not feel more than a tingling sensation when the stimulation is applied. Sometimes you may not feel anything. However, if you feel significant discomfort, you can adjust your setting downwards.

How will I know I am using the device correctly?

At the first visit the research nurse will work with you to make sure you are comfortable and confident in using the device.

What if my 30 mins. on the device is interrupted?

You should add on the remaining by switching the device 'off' and 'on' again. Make sure the total treatment time per session is 30 mins. Make a note of any interruption in your log book.

What if I don't manage to complete the 30 mins on the device?

Make a note in your log book.



What if I miss a session on the prescribed day?

If you miss during the first-phase of stimulation, which is daily use for 14 days, carry on with your normal daily sessions and make a note.

If you miss your weekly session, you can stimulate yourself on the next day or when you remember prior to your next weekly stimulation. You should continue with the schedule thereafter, and make a note of this in your log book.

What support will I have?

- Someone from the study team will phone you:
  - Between day 1 - 4 (the day will be agreed beforehand)
  - Day 5 -10 (preferably day 7)
- If you have any emergency you should seek assistance as appropriate via NHS helpline, visiting A&E or calling the emergency services. This is vital. Please always err on the side of caution.
- If you have any health-related issue/concern or have any study-related queries, you can call the study team.

- If you are having problems with your device, or do not understand what you need to do, you can call the device team particularly so in your first two weeks of device usage. After that you can always contact your study team.
- If you have any health concerns regarding your treatment you should call the study team in first instance on the number above.
- Please note if you visit your GP or any other healthcare services, please do let study team know about that later.

Contact Details:

Afferent  
Medical  
Solutions Ltd



 Barts and The London  
School of Medicine and Dentistry  
William Harvey Research Institute