

**THE EAR CENTER OF GREENSBORO, P.A.**  
**Esteem II Clinical Trial 0204 – Participant Appointments Summary**

APPOINTMENT	DATE/TIME	EXPLANATION
<b>Day #1</b>		
INITIAL VISIT		Purpose: to determine candidacy for Protocol 0204. Screening informed consent will be signed. Otogram hearing testing, watch informational Esteem DVD, medical history and physical examination by Dr. Kraus, informed consent process and signing of informed consent document. Protocol 0204 questionnaire completion.
CT SCAN OF HEAD & EARS		Purpose: to determine status of ear anatomy and permit mastoid measurements for transducer fit. Performed at Southeastern Radiology.
PREGNANCY TEST (for women of child bearing age)		Purpose: to determine if participant is pregnant. Women of child bearing age who have not had a hysterectomy or tubal ligation are required to have a negative pregnancy test in order to participate in the research study.
QUESTIONNAIRES		Purpose: to gather participant specific information concerning hearing ability, etc.
<b>Day #2</b>		
BASELINE HEARING TESTING WITH & WITHOUT HEARING AIDS		Purpose: to measure preoperative hearing ability with and without hearing aids. A full audiometric evaluation will be performed as per Protocol 0204 requirements.
<b>Days to be Determined</b>		
PREOP EXAM		Purpose: to re-examine your ears and general medical condition prior to surgery. Review surgery and answer questions.
SURGERY		The surgery will be conducted at the SCA Surgical Center of Greensboro, 1211 Virginia Street, Greensboro, NC. The procedure may take 4-5 hours and is performed under general anesthesia.
POST OP APPOINTMENTS		You will be required to return for 2-6 follow up appointments, depending on recovery. Your first appointment will be to remove skin sutures/staples and check healing progress.
DEVICE ON		8 weeks after the surgery, you will return to have the device turned-on. You will leave the office with your device turned on. This is a great time to bring your

		spouse, friend, or family member. Estimated . time of the appointment is 1-11/2 hrs. The device will not be finely adjusted to permit you to adjust to your new hearing ability.
FORMAL DEVICE ACTIVATION & ADJUSTMENTS		One week following your Device-on visit, you will return for computer adjustment and fine tuning of your Esteem device. More intensive hearing tests will be performed. Estimated time for the appointment is 3-4 hrs.
ONE MONTH		One month after Device-on, you will return for 3-4 hrs of reprogramming and testing.
TWO MONTHS		Two months after Device-On, you will return for 3-4 hrs of reprogramming and testing.
FOUR MONTHS		Four months after Device-On, you will return for 3-4 hrs of reprogramming and testing.
TEN MONTHS		Ten months after Device-On, you will return for 3-4 hrs of reprogramming and testing.
1 YEAR		1 year after Device-On, you will return for 3-4 hrs of reprogramming and testing.
2 YEAR		2 years months after Device-On, you will return for 3-4 hrs of reprogramming and testing.
3 YEAR		3 years after Device-On, you will return for 3-4 hrs of reprogramming and testing.
4 YEAR		4 years after Device-On, you will return for 3-4 hrs of reprogramming and testing.
5 YEAR		5 years after Device-on, you will return for 3-4 hrs of reprogramming and testing.

***Please call our audiology department, (3365) 273-9932, if you have any questions.***