

KTL/ULTRA/EU Environment and Climate contract No ENV4-CT97-0568
 AMBULATORY ECG (HOLTER) RECORDINGS IN ULTRA 2 STUDY

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<input type="checkbox"/> Full SOP <input type="checkbox"/> Working SOP # pages _____		Coordinator: ___/ ___/ ___ _____			
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Ambulatory ECG (Holter) Recordings in ULTRA 2

1. PURPOSE AND APPLICABILITY

The purpose of this ECG SOP is to ensure that all Holter recordings within ULTRA 2 study are done in the same way by each field worker in each participating centre. This SOP should be followed in every Holter recording done in ULTRA 2 study.

2. DEFINITIONS

ECG: electrocardiography

Holter: ambulatory ECG recording

KTL: National Public Health Institute, Finland

PI: principal investigator

3. REFERENCES

Froelicher VF, Quaglietti SE. Handbook of ambulatory cardiology. Little & Brown 1997.

Moss A. Noninvasive electrocardiology: clinical aspects of Holter monitoring. Saunders 1995.

Braunwald E. Heart disease: a textbook of cardiovascular medicine. Vol. 1 & 2. 5. edition. Philadelphia, Saunders, 1997.

Medilog MR63 Ambulatory monitoring unit. User Guide. Oxford Medical Limited 1997.

SOP of the flow of the clinical visit in ULTRA 2, SOP ULTRA/KTL-F-2.(*

SOP of spirometry in ULTRA 2 study, SOP ULTRA/ UoW - F - 1.(*

*) This statement refers to the latest SOP revision available. Make sure that you know and have it.

4. DISCUSSION

N.A.

5. RESPONSIBILITIES

KTL is responsible for the developing and editing the contents of the SOP for Holter recordings (ULTRA/KTL-F-1.0). Any person who changes this procedure is responsible for ensuring that the change has been properly documented, the SOP changed, reviewed and approved by the local principal investigator(s).

The PI:s in each centre are responsible for implementation of this SOP.

6. EQUIPMENT AND MATERIALS

- a) equipment: ambulatory ECG recorder (Oxford MR-63) with patient cable, single use disposable electrodes (Blue Sensor R-00-S), C-60 cassette tape for recording (TDK AD C-60 or Maxell), Oxford XE45 unit to connect the recorder to the ECG recorder, ECG recorder to register a rhythm strip, a stopwatch, a computer work station with relevant software (Oxford Medilog Excel II) for analyses of the recordings (needed only in Kuopio University Hospital)
- b) paper materials: clinical visit log book / questionnaire
- c) materials: skin cleaning liquid (80% ethanol) and sand paper (nro 240), batteries (two per a recorder, alkaline AA LR6-size), paper for ECG recordings (rhythm strips), adhesive tape for fixing the electrodes and cables to the skin, skin hair shaver, isopropanol and cotton swabs to clean the recorder, cleaned benzin to clean the patient cables

7. PROCEDURE

7.1 Preparation

7.1.1 Preparation of the recorder and the cassette tape

Mark identification codes (number) to each recorder and patient cable system beforehand. These codes must be written down in the clinical visit log book to ensure the identification of the recorder and patient cable system used in each registration. It is recommended that also a logbook (e.g. a booklet) of the recorders is kept, in which it is marked when batteries are changed, possible malfunctioning etc.

Clean the recorder daily with isopropanol according the instructions of the manufacturer. Use always a new cassette. Mark the cassette with the procedure identification code. Wind the leader tape so that it is not visible. The batteries should be changed after about 10 recordings. This results, when all recorders are used evenly, that the batteries could be changed weekly, e.g. a new set of batteries every Monday. The patient cables should be cleaned with benzin when needed.

7.1.2 Medication use prior the Holter recording

There is no need to modify daily medication because of the clinical visit with the exception of short-acting medication for respiratory diseases (asthma). The detailed instructions of the

medication use are in the SOP for spirometry (ULTRA/UoW-F-1.0). Medication use prior the Holter monitoring, during the day of the clinical visit, should be carefully documented. Medication use is not a criterion for not conducting the measurements.

7.2 Steps to follow

A good contact between skin and the electrode and a careful fixing of the electrodes has a crucial impact on the quality of the recording.

1. The subject takes clothes off from the upper body. During the recording, use of a cotton shirt is recommended, e.g. a T-shirt. The subject is in sitting position.
2. Shave the skin hairs when necessary from the places where the electrodes will be fixed. See Figure 1. for the places of the electrodes.
3. Clean the skin with alcohol and sandpaper from the same places to remove fat and skin debris
4. Put the electrodes accordingly
5. Place the cassette (C-60) marked with the identification code to the recorder after winding the leader tape. Place the A-side up.
6. Connect the cables to the electrodes according the colour codes, see Figure 1.
7. Connect the ECG recorder with its cables system to XE45 unit. Connect the XE45 cable to the Holter recorder.
8. Ask the subject to supine position.
9. Put the XE45 on.
10. Start the ECG recording by putting the Holter recorder on and pressing the event marker at the same time.
11. Check the quality of the signal, and register ECG for 1 minute to a paper, use paper speed of 25 mm/sec. If required, check the electrodes, cable and recorder. After 1 min ECG strip, stop the recording and disconnect the XE45.
12. Fix the electrodes and cables with stress loops using adhesive tape.
13. Start the recording. **Set the time of the Holter recorder to 00.00 (see the User Guide) and at the same time start the stopwatch (= 0 time point). Mark the real time to the clinical visit logbook.** Wait the gain setting period of 45 sec:s (beeps every 5 sec), See 4.6 in User Guide. It is important that the subject remains still during this period. Then, a calibration signal is recorded for a minute, and only after that the normal ECG signal collection will be started, See 4.8 in User Guide..
14. Wait for 1 min, the calibration signal is recorded.
15. Follow the flow of the clinical visit. From the stopwatch, mark the exact time points of every specific procedure during the clinical visit to the logbook. Remember to press the event marker in the beginning and in the end of the procedures.
13. After completing the procedures of the clinical visit, stop the recording according the instructions of the recorder, 4.9 in User Guide.
14. Record the 1 minute rhythm strip via XE45 in the same way as in the beginning of the recording.
15. Take the electrodes away from the skin and clean the skin.

7.3 Procedure identification

Assign each recording (cassette) with a unique identification code of one set of letters and two sets of numbers as follows:

In the beginning, the project name ULTRA 2 and procedure identification ECG are stated. After this, a set of three numbers indicates the study subject and center: 100 - 299 = Amsterdam, 300 - 499 = Erfurt, and 500 - 699 = Helsinki. Finally, a 6-number set indicates the date of the recording (DDMMYY).

Example: ULTRA2-ECG-534-010399 indicates that the recording has been done in ULTRA 2 study in Helsinki to subject with an identification number 534 on the first of March, 1999.

7.4 Quality control

Careful cleaning of the skin and fixing of the electrodes ensure a good signal transfer. The recording of a rhythm strip in the beginning and at the end of the Holter recording helps to notice if there were problems in signal transfer. As the rhythm strip is recorded through the recorder used in the ambulatory measurement, the use of a monitor to test the signal is not necessary.

Any deviations from the protocol or any difficulties during the recording should be marked the clinical visit log book.

All the recordings must be coded as above. In each center, all recorders should be used evenly.

The tapes will be analyzed by one laboratory (Dept. of Clinical Physiology and Nuclear Medicine, Kuopio University Hospital, Finland). If poor quality recordings are found, the study centre will be immediately contacted to avoid further poor quality recordings. As the tapes are sent weekly to the analyzing laboratory, it is important that the latest tapes recorded with different recorders are readily available when the package is opened to allow a quick check of the quality of the recorders and response when needed (e.g. mark them with stickers). In the laboratory, there will be double analyses of 20 tapes as quality control by all nurses (5-6 nurses) taking part in the analyses.

8. DATA RECORDS

In the ULTRA 2 study, ambulatory ECG recordings (Holter) are conducted during the clinical visit. At the same time, a clinical visit log book is filled in, which includes data on time of the start and end of each procedure in the clinical visit protocol. In addition, a 1-minute ECG recording on a paper print is collected in the beginning and at the end of the Holter recording. The data are recorded in ULTRA 2 study subjects.

The Holter tapes and copies of the respective clinical visit log books are sent weekly to Kuopio University Hospital. No protection against X-rays is needed. The address is

Department of Clinical Physiology / ULTRA
Kuopio University Hospital
P.O.Box 1777
FIN-70211 Kuopio, Finland

fax: +358 - 17 - 173 244

9. SAMPLE ARCHIVING

The sample archiving will be conducted in the institutes according the respective information protection rules. The original ECG paper prints and clinical visit log books are to be archived in the respective institutes. The original Holter tapes will be archived in KTL until the results have completely been reported. A copy of the data and paper prints of the analyses will be archived in Kuopio University Hospital.

10. IMPLEMENTATION AND APPLICATION

The instructions of the manufacturer of the Holter recorders, the SOPs for spirometry (ULTRA/UoW-F-1.0) and flow of the clinical visit in ULTRA 2 study (ULTRA/KTL-F-2.0) and the study protocol manual of ULTRA 2 include also information to implement and apply the present SOP properly.

This SOP will be distributed by KTL ULTRA center to other ULTRA centers by mail or telefax. Reception of a new SOP or revision should always be confirmed to KTL ULTRA center.

11. ATTACHMENTS

Figure 1. Figure of the places of the electrodes

Figure 2. Local and temporal deviation from or local change of SOP ULTRA/KTL-F-1.0.

Figure 3. SOP confirmation sheet.

Figure 1. The places of the electrodes.

5-Lead

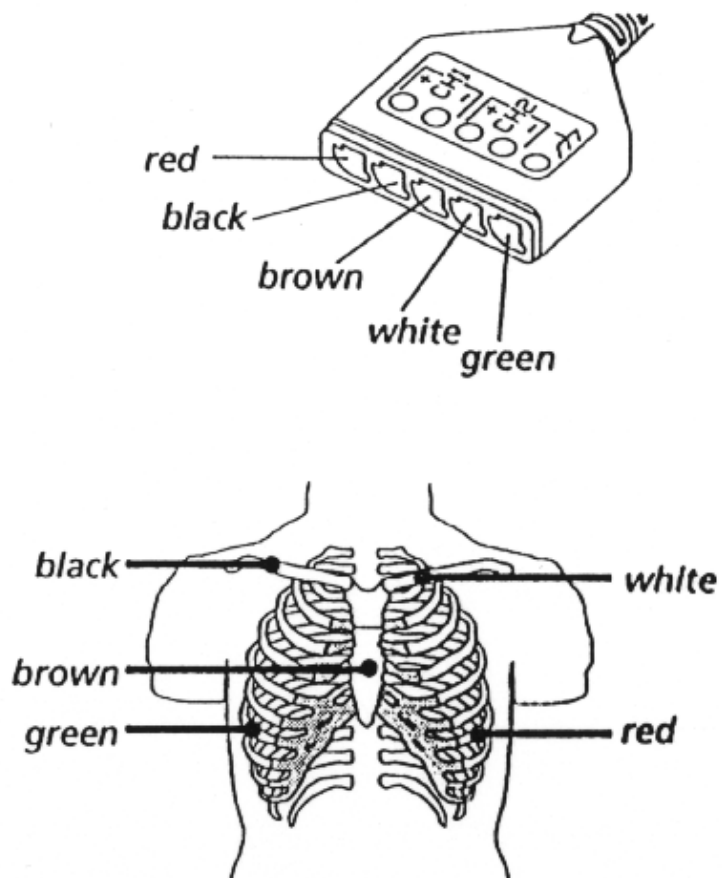


Figure 2. Local and temporal deviation from or local change of a SOP ULTRA/KTL-F-1.0.

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Begin date: __/__/__ End date: __/__/__	Date and Signature: __/__/__ _____
Original text(s); full paragraph, page No:	Changed text(s), full paragraph:

Figure 3.

SOP CONFIRMATION SHEET AMBULATORY ECG (HOLTER) RECORDINGS IN ULTRA 2 STUDY

This SOP has been received by Principal Investigator of

Research center _____ Date ____ / ____ / _____

Signature of PI: _____

INSTRUCTIONS :

- 0) **Keep this sheet attached to the original copy of the corresponding SOP**
- 1) When copying the SOP, mark the date of copying for each copy, number each copy
- 2) When delivering the SOP copy, take the signature and mark the date
- 3) When delivering a new revision to this SOP, collect previous SOP copies away and confirm with signature and mark the date
- 4) After each change fax this sheet to coordinator

Copy	Date of the copy	Delivered to Signature	Date of delivery	Received back PI signature	Received back Date
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Coordinator fax : + 358 - 17 - 201 265