

User Manual: Simultaneously recorded ECGs from collar bone and wrist during isolated motion activities

Tool Reference

RST Reference Number: RST24IP01.01

Date of Publication: 08/08/2023

Recommended Citation: U.S. Food and Drug Administration. (2023). *ECG Noise Extraction Tool (ECGNEXT)* (RST24IP01.01). <https://cdrh-rst.fda.gov/ecg-noise-extraction-tool-ecgnext>

For more information

[Catalog of Regulatory Science Tools to Help Assess New Medical Devices](#)

Disclaimer

About the Catalog of Regulatory Science Tools

The enclosed tool is part of the Catalog of Regulatory Science Tools, which provides a peer-reviewed resource for stakeholders to use where standards and qualified Medical Device Development Tools (MDDTs) do not yet exist. These tools do not replace FDA-recognized standards or MDDTs. This catalog collates a variety of regulatory science tools that the FDA's Center for Devices and Radiological Health's (CDRH) Office of Science and Engineering Labs (OSEL) developed. These tools use the most innovative science to support medical device development and patient access to safe and effective medical devices. If you are considering using a tool from this catalog in your marketing submissions, note that these tools have not been qualified as [Medical Device Development Tools](#) and the FDA has not evaluated the suitability of these tools within any specific context of use. You may [request feedback or meetings for medical device submissions](#) as part of the Q-Submission Program.

For more information about the Catalog of Regulatory Science Tools, email OSEL_CDRH@fda.hhs.gov.

Data recording details:

This data was collected to evaluate the performance of the ECG Noise Extraction Tool ([ECGNExT](https://github.com/dbp-osel/ECGNExT)) [1, 2] as reported in [3]. The software code for ECGNExT is available at <https://github.com/dbp-osel/ECGNExT>.

The study was approved by the FDA IRB (Study #2020-CDRH-007). Informed consent was received from 30 participants (22 male, 8 female, age (Mean \pm SD): 41 \pm 9) who were then enrolled in the study. Consistent with the protocol, all participants were willing and able to perform a series of simple instructed motions, had no known cardiac conditions or active implantable devices, and were not pregnant. Ag/AgCl gel electrodes (from ADInstruments) were placed on the right collar bone, right wrist, and two on the left iliac bone for reference. Single-lead ECGs were simultaneously recorded from the right collar bone and right inner wrist sites using the left iliac bone electrodes as references. The diagram of Fig. 1 and Table I illustrate the signals and their corresponding names in the recorded data files (Data Label column in Table I):

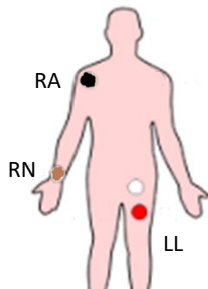


Fig. 1: Illustrates the positions of electrodes on the body.

Table I: Description of ECG electrodes, their positions, naming and corresponding variable names in the dataset.

Wire Color	Body Position	Wire/Electrode Label	Data Label
Black	Collar Bone	RA	ECG_REF
White	Left Leg	LL	ECG_REF
Brown	Right Wrist	RN	ECG_Wrist
Red	Left Leg	LL	ECG_Wrist

All data was recorded using a two-channel bio amplifier (FE232) and a PowerLab 16/35 data acquisition unit from ADInstruments. The sampling rate was set to $f_s = 1000$ samples per second and the “Mains Filtering” feature of the unit (a filtering feature offered by the data acquisition software (LabChart8) to attenuate powerline noise) was set to active. Each channel in the bio amplifier offers a differential input where wires from RA and RN electrodes were connected to the positive inputs of those channels and wires from the LL electrodes were connected to the negative inputs. This configuration resulted that all ECGs would be inverted in the dataset. The amplitude settings were not altered in the bio amplifier or PowerLab and therefore the recordings were measured in Volts.

Participants were asked to sit still and calm in a chair and perform the independent and separate activities as listed in Table II with their right hand for a duration of at least one-minute each while their ECGs were being recorded.

Each activity was performed to isolate movement to the right wrist location only and each activity was preceded by a one-minute period without any motion for collecting baseline ECGs. The diagram below (Fig. 1) illustrates the order of activities and no motion periods and how the data was collected from each participant.

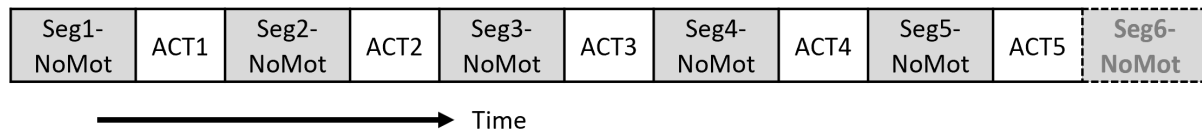


Fig. 2: Order of recorded data based on the order of activities being performed.
See Table II for descriptions of each activity.

Of the 30 participants, one dataset did not cover the entire set of activities as listed above and was not included in this dataset as it is not possible to integrate it due to missing data fields. A total of 145 segments (5 activities * 29 participants) of paired ECG_REF and ECG_Wrist signals were collected as the activities were being performed for approximately 60 s each.

Data processing notes:

The shortest and the longest ECG segment recordings in the dataset are 56 s and 173 s long, respectively. The recorded data for the entirety of each activity is included in the data set. As a result, varying lengths of data can be seen in the dataset for each pair of ECGs (ECG_REF and ECG_Wrist pairs). Each segment was restricted to 60 s in our published analysis [3], however. In some instances, both during activity and no motion periods, significant noise and motion artifacts are observed in ECG_REF. These unexpected noise and motion artifacts in ECG_REF are beyond the typical range of the ECG_REF signals as observed during the controlled motion activities and no motion instances. Rather, these artifacts are mainly due to random movements of the participants for reasons such as refreshing their position, experiencing a cough during the recording, or poor quality of sensors. Due to the objective of our previous analysis, we had identified shorter lengths (between 30 and 60 seconds) with clean ECG_REF from 19 of these activity periods as described in [3] that were used for the analysis in that study. In addition, 5 datasets were specifically identified as corrupt due to poor sensor quality and were entirely excluded from the study in [3]. However, the data that is being shared here has not gone through that removal process and the entirety of the collected data with their full lengths of more than 60 s (min: 56 s and max: 173 s) is available for every segment. Start and end indices of the clean ECG_REF segments used for the analysis in [3] are included in the data file in case users are interested to access only those portions of the data (see description of the “segIndRef” variable below). Lastly, the shaded segment in the diagram (Seg6-NoMot) was not included in our previous analysis [3] to prevent imbalance between no-motion data and data collected during the activities but is included in the current dataset.

Description of data in each file:

There is one .mat file containing the ECG data of each participant. MATLAB variables included in each .mat file are described below:

1. **ECG_REF**: This is a structure variable with the fields containing the ECGs for each activity as listed in Table II, and named directly after each activity. For example, the field name **FingTap** corresponds to the Finger Tapping activity. Table II links the field names of the ECG data structure to the activity codes. The field names in the Table are ordered as they appear in the structure. ECGs in the **ECG_REF** data structure are recorded from the collar bone area and are expected to be free from artifacts induced by the instructed activities.
2. **ECG_Wrist**: This is also a structure variable same as the **ECG_REF** structure except that the ECGs in this structure are recorded from the wrist area and are expected to contain artifacts induced by the instructed activities.
3. **fs**: This variable stores the value of sampling rate of data recording for each participant. While the value of **fs** is set to 1000 across all files, it is stored in each file to enable individual file processing and ensure consistency.
4. **segIndRef**: This variable is also a structure with the same field names as those of **ECG_REF** and **ECG_Wrist**. Each field in this structure carries the start and end indices of ECG segments that are free from motion artifact and noise in **ECG_REF**. These values may not be needed when using the entire ECG stream from **ECG_REF** and/or **ECG_Wrist**. However, they are helpful when the intent would be to access only segments of the ECG with no motion artifact and noise in **ECG_REF**. The code example to use this variable is also included in the script accompanying this dataset.

Table II: Structure fields in the dataset files and their link to the activities illustrated in Fig. 1.

No.	Field Name	Activity Encoding	Activity	Activity Description
1	Seg1_NoMot	Seg1-NoMot	No Motion	No activity, sitting calm.
2	FingTap	ACT1	Finger Tapping	Tapping the fingers on the chair arm.
3	Seg2_NoMot	Seg2-NoMot	No Motion	No activity, sitting calm.
4	ArmW	ACT2	Arm Waving	Waving the arm from elbow down.
5	Seg3_NoMot	Seg3-NoMot	No Motion	No activity, sitting calm.
6	WristRot	ACT3	Wrist Rotating	Rotations around the wrist area without moving the rest of the arm.
7	Seg4_NoMot	Seg4-NoMot	No Motion	No activity, sitting calm.
8	ElectTap	ACT4	Electrode Tapping	Tapping on the outer electrode surface on the right wrist with left hand.
9	Seg5_NoMot	Seg5-	No Motion	No activity, sitting calm.

No.	Field Name	Activity Encoding	Activity	Activity Description
		NoMot		
10	MakeFist	ACT5	Fist Making	Different movements involving making a fist and other finger motions.
11	Seg6_NoMot	Seg6-NoMot	No Motion	No activity, sitting calm.

Disclaimer:

The mention of commercial products, their sources, or their use in connection with material reported herein is not to be construed as either an actual or implied endorsement of such products by the Department of Health and Human Services. This article reflects the views of the author and should not be construed to represent FDA's views or policies.

References:

- [1] L. Galeotti and C. G. Scully, "A method to extract realistic artifacts from electrocardiogram recordings for robust algorithm testing," *Journal of Electrocardiology*, vol. 51, no. 6, Supplement, pp. S56-S60, 2018/11/01/ 2018, doi: 10.1016/j.jelectrocard.2018.08.023.
- [2] "ECG Noise Extraction Tool (ECGNEXT)." <https://www.fda.gov/medical-devices/science-and-research-medical-devices/ecg-noise-extraction-tool-ecgnext> (accessed 06/04/2024, 2024).
- [3] A. Suliman, M. Farahmand, L. Galeotti, and C. G. Scully, "Clinical Evaluation of the ECG Noise Extraction Tool as a Component of ECG Analysis Algorithms Evaluation," *IEEE Transactions on Biomedical Engineering*, pp. 1-10, 2024, doi: 10.1109/TBME.2024.3386493.