

Supplemental Material

**Arrhythmias detection in hemodialysis patients with wearable device:
a two-phase observational study**

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Supplementary Methods

Additional information about operation methods of devices

The two types of devices utilized in the study were as follows: (1) The reference standard device is the ambulatory ECG monitoring (CT-086S) by Hangzhou Baihui Medical Equipment Co., Ltd., China, compatible with specialized software. To use, secure the disposable electrode patch onto the recorder with snap buttons, remove the plastic film, and adhere the recorder to the body as instructed. Press the power button for three seconds to activate the device, which will begin acquiring ECG signals. For Lepu ER1 ECG recording, a medicine resident installs the ECG electrode via the buckle, attaches the recorder to the chest with the “R” marker up and at a 45-degree angle to the sternum, and records the dynamic ECG output after preparing the chest with 95% alcohol, abrasive paper, or a shaver. (2) Wearable device: the Lepu ER1 single-lead dynamic ECG recorder (Lepu ER1) (Shenzhen Yuandong Innovation Technology Co., Ltd., China) is a single-lead device that can continuously monitor ECG for 24 hours. It offers flexible wearing options, including electrode patches and chest straps, to accommodate the needs of diverse users and scenarios. During the design of Lepu ER1, gender differences were also taken into consideration to ensure a comfortable wearing experience for all users. Upon detecting the ECG signal, the device would automatically power on, with the signal light changing to a constant green state, indicating the start of data acquisition. This device is compatible with the smartphone application “Lepu Health”, enabling researchers download intelligent reports after the analysis is completed.

Signal processing and AI Algorithm of Lepu ER1, and data synchronization

Lepu ER1 Signal Processing and AI Algorithm

The Lepu ER1 device acquires ECG signals and processes them using the AI-ECG analysis software in accordance with the specifications described in the product’s official documentation and regulatory filings (AI-ECG Analysis Software Registration Certificate No.: NMPA 20223211142; Electrocardiograph Recorder Registration Certificate No.: Guangdong MPA 20202071404).

Temporal Synchronization and Signal Quality Control

Data acquisition from both the Lepu ER1 and the reference 24-hour Holter ECG was initiated manually and simultaneously by trained personnel. Although precise timestamp alignment was not feasible, synchronized start times minimized temporal discrepancies. Signal quality was continuously monitored during recordings. Segments with substantial artifacts—such as prolonged flatlines, abnormal noise, or signal dropouts—were excluded from analysis. No interpolation was applied to missing segments to avoid bias introduction.

Additional information about calculation formulas

In this study, indicators used in evaluation of diagnosis of arrhythmias by Lepu ER1 are presented. Calculation formulas of the true positive (TP), false positive (FP), true negative (TN), false negative (FN), and sensitivity (positive predictive value, TPR), specificity (true negative rate, TNR) and accuracy for arrhythmia diagnosis are shown in **Supplementary Table S1 and Table S2**.

Supplementary Table S1. Evaluation indicators and calculation formulas of diagnosis performance of wearable device (Lepu ER1).

		Standard reference	
		Positive	Negative
Wearable device	Positive	a	b
	Negative	c	d
	Total	a+c	b+d

Note: $TP = a / (a + c)$; $FP = b / (b + d)$; $TN = d / (b + d)$; $FN = c / (a + c)$. TP= True Positive, refers to individuals who actually have a certain disease or characteristic and are correctly identified as positive by the diagnostic test or screening. FN= False Negative, indicates individuals who actually have a certain disease or characteristic but are incorrectly identified as negative by the diagnostic test or screening. FP= False Positive, refers to individuals who are actually healthy or do not have a certain characteristic but are incorrectly identified as positive by the diagnostic test or screening. TN= True Negative, indicates individuals who are actually healthy or do not have a certain characteristic and are correctly identified as negative by the diagnostic test or screening.

Supplementary Table S2. Evaluation indicators and calculation formulas of diagnosis performance of wearable device (Lepu ER1).

Evaluation indicators	Calculation formulas
PPV	$TP / (TP + FP)$
Sensitivity	$TP / (TP + FN)$
NPV	$TN / (TN + FN)$
TNR (specificity)	$TN / (TN + FP)$
Accuracy	$(TP + TN) / (TP + TN + FP + FN)$

Note: PPV= positive predictive value, it represents the proportion of actually diseased samples (true positives) among all test-positive samples. Sensitivity represents the proportion of correctly identified diseased samples (positives) among all actually diseased samples. NPV = negative predictive value, it represents the proportion of actually healthy samples (true negatives) among all test-negative samples. TNR (specificity)= true negative rate, it represents the proportion of correctly identified healthy samples (negatives) among all actually healthy samples. Accuracy measures the proportion of correctly predicted observations among the total observations. It is the ratio of the sum of true positives and true negatives to the total number of observations. TP, FP, TN and FN were explained in the note of **Supplementary Table S1**.

Definitions and detection criteria for arrhythmia subtypes

The diagnosis of the reference standard Holter monitoring (CT-086S) was reported by experienced senior clinicians from the Dynamic ECG Room of West China Hospital. Wearable device (Lepu ER1) reports were download from smartphone application “Lepu Health” with structured systematical analytical algorithms encompassing following key parameters: rhythm, heart rate, P-wave analysis, PR interval, QRS complex duration, T-wave inversion, ST-segment elevation, and QT interval. The diagnosis and detection of arrhythmia subtypes were as followed:

Bradyarrhythmia: Defined as an average heart rate of less than 60 beats per minute.

Atrial Fibrillation (AF): Characterized by the absence of organized P waves, presence of fibrillatory waves, and an irregularly irregular ventricular rhythm, sustained for at least 30 seconds on ECG.

Premature Atrial Beats (PABs): Defined in this study as ≥ 100 ectopic atrial beats detected over a 4-hour monitoring period in this study, identified by premature P waves with altered morphology, typically followed by a narrow QRS complex and a non-compensatory pause.

Premature Ventricular Beats (PVBs): Defined as ≥ 100 ectopic ventricular beats within a 4-hour period in this study, presented as premature, wide QRS complexes (≥ 120 ms), not preceded by P waves, and typically followed by a full compensatory pause.

Paroxysmal Atrial Tachycardia (PAT): Denoted by abrupt episodes of regular atrial rhythm with a rate exceeding 100 beats per minute, typically initiated by a premature atrial contraction, and lasting at least 30 seconds.

Paroxysmal Ventricular Tachycardia (PVT): Characterized by three or more consecutive premature ventricular beats with a ventricular rate > 100 bpm, lasting less than 30 seconds, with either monomorphic or polymorphic QRS complexes.

Additional information about heart rate variability (HRV)

Heart rate variability (HRV), provided information about sympathovagal balance. These parameters

used in this study including SDNN, SDANN and pNN50. Measurements of HRV retrieved are shown in **Supplementary Table S3**. Standard deviation of RR intervals (SDNN) is an overall index of the amplitude of HRV oscillations. Square root of the mean squared difference of successive RR intervals (RMSSD) was utilized as a measure of cardiac vagal modulation.

Supplementary Table S3. Heart rate variability (HRV) parameters.

Note: IBI = interbeat intervals.

Parameter	Units	Description	Normal range (mean $\pm$ SD or range)
SDNN	ms	Standard deviation of RR intervals, normal-to-normal IBI	141 $\pm$ 39
SDANN	ms	Standard deviation of all 5-min mean normal RR intervals	127 $\pm$ 35
pNN50	/	Percentage of adjacent RR intervals differing by more than 50 milliseconds	1% - 12%

Performance of wearable device to detect arrhythmia

Supplementary Table S4. Performance of wearable device to detect premature atrial beats.

		CT-086S (Standard reference)		Total
		Yes	No	
Lepu ER1	Yes	18	1	19
	No	13	153	168
	Total	31	154	185

Supplementary Table S5. Performance of wearable device to detect atrial fibrillation.

		CT-086S (Standard reference)		Total
		Yes	No	
Lepu ER1	Yes	8	11	19
	No	1	165	166
	Total	9	176	185

Supplementary Table S6. Performance of wearable device to detect premature ventricular beats.

		CT-086S (Standard reference)		Total
		Yes	No	
Lepu ER1	Yes	8	1	9
	No	3	173	176
	Total	11	174	185

Supplementary Table S7. Performance of wearable device to detect bradyarrhythmias.

		CT-086S (Standard reference)		Total
		Yes	No	
Lepu ER1	Yes	4	0	4
	No	1	180	181
	Total	5	180	185

Supplementary Table S8. Performance of wearable device to detect paroxysmal atrial tachycardia.

		CT-086S (Standard reference)		Total
		Yes	No	
Lepu ER1	Yes	26	9	35
	No	17	133	150
	Total	43	142	185

Supplementary Table S9. Performance of wearable device to detect paroxysmal ventricular tachycardia.

		CT-086S (Standard reference)		Total
		Yes	No	
Lepu ER1	Yes	5	1	6
	No	2	177	179
	Total	7	178	185

Supplementary Table S10. Multi-class confusion matrix for stratified arrhythmia classification.

Predict True	Bradyarrhythmias	AF	PVB	PAB	PAT	PVT	No arrhythmias
Bradyarrhythmias	2	0	0	0	0	0	0
AF	0	3	0	2	0	0	0
PVB	0	0	1	0	0	0	1
PAB	0	2	0	15	1	0	5
PAT	0	0	0	1	5	1	4
PVT	0	0	0	0	0	3	1
No arrhythmias	1	3	0	6	0	0	108

Abbreviation: AF = Atrial fibrillation, PAB = Premature atrial beats, PVB = Premature ventricular beats, PAT = Paroxysmal atrial tachycardia, PVT = Paroxysmal ventricular tachycardia.

Patients' characteristics associated with *Benefits from wearable device*

The definition of “benefit from wearable devices” is a significant correlation between populations with specific characteristics and the use of wearable devices for the accurate diagnosis of arrhythmias. The demographic and clinical variables were further screened by LASSO binary logistic regression. We firstly identified potential factors for Benefit From wearable device, including age (β coefficient, 0.60

Correlation factors	Beta coefficient	OR	95%CI	P value
Age between 50 – 65	0.6	3.62	1.75 - 7.47	0.0005
Age over 65 years old	0.72	4.17	1.70 - 10.22	0.0018
Diabetes mellitus	0.05	1.30	0.59 - 2.90	0.5152
Hypercalcemia	-0.20	0.59	0.24 - 1.44	0.6405
Hypokalemia	0.48	0.77	0.38 - 1.56	0.4655

for between 50 – 65 years old and 0.72 > 65 years old, compared with < 50 years old), diabetes mellitus (β coefficient, 0.05, compared with patients without diabetes mellitus), hypercalcemia (β coefficient, -0.20, compared with normal serum calcium) and hypokalemia (β coefficient, 0.48, compared with normal serum potassium) as correlation factors (**Supplementary Table S10**).

Supplementary Table S11. Correlation factors selected by LASSO-logistic regression model.

Note: CI = confidence interval, OR = odds ratio.

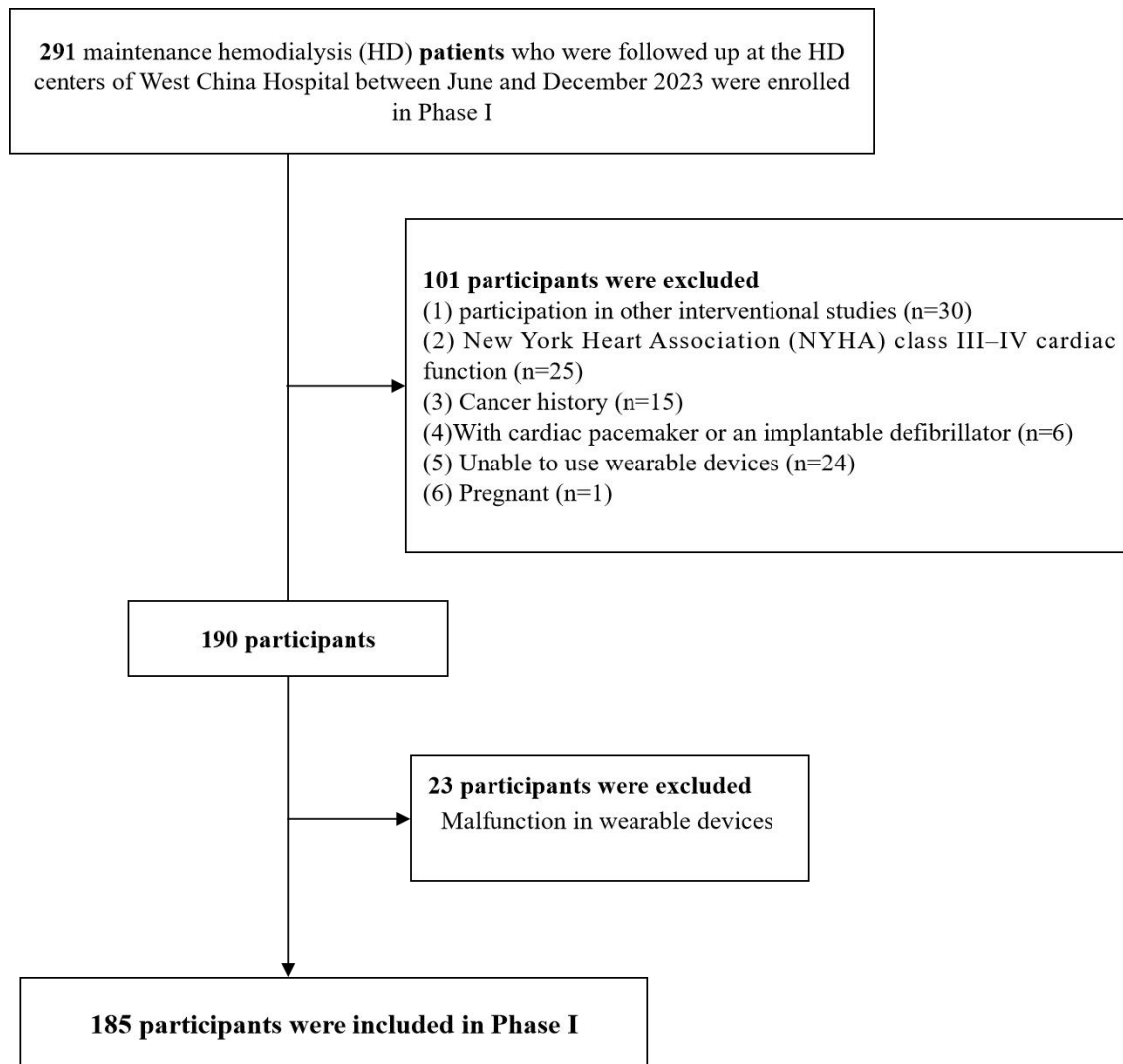
Arrhythmic detection of Lepu ER1 and clinical events in external implementation cohort

In external implementation cohort (Phase II), the observed events included 8 palpitation (17.0%), 9 hypertension (2.5%), 14 hypotension (4.0%), 11 convulsions (3.1%), 1 gastrointestinal reaction (0.3%), and 4 cases of hyperglycemia (1.1%).

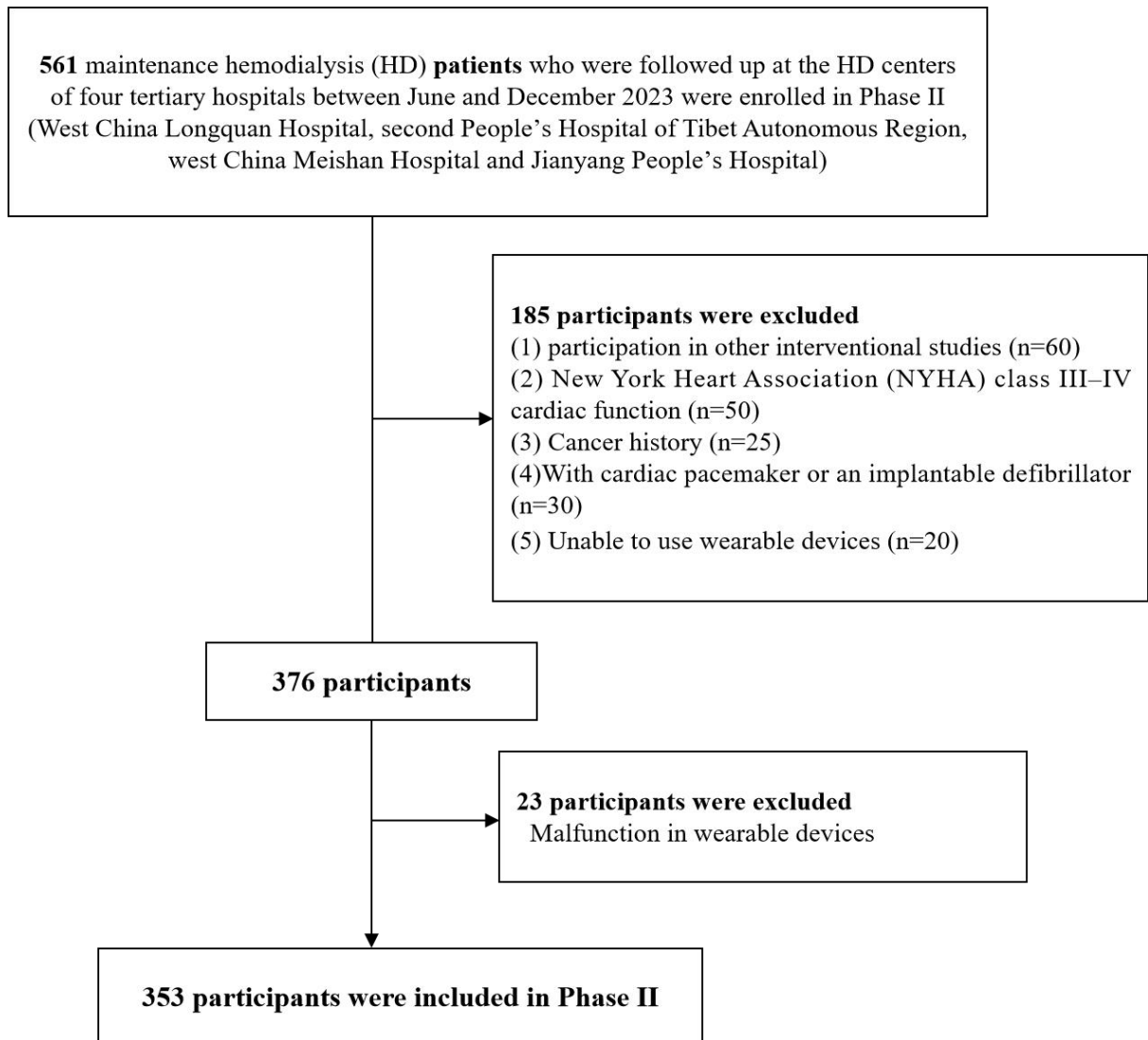
Among patients with clinical events, 23 (48.9%) had concurrent arrhythmias detected by wearable device. Conversely, among asymptomatic patients, 97 (31.7%) had arrhythmias identified, and 209 (68.3%) had neither arrhythmias nor symptoms. A statistically significant difference was observed between these two groups in the correlation between clinical symptoms and arrhythmia detection by Lepu ER1 ($P = 0.031$) (**Supplementary Table S12**).

Supplementary Table S12. The arrhythmic detection of Lepu ER1 and clinical events in external implementation cohort (Phase II).

	All subjects n=353 [n (%)]	No arrhythmia n=233 [n (%)]	Arrhythmia n=120[n (%)]	<i>P</i> value
Clinical events during dialysis	47 (13.3)	24 (10.3%)	23 (19.2%)	0.031
Palpitation	8 (17.0)	4 (1.7%)	4 (3.3%)	0.153
Hypertension	9 (2.5)	5 (2.1%)	4 (3.3%)	0.154
Hypotension	14 (4.0)	5 (2.1%)	9 (7.5%)	0.150
Convulsions	11 (3.1)	6 (2.6%)	5 (4.2%)	0.152
Gastrointestinal reactions	1 (0.3)	1 (0.4%)	0 (0%)	0.150
Hyperglycemia	4 (1.1)	3 (1.3%)	1 (0.8%)	0.150
No clinical events occurred during dialysis	306 (86.7)	209 (89.7%)	97 (80.8%)	Ref

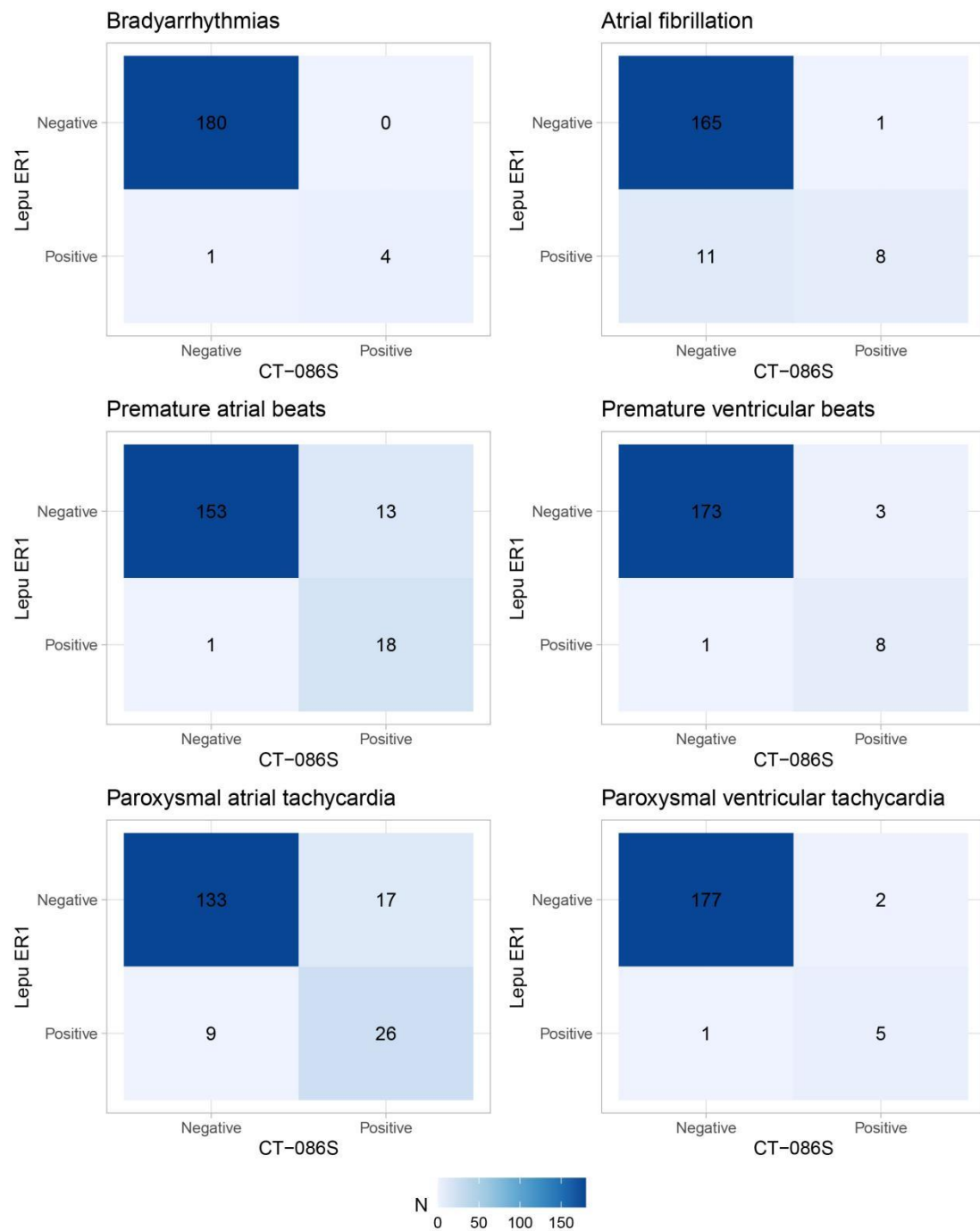


Supplementary Figure S1. Flowchart of participant selection in Phase I.

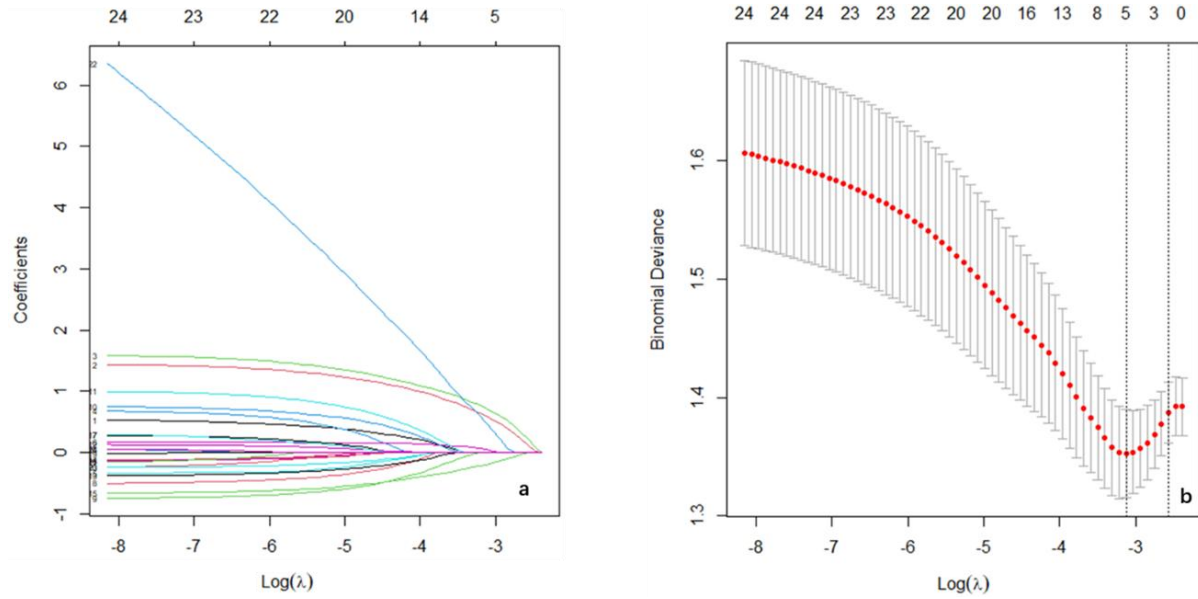


Supplementary Figure S2. Flowchart of participant selection in Phase II.

Supplementary Figure S3. Confusion matrices for stratified arrhythmia classification.



Identifying relevant factors for the benefits of wearable devices using LASSO Regression



Supplementary Figure S4. Identification of the correlation factors of *Benefit From WDs* by LASSO regression. A, LASSO coefficient profiles of the 24 variables. For the optimal lambda, 4 variables with a non-0 coefficient were selected. B, The cross-validation results. Following verification of the optimal parameter (lambda) in the least absolute shrinkage and selection operator model, dashed vertical line was plotted according to 1 standard error criterion Likelihood deviance (binomial) curve and log (lambda).