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# ***Addendum for DS-7200 System Operation Manual***

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## 12-Lead ECG Analysis Function

CE 0086

- Before using this device, read this manual thoroughly.
- Store this manual near the device where it can be always referred.



**CE 0086 This device bears the CE label in accordance with the provisions of Medical Device Directive 93/42/EEC.**

The above mark "CE" is applied to the product that operates on 230V, 50Hz.

THE PERSONS RESPONSIBLE FOR PLACING DEVICES ON THE EC MARKET  
UNDER MDD 93/42/EEC

**EC REP** FUKUDA DENSHI UK  
13 WESTMINSTER COURT, HIPLEY STREET OLD WOKING, SURREY, GU22 9LG, U.K.

**CAUTION:**

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- If this manual has pages missing or out of order, contact Fukuda Denshi for replacement.
- Only physician or persons instructed by physicians are allowed to use the equipment.
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Printed in Japan

Thank you for purchasing the DS-7200.

This addendum explains the additional information of the 12-Lead ECG analysis function that will be effective from software version 06.

If you have any questions, please contact your nearest service representative.

## Procedure to Use the 12-Lead ECG Analysis Function

### ⚠ WARNING

- The DS-7200 with 12-Lead ECG analysis is designed to acquire and interpret ECG data from a resting, supine patient. If ECG signals from moving or shaking patients are acquired, erroneous 12-lead interpretation result may occur. Always ensure that the patient is kept motionless during 12-lead ECG signal acquisition and analysis.
- The 12-Lead ECG analysis is intended for use with adult and pediatric patients.

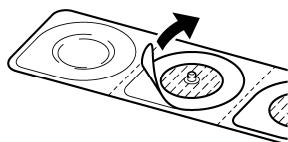
### 1 Attach the electrodes to the patient.

### ⚠ CAUTION

- Always use the same type of electrodes. If different types of electrodes are used at the same time, the difference between the polarization potential from each electrode may interfere with the monitoring.
- ECG applied part is a type CF, but not intended for direct applications to patients' heart.



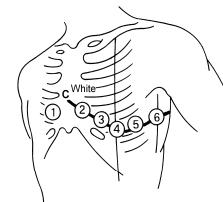
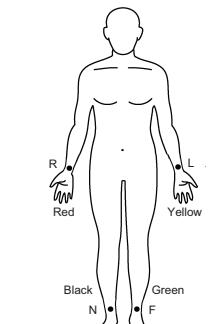
Clean the electrode sites with alcohol wipes or other skin preparation. If necessary, shave the electrode sites to remove excessive hair.



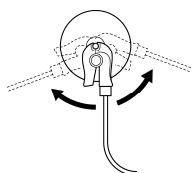
Remove the disposable electrode from its packing.  
Pay attention not to touch the electrode gel.

When acquiring 12-lead ECG signals, Fukuda Denshi recommends placing the limb electrodes anywhere along the arms and legs as shown below.

| Symbol | Color        | Electrode Site   |
|--------|--------------|--|
| R      | Red          | On the right arm   |
| L      | Yellow       | On the left arm  |
| F      | Green        | On the left leg  |
| N      | Black        | On the right leg   |
| C      | White        | The fourth intercostal space at the right sternal border               |
| C2     | Yellow/White | The fourth intercostal space at the left sternal border                |
| C3     | Green/White  | On the midway between C2 and C4.                                       |
| C4     | Brown/White  | The fifth intercostal space on the left midclavicular line             |
| C5     | Black/White  | On the left anterior axillary line at the same horizontal level as C4  |
| C6     | Violet/White | On the left midaxillary line at the same horizontal level as C4 and C5 |



## 2 Attach the lead cables "No. 500403100" (chest) and "No. 3380.0612.17" (limb, 90/150cm) to the electrode on the patient.



Attach the ECG lead cable end to the electrode (convex part). Turn right and left to verify that it is securely attached.

### CAUTION

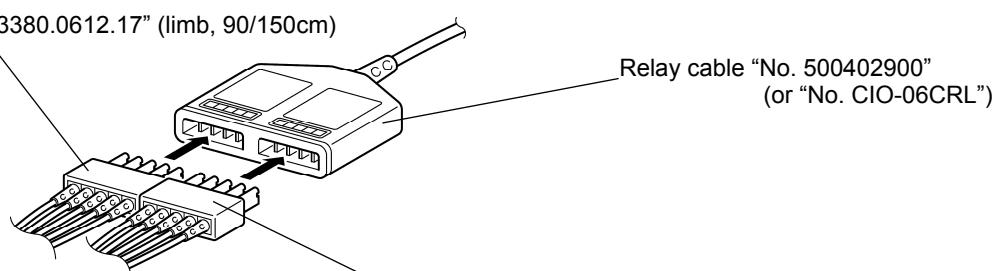
- The indication for continuous use of the electrodes is about one day.
- Replace the electrode if the skin contact gets loose due to perspiration, etc.
- When an electrode is attached to the same location for a long period, some patients may develop skin irritation. Check the patient's skin condition periodically and change the electrode site as required.



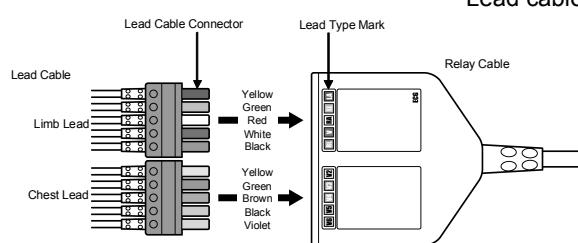
Refer to "12. Accessories - Optional Accessories ECG, Impedance Respiration Measurement" in the DS-7200 operation manual <Maintenance> for details.

## 3 Connect the ECG lead cables to the relay cable "No. 500402900" (or "No. CIO-06CRL").

Lead cable "No. 3380.0612.17" (limb, 90/150cm)



Lead cable "No. 500403100" (chest)



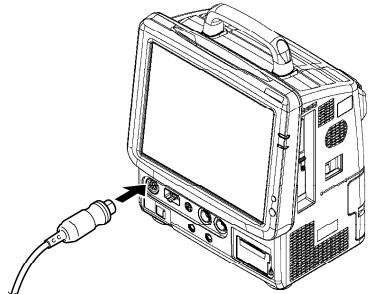
## ⚠ CAUTION

- You must use the 10-electrode lead cable for 12-Lead ECG analysis. If you are using a 3, 4, or 5-electrode lead cable, 12-Lead ECG analysis will not function.
- When connecting the ECG lead cable and ECG relay cable, be sure to match the color of the ECG lead cable connector part and lead type mark color on the ECG relay cable.

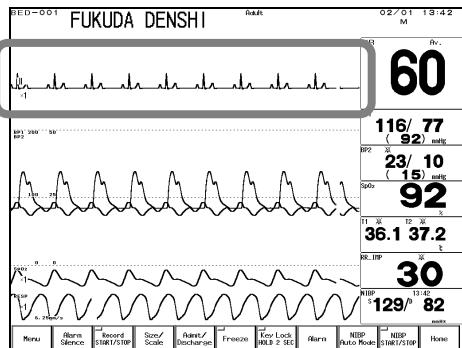


Refer to "12. Accessories - Optional Accessories ECG, Impedance Respiration Measurement" in the DS-7200 operation manual <Maintenance> for details.

### 4 Plug in the ECG relay cable to the ECG input connector (green) on the DS-7200.



### 5 Verify that the ECG waveform is displayed on the monitor.

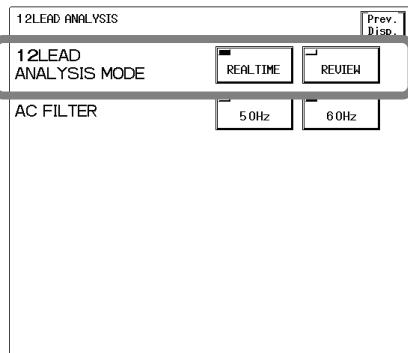


## 6 Verify the settings for 12-Lead analysis function.

### [12-Lead Analysis Setup]

- Press the **Menu** → **System Configuration** → **12LEAD ANALYSIS** keys to display the 12-Lead analysis setup menu.

#### 12-Lead Analysis Mode



Select the analysis mode (REAL TIME/ REVIEW).

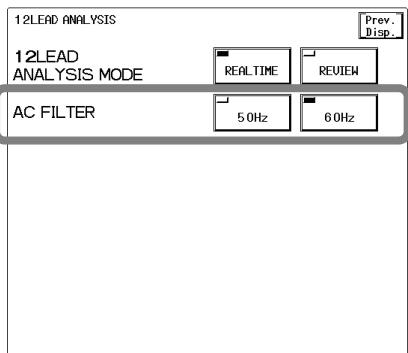
##### Real Time Analysis (Default):

The waveforms will be analyzed for 10 seconds after pressing the **ANALYZE** key.

##### Review Analysis:

The waveforms for 10 seconds prior to pressing the **ANALYZE** key will be analyzed.

#### AC Filter



Select the AC filter frequency (50/ 60Hz).

50Hz : Eliminates 50Hz AC interference.  
60Hz (Default) : Eliminates 60Hz AC interference.

## [Print Format Setup]

The print format for the 12-lead with analysis report can be set on the 12-Lead Record Setup menu.

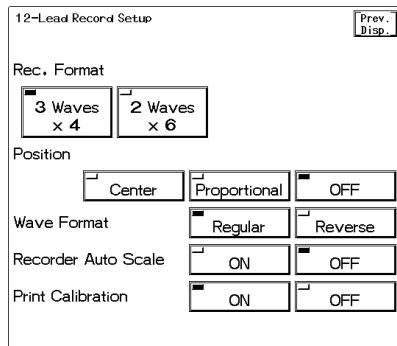
- Press the **Menu** → **System Configuration** → **Record** → **12-Lead** keys.

The 12-Lead Record Setup menu will be displayed. The setup screen may differ depending on the network printer configuration.

**Reference**

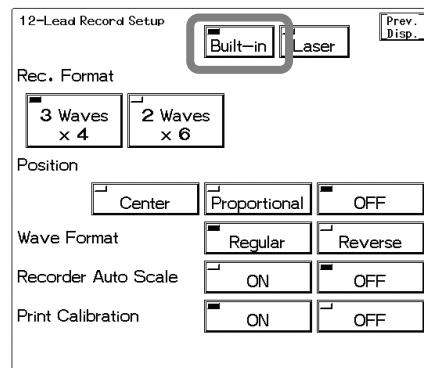
To use the laser printer, TCP/IP network setup is necessary. For procedure, refer to “9. Installation - TCP/IP Network Connection Network Connection (Printer)” in the DS-7200 operation manual <Maintenance>.

If the network printer configuration is “OFF” (Default), the following 12-Lead Record Setup menu will appear. This menu is available only for the built-in recorder setting.

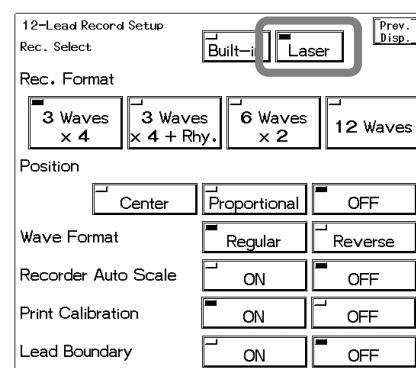


- Rec. Format : Fixed as “3 Waves x 4” for 12-lead with analysis report.
- Position : Center / Proportional / OFF (Default)
- Wave Format : Regular (Default) / Reverse
- Recorder Auto Scale : ON / OFF (Default)
- Print Calibration : ON (Default)/ OFF

If the network printer configuration is “ON”, the following 12-Lead Record Setup menu will appear.



<When **Built-in** is selected.>



<When **Laser** is selected.>

When **Built-in** (Default) is selected:

- Rec. Format : Fixed as “3 Waves x 4” for 12-lead with analysis report.
  - 1st column: I, II, and III
  - 2nd column: aVR, aVL, and aVF
  - 3rd column: V1, V2, and V3
  - 4th column: V4, V5, and V6
- Position : Center / Proportional / OFF (Default)
- Wave Format : Regular (Default) / Reverse
- Recorder Auto Scale : ON / OFF (Default)
- Print Calibration : ON (Default)/ OFF

|   |   |
|---|---|
| When <input type="checkbox"/> <b>Laser</b> is selected; |   |
| • Rec. Format   | : Fixed as "6 Waves x 2" for 12-lead with analysis report.<br>1st column: I, II, III, aVR, aVL, and aVF<br>2nd column: V1, V2, V3, V4, V5, and V6 |
| • Position  | : Center / Proportional / OFF (Default)   |
| • Wave Format   | : Regular (Default) / Reverse   |
| • Recorder Auto Scale                                   | : ON / OFF (Default)  |
| • Print Calibration                                     | : ON (Default)/ OFF   |
| • Lead Boundary   | : Invalid for 12-lead with analysis report.   |

|             |  |
|-------------|--|
| <b>NOTE</b> | <ul style="list-style-type: none"> <li>● For the built-in recorder, the print format for the 12-lead with analysis report is fixed as "3 Waves x 4".</li> <li>● For the laser printer, the print format for the 12-lead with analysis report is fixed as "6 Waves x 2".</li> <li>● The DS-7200 does not send 12-Lead ECG analysis result to any central monitor on the wired and wireless network. Therefore, no central monitor can record and display 12-Lead ECG analysis result performed by the DS-7200.</li> </ul> |
|-------------|--|



Refer to "4. Monitoring Setup - Recording Setup 12-Lead Waveform Recording" in the DS-7200 operation manual <Monitoring Operation> for details.



Refer to the "12-Lead ECG Analysis Result Report" section in this instruction for details.

## 7 Verify correct patient information has been entered, such as Patient Age, Sex (Male/Female), and Class (Adult/Child). These are especially important for proper 12-Lead ECG analysis. If not specified or incorrect, enter the correct information.



Refer to "5. Admit / Discharge of a Patient - Admitting a Patient" in the DS-7200 operation manual <Monitoring Operation> for details.



- Select "Used" for the pacemaker setting on the patient admit/discharge menu if a patient has a pacemaker.
- The threshold values for classification of 12-Lead ECG interpretation and Minnesota code are set by age and sex as follows:
  1. Male and Female of ages 19 years old and above
  2. Male of age 12 through 18 years old
  3. Female of age 12 through 18 years old
  4. Male and Female of ages 3 through 11 years old
  5. Male and Female of ages below 2 years old
- If no patient information (i.e. Patient Class: Adult (Default), Patient Sex: Undetermined (Default), and Patient Age: 0 (Default)) has been entered, the system algorithm will handle the patient as a "35 years old Male".
- Before the analysis, make sure the patient classification ( **Adult** /  **Child**) is properly selected. If  **Neonate** is selected, the 12-Lead ECG analysis will not function.
- Enter the age of patient if known. If no age information (i.e. "0": Default), has been entered, the system algorithm will handle the patient as a "35 years old."
- Enter the sex of patient if known. If no sex information (i.e. "Undetermined": Default), has been entered, the system algorithm will handle the patient as a "Male."
- If the patient classification is set up as "Child" and no age (i.e. "0": Default) has been entered, the system algorithm will handle the patient as "Less than 2 years old."

## 8 Verify the 12-Lead ECG waveforms on the 12-Lead display.



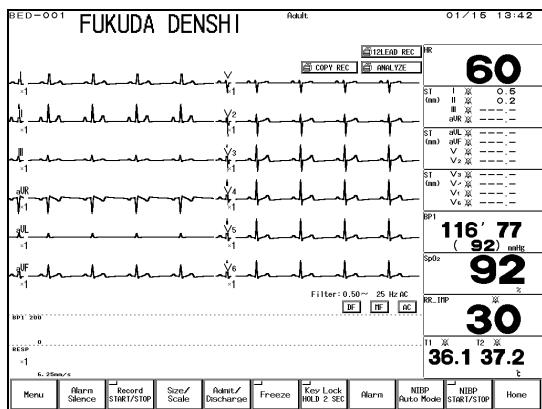
### WARNING

The frequency response and resolution of the monitor screen is not intended for diagnostic and ST segment interpretation. Use a recorder that provides the required resolution for this purpose.

- Press the **Menu** → **Display Config.** keys. Select “12-lead” for the display mode.

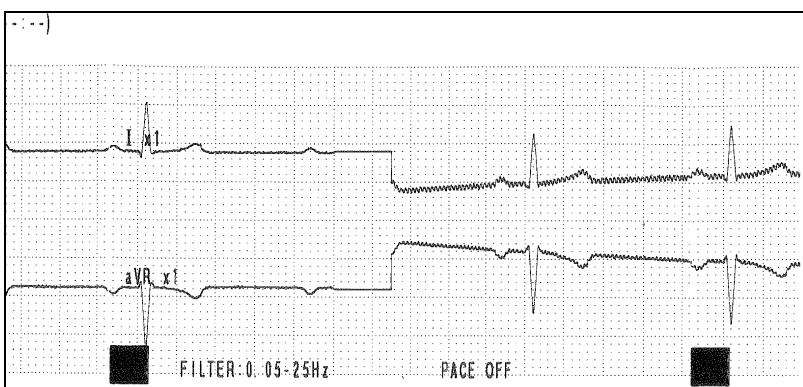
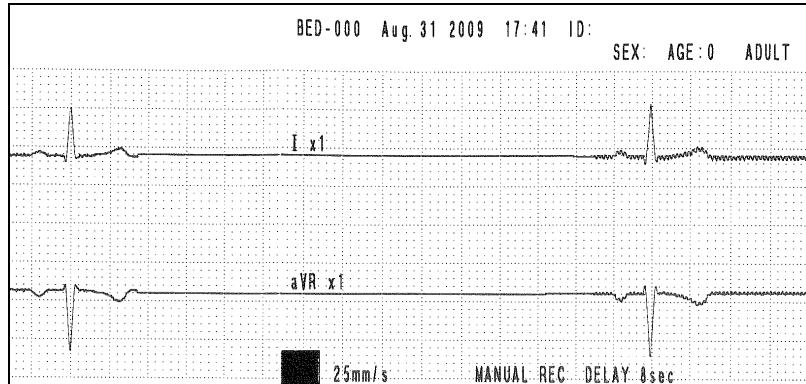


Refer to “4. Monitoring Setup - Display Configuration To Configure the Display 12-Lead Mode” in the DS-7200 operation manual <Monitoring Operation> for details.



## NOTE

- If the display mode is changed to 12-Lead, the following ECG filter settings on the ECG Parameter Setup will be invalid.
  - Filter (Monitor/ESIS/DIAG.)
  - AC Filter (ON/OFF)
  - ECG Drift Filter (ON/OFF)
 For the 12-Lead ECG filter settings, use the filter setting keys, **[DF]**, **[MF]**, and **[AC]** key, that will appear on the 12-Lead display.
  - DF filter (Default): 0.05 Hz (OFF)
  - MF filter (Default) : 150 Hz (OFF)\* (When AC filter is OFF)  
75 Hz (OFF) (When AC filter is ON)
  - AC filter (Default): OFF (No "AC" message above the **[AC]** key)
    - \* If 3-electrode lead is used, it will be 100Hz (OFF).
- Time constant (Low-frequency response) for the 12-Lead display is 3.2 seconds (Default). It depends on the above DF filter setting.
- By the following key operations, the ECG waveform display might become the baseline for a few seconds or a notch might appear on the ECG waveform due to the change in frequency characteristic. This will appear on the display, recording, and recall waveform.
  - When the display mode is changed to 12-Lead.
  - When 12-Lead mode display is changed to others.
  - When DF, MF, or AC filter setting is changed.



- 9** Press the **DF**, **MF**, and **AC** key on the 12-Lead display to eliminate artifacts in the ECG waveform, if needed.

**Drift Filter - DF (Default): 0.05 Hz (OFF)**

Pressing the **DF** key will sequentially change the setting in the following order.

0.05 (OFF) → 0.25 → 0.50 → 0.05 (OFF) (Hz)

**Muscle Filter - MF (Default) : 150 Hz (OFF) (When AC filter is OFF)  
75 Hz (OFF) (When AC filter is ON)**

Filter: 0.05 ~ 35 Hz AC  
  

Pressing the **MF** key will sequentially change the setting in the following order.

150 (OFF) → 25 → 35 → 150 (OFF) (Hz) (When AC filter is OFF)  
75 (OFF) → 25 → 35 → 75 (OFF) (Hz) (When AC filter is ON)

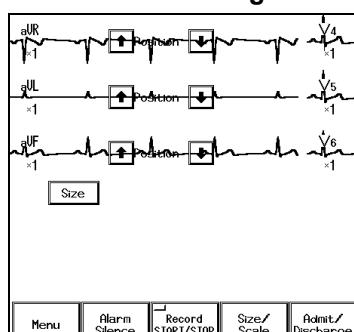
**AC Filter - AC (Default): OFF (No "AC" message on the **AC** key)**

Pressing the **AC** key will sequentially change the setting in the following order.

OFF (No "AC" message) → ON ("AC" message) → OFF

- DF (Drift Filter): Eliminates baseline drifts in the ECG.  
MF (Muscle Filter): Eliminates muscle artifacts in the ECG.  
AC (AC Filter): Eliminates AC interference in the ECG.

- 10** Press the **Size/Scale** key, and adjust the size and position of the 12-Lead ECG waveform using the displayed **Size** and Position **↑**, **↓** keys as necessary.



**Size (Default) : x1**

Pressing the **Size** key will sequentially change the size for all of 12-Lead ECG waveforms in the following order.

x1 → x2 → x4 → x1/4 → x1/2 → x1

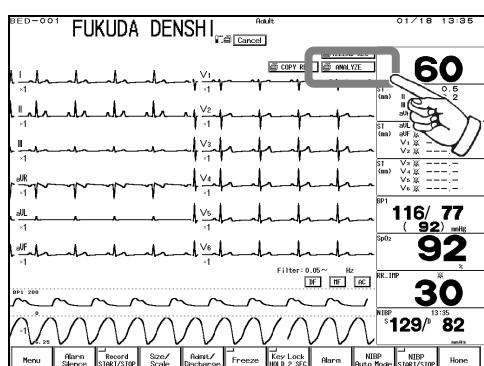
**Position:**

Use the **↑**, **↓** keys to adjust the waveform baseline position.

By pressing the **Size/Scale** or **Home** key, the **Size** and Position **↑**, **↓** keys will disappear.

- 11** Press the **ANALYZE** key to perform 12-Lead analysis and output the result on the built-in recorder or laser printer.

|             |   |
|-------------|---|
| <b>NOTE</b> | <ul style="list-style-type: none"> <li>● The analysis result and interpretation will not be displayed on the monitor screen.</li> <li>● When displaying the 12-lead waveform, it is recommended to set <b>Fixed</b> for "Arrhy. Analysis Filter" ("Hospital Setup").</li> </ul> |
|-------------|---|



For the built-in recorder, recording can be cancelled by pressing the **Record START/STOP** key.

When laser printer is set as the output recorder, a laser printer icon will be displayed inside the **ANALYZE** key.



For the laser printer, printing can be cancelled by pressing the **Cancel** key.

- The 12-Lead analysis will be completed in a couple of seconds.
- The waveform for each lead will be printed in the same phase.
- The printing duration of the waveforms for each format are as follows.

| <b>Output Recorder</b> | <b>Output Format</b>  | <b>Printing Duration</b> |
|------------------------|---|--------------------------|
| Built-in Recorder      | <p>“3 Waves x 4”</p> <p>1st column: I, II, and III<br/>     2nd column: aVR, aVL, and aVF<br/>     3rd column: V1, V2, and V3<br/>     4th column: V4, V5, and V6</p> | 10 sec.                  |
| Laser Printer          | <p>“6 Waves x 2”</p> <p>1st column: I, II, III, aVR, aVL, and aVF<br/>     2nd column: V1, V2, V3, V4, V5, and V6</p>   | 10 sec.                  |



Refer to “4. Monitoring Setup - Recording Setup 12-Lead Waveform Recording” in the DS-7200 operation manual <Monitoring Operation> for details.



Refer to the “12-Lead ECG Analysis Result Report” section in this instruction for details.

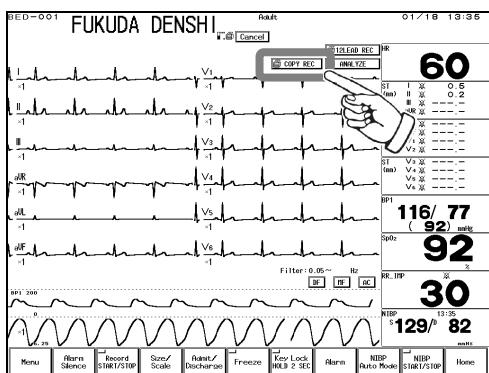
**12 If necessary, press the **COPY REC** key to print the stored 12-Lead ECG analysis result again.**



- If the power is turned OFF, the stored analysis result data will be erased.
- If the patient is discharged, the stored analysis result data will be erased.

**NOTE**

The **COPY REC** key will be displayed only when there is stored 12-lead ECG analysis result data. Pressing this key will output only the latest stored analysis result.



For the built-in recorder, recording can be cancelled by pressing the **Record START/STOP** key.

When laser printer is set as the output recorder, a laser printer icon will be displayed inside the **COPY REC** key.



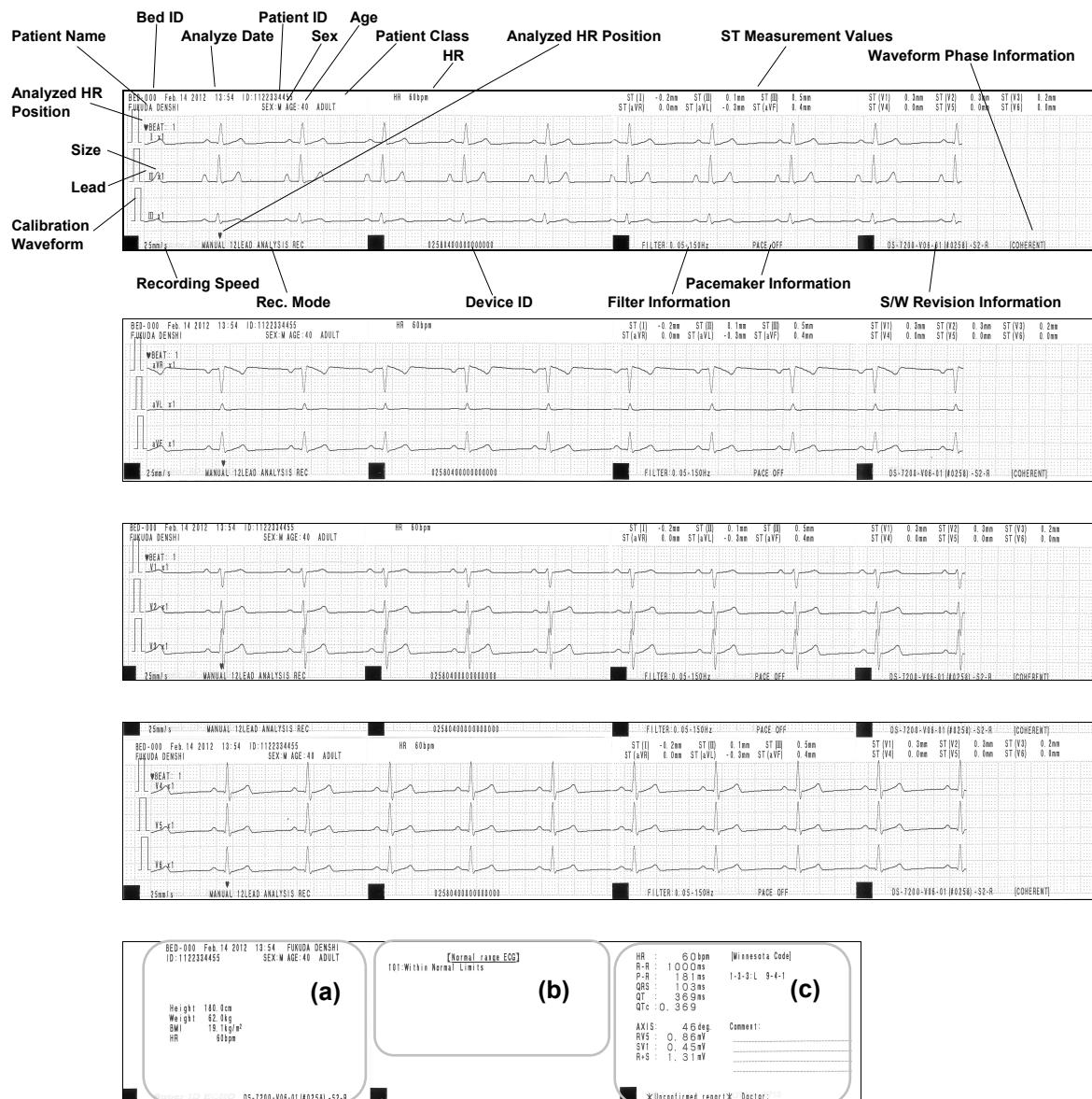
For the laser printer, printing can be cancelled by pressing the **Cancel** key.

## 12-Lead ECG Analysis Result Report

### NOTE

- If no patient information (i.e. Patient Class: Adult (Default), Sex: Undetermined (Default), and Age: 0 (Default)) has been entered, "Adult", "35 years old", and "Male" will be recorded on the report.
- If the patient class is set up as "Child" and no age (i.e. "0": Default) and sex (i.e. Undetermined: Default) information have been entered, "Child", "2 years old", and "Male" will be recorded on the report.

### ● Examples of Built-in Recorder Output



● Description for the Built-in Recorder Output

(a)

Patient Information: BED-001 Dec. 18 2009 19:17  
ID: SEX:M AGE:35 ADULT

Height, Weight, BMI, and HR:  
Height 0.0cm  
Weight 0.0kg  
BMI 0.0kg/m<sup>2</sup>  
HR 80bpm

Notes, Lead off information  
(If no information, no message will appear.)

S/W Revision Information: DS-7200-V04-01 (#9216) -S2-R

(b)

Overall Judgment: [Normal range ECG]

Arrhythmia Interpretation: 101:Within Normal Limits

ECG Waveform Interpretation

(c)

Measurement Values:  
HR : 80 bpm  
R-R : 749ms  
P-R : 170ms  
QRS : 90ms  
QT : 349ms  
QTc : 0.403

Minnesota Code: [Minnesota Code]  
9-4-1

Comment Field: Comment:

Doctor Signature Field: \*

OP-124TE      LOT No. 2928

\*Unconfirmed Report\*SiDoctor., LTD.

● Examples of Laser Printer Output

|   |                    |                                   |                          |
|---|--------------------|-----------------------------------|--------------------------|
| 12L analysis record    BED-000    Feb.14 2012 13:55    ID:1122334455                    |                    | M 40Yrs<br>ADULT    FUKUDA DENSHI | (a) 1/2                  |
| Analysis Date<br>Feb.14 2012 13:55:51   | 【Normal range ECG】 |                                   | 101:Within Normal Limits |
| Height 180.0 cm    Weight 62.0 kg<br>BMI 19.1 kg/m <sup>2</sup><br>HR 60 bpm<br>BEAT: 1 |                    |                                   | (b)                      |
| <p style="text-align: center;">(c)</p>  |                    |                                   |                          |
| 25mm/s    MANUAL REC  | FILTER:0.05-150Hz  | PACE OFF                          | [COHERENT] (d)           |

|  |                                   |   |            |
|--|-----------------------------------|---|------------|
| 12L analysis record    BED-000    Feb.14 2012 13:55    ID:1122334455   |                                   | M 40Yrs<br>ADULT    FUKUDA DENSHI         | 2/2        |
| HR : 60 bpm<br>R-R : 1000 ms    AXIS: 46 deg.<br>P-R : 181 ms    Rv5 : 0.86 mV<br>QRS : 103 ms    Sv1 : 0.45 mV<br>QT : 369 ms    R+S : 1.31 mV<br>QtC : 0.369 | [Minnesota Code]<br>1-3-3:L 9-4-1 | Comment:<br>*Unconfirmed report * Doctor: | (e)        |
|  |                                   |   |            |
| 25mm/s    MANUAL REC   | FILTER:0.05-150Hz                 | PACE OFF                                  | [COHERENT] |

## ● Descriptions for the Laser Printer Output

(a)

12L analysis record    BED-000 Sep. 02 2009 14:18 ID:1122334455    40Yrs ADULT TOM    1/2

Patient Information (Bed ID, Analyzed Date, Patient ID, Age, Name, Sex, Classification)

(b)

Analyzed Date: Sep. 02 2009 14:18:20

Overall Judgment: **Abnormal ECG**

ECG Waveform Interpretation: 864:Runs of PVC

Notes: RR?

Height: 180.0 cm Weight: 62.0 kg  
BMI: 19.1 kg/m<sup>2</sup>  
HR: 90 bpm  
BEAT: 4

Analyzed HR Position: Height, Weight, BMI, and HR

Notes: (If no information, no message will appear.)

Arrhythmia Interpretation: S/W Revision Information: DS-7200-V04-01(+0215)-S2-R

Lead off information: (If no information, no message will appear.)

(c)

ST Measurement Value: 0.2 mm

Size: 0.1 mm, 0.5 mm, 0.0 mm, -0.3 mm, 0.4 mm

Lead: I, II, III, aVR, aVL, aVF

Calibration Waveform: 25mm/s

Analyzed HR Position: Heart icon indicating position

(d)

Recording Speed: 25mm/s

Rec. Mode: MANUAL REC

Filter Information: FILTER: 0.05-150Hz

Pacemaker Information: PACE OFF

Waveform Phase Information: [COHERENT]

(e)

Measurement Values: HR: 90 bpm, R-R: 662 ms, P-R: 169 ms, QRS: 91 ms, QT: 351 ms, QTc: 0.431 ms, AXIS: 45 deg., RV5: 1.10 mV, SV1: 0.57 mV, R+S: 1.67 mV

Minnesota Code: 8-2-2, 9-4-1

Doctor Signature Field: \*Unconfirmed report\* Doctor

Comment Field: Comment: \_\_\_\_\_

### ● Basic Measurement

The basic measurement values provided in the report are as follows.

|             |   |
|-------------|---|
| Heart rate: | Heart rate obtained by basic arrhythmia measurement   |
| R-R:        | Heart rate obtained from average R-R time of detailed arrhythmia measurement  |
| P-R:        | R-R time of basic arrhythmia measurement<br>The average value of heart rates in which one P-wave has been found is calculated first, and then the average value is recalculated based on the R-R time within $\pm 25\%$ of the value calculated first.  |
| QT:         | P-R time of basic waveform measurement  |
| QTc:        | Average value of measurements with leads I to V6<br>QT time of basic waveform measurement<br>Average value of measurements with leads I to V6<br>QTc time of basic arrhythmia measurement<br>The value is obtained using the following expression:<br>$QTc = \text{Average waveform QT time} \sqrt{\frac{\text{Average R-R time of arrhythmia (sec.)}}{3(II + III)/(2 \times I + II - III)}}$ Where, I, II, and III are the sum of the maximum (signed) value of amplitude of Q, R, S, R', and S' waves |
| R V5/V6:    | Maximum value of R and R' wave of V5 lead or V6 lead in detailed waveform measurement<br>V5 lead > V6 lead: RV5<br>V5 lead $\leq$ V6 lead: RV6  |
| SV1:        | Maximum (absolute) value of Q, S, and S' wave of V1 lead in detailed waveform measurement   |
| R+S:        | Sum of the amplitude of "RV5/RV6" and "SV1"   |



For interpretation of these results, refer to "**AUTOMATED ECG ANALYSIS SYSTEM PROGRAM GUIDE BOOK PI-20E**".

### ⚠ WARNING

- The interpretations and the Minnesota codes given by the DS-7200 with 12-Lead ECG analysis do not demonstrate the type or the degree of development of cardiac diseases. Consequently, the 4-stage ranking in comprehensive judgment is based only on the electrocardiographic point of view. There might be a case where an abnormality in the ECG does not necessarily indicate that the patient has a cardiac disease (an abnormality in the ECG may occur due to other causes) although the possibility that the patient has organic heart disease is high.
- On the other hand, there may be a case where preclinical coronary atherosclerosis may be present although no abnormality is found in the ECG interpretation.
- All computerized ECG analysis results should be reviewed by a physician before making decision for the patient treatment.

## Maintenance for the 12-Lead ECG Analysis Function

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### ● Maintenance Check



For maintenance, refer to "10. Maintenance – Maintenance Check" in the DS-7200 operation manual <Maintenance>.

### ● Troubleshooting

#### The **[ANALYZE]** key on the 12-Lead display does not function.

- Cause 1 : A cable other than 10-electrode lead cable, such as 3, 4, 5-electrode lead cable is connected.  
Solution : Use only 10-electrode lead cable for 12-Lead ECG analysis.
- Cause 2 : The relay cable for 12-Lead ECG is disconnected.  
Solution : Check the relay cable connection.
- Cause 3 : If the patient classification is set to "Neonate", the 12-Lead ECG analysis will not function.  
Solution : Select "Adult" or "Child" for patient classification.

#### The **[COPY REC]** key on the 12-Lead display does not function.

- Cause 1 : The 12-Lead ECG analysis have not been performed yet.  
Solution : The **[COPY REC]** key will be enabled only if there is stored 12-Lead ECG analysis result data. Perform the 12-Lead ECG analysis.

#### "35 years old" and "Male" are always recorded on the 12-Lead analysis report.

- Cause 1 : No patient information (i.e. Patient Class: Adult (Default), Sex: Undetermined (Default), and Age: 0 (Default)) has been entered. By the above condition, the algorithm will handle all patients in the same manner as "35 years old" and "Male" and then "35 years old". Therefore, "35 years old" and "Male" will be recorded on the report.  
Solution1 : Enter age and sex if patient information is known.

#### "2 years old" and "Male" are always recorded on the 12-Lead analysis report.

- Cause 1 : The patient class is set up as "Child" and no age (i.e. "0": Default) and sex (i.e. Undetermined: Default) information have been entered. By the above condition, the algorithm will handle all patients in the same manner as "less than 2 years old" and "Male". Therefore, "2 years old" and "Male" will be recorded on the report.  
Solution 1 : Enter age and sex information if child patient information is known.  
Solution 2 : Change the patient class to "Adult" and enter age and sex if adult patient information is known.



For other troubleshooting of ECG, refer to "10. Maintenance – Troubleshooting ECG" in the DS-7200 operation manual <Maintenance>.

## Specification of the 12-Lead ECG Analysis Function

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### ● Specification

|   |   |
|---|---|
| Leads                                   | : Standard 12 leads   |
| Sensitivity                             | : 1/4, 1/2, 1, 2, 4   |
| Polarization voltage                    | : $\pm 825\text{mV}$ or above   |
| Frequency response                      | : 0.05 to 150Hz   |
| Time constant (Low-frequency response): |   |
|   | 3.2 sec.  |
| Common mode rejection ratio:            |   |
|   | 80dB or above   |
| Input impedance                         | : $5\text{M}\Omega$ or above  |
| Internal noise                          | : $30\mu\text{Vp-p}$ or lower   |
| Sampling rate                           | : 8000/Sec/CH   |
| Filters                                 | : AC filter: - 20 dB or less at 50 Hz or 60 Hz<br>MF (Muscle filter): - 3 dB (- 6 dB/oct) at 35 Hz or 25 Hz<br>DF (Drift filter): - 3 dB or less at 0.25 Hz or 0.5 Hz |
| Basic measurement value:                | Heart rate, R-R time, P-R time, QRS time, QT time, QTc, electrical axis, SV1, RV5(6)  |
| Interpretation and code                 | : Approx. 120 types   |
| Minnesota code                          | : Approx. 130 types   |
| Grade judgment                          | : 4 types   |



For other specification of ECG, refer to "11. Technical Information - Specification / Performance Performance ECG" in the DS-7200 operation manual <Maintenance>.

Battery operation time : Approx. 3 hours (with EN 60601-2-51 test method)



For the details of the indication of operation time, refer to "2. Basic Operation - Preparation for Monitoring To Use with the Battery Pack" in the DS-7200 operation manual < General Description >.

### ● Safety Standard Requirement

The DS-7200 with 12-Lead ECG analysis conforms to safety requirements and achieves basic performance stipulated by safety standards, EN 60601-2-25 (1999) and EN 60601-2-51 (2003). The following performance is assured for the tests required for those standards.

## 1. Automated measurements on ECGs

### 1.1 How to determine the amplitude of P wave, QRS wave, ST, and T wave

Amplitude of P1A and P2A: The first waveform is defined as P1A and the second as P2A, with biphasic property taken into consideration. The value from the base point (start point of P wave) to the peak is defined as the amplitude of each waveform.

Amplitude of QRS wave: The first upward deflection is defined as the R wave, the downward deflection that appears before the R wave is the Q wave, and the downward deflection that appears after the R wave is the S wave. The value from the base point (beginning of the QRS wave) to the peak is defined as the amplitude of each waveform.

Amplitude of ST: The amplitude at the end of the QRS wave with the QB-TE line defined as the baseline.

Amplitude of T1A and T2A: The first waveform is defined as T1A and the second as T2A, with biphasic property taken into consideration. The value from the QB-TE baseline to the peak is defined as the amplitude of each waveform.

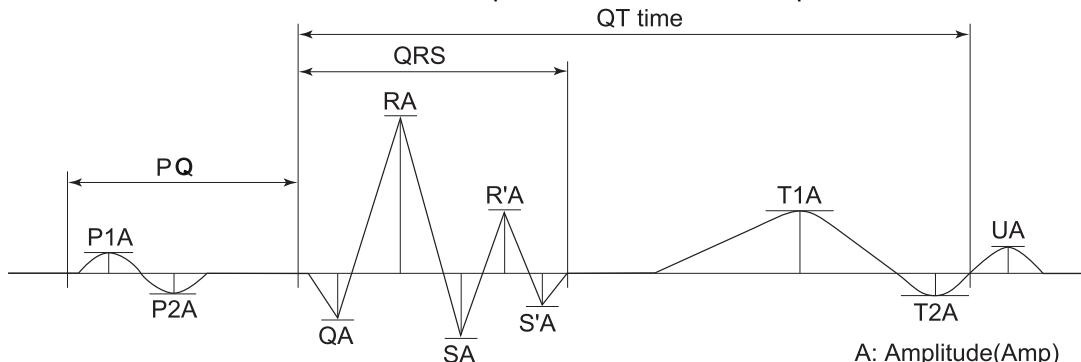


Fig. Determining the amplitude

### 1.2 Handling of isoelectric part of QRS wave

Measurement of the isoelectric part is not performed.

### 1.3 Minimum allowable wave and stability of measurement

The minimum amplitude value recognizable as a waveform is  $30\mu V$ .

### 1.4 Stability of measurements against NOISE

#### 1.4.1 Result

| Global measurement | Type of added NOISE | Disclosed differences |                         |
|--------------------|---------------------|-----------------------|-------------------------|
|                    |                     | Mean (ms)             | Standard deviation (ms) |
| P-duration         | High frequency      | 6.2                   | 5.0                     |
| P-duration         | Line frequency      | 14.4                  | 16.0                    |
| P-duration         | Base-line           | 23.0                  | 11.7                    |
| QRS-duration       | High frequency      | 2.6                   | 6.1                     |
| QRS-duration       | Line frequency      | 15.4                  | 18.6                    |
| QRS-duration       | Base-line           | 5.4                   | 8.6                     |
| QT- interval       | High frequency      | 3.8                   | 5.7                     |
| QT- interval       | Line frequency      | 4.6                   | 6.6                     |
| QT- interval       | Base-line           | 18.4                  | 23.6                    |

Note) Filter OFF.

## 2. Automated ECG interpretation

### 2.1 Accuracy of waveform analysis

#### 2.1.1 Target

Evaluation by waveform analysis was performed for “normal range”, “myocardial infarct”, and “LVH”. For the evaluation in the normal range, 249 ECG's were used and were read by multiple cardiovascular doctors. For the evaluation of myocardial infarct, 115 ECG's were used with the diagnosis verified by Percutaneous Coronary Intervention (PCI). For the evaluation of LVH, 63 ECG's were used with the diagnosis verified by echo.

The symptoms other than LVH or myocardial infarct are excluded from the target of evaluation.

#### 2.1.2 Procedure

Sensitivity, specificity, and positive predictive value are found for the symptoms targeted in 2.1.1.

#### 2.1.3 Result

| Diagnostic category       | Number of ECGs tested | Sensitivity (%) | Specificity (%) | Positive Predictive Value (%) |
|---------------------------|-----------------------|-----------------|-----------------|-------------------------------|
| Normal                    | 249                   | 88.0 (219)      |                 | 92.4                          |
| Myocardial Infarction(AL) | 71                    | 88.7 (63)       | 100.0           | 100.0                         |
| Myocardial Infarction(PI) | 44                    | 88.6 (39)       | 99.2            | 95.1                          |
| LVH                       | 63                    | 87.3 (55)       | 88.8            | 64.0                          |

(Average age: 54.24 (SD: ±18.34), Male: 267, Female: 160, Race: Japanese)

### 2.2. Accuracy of rhythm analysis

#### 2.2.1 Target

Evaluation by rhythm analysis was performed for “sinus rhythm”, “auricular fibrillation (atrial flutter)”, “pacemaker rhythm”, “supraventricular extrasystole”, “ventricular extrasystole”, and “atrioventricular block (degree I, II, and III)”. For all the evaluations by rhythm analysis, 2199 ECG's were used and were read by multiple heart specialists. Atrioventricular junctional rhythm, atrioventricular dissociation, escape beat, sinoatrial block, supraventricular tachycardia, ventricular tachycardia, ventricular rhythm, atrial flutter, and left atrium rhythm, which occurred at low frequency statistically, were excluded from the target of evaluation.

#### 2.2.2 Procedure

Sensitivity, specificity, and positive predictive value are found for the symptoms targeted in 2.2.1.

#### 2.2.3 Result

| Diagnostic category                  | Number of ECGs tested | Sensitivity (%) | Specificity (%) | Positive Predictive Value (%) |
|--------------------------------------|-----------------------|-----------------|-----------------|-------------------------------|
| Sinus rhythms                        | 1602                  | 98.9 (1585)     |                 | 97.1                          |
| Atrial Fibrillation (atrial flutter) | 103                   | 93.2 (96)       | 99.9            | 99.0                          |
| Pacemaker rhythm                     | 240                   | 80.0 (192)      | 99.9            | 99.5                          |
| SVPC                                 | 60                    | 83.3 (50)       | 100.0           | 100.0                         |
| VPC                                  | 58                    | 98.3 (57)       | 99.8            | 93.4                          |
| AV-Block I                           | 96                    | 96.9 (93)       | 99.3            | 89.4                          |
| AV-Block II                          | 20                    | 70.0 (14)       | 100.0           | 100.0                         |
| AV-Block III                         | 20                    | 70.0 (14)       | 100.0           | 100.0                         |

(Average age: 58.74 (SD: ±18.00), Male: 1315, Female: 884, Race: Japanese)

## Default and Backup of the Setup Item

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This section shows the selection, default setting, and backup status for setup items related to 12-Lead ECG analysis function.

\*\*○” : Setup item will be retained even when the power is turned OFF.

### ● 12-Lead ECG Analysis Setup

| Item                  | Selection         | Default   | Backup |
|-----------------------|-------------------|-----------|--------|
| 12 Lead Analysis Mode | Real Time, Review | Real Time | ○      |
| AC Filter             | 50Hz, 60Hz        | 50Hz      | ○      |

### ● Filter and Size Setup on 12-Lead ECG display

| Item               | Selection  | Default    | Backup |
|--------------------|--|------------|--------|
| DF (Drift Filter)  | 0.05 (OFF), 0.25, 0.50 Hz  | 0.05 (OFF) | ○      |
| MF (Muscle Filter) | 25, 35, 150 (OFF) Hz<br>(When AC filter is OFF)<br>* If 3-electrode lead is used, it will be 100Hz (OFF).<br>25, 35, 75 (OFF) Hz<br>(When AC filter is ON) | 150 (OFF)  | ○      |
| AC (AC Filter)     | OFF, ON  | OFF        | ○      |
| Waveform Size      | ×1/4, ×1/2, ×1, ×2, ×4   | ×1         | ○      |

### ● 12-Lead Record Setup

| Item                                 | Selection   | Default                       | Backup   |                               |   |  |   |  |  |  |
|--------------------------------------|---|-------------------------------|--|-------------------------------|---|--|---|--|--|--|
| Recorder                             | Built-in, Laser   | Built-in                      | ○  |                               |   |  |   |  |  |  |
| Rec. Format                          | <table border="1"> <tr> <td>Built-in</td> <td>&lt;12-Lead&gt;<br/>3 Waves × 4, 2 Waves × 6</td> <td>&lt;12-Lead&gt;<br/>3 Waves × 4</td> <td rowspan="2">○</td> </tr> <tr> <td></td> <td colspan="2">&lt;12-Lead with Analysis Report&gt;<br/>* Fixed as "3 Waves × 4"<br/>1st column: I, II, III<br/>2nd column: aVR, aVL, aVF<br/>3rd column: V1, V2, V3<br/>4th column: V4, V5, V6</td> </tr> </table>     | Built-in                      | <12-Lead><br>3 Waves × 4, 2 Waves × 6                                | <12-Lead><br>3 Waves × 4      | ○ |  | <12-Lead with Analysis Report><br>* Fixed as "3 Waves × 4"<br>1st column: I, II, III<br>2nd column: aVR, aVL, aVF<br>3rd column: V1, V2, V3<br>4th column: V4, V5, V6 |  |  |  |
| Built-in                             | <12-Lead><br>3 Waves × 4, 2 Waves × 6   | <12-Lead><br>3 Waves × 4      | ○  |                               |   |  |   |  |  |  |
|                                      | <12-Lead with Analysis Report><br>* Fixed as "3 Waves × 4"<br>1st column: I, II, III<br>2nd column: aVR, aVL, aVF<br>3rd column: V1, V2, V3<br>4th column: V4, V5, V6   |                               |  |                               |   |  |   |  |  |  |
|                                      | <table border="1"> <tr> <td>Laser</td> <td>&lt;12-Lead&gt;<br/>3 Waves × 4, 3 Waves × 4+Rhy.,<br/>6 Waves × 2, 12 Waves</td> <td>&lt;12-Lead&gt;<br/>3 Waves × 4+Rhy.</td> <td rowspan="2">○</td> </tr> <tr> <td></td> <td colspan="2">&lt;12-Lead with Analysis Report&gt;<br/>* Fixed as "6 Waves × 2"<br/>1st column: I, II, III, aVR, aVL, aVF<br/>2nd column: V1, V2, V3, V4, V5, V6</td> </tr> </table> | Laser                         | <12-Lead><br>3 Waves × 4, 3 Waves × 4+Rhy.,<br>6 Waves × 2, 12 Waves | <12-Lead><br>3 Waves × 4+Rhy. | ○ |  | <12-Lead with Analysis Report><br>* Fixed as "6 Waves × 2"<br>1st column: I, II, III, aVR, aVL, aVF<br>2nd column: V1, V2, V3, V4, V5, V6                             |  |  |  |
| Laser                                | <12-Lead><br>3 Waves × 4, 3 Waves × 4+Rhy.,<br>6 Waves × 2, 12 Waves  | <12-Lead><br>3 Waves × 4+Rhy. | ○  |                               |   |  |   |  |  |  |
|                                      | <12-Lead with Analysis Report><br>* Fixed as "6 Waves × 2"<br>1st column: I, II, III, aVR, aVL, aVF<br>2nd column: V1, V2, V3, V4, V5, V6   |                               |  |                               |   |  |   |  |  |  |
| Position                             | Center, Proportional, OFF   | OFF                           | ○  |                               |   |  |   |  |  |  |
| Wave Format                          | Regular, Reverse  | Regular                       | ○  |                               |   |  |   |  |  |  |
| Recorder Auto Scale                  | ON, OFF   | OFF                           | ○  |                               |   |  |   |  |  |  |
| Print Calibration                    | ON, OFF   | ON                            | ○  |                               |   |  |   |  |  |  |
| Lead Boundary<br>(For laser printer) | ON, OFF<br>* Invalid for 12-lead with analysis report.  | OFF                           | ○  |                               |   |  |   |  |  |  |





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