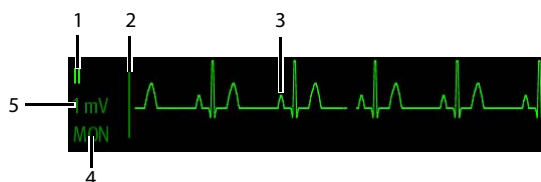


7.6.3 ECG Waveform Area

The ECG waveform area displays:

1. ECG Lead
2. ECG scale bar
3. ECG waveform
4. ECG filter setting
5. ECG scale



7.6.4 About the ECG Waveform Area

- The ECG waveform, scale indicator, lead, and filter settings display in the configured ECG color.
- The ECG waveform area provides scrolling, real-time waveform data and an erase bar to provide a time indicator of oldest and new data.
- The ECG waveform area scrolls the waveform in the configured sweep speed.
- The ECG waveform area rails the top most value when the waveform exceeds the upper scale limit for real-time waveforms.
- The ECG waveform area rails the bottom most value when the waveform exceeds the lower scale limit for real-time waveforms.
- The ECG waveform area indicates a Pacer indicator when a pace pulse is detected and Paced is enabled.

7.7 ST Monitoring

ST segment analysis calculates ST segment elevations and depressions for individual leads and then displays them as numerics in the ST area. A positive value indicates ST segment elevation; a negative value indicates ST segment depression.

ST monitoring is intended for adult and pediatric patients.

7.7.1 ST Safety Information



WARNING

- **ST values may be affected by such factors as some drugs or metabolic and conduction disturbances.**
 - **ST deviation is often calculated at a fixed offset from the J point. Changes in heart rate may affect ST.**
 - **The ST deviation measurement algorithm has been tested for accuracy. The significance of ST segment changes needs to be determined by a physician.**
 - **The TM80/TM70 provides ST deviation level change information. The clinical significance of the ST level change information should be determined by a physician.**
-

7.7.2 Switching ST Monitoring On and Off

The ST monitoring function is disabled by default. Before you start ST monitoring, enable the ST function.

1. On the main screen, tap the HR digital area or ECG waveform area to enter the **[ECG]** menu.
2. In the **[ECGParameter Setup]** section, tap **[ST]**.
3. Switch on **[ST Analysis]**.

Reliable ST monitoring can hardly be ensured if:

- You are unable to get a lead that is not noisy.
- Arrhythmias such as atrial fib/flutter cause irregular baseline.
- The patient is continuously ventricularly paced.
- The patient has left bundle branch block.

In these cases, you may consider switching ST monitoring off.

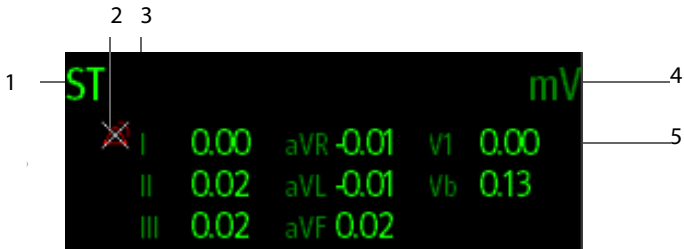
7.7.3 Displaying ST Numerics

When **[ST Analysis]** is switched on, ST digital area is displayed on the screen. The location of the ST digital area is dependent on the display configurations. For how to set the location of the ST digital area, refer to **"Configuring the Display" on page 4 - 2**.

Numerics displayed in the ST digital area are different according to the lead type:

- When the 3-lead ECG leadwires are used, the ST digital area is not displayed. A ST value is displayed in the HR digital area.
- When the 5-lead ECG leadwires are used, seven ST values (ST-I, ST-II, ST-III, ST-aVR, ST-aVL, ST-aVF, ST-V) are displayed in the ST digital area.
- When the 6-lead ECG leadwires are used, eight ST values (ST-I, ST-II, ST-III, ST-aVR, ST-aVL, ST-aVF, ST-Va, ST-Vb) are displayed in the ST digital area.

This example shows the ST digital area when the 6-lead ECG leadwires are used. Your screen may look slightly different:



1. Parameter label
2. ST alarm activation state off icon
3. Lead label
4. ST unit
5. ST numerics: a positive value indicates ST segment elevation, and a negative value indicates ST segment depression.

7.7.4 Setting ST Alarms

1. Tap the ST digital area to enter the **[ST]** menu.
2. Tap **[ST Alarm Setup]**.
3. In the **[Setup]** section, tap **[ST Alarm Mode]** and then select the desired mode:
 - ◆ **[Absolute]**: you can separately set the alarm properties for each ST alarm. After selecting this option, the **[Auto Limits]** option is displayed where you can initiate auto adjustment of alarm limits.
 - ◆ **[Relative]**: it is the default option. You can set the alarm properties for **[ST Single]** and **[ST Dual]** alarms.

4. In the **[Alarms]** section, configure the options described in the following table.

Options	Description	Settings*
ST-I, ST-II, ST-III, ST-aVR, ST-aVF, ST-V, ST-Va, ST-Vb	These options are displayed when [ST Alarm Mode] is set to [Absolute] . The lead label behind ST is consistent with the ECG cable type selected.	On, Off
		Upper alarm limit range: 0.2 mV to 2.0 mV; the default is 0.2mV ; the step is 0.01mV Lower alarm limit range: -2.0 mV to 0 mV; the default is -0.2mV ; step is 0.01mV
		Alarm priority: Low, Med , High
ST Single	These options are displayed when [ST Alarm Mode] is set to [Relative] .	On, Off
		Upper alarm limit range: 0 mV to 2.0 mV; the default is 0.1mV ; the step is 0.01mV Lower alarm limit range: -2.0 mV to 0 mV; the default is -0.1mV ; step is 0.01mV
		Alarm priority: Low, Med , High
ST Dual		On, Off
		Upper alarm limit range: 0 mV to 2.0 mV; the default is 0.1mV ; the step is 0.01mV Lower alarm limit range: -2.0 mV to 0 mV; the default is -0.1mV ; step is 0.01mV
		Alarm priority: Low, Med , High

* The factory default settings are in bold.

7.8 QT/QTc Interval Monitoring

The QT interval is defined as the time between the beginning of the Q-wave and the end of the T-wave. It measures the total duration of ventricular depolarization (QRS duration) and repolarization (ST-T). QT interval monitoring can assist in the detection of long QT syndrome.

The QT interval has an inverse relationship to heart rate. Faster heart rates shorten the QT interval and slower heart rates prolong the QT interval. Therefore, several formulas can be used to correct the QT interval for heart rate. The heart rate corrected QT interval is abbreviated as QTc.

QT/QTc interval monitoring is intended for adult and pediatric patients.

7.8.1 QT/QTc Monitoring Limitations

Some conditions may make it difficult to achieve reliable QT/QTc monitoring, for example:

- R-wave amplitudes are too low
- The presence of frequent ventricular ectopic beats
- Unstable RR intervals
- P-waves tending to encroach on the end of the previous T-wave at high heart rates
- The T-wave is very flat or T-wave are not well defined
- The end of the T-wave is difficult to delineate because of the presence of U-waves
- QTc measurements are not stable
- In the presence of noise, asystole, ventricular fibrillation, atrial fibrillation, and ECG lead off

For these cases you should select a lead with good T-wave amplitude and no visible flutter activity, and without a predominant U-wave or P-wave.

Some conditions such as left or right bundle branch block or hypertrophy can lead to a widened QRS complex. If a long QTc is observed you should verify it to ensure that it is not caused by QRS widening.

Because normal beats followed by ventricular beats are not included in the analysis, no QT measurement will be generated in the presence of a bigeminy rhythm.

If the heart rate is extremely high (over 150bpm for adults and over 180bpm for pediatrics and neonates), QT will not be measured. When the heart rate changes, it can take several minutes for the QT interval to stabilize. For reliable QTc calculation it is important to avoid measurements when the heart rate is changing.

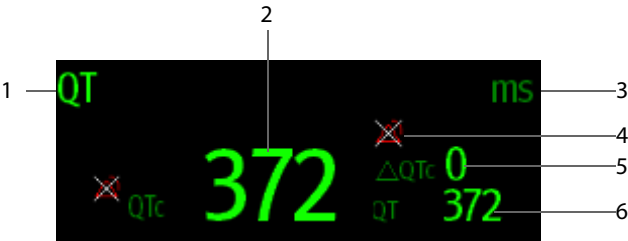
7.8.2 Enabling QT/QTc Monitoring

The QT monitoring function is disabled by default. Before you start QT monitoring, enable the QT function. To do so, follow this procedure:

1. On the main screen, tap the HR digital area or ECG waveform area to enter the [ECG] menu.
2. In the [ECGParameter Setup] section, tap [QT/QTc].
3. Switch on [QT Analysis].

7.8.3 **Displaying QT/QTc Numerics and Segments**

After [QT Analysis] is switched on, QT digital area is displayed on the screen. The location of the QT digital area is dependent on the display configurations. For how to set the location of the QT digital area, refer to *"Configuring the Display" on page 4 - 2.*



- 1. Parameter label
- 2. QTc value
- 3. Measurement unit
- 4. Alarm activation state off icon
- 5. ΔQTc value (the difference between the current and baseline QTc values)
- 6. QT value

7.8.4 **Setting QT Alarms**

- 1. Tap the QT digital area to enter the [QT/QTc] menu.
- 2. Tap [QT/QTc Alarm Setup].
- 3. Configure the options described in the following table.

Options	Description	Settings*
QTc	Configures whether to trigger the QTc alarm.	On, Off
		Upper alarm limit range: 200 ms to 800ms; step is 1ms For adult: the default is 500 ms . For pediatric: the default is 480 ms .
		Alarm priority: Low, Med , High

* *The factory default settings are in bold.*

Options	Description	Settings*
Delta QTc	Configures whether to trigger the Delta QTc alarm.	On, Off
		Upper alarm limit range: 30ms to 200 ms; the step is 1ms The default is 60 ms .
		Alarm priority: Low, Med , High

* The factory default settings are in bold.

4. Tap  to return to the previous menu.

7.9 Arrhythmia Monitoring

Arrhythmia monitoring is intended for adult and pediatric patients.

7.9.1 Arrhythmia Safety Information



WARNING

- Heart rate reading may be affected by cardiac arrhythmias. Do not rely entirely on heart rate alarms when monitoring patients with arrhythmia. Always keep these patients under close surveillance.
- The arrhythmia analysis program is intended to detect ventricular arrhythmias and atrial fibrillation. It is not designed to detect atrial or supraventricular arrhythmias. It may incorrectly identify the presence or absence of an arrhythmia. Therefore, a physician must analyze the arrhythmia information with other clinical findings.

**CAUTION**

- **Since the arrhythmia detection algorithm sensitivity and specificity are less than 100%, sometimes there may be some false arrhythmias detected and also some true arrhythmia events may not be detected. This is especially true when the signal is noisy.**
 - **The ECG size and minimum QRS detection threshold settings affect arrhythmia detection and heart rate calculation sensitivity.**
 - **If QRS amplitude is low, the monitor might not be able to calculate heart rate and false asystole calls may occur. During the learning phase of the algorithm, arrhythmia detection may not be available. So you should closely monitor patient condition during and for several minutes after the learning phase to allow the algorithm to reach optimal detection performance.**
-

7.9.2 Arrhythmia Events

This section lists all arrhythmia events and their criteria.

7.9.2.1 Lethal Arrhythmia Events

Arrhythmia message	Description
Asystole	No QRS complex detected within the set time interval in the absence of ventricular fibrillation or chaotic signal.
V-Fib/V-Tach	A fibrillatory wave for 6 consecutive seconds. A dominant rhythm of adjacent PVCs and the ventricular rate is greater than the V-tach rate limit.
V-Tach	The number of consecutive PVCs is greater than or equal to the V-Tach PVCs limit, and the ventricular rate is greater than or equal to the V-Tach rate limit.

7.9.2.2 Nonlethal Arrhythmia Events

Arrhythmia message	Description
Vent Brady	The number of consecutive PVCs is greater than or equal to V brady PVC limit and the ventricular rate is less than the V brady rate limit.
Extreme Tachy	The heart rate is greater than the extreme tachycardia limit.
Extreme Brady	The heart rate is less than the extreme bradycardia limit.
R on T	R on T PVC is detected.
Run PVCs	More than two consecutive PVCs, but lower than the V brady PVCs limit, and the ventricular rate is lower than the V-Tach rate limit.
Couplet	A Pair of PVCs detected in between normal beats.
Multiform PVC	Multiform PVCs detected in Multif. PVC's Window (which is adjustable).
PVC	One PVC detected in between normal beats.
Bigeminy	A dominant rhythm of N, V, N, V, N, V.
Trigeminy	A dominant rhythm of N, N, V, N, V, N, V, N, V.
Tachy	The heart rate is greater than the tachycardia limit.
Brady	The heart rate is lower than the bradycardia limit.
Pacer not Capture	No QRS complex detected for 300 ms following a pace pulse (for paced patients only).
Pacer not Pacing	No pace pulse detected for 1.75 x average R-to-R intervals following a QRS complex (for paced patients only).
Missed Beats	At least 3 consecutive Ns, and The current RR interval is greater than 1.5 x previous RR interval, and The next RR interval is lower than 1.5 x average RR interval, and HR lower than 100 and the current RR interval is greater than 1.75 x average RR interval, or HR is greater than or equal to 100 and the current RR interval is greater than 1000 ms.
Nonsus V-Tach	The number of consecutive PVCs is lower than the V-Tach PVCs limit but greater than 2, and the ventricular rate is greater than or equal to the V-Tach Rate limit.
Vent Rhythm	The number of consecutive PVCs is greater than or equal to the V Brady PVCs limit, and ventricular rate is greater than or equal to the V Brady Rate limit but lower than V-Tach Rate limit.
Pause	No QRS complex is detected within the set time threshold of pause.
Irr Rhythm	Consistently irregular rhythm (N, irregular RR interval change is greater than 12.5%)

Afib	P wave is absent and normal beat RR intervals are irregular.
PVCs/min	PVCs/min exceeds high limit.
Pauses/min	Pauses/min exceeds high limit.
Irr. Rhythm End	Irregular rhythm no longer detected for the irregular rhythm end delay time.
Afib End	Atrial fibrillation no longer detected for the Afib end delay time.

Note: N: normal beat; V: ventricular beat

7.9.3 Changing Arrhythmia Settings

7.9.3.1 Changing Arrhythmia Alarm Settings

1. On the main screen, tap the HR digital area or ECG waveform area to enter the **[ECG]** menu.
2. In the **[ECGParameter Setup]** section, tap **[Arrhythmia]**.
3. Tap **[Arrhythmia Alarm Setup]**. The **[Arrhythmia Alarm Setup]** menu is displayed.
4. In the **[Setup]** section, select the desired item:
 - ◆ **[All On]**: switches on all arrhythmia alarms
 - ◆ **[All Off]**: switches off all arrhythmia alarms
 - ◆ **[Lethals Only]**: switches on all the lethal arrhythmia alarms only. Other types of arrhythmia alarms are off.
5. In the **[Alarms]** section, configure the options described in the following table.

Options	Description	Settings*
Asystole	Configures arrhythmia alarms.	On, Off
		Asystole Delay: 3 seconds to 10 seconds The default is 5 Seconds .
		Alarm priority: High
V-Fib/V-Tach		On, Off
		Alarm priority: High
V-Tach		On, Off
		V-Tach PVCs: 3 beats to 99 beats; the default is 6 beats . V-Tach Rate: 100 bpm~200 bpm; the default is 130 bpm .
		Alarm priority: High

* The factory default settings are in bold.

Options	Description	Settings*
Vent Brady	Configures arrhythmia alarms.	On, Off
		V Brady PVCs: 3 beats to 99 beats; the default is 5 beats .
		V Brady Rate: 15 bpm to 60 bpm; the default is 40 BPM .
		Alarm priority: High
Extreme Tachy		On, Off
		Extreme Tachy: 61 bpm to 300 bpm; the default is 160 bpm for adult and 180 bpm for pediatric.
		Alarm priority: High
Extreme Brady		On, Off
		Extreme Brady: 15 bpm to 119 bpm; the default is 35 bpm for adult and 50 bpm for pediatric.
		Alarm priority: High
R on T		On, Off
		Alarm priority: Prompt, Low, Med , High
Run PVCs		On, Off
		Alarm priority: Prompt, Low , Med, High
Couplet		On, Off
		Alarm priority: Prompt , Low, Med, High
Multiform PVC		On, Off
		Multif PVCs Window: 3 beats to 31 beats; the default is 15 beats .
		Alarm priority: Prompt, Low, Med , High
PVC		On, Off
		Alarm priority: Prompt , Low, Med, High

* The factory default settings are in bold.

Options	Description	Settings*
Bigeminy	Configures arrhythmia alarms.	On, Off
		Alarm priority: Prompt, Low, Med , High
Trigeminy		On, Off
		Alarm priority: Prompt, Low, Med , High
Tachy		On, Off
		Tachy: 60 bpm to 299 bpm; the default Tachy threshold is consistent with the HR upper alarm limit.
		Alarm priority: Med , High
Brady		On, Off
		Brady: 16 bpm to 120 bpm; the default Brady threshold is consistent with the HR lower alarm limit.
		Alarm priority: Med , High
Pacer Not Capture		On, Off
		Alarm priority: Prompt , Low, Med, High
Pacer Not Pacing		On, Off
		Alarm priority: Prompt , Low, Med, High
Missed Beats		On, Off
		Alarm priority: Prompt , Low, Med, High
Nonsus V-Tach		On, Off
		Alarm priority: Prompt, Low, Med , High
Vent Rhythm		On, Off
		Alarm priority: Prompt, Low, Med , High
Pause		On, Off
		Pause Time: 1.5s, 2.0s, 2.5s, 3.0s; the default is 2.0 sec .
		Alarm priority: Prompt, Low , Med, High

* The factory default settings are in bold.

Options	Description	Settings*
Irr Rhythm	Configures arrhythmia alarms.	On, Off
		AF/Irr Rhy End Time: 0, 1 min, 2 min, 3 min, 4 min, 5 min, 10 min, 15 min, 30 min; th default is 2 Minutes .
		Alarm priority: Prompt , Low
A-Fib		On, Off
		AF/Irr Rhy End Time: 0, 1 min, 2 min, 3 min, 4 min, 5 min, 10 min, 15 min, 30 min; th default is 2 Minutes .
		Alarm priority: Prompt , Low, Med, High
PVCs/min		On, Off
		PVCs High: 1 to 100; the default is 10 .
		Alarm priority: Prompt, Low, Med , High
Pauses/min		On, Off
		Pauses High: 1 to 15; the default is 8 .
		Alarm priority: Prompt, Low, Med , High

* The factory default settings are in bold.



WARNING

- If you switch off all arrhythmia alarms, the monitor will not alarm for any arrhythmia event. This may result in a hazard to the patient. Always keep the patient under close surveillance.

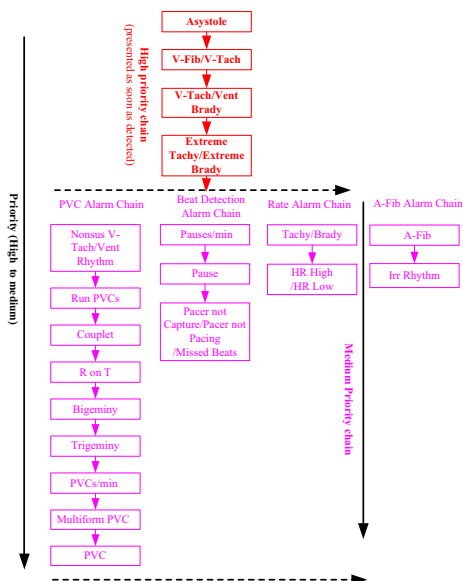
NOTE

- **The priority of lethal arrhythmia alarms is always high.**
 - **When the TM80/TM70 is connected to the CMS, any changes made either at the TM80/TM70 or the CMS will be communicated to the other side. But when lethal arrhythmia alarms are switched off at the CMS, you can change lethal arrhythmia alarms settings at the CMS only.**
 - **When lethal arrhythmia alarms are switched off at the CMS, the  icon is displayed on the lethal arrhythmia alarms at the TM80/TM70.**
 - **If any of the lethal arrhythmia alarms is switched off, the ECG waveform area displays the “Lethals Off” message.**
-

Normally, an arrhythmia alarm is presented when an alarm condition is detected. However, there are certain situations that can inhibit audible and visible alarm indications even though an alarm condition was detected.

7.9.3.2 Arrhythmia Alarm Chains

If multiple alarms overlap, announcing all of the detected alarm conditions would be confusing, and a more serious condition might be overlooked. So arrhythmia alarms are prioritized by alarm “chains”.



7.9.3.3 Setting Arrhythmia Alarm Timeout Period

The arrhythmia algorithm can disable alarm light and alarm tone for designated period of time when certain arrhythmia alarms are detected.

You can set the arrhythmia alarm timeout period at the CMS. For how to set the arrhythmia alarm timeout period, refer to **"Configuring the Arrhythmia Shield Time" on page 12 - 23**.

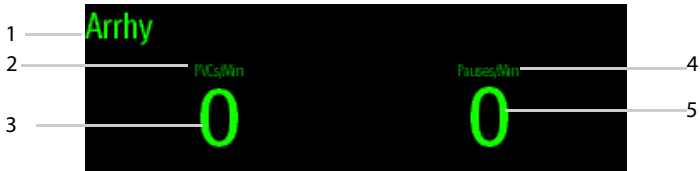
NOTE

- **For the following alarms, alarm light and alarm tone cannot be disabled:** HR high, HR low, Tachycardia, Bradycardia, Afib End, Irr. Rhythm End.
- **The timeout period is only applicable to the alarms in the medium priority chains and atrial fibrillation chain. For the alarms in the high priority chain, alarm tone and alarm light are presented as soon as the alarm condition is detected.**
- **Alarm indication rules for alarms in the atrial fibrillation chain are the same with those for the medium priority chains.**

7.9.4 Understanding the Arrhythmia Display

The arrhythmia I area displays:

1. Parameter label
2. PVCs per minute label
3. PVCs per minute value
4. Pauses per minute label
5. Pauses per minute value



7.10 Relearning

Changes in ECG template could result in incorrect arrhythmia alarms and/or inaccurate heart rate.

ECG relearning allows the TM80/TM70 to learn new ECG template so as to correct arrhythmia alarms and HR value. Once learning is complete, the dominant QRS complex is stored as a reference template. The reference template is used as a normal morphology of that patient and it is compared with incoming beats to identify possible arrhythmias.

NOTE

- **ST Analysis must be turned on before it will relearn.**

7.10.1 Automatically Initiating an ECG Relearning

Auto arrhythmia relearning is initiated in the following situation:

- TM80/TM70 power-up
- Return to normal monitoring from the Standby mode
- Enabling ST or Arrhythmia analysis
- The lead has been changed in ECG 1 waveform (3 lead only)
- Patient size changes

7.10.2 Manually Initiating an ECG Relearning

1. Tap the QT digital area to enter the **[QT/QTc]** menu.
2. Tap **[Relearn]**.

OR

1. On the main screen, tap the HR digital area or ECG waveform area to enter the **[ECG]** menu.
 2. In the **[ECGParameter Setup]** section, tap **[Arrhythmia]**.
 3. Tap **[Relearn]**.
-



CAUTION

- **Initiate ECG relearning only during periods of normal rhythm and when the ECG signal is relatively noise-free. If ECG learning takes place during ventricular rhythm, the ectopics may be incorrectly learned as the normal QRS complex. This may result in missed detection of subsequent events of V-Tach and V-Fib.**
-

8

Monitoring SpO₂ (Optional)

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Safety.....	8-3
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Understanding the SpO2 Display	8-12

8.1 Introduction

The chapter describes the SpO₂ monitoring function, including connecting the SpO₂ module, configuring the SpO₂, and monitoring the SpO₂. For details about the SpO₂ parameter setup at the Central Monitoring System, refer to **Chapter 12 Monitoring with the TM80/TM70 at the CMS**.

SpO₂ monitoring is a non-invasive technique used to measure the amount of oxygenated hemoglobin and pulse rate by measuring the absorption of selected wavelengths of light. The light generated in the probe passes through the tissue and is converted into electrical signals by the photo detector in the probe. The SpO₂ module processes the electrical signal and displays a waveform and digital values for SpO₂ and pulse rate.

The TM80/TM70 can be configured with Masimo SpO₂ module, Nonin SpO₂ module, or Nellcor SpO₂ module.

NOTE

- **A functional tester or SpO₂ simulator cannot be used to assess the accuracy of a SpO₂ module or a SpO₂ sensor.**
- **This device is calibrated to display functional oxygen saturation.**
- **A pulse oximeter should not be used as an apnea monitor.**
- **Pulse rate measurement is based on the optical detection of a peripheral flow pulse and therefore may not detect certain arrhythmias. The pulse oximeter should not be used as a replacement or substitute for ECG based arrhythmia analysis.**
- **The MS board pulse oximeter can be used during defibrillation, but the readings may be inaccurate for a short time.**

8.2 Measurement Limitations

If the SpO₂ measurement seems out of range or inaccurate, check the patient's vital signs. Then check the equipment and SpO₂ sensor. The following factors may influence the accuracy of measurement:

- Ambient light
- Physical movement
- Low perfusion
- Electromagnetic interference

- Dysfunctional hemoglobin, such as carboxyhemoglobin (COHb) and methemoglobin (MetHb)
- Presence of certain dyes, such as methylene and indigo carmine
- Inappropriate positioning of the SpO₂ sensor, or use of incorrect SpO₂ sensor
- Drop of arterial blood flow to immeasurable level caused by shock, anemia, low temperature or vasoconstrictor.

8.3 Safety

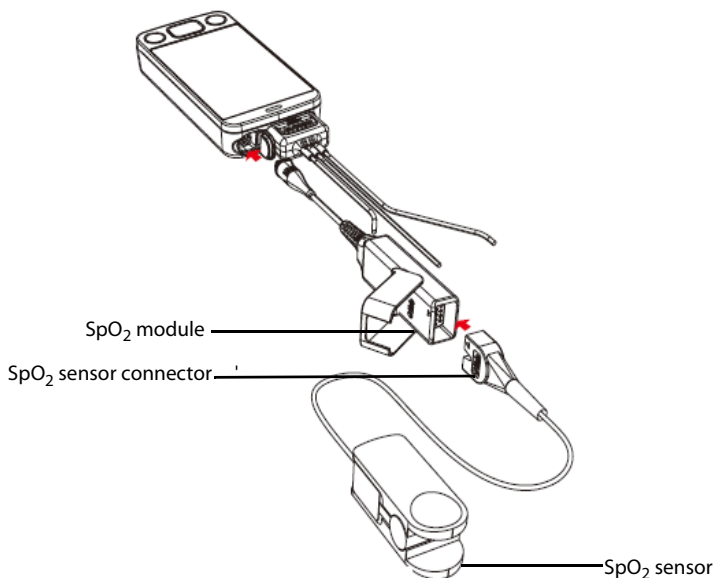


WARNING

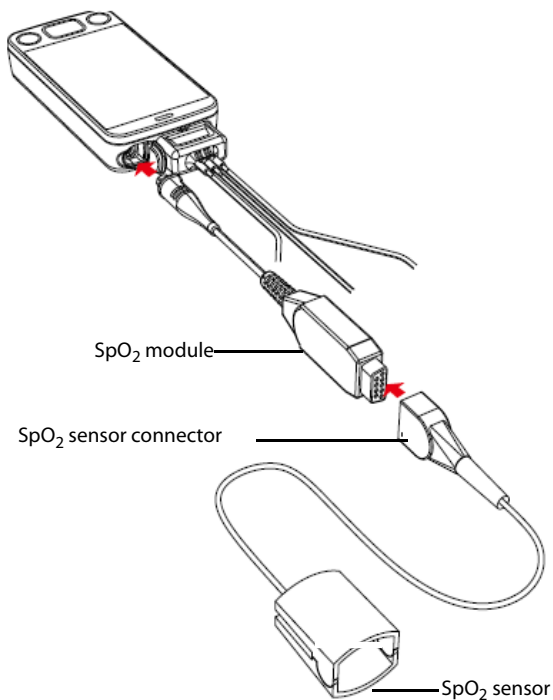
- **Only use SpO₂ sensors specified in this manual. Follow the SpO₂ sensor's instructions for use and adhere to all warnings and cautions.**
 - **The operator is responsible for checking the compatibility of the pulse oximetry monitor, sensor, and patient cable prior to use. Incompatible components can result in degraded performance and/or device malfunction.**
 - **When a trend toward patient deoxygenation is indicated, blood samples should be analyzed by a laboratory co-oximeter to completely understand the patient's condition.**
 - **Do not use SpO₂ sensors during magnetic resonance imaging (MRI). Induced current could potentially cause burns. The sensor may affect the MRI image, and the MRI unit may affect the accuracy of the oximetry measurements.**
 - **Prolonged and continuous monitoring may increase the temperature of the sensor and cause the patient discomfort. It is especially important to check the sensor placement, and ensure proper attachment on patients suffering from poor perfusion or skin sensitivity. Check the sensor location every two to three hours and move to another location if the skin deteriorates. More frequent examinations may be required for different patients.**
 - **Check accessory compatibility prior to use. Incompatible accessories may degrade the device's performance and may cause harm to the patient.**
 - **Do not use disposable SpO₂ sensor for multiple times. Otherwise, inaccurate SpO₂ measurement may occur.**
-
-

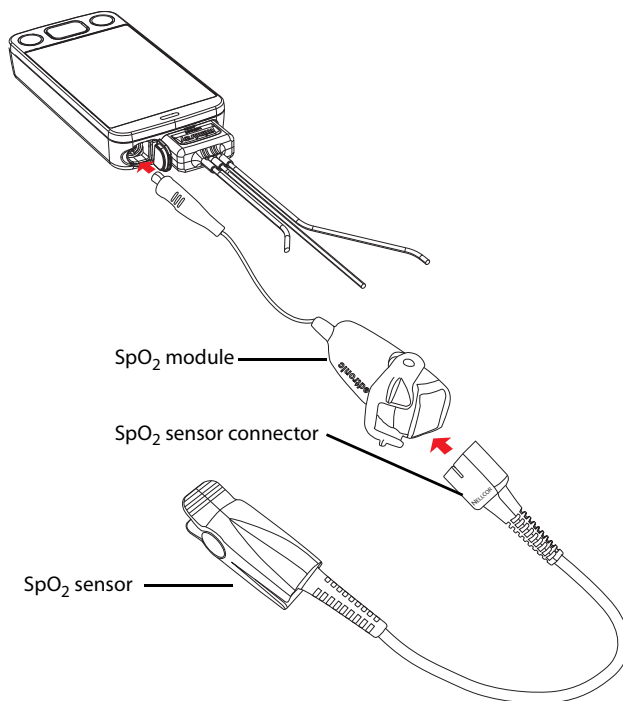
8.4 Connecting the SpO₂ Module

Connect the SpO₂ module to the TM80/TM70. The TM80/TM70 can auto detect the SpO₂ module type when the SpO₂ module is connected.



Connecting the Masimo SpO₂ module

Connecting the Nonin SpO₂ module

Connecting the Nellcor SpO₂ module

8.5 Changing the SpO₂ Settings

You can change the SpO₂ settings from the [SpO₂] menu.

8.5.1 Configuring the SpO₂ Setup

Enter the [SpO₂] menu in either of the following ways:

- On the main screen, tap the SpO₂ digital area or SpO₂ waveform area to enter the [SpO₂] menu.
 - In the main menu, tap [Parameter Setup] → [SpO₂] to enter the [SpO₂] menu.
1. In the [Setup] section of the [SpO₂] menu, select the options described in the following table.

Options	Description	Settings*
Display PI (Masimo only)	Configures whether or not to show the perfusion index (PI) value in the digital area. The perfusion index allows clinicians to assess the pulse strength at the monitoring site for optimal sensor placement. PI gives the numerical value for the pulsatile portion of the measured signal caused by arterial pulsation. PI is an indicator of the pulsatile strength.	On, Off
Sensitivity (Masimo only)	Selects the sensitivity mode depending upon signal quality and patient motion. High: This mode should be used for the sickest patients, where obtaining a reading is most difficult. High Sensitivity is designed to interpret and display data for even the weakest of signals. This mode is recommended during procedures and when clinician and patient contact is continuous. Normal: This mode provides the best combination of sensitivity and probe off detection performance. This mode is recommended for the majority of patients. APOD (Adaptive Probe Off Detection): This mode is the least sensitive in picking up a reading on patients with low perfusion but has the best detection for probe-off conditions. This mode is useful for patients that are at particular risk of the sensor becoming detached (pediatric, combative, etc.)	High, Normal, and APOD

* *The factory default settings are in bold.*

Options	Description	Settings*
Averaging (Masimo only)	The user-selectable averaging feature allows the clinician to select the desired level of visibility to subtle variations in the measured value. Depending on the patient acuity and area of care, shorter averaging times are sometimes preferred (sleep testing) over longer averaging times (telemetry) and vice-versa. 8-second averaging is generally considered the most common averaging interval and recommended for most patients since it is short enough to provide visibility to subtle desaturations while also being long enough to minimize major changes in SpO₂ due to quick, transitory desaturations. Although averaging times greater than 10 seconds are more likely to reduce visibility to rapid, brief desaturations, this may be desirable in care areas where brief desaturations that do not require clinician intervention occur more often (such as NICU). It is also recommended that this be enabled as a “sticky” configuration so as to hold the setting after power cycles.	2-4 sec, 4-6 sec, 8 sec , 10 sec, 12 sec, 14 sec, 16 sec
Fast SAT (Masimo only)	Selects whether or not to enable FastSat. FastSat enables rapid tracking of arterial oxygen saturation changes.	On , Off
Sat-Seconds (Nellcor only)	Selects the amount of time that SpO ₂ saturation may be outside the set limits before an alarm sounds.	Off , 10s, 25s, 50s, 100s
Color	Selects the SpO ₂ waveform color.	16 colors The default color is cyan.

* The factory default settings are in bold.

2.
- Tap  to exit the [SpO₂] menu.

8.5.2 Configuring the SpO₂ Waveform

1. In the [**Waveform**] section of the [**SpO₂**] menu, select the options described in the following table.

Options	Description	Settings*
Speed	Selects the SpO ₂ pleth waveform speed.	6.25 mm/s, 12.5 mm/s , 25 mm/s
Display SIQ (Masimo only)	Selects whether or nor to show the Signal Index Quality (SIQ) in the SpO ₂ waveform area. The SIQ wave indicates the confidence associated with the saturation measurement and timing of the pulse. Higher pulse is a better signal.	On , Off

* The factory default settings are in bold.

2. Tap  to exit the [**SpO2**] menu.

8.5.3 Configuring SpO₂ Alarm Settings

You can change the SpO₂ and SpO₂ Desat alarm properties. You can also set whether to measure SpO₂ and NIBP simultaneously.

1. In the [**Alarms**] section of the [**SpO₂**] menu, select the options described in the following table.

Options	Description	Settings*
SpO ₂ Alarm Setup	Configures whether to switch on SpO ₂ and SpO ₂ Desat alarms. [SpO₂] and [Desat] default to be switched on. After tapping [SpO₂] or [Desat] you can configure alarm limits and alarm priority.	For SpO ₂ : Alarm switch: On , Off Alarm limit range: 0% to 100%; The default alarm upper limit is 100% . The default alarm low limit is 90%. Alarm Priority: Med , High
		For Desat: Alarm switch: On , Off Alarm limit range: Lower alarm limit is not higher than the SpO ₂ lower alarm limit. The default alarm low limit is 80% . Alarm Priority: High
NIBP Simul	When monitoring SpO ₂ and NIBP on the same limb simultaneously, you can switch on NIBP Simul to lock the SpO ₂ alarm status until the NIBP measurement ends. If you switch off NIBP Simul , low perfusion caused by NIBP measurement may lead to inaccurate SpO ₂ readings and therefore cause false physiological alarms.	On, Off

* The factory default settings are in bold.

2. Tap  to exit the [**SpO₂**] menu.

8.6 SpO₂ Measurement

8.6.1 Identifying SpO₂ Modules

To identify which SpO₂ module you are using, see the company logo on the SpO₂ module.

- Masimo SpO₂ module: purple, with a logo of Masimo SET.
- Nonin SpO₂ module: blue, with a logo of Nonin.
- Nellcor SpO₂ module: grey, with a logo of Nellcor.

8.6.2 Applying the Sensor

1. Select an appropriate sensor according to the module type, patient size, and weight.
2. Remove colored nail polish from the application site.
3. Apply the sensor to the patient.
4. Connect the sensor to the SpO₂ module and the SpO₂ module to the TM80/TM70.

The SpO₂ measurement displays when the TM80/TM70 detects that a sensor is connected to the patient.



WARNING

- **When equipped with Masimo SpO₂ module, use only Masimo SpO₂ sensors specified in this manual. Use of other SpO₂ sensors may cause improper oximeter performance.**
 - **When equipped with Nonin SpO₂ module, use only Nonin SpO₂ sensors specified in this manual. Use of other SpO₂ sensors may cause improper oximeter performance.**
 - **When equipped with Nellcor SpO₂ module, use only Nellcor SpO₂ sensors specified in this manual. Use of other SpO₂ sensors may cause improper oximeter performance.**
 - **Do not disconnect the Nonin SpO₂ sensor connector from the Nonin SpO₂ module during defibrillation.**
 - **If the sensor is too tight because the application site is too large or becomes too large due to edema, excessive pressure for prolonged periods may result in venous congestion distal from the application site, leading to interstitial edema and tissue ischemia.**
-



CAUTION

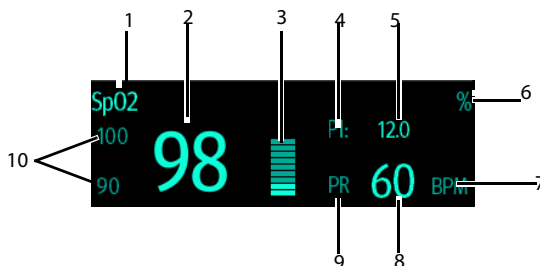
- **Many patients suffer from poor peripheral perfusion due to hypothermia, hypovolemia, severe vasoconstriction, reduced cardiac output, etc. These symptoms may cause a loss in vital sign readings.**

8.7 Understanding the SpO₂ Display

8.7.1 SpO₂ Digital Area

The SpO₂ digital area displays:

1. Parameter name
2. SpO₂ value
3. Perfusion indicator
4. Perfusion index (PI) label
5. Perfusion index value
6. SpO₂ unit of measure
7. PR measurement unit
8. PR value
9. Pulse rate (PR) label
10. Alarm high limit and low limit. When SpO₂ alarm is switched off, the activation state off icon  instead of alarm limits is displayed.



Masimo SpO₂ digital area

Nonin SpO₂ digital areaNellcor SpO₂ digital area

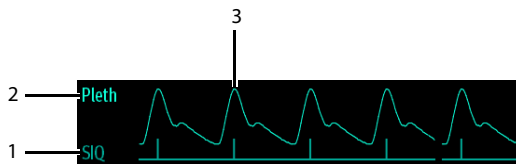
8.7.2 About the SpO₂ Digital Area

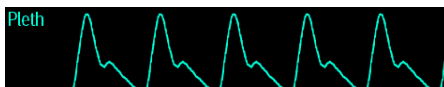
- The SpO₂ digital area displays in units of % with a resolution of 1%.
- The SpO₂ PR value displays in units of bpm with a resolution of 1 bpm.
- Displays Masimo PI resolution as 0.01 when the PI value is smaller than 10%.
- Displays Masimo PI resolution as 0.1 when the PI value is greater than or equal to 10%.
- If the SpO₂ measurement or PR is invalid, "--" displays in place of digits.

8.7.3 SpO₂ Waveform Area

The SpO₂ waveform area displays:

1. Signal Index Quality (SIQ)
2. Area name
3. Pleth waveform

Masimo SpO₂ waveform area (SIQ enabled)



Nonin SpO₂ and Nellcor SpO₂ waveform area

8.7.4 About the SpO₂ Waveform Area

- Displays in the configured SpO₂ color.
- Provides scrolling, real-time waveform data.
- Scrolls the waveform in the configured sweep speed.
- Automatically scales the SpO₂ waveform data area to maximize the vertical height of the Pleth waveform for the data range.
- If using Masimo SpO₂, the Signal Quality Index (SIQ) will display below the waveform if enabled.

8.8 Masimo Information



Masimo Patents

This posting serves as notice under 35 U.S.C. §287(a) for Masimo patents: <http://www.masimo.com/patents.htm>.

No Implied License

Possession or purchase of this device does not convey any express or implied license to use the device with unauthorized sensors or cables which would, alone, or in combination with this device, fall within the scope of one or more of the patents relating to this device.

8.9 Nellcor Information



Nellcor Patents

This posting serves as notice under 35 U.S.C. §287(a) for Covidien patents: <http://www.covidien.com/patents>.

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Possession or purchase of this device does not convey any express or implied license to use the device with unauthorized replacement parts which would, alone, or in combination with this device, fall within the scope of one or more of the patents relating to this device.

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9

Monitoring Resp (Optional)

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9.1 Introduction

Impedance respiration is measured across the thorax. When the patient is breathing or ventilated, the volume of air changes in the lungs, resulting in impedance changes between the electrodes. Respiration rate (RR) is calculated from these impedance changes, and a respiration waveform appears on the screen.

Resp monitoring is intended for adult and pediatric patients.

9.2 Resp Safety Information

WARNING

- **The respiration measurement does not recognize the cause of no chest movement. It only indicates an alarm if no breath is detected when a pre-adjusted time has elapsed since the last detected breath. Therefore, it cannot be used for diagnostic purpose.**
 - **If operating under conditions according to the EMC Standard IEC 60601-1-2 (Radiated Immunity 3V/m), field strengths above 3V/m may cause erroneous measurements at various frequencies. Therefore, it is recommended to avoid the use of electrically radiating equipment in close proximity to the respiration measurement unit.**
 - **The impedance respiration measurement may cause rate changes in Minute Ventilation Rate Responsive Pacemakers. Set the pacemaker rate responsive mode off or disable the impedance respiration measurement on the monitor.**
-

CAUTION

- **Only use parts and accessories specified in this manual.**
 - **Respiration monitoring is not for use on the patients who are very active, as this will cause false alarms.**
-

9.3 Preparing for Resp Monitoring

9.3.1 Preparing the Patient

Proper skin preparation is essential in obtaining an accurate ECG reading. Electrode sites should be clean and dry and should provide a smooth flat surface. Incidental electrical activity and inaccurate readings may arise from incorrect skin preparation.

The following procedure is recommended for secure electrode application:

1. Shave the chest hair from the electrode sites in a circular area with a diameter of 2 to 4 inches.
2. Use a dry gauze pad to remove excess skin oils, skin cells and residue from the electrode sites. Never rub the skin until it is raw or bleeding.

9.3.2 Placing the Electrodes

As the Respiration measurement adopts the standard ECG electrode placement, you can use different ECG cables.

For more information, refer to *"Placing the Electrodes" on page 7 - 5*.

CAUTION

- **Correct electrodes placement can help to reduce cardiac overlay: avoid the liver area and the ventricles of the heart in the line between the respiratory electrodes. This is particularly important for neonates.**
 - **Some patients with restricted movements breathe mainly abdominally. In these cases, you may need to place the left leg electrode on the left abdomen at the point of maximum abdominal expansion to optimize the respiratory wave.**
 - **In clinical applications, some patients (especially neonates) expand their chests laterally, causing a negative intrathoracic pressure. In these cases, it is better to place the two respiration electrodes in the right midaxillary and the left lateral chest areas at the patient's maximum point of the breathing movement to optimize the respiratory waveform.**
 - **To optimize the respiration waveform, place the RA and LL electrodes diagonally when monitoring respiration with ECG Lead II.**
 - **Periodically inspect the electrode application site to ensure skin quality. If the skin quality changes, replace the electrodes or change the application site.**
-

NOTE

- **Store the electrodes at room temperature. Open the electrode package immediately prior to use.**
- **Check that the electrode packages are intact and not expired. Make sure the electrode gel is moist.**

9.4 Changing Resp Settings

You can change the Resp settings from the [Resp] menu.

9.4.1 Configuring the Resp Setup

Enter the [Resp] menu in either of the following ways:

- On the main screen, tap the Resp digital area or Resp waveform area to enter the [Resp] menu.
 - In the main menu, tap [Parameter Setup] → [Resp] to enter the [Resp] menu.
1. In the [Setup] section of the [Resp] menu, select the options described in the following table.

Options	Description	Settings*
NCM Alarm Delay Time	Select the delay for no chest movement alarm.	10 s, 15 s, 20 s , 25 s, 30 s, 35 s, 40 s
Color	Select the color of RR value and Resp waveform.S	16 colors The default color is yellow.

* The factory default settings are in bold.

2. Press  to return to the main screen.

9.4.2 Configuring the Resp Waveform

1. In the **[Waveform]** section of the **[Resp]** menu, select the options described in the following table.

Options	Description	Settings*
Gain	Selects the Resp waveform size.	×0.25, ×0.5, ×1, ×2 , ×3, ×4, ×5
Speed	Selects the Resp waveform speed.	3 mm/s, 6.25 mm/s , 12.5 mm/s, 25 mm/s

* The factory default settings are in bold.

2. Press  to return to the main screen.

9.4.3 Configuring the Resp Alarm Settings

1. In the **[Alarms]** section of the **[Resp]** menu, tap **[Resp Alarm Setup]**.
2. Select the options described in the following table.

Options	Description	Settings*
RR	Configures whether to switch on the Respiration alarm. RR defaults to be switched on. After tapping RR , you can configure alarm limits and alarm priority.	On , Off
		Alarm limit range: 0 RPM to 100 RPM The default alarm upper limit is 30 RPM . The default alarm lower limit is 8 RPM.
		Alarm Priority: Low, Med , High
No Chest Movement	The TM80/TM70 will trigger the “No Chest Movement” alarm if the patient has stopped breathing for longer than the set apnea time. This option defaults to be switched on. When the TM80/TM70 is connected to the Central Monitoring System, switching on or off this option at the Central Monitoring System also switches it on or off at the TM80/TM70, and vice versa. After tapping this option, you can configure the alarm priority.	Alarm Priority: High

* The factory default settings are in bold.

9.5 Understanding the Resp Display

9.5.1 Resp Digital Area

The Resp digital area displays:

1. Parameter name
2. Measurement unit
3. Respiration rate (RR) value
4. Alarm high limit and low limit. When RR alarm is switched off, the activation state off icon  instead of alarm limits is displayed.



- The Resp area displays respiration rate in the unit of rpm with a resolution of 1 rpm.
- If the Resp measurement is invalid, "--" displays in place of the RR value.

9.5.2 Resp Waveform Area

The waveform area displays:

1. Parameter name
2. Resp waveform
3. Resp waveform gain
4. Resp Lead



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10

Monitoring NIBP (Optional)

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10.1 Introduction

NIBP (non-invasive blood pressure) data is measured by BP10 using the oscillometric method. This measurement can be used for adult and pediatric patients. NIBP data is transferred from the BP10 to the TM80/TM70.

You can pair and unpair a TM80/TM70 with a BP10 via the Mindray Patient Area Network (MPAN) functionality.

Once a TM80/TM70 is paired successfully with a BP10, measured NIBP data and NIBP-related alarms will be displayed on the TM80/TM70 main screen. Besides, the TM80/TM70 allows you to perform some operations on the BP10.

For the functionalities and operations of the BP10, refer to **BP10 NIBP Module Operator's Manual (P/N 046-008269-00)**.

For the specifications of MPAN, refer to **"Bluetooth Specification" on page A - 12**.

10.2 Pairing the TM80/TM70 with the BP10

10.2.1 Pairing Procedure

Before pairing the TM80/TM70 with a new BP10, first unpair the already connected BP10 by following steps in **"Unpairing the TM80/TM70 with the BP10" on page 10 - 4**.

To pair the TM80/TM70 with the BP10, follow this procedure:

1. Press the MPAN key on the right panel of the BP10. The "Pairing..." message will display in the message area of the BP10.
2. Press  to enter the main menu of the TM80/TM70.
3. Tap **[Wireless Modules]**.
4. Tap **[MPAN]**, and then select **[Monitor/Sensor]**.
The TM80/TM70 starts searching the BP10 devices in the vicinity and displays the devices that can be connected under **[Devices]**. Make sure that the device you wish to connect appears in the list of devices. If not, repeat Steps 1 to 4.
5. In the list of devices, select your desired device and tap **[Connect]**. Once the device is connected successfully, the status will be changed from **[Disconnect]** to **[Connected]**.
6. Start an NIBP measurement from TM80/TM70 to verify that desired BP10 module is paired, and the NIBP measurement displayed on the BP10 are consistent with that displayed on the TM80/TM70.

WARNING

- **Do not pair a TM80/TM70 with an undesired BP10. If a TM80/TM70 is paired with an undesired BP10, the patient category may be not applicable for the patient and the measured NIBP data may be incorrect.**
-
-

NOTE

- **Make sure that you have selected the correct BP10 to pair it with the TM80/TM70.**
 - **If you pair a TM80/TM70 with a BP10 when NIBP measurement mode is set to [ABPM] at BP10, the system responses after successful pairing are slightly different from that when the NIBP measurement mode is set to [Manual], [Auto], or [Sequence]. For the differences, see "System Responses after Successful Pairing" on page 10 - 3.**
-

10.2.2 System Responses after Successful Pairing

Once a TM80/TM70 is paired successfully with a BP10, the following system responses occur:

- The  icon will be changed to  in the top-right corner of the TM80/TM70's screen. Besides, the  appears in the top-right corner of the BP10.
- The status of the BP10 which is paired successfully with the TM80/TM70 is displayed as **[Connected]**. Besides, the "Pairing Successful" displays in the BP10's message area for about 10 seconds.
- When NIBP measurement mode is set to **[ABPM]** at BP10 and the BP10 is paired successfully with the TM80/TM70, the wireless setup confirmation message "Select Yes to continue Patient in BP10. Select No to continue Patient in Telemetry" will display on the main screen of the TM80/TM70.
 - ◆ **[Yes]:** Patient-related settings comes from BP10 and ongoing NIBP measurement for current patient will not stop.
 - ◆ **[No]:** Patient-related settings at BP10 comes from the TM80/TM70. Besides, NIBP measurement for the patient monitored by BP10 will stop and the data history related to this patient will be cleared at BP10.
 - ◆ If neither **[Yes]** nor **[No]** is selected, the wireless setup confirmation message will disappear in three minutes. Besides, the "Pairing failure" message will be displayed in the prompt message area of the TM80/TM70. The "MPAN Disconnected" message is displayed in the message area of the BP10. In this

case, follow steps in **Pairing the TM80/TM70 with the BP10** on **Page 10-2** to pair the TM80/TM70 with the BP10 again.

- When NIBP measurement mode is set to **[Manual]**, **[Auto]**, or **[Sequence]** and the BP10 is paired successfully with the TM80/TM70, the wireless setup confirmation message "Select Yes to continue Patient in BP10. Select No to continue Patient in Telemetry." will not be displayed. Patient-related settings from the TM80/TM70 will be transferred to the BP10. But NIBP-related settings displayed on the main screen of the TM80/TM70 will come from the BP10. The patient monitored by BP10 will be discharged automatically and the data history related to this patient will be cleared.
- Patient Category can be changed at the TM80/TM70 only.
- A patient cannot be discharged from the BP10 and NIBP-related settings are grayed out at BP10. To discharge a patient from BP10, you need to unpair the BP10 from the TM80/TM70, refer to **"Unpairing the TM80/TM70 with the BP10" on page 10 - 4**.

10.3 Unpairing the TM80/TM70 with the BP10

You can unpair the TM80/TM70 with the BP10 either via the TM80/TM70 or via the BP10.

10.3.1 Unpairing via the TM80/TM70

Follow this procedure to unpair the TM80/TM70 with the BP10 via the TM80/TM70.

1. Press  to enter the main menu of the TM80/TM70.
2. Tap **[Wireless Modules]**.
3. Select the device you wish to disconnect from the TM80/TM70 from the devices list under **[Devices]** and tap **[Disconnect]**. The connected device is disconnected from the TM80/TM70.

You can also follow this procedure to unpair it with the BP10.

1. Press the  key to enter the main menu of the TM80/TM70.
2. Tap **[Wireless Modules]**.
3. Tap **[MPAN]**.
4. Select **[Off]** or **[Sensor]**.

10.3.2 Unpairing via BP10

1. Press the MPAN key on the BP10.
2. Select **[Yes]** when the prompt message “Are you sure you want to close MPAN and unpair BP10?” appears.

CAUTION

- **Before moving a TM80/TM70 or BP10 to another area, unpair them first.**
 - **Before admitting a new patient at a BP10, you need to unpair it with a TM80/TM70 first.**
-

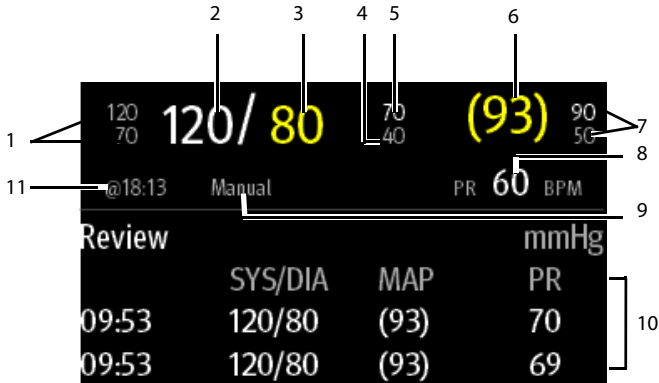
10.3.3 System Responses after Successful Unpairing

When the TM80/TM70 is unpaired with the BP10 successfully:

- The status of the BP10 connected previously will be changed to **[Disconnect]** under **[Devices]** on the TM80/TM70.
- The  icon will be changed to  in the top-right corner of the TM80/TM70's screen and of the BP10.
- Measured NIBP values on the main screen of the TM80/TM70 is displayed as “---” indicating invalid values.

10.4 Screen Display after Pairing a TM80/TM70 with a BP10

When a TM80/TM70 is paired with a BP10 successfully, measured NIBP values will be displayed on the main screen of the TM80/TM70 as shown in the following figure.



1. Systolic pressure alarm limits
2. Systolic pressure
3. Diastolic pressure
4. Diastolic pressure low limit
5. Diastolic pressure high limit
6. Mean pressure (displayed after measurement is completed) or cuff pressure (displayed during measurement)
7. Mean pressure alarm limit
8. Pulse rate
9. NIBP measurement mode: Manual, Auto, Seq., ABPM.
10. NIBP measurement history area: displays NIBP measurement history information.
11. NIBP measurement time: displays the time when NIBP measurement starts.

10.5 Interactions after Pairing a TM80/TM70 with a BP10

10.5.1 Overview of Interactions

Once a TM80/TM70 is paired successfully with a BP10, the interactions proceed as shown below.

Action	At the TM80/TM70	At the BP10
Start NIBP measurement	Yes	Yes
Stop NIBP measurement	Yes	Yes
Stop All NIBP measurements	Yes	Yes
NIBP STAT	Yes	Yes
Set initial pressure	Yes	No
Set NIBP measurement mode	Yes	No
Configure settings related to [Auto] measurement mode	Yes	No
Configure settings related to NIBP [Sequence] measurement mode	Yes	No
Set NIBP settings related to NIBP [ABPM] measurement mode	Yes	No
Set venipuncture	No	Yes
Set the cuff pressure for venipuncture	No	Yes

10.5.2 Operating the BP10 via the TM80/TM70

When the TM80/TM70 is paired successfully with the BP10, you can tap anywhere in the NIBP parameter area on the main screen of the TM80/TM70 to access the **[NIBP]** menu.

In the **[Actions]** section of the **[NIBP]** menu, you can:

- Tap **[Start]** to start NIBP measurement at the BP10.
- Tap **[Stop]** to stop an ongoing NIBP measurement at the BP10.
- Tap **[NIBP STAT]** to start the series measurement in continuous mode at the BP10.
- Tap **[Stop All]** to cancel the series measurement in Auto, Sequence, or ABPM mode at the BP10.

10.5.3 NIBP Operations at the TM80/TM70

In the **[Setup]** section of the **[NIBP]** menu at the TM80/TM70, you can:

- Tap **[Mode]** to set NIBP measurement mode to one of the following: Manual, Auto, Seq. ABPM.
- Tap **[ABPM]** to configure ABPM-related settings: Day, Night, Start, Interval.
- Tap **[Auto]** to set NIBP measurement interval to one of the following: 1 min, 2 min, 2.5 min, 3 min, 5 min, 10 min, 15 min, 20 min, 30 min, 1h, 1.5h, 2h, 3h, 4h, 8h.
- Tap **[Seq.]** to configure sequence-related settings: P1, P2, P3, P4, P5
- Tap **[Initial Pressure]** to set the initial cuff pressure.
- Tap **[Color]** to select your desired color in which NIBP measurement results will be displayed on the main screen of the TM80/TM70. 16 color options are available. Tap your desired color and this color will be displayed on the right of **[Color]**.

For detailed description of NIBP-related operations and settings, refer to **BP10 NIBP Module Operator's Manual (P/N 046-008269-00)**.

10.5.4 Adjusting NIBP Limits

1. In the **[Alarms]** section of the **[NIBP]** menu, tap **[NIBP Alarm Setup]**.
2. Configure the options described in the following table.

Options	Description	Settings*
SYS	Configures whether to trigger the NIBP systolic pressure alarm.	On, Off
		Alarm limit range: For adult: 41 mmHg to 269 mmHg; the default alarm upper limit is 160 mmHg and the default alarm low limit is 90mmHg For pediatric: 41 mmHg to 199 mmHg; the default alarm upper limit is 120 mmHg and the default alarm low limit is 70mmHg
		Alarm priority: Med , High

* The factory default settings are in bold.

Options	Description	Settings*
DIA	Configures whether to trigger the NIBP diastolic pressure alarm.	On, Off
		Alarm limit range: For adult: 11 mmHg to 209 mmHg; the default alarm upper limit is 90 mmHg and the default alarm low limit is 50mmHg For pediatric: 11 mmHg to 149 mmHg; the default alarm upper limit is 70 mmHg and the default alarm low limit is 40mmHg
		Alarm priority: Med , High
MAP	Configures whether to trigger the NIBP mean pressure alarm.	On, Off
		Alarm limit range: For adult: 21 mmHg to 229mmHg; the default alarm upper limit is 110 mmHg and the default alarm low limit is 60mmHg For pediatric: Alarm limit range: 21 mmHg to 164 mmHg; the default alarm upper limit is 90 mmHg and the default alarm low limit is 50mmHg
		Alarm priority: Med , High
SYS Extreme	Configures whether to trigger the extreme NIBP systolic pressure alarm.	On, Off
		Alarm limit range: For adult: 40 mmHg to 270 mmHg; the default alarm upper limit is 175 mmHg and the default alarm low limit is 75 mmHg For pediatric: 40 mmHg to 200 mmHg; the default alarm upper limit is 130 mmHg and the default alarm low limit is 60mmHg
		Alarm priority: High

* The factory default settings are in bold.

Options	Description	Settings*
DIA Extreme	Configures whether to trigger the extreme NIBP diastolic pressure alarm.	On, Off
		Alarm limit range: For adult: 10 mmHg to 210 mmHg; the default alarm upper limit is 105 mmHg and the default alarm low limit is 35 mmHg For pediatric: 10 mmHg to 150 mmHg; the default alarm upper limit is 80 mmHg and the default alarm low limit is 30mmHg
		Alarm priority: High
MAP Extreme	Configures whether to trigger the extreme NIBP mean pressure alarm.	On, Off
		Alarm limit range: For adult: 20 mmHg to 230 mmHg; the default alarm upper limit is 125 mmHg and the default alarm low limit is 45 mmHg For pediatric: 20 mmHg to 165 mmHg; the default alarm upper limit is 100 mmHg and the default alarm low limit is 40mmHg
		Alarm priority: High

* The factory default settings are in bold.

NOTE

- The upper alarm limit of systolic pressure, diastolic pressure, and mean pressure cannot be greater than that of extreme systolic pressure, extreme diastolic pressure, and extreme mean pressure.
- The lower alarm limit of systolic pressure, diastolic pressure, and mean pressure cannot be less than that of extreme systolic pressure, extreme diastolic pressure, and extreme mean pressure.

11

Review

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11.1 Introduction

Trends are patient data collected over time and displayed in a tabular form to give you a picture of how your patient's condition is developing. You can review the trend data in the [List Trends] menu.

11.2 Entering the List Trends Menu

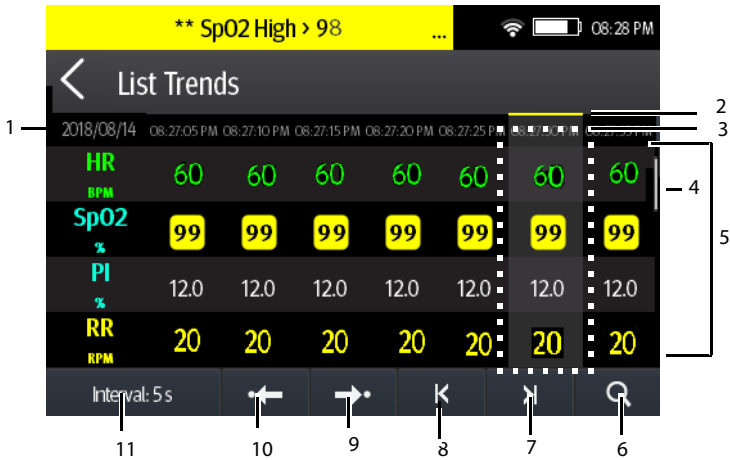
- 1. Press the  key to enter the main menu.
- 2. Tap [Review].
- 3. Tap [List Trends].

11.3 Example List Trends

The latest trend data is displayed in the right most column. HR is always displayed in the first row of the list trends. When you flick your finger up or down the list trends, parameters and their trend data will be automatically moved up or down.

The following figures are for reference only.

■ Example List Trends menu



1. Current system date and trend data time. The interval of the trend data time is dependent on the option selected for **[Interval]**.
2. Event type indicator: different color blocks indicate different types of events:
 - ◆ Red: high priority alarm event
 - ◆ Yellow: medium priority alarm event
 - ◆ Cyan: low priority alarm event
 - ◆ Green: manual event
 - ◆ White: operation-related event
3. Highlighted column: indicates the trend data currently selected.
4. Vertical bar: indicates the position of currently displayed parameters in all the parameters
5. Digital area: displays numeric values at the cursor indicated time. The background color of numeric values indicates the alarm priority.
 - ◆ Red: high priority alarm event
 - ◆ Yellow: medium priority alarm event
 - ◆ Cyan: low priority alarm event
6. Search button: allows searching trend data within the specific time range. For more information regarding the search functionality, refer to **"Searching Trend Data" on page 11 - 5**.
7. Next page button: tapping this button moves to the right-most column of the review page.
8. Previous page button: tapping this button moves to the left-most column of the review page.
9. Next event button: tapping this button locates the next event.
10. Previous event button: tapping this button locates the previous event.
11. Interval setup button: tapping this button goes to the **[Interval]** menu. For more information regarding this menu, refer to **"Changing the Resolution of Trend Data" on page 11 - 4**.

- Example List trends data search screen. This screen is displayed after you tap the  button in the List Trends menu.



1. Slider: indicates the position of current window time in the entire time length. Dragging the slider left or right enables you to locate the trend data at a specific time and also refreshes trend data in current window accordingly.
2. Timeline: indicates the entire time length
 - ◆ : indicates the time length of reviewable trend data.  can be moved within this time length.
 - ◆ : indicates no patient monitoring.  cannot be moved within this time length.
 - ◆ Different color blocks at the timeline indicate events of different types. See the color definition for the event type indicator.

11.4 Changing the Resolution of Trend Data

1. Enter the [List Trends] menu by following steps in **"Entering the List Trends Menu" on page 11 - 2**.
2. Tap [Interval] in the lower left corner of this menu.
3. Tap [Display Interval].
4. Select the desired option.
 - ◆ [5 s] or [30 s]: select to view up to 4 hours of list trends at an interval of 5 seconds or 30 seconds.

- ◆ [1 min], [5 min], [10 min], [15 min], [30 min], [1 h], [2 h], [3 h]: select to view up to 48 hours of list trends at selected interval.

11.5 Searching Trend Data

1. Enter the [List Trends] menu by following steps in ***"Entering the List Trends Menu" on page 11 - 2.***
2. Tap the  button.
3. Drag the  button to locate the trend data at the desired time length.

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12

Monitoring with the TM80/TM70 at the CMS

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12.1 Introduction

The chapter describes detailed configurations and data displayed on the BeneVision CMS once the TM80/TM70 are connected to the CMS.

When the TM80/TM70 is successfully connected to the CMS, the TM80/TM70 provides the following functions.

- The TM80/TM70 can transmit parameter values, waveforms, alarm settings, and events to the CMS. From the CMS, you can check the patient's monitoring data and alarms.
- Patient information, alarm settings, and alarm status can be synchronized between the TM80/TM70 and the CMS.
- If the TM80 is temporarily disconnected from the CMS, it can resend up to data of the last two hours once it is reconnected to the CMS while it can only resend data of the last 10 seconds for TM70 when it's disconnected and then reconnected to the CMS.
- The TM80/TM70's screen is off.

12.2 Safety



CAUTION

- **Wireless network designing, deploying, debugging, and maintenance should be executed by Mindray service personnel or authorized technicians.**
 - **Always set the wireless network according to local wireless regulations.**
 - **Keep network authentication information, for example password, safe, protecting the network from being accessed by unauthorized users.**
 - **Do not connect non-medical devices to the monitor network.**
 - **If wireless network signal is poor, there may be a risk of CMS data loss.**
 - **RF interference may result in wireless network disconnection.**
 - **Disconnecting from the network may result in CMS data loss and function failure. Check the patient in case of network disconnection and solve the network problem as soon as possible.**
 - **Ensure that the monitor IP address setting is correct. Changing the network settings may result in network disconnection. Contact your service personnel if you have any problems on setting the IP address.**
-

12.3 Physiological Alarms

At the CMS, you can view and change the physiological alarm limits and alarm levels in the **[Alarm Setup]** menu. For details on how enter the **[Alarm Setup]** menu, see *BeneVision Central Monitoring System Operator's Manual (P/N 046-007960-00)*.



WARNING

- **Be aware that the devices in your care area may each have different alarm settings to suit different patients. Always check that the alarm settings are appropriate for your patient before you start monitoring.**
- **A potential hazard can exist if different alarm presets are used for the same or similar equipment in any single area, such as an intensive care unit or cardiac operating room.**
- **Make sure that the alarm limits settings are appropriate for your patient before monitoring.**
- **When monitoring patients that are not continuously attended by a clinical operator, properly configure the alarm system and adjust alarm settings as per the patient's condition.**
- **Setting alarm limits to extreme values may cause the alarm system to become ineffective. For example, high oxygen levels may predispose a premature infant to retrolental fibroplasia. If this is a consideration do NOT set the high alarm limit to 100%, which is equivalent to switching the alarm off.**
- **If you switch off all arrhythmia alarms, the CMS cannot give any arrhythmia alarms. Always keep the patient under close surveillance.**

12.4 Factory Default Parameter Alarm Settings

The following table lists the factory default alarm settings for all parameters.

Parameters	Activati on State	Alarm High Limit	Alarm Low Limit	Alarm Priority	Alarm Outputs
HR/PR Unit of mea- sure: bpm Invalid data: "___"	On, Off	For adult: (Low limit + 2) to 300 Default: 120 For pediatric: (Low limit + 2) to 350) Default: 160	For adult: 15 to (high limit - 2) Default: 50 For pediati- ric: 15 to (high limit - 2) Default: 75	High, Med	On, Off
ST Single Unit of mea- sure: mV Invalid data: "___"	On, Off	For adult and pediatric: (Low limit + 0.2) to 2.00 Default: 0.1	For adult and pediati- ric: -2.00 to (high limit – 0.2) Default: -0.1	High, Med , Low	
ST Dual Unit of mea- sure: mV Invalid data: "___"					
QTc Unit of mea- sure: ms Invalid data: "___"		For adult: 200 to 800 Default: 500 For pediatric: 200 to 800 Default: 480	For adult and pediati- ric: None		
ΔQTc* Unit of mea- sure: ms Invalid data: "___"		For adult and pediatric: 30 to 200 Default: 60	For adult and pediati- ric: None		
RR Unit of mea- sure: rpm Invalid data: "___"	On, Off	For adult and pediatric: 10 to 100 Default: 30	For adult and pediati- ric: 0 to 55 Default: 8		

Notes:

Δ QTc is only available for Advanced ECG Algorithm.

The factory default settings are in bold.

Parameters	Activati on State	Alarm High Limit	Alarm Low Limit	Alarm Priority	Alarm Outputs
SpO ₂ Unit of mea- sure: % Invalid data: "___"	On, Off	For adult and pediatric: (Low limit + 2) to 100 Default: 100	For adult and pedi- atric: 0 to (high limit - 2) Default: 90	High, Med	On, Off
SpO ₂ Desat Unit of mea- sure: % Invalid data: "___"		For adult and pediatric: None	For adult and pedi- atric: 0 to 100 Default: 80	High	
NIBP-S Unit of mea- sure: mmHg Invalid data: "___"		For adult: (Low limit + 5) to 270 Default: 160	For adult: 40 to (high limit - 5) Default: 90	High, Med	
NIBP-D Unit of mea- sure: mmHg Invalid data: "___"		For adult: (Low limit + 5) to 210 Default: 90	For adult: 10 to (high limit - 5) Default: 50		
NIBP-M Unit of mea- sure: mmHg Invalid data: "___"		For adult: (Low limit + 5) to 230 Default: 110	For adult: 20 to (high limit - 5) Default: 60		

Notes:

ΔQTc is only available for Advanced ECG Algorithm.

The factory default settings are in bold.

NOTE

- **The SpO₂ Desat alarm limit is restricted such that the alarm limit can not be higher than the SpO₂ low limit.**

12.5 Factory Default Arrhythmia Alarm Settings

Name	Activation State	Alarm Priority	Alarm Outputs
Asystole	On, Off	High	On, Off
V-Fib/V-Tac			
V-Tac			
Vent Brady			
Extreme Tachy			
Extreme Brady			
PVCs/min	On, Off	High, Med , Low, Prompt	
R on T			
Run PVCs		High, Med, Low , Prompt	
Couplet		High, Med, Low, Prompt	
PVC			
Vent Rhythm	On, Off	High, Med , Low, Prompt	
Bigeminy	On, Off		
Trigeminy			
Tachy			
Brady			
Pacer Not Pacing			
Pacer Not Capture		High, Med, Low, Prompt	
<i>Notes</i> The factory default settings are in bold.			

Name	Activation State	Alarm Priority	Alarm Outputs
Missed Beats	On, Off	High, Med, Low, Prompt	On, Off
Multiform PVC		High, Med , Low, Prompt	
Nonsus V-Tac			
Pause		High, Med, Low , Prompt	
A-Fib		High, Med, Low, Prompt	
Irr Rhythm		Low, Prompt	
Pauses/min		High, Med , Low, Message	
<i>Notes</i> The factory default settings are in bold.			

NOTE

- **When Paced is set to Yes, the Missed Beat (MIS) alarm is reported as the Pacer Not Capture (PNC) or Pacer Not Pacing (PNP) alarm.**
- **The priority of lethal arrhythmia alarms is always high. It is unchangeable.**

In addition, the activation state of some arrhythmias can be set as a whole with the following buttons that are at the bottom of the **[Arrhythmia Alarms]** tab.

Button	Description
Lethals Only	Sets the lethal arrhythmia alarms to on and all non-lethal arrhythmia alarms to off.
All On	Sets all arrhythmia alarms to on.
All Off	Sets all arrhythmia alarms to off.

12.6 Arrhythmia Threshold Settings

When an arrhythmia violates its threshold, an alarm is triggered. When HR is less than 30 bpm, it is recommended to set asystole delay to 10 s.

Arrh. event	Range or Option	Default	Step	Unit of measure
PVCs /min	1 to 100	10	1	minute
Pauses/min	1 to 15	8	1	None
Asystole Delay	3 to 10	4	1	second
Tachy(HRHigh)	60 to 300	Adult: 120 Pediatric: 160	5	bpm
Brady(HR Low)	Adult: 15 to 115 Pediatric: 15 to 120	Adult: 50 Pediatric: 75	5	bpm
Extreme Tachy	60 to 300	Adult: 160 Pediatric: 180	5	bpm
Extreme Brady	Adult: 15 to 115 Pediatric: 15 to 120	Adult: 35 Pediatric: 50	5	bpm
Multif PVC Window	3 to 31	15	1	beat
V-Tac Rate	100 to 200	130	5	bpm
V-Tac PVC	3 to 99	6	1	beat
Pause Threshold	1.5, 2, and 2.5	2	0.5	second
V Brady Rate	15 to 60	40	5	bpm
V Brady PVCs	3 to 99	5	1	beat

12.7 ECG Monitoring

At the CMS, you can view and change the ECG settings in the **[ECG]** tab.

To enter the **[ECG]** tab, follow this procedure:

1. Select the ECG digital area or waveform area to enter the **[ECG]** menu on the ViewBed screen of the CMS.
2. Select the **[ECG]** tab.

12.7.1 Changing ECG Alarm Properties

- 1. From the [ECG] tab, select the [Alarm] section.
- 2. Set the desired alarm properties.

For the default alarm properties, See **"Factory Default Parameter Alarm Settings" on page 12 - 3.**

12.7.2 Changing ECG Wave Settings

- 1. From the [ECG] tab, select the [Setup] section.
- 2. Set the desired items.

Options or Buttons	Description	Default Setting
ECG 1	Select the desired ECG lead and set the corresponding gain for ECG 1.	II
ECG 2 (5-lead, 6-lead)		I
Va (For 6-lead only)		Va
Vb (For 6-lead only)		Vb
ECG Gain	Configures the size of each ECG waveform.	x1
Speed	Configures the ECG wave speed.	25 mm/s
Filter	Configures the ECG filter in all operating modes. ■ [Monitor]: use under normal measurement conditions. ■ [ST]: use when the ST monitoring is applied.	Monitor
Notch Filter	Configures whether or not to switch on the notch filter.	On
Lead Set	3-Lead, 5-Lead, 6-Lead	

* The factory default settings are in bold.

12.7.3 Changing Pacer Settings

1. From the **[ECG]** tab, select the **[Pacer]** section.
2. Set the desired items.

Options or Buttons	Description	Default Setting
Paced	The option is not configurable at the CMS. The paced status can be set at the TM80/ TM70 only. See "Checking the Paced Status" on page 7 - 11 for details.	None
Pacer Reject	Configures whether or not to reject the pace pulses. ■ On: the pace pulses are not counted as extra QRS complexes. ■ Off: the pace pulses are not rejected.	Off
	This option is only available when [Paced] is set to [Yes] .	

12.7.4 Adjusting the Minimum QRS Detection Threshold

To avoid false asystole alarms when the R wave amplitude is low and missed asystole alarms during ventricular standstill (tall P waves, but no QRS), a means to manually adjust the minimum QRS detection threshold is provided.

To adjust the QRS detection threshold, follow this procedure:

1. From the **[ECG]** tab, select the **[QRS Threshold]** section.
2. Select the arrow buttons to adjust the QRS threshold. Selecting **[Defaults]** resets the QRS threshold to the default value (0.16 mV).

CAUTION

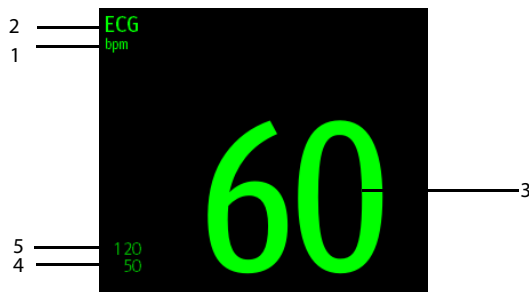
- **The setting of QRS threshold can affect the sensitivity of arrhythmia, ST, QT/QTc detection, and heart rate calculation.**
- **If QRS amplitude is low, the monitor might not be able to calculate heart rate and false asystole may occur.**

12.7.5 ECG Display

ECG Digital Area

The ECG digital area displays:

1. HR unit
2. Parameter label
3. HR value
4. Low HR alarm limit
5. High HR alarm limit



ECG digital area

NOTE

- If an alarm for a parameter is disabled, the  symbol is displayed on the right of this parameter.

ECG Waveform Area

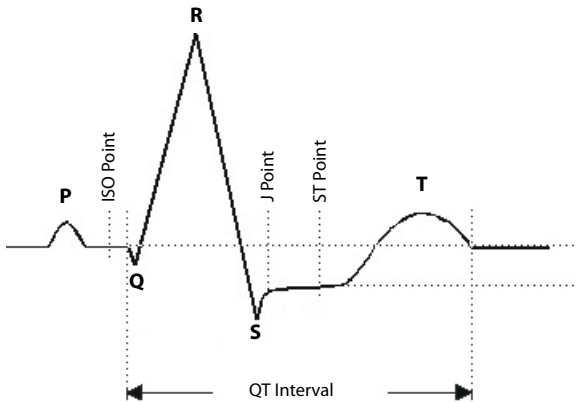
The ECG waveform area displays:

1. ECG Lead
2. ECG waveform size
3. ECG filter setting
4. Notch filter setting
5. ECG waveform
6. ECG scale



12.8 QT Monitoring

A normal ECG waveform (as shown in the following figure) typically includes a sharp and well defined QRS complexes with consistent spacing between R waves, and an ECG baseline that is free of noise and artifact.



A normal ECG waveform (for QT monitoring)

The QT interval in an ECG lead is the time interval from the onset of the earliest deflection in the QRS complex to the end of the T wave. QT monitoring can assist in the detection of prolonged QT interval syndrome.

12.8.1 Measurement Limitations

QT/QTc values are calculated with a 3/5/6-leadwire ECG cables.

12.8.2 Entering the QT Tab

To enter the [QT] tab, follow this procedure:

1. Select the ECG digital area or waveform area to enter the [ECG] menu on the ViewBed screen of the CMS.
2. Select the [QT] tab.

12.8.3 Changing QT Alarm Properties

To set QT alarm properties, follow this procedure:

1. From the [QT] tab, select the [Alarm] section.
2. Set the desired alarm properties.

For the default alarm properties, See **"Factory Default Parameter Alarm Settings" on page 12 - 3**.

12.8.4 Changing QT Settings

To change QT related settings, follow this procedure:

1. From the [QT] tab, select the [Setup] section.
2. Set the desired items.

Options	Description	Default Setting
QT Analysis	Enables or disables QT analysis.	Off
QT View	Select to display the QT View menu.	None
	This button is only available for the advanced ECG algorithm. See "QT View Menu" on page 12 - 13 for details.	
Set Baseline	Configures the baseline to quantify changes in the QTc value.	None

12.8.5 QT View Menu

Select [QT View] at the bottom of the [QT] menu to enter the [QT View] menu.

In the [QT View] menu, you can view a snapshot of the real-time wave and to verify that the QT algorithm detects correct Q and T points.

The [QT View] menu displays, as shown in the following figure:

- The current waveform and parameter values display in green.

- The template waveform and parameter values display in white.
- The Q and T points are marked with a vertical line.
- The ΔQ_{Tc} value is equal to the current Q_{Tc} value minus the template Q_{Tc} value.
- In some conditions, no QT measurement can be calculated. Then the cause of failed QT measurement is shown at the bottom of the QT digital area and the message “Cannot Analyze QT” is shown in the technical alarm area.



QT View menu

Using the buttons described in the following table as desired.

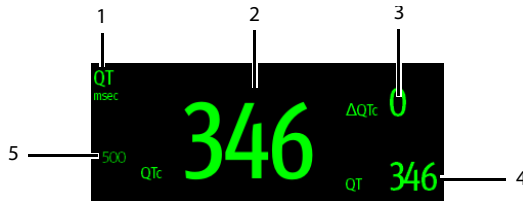
Buttons	Description	Settings*
Left or right arrow	Select the desired lead to display on the [QT View] menu screen by selecting the left or right arrow.	II, I, III, aVR, aVL, aVF, V
Set Baseline	Set an ST baseline when ST values become stable.	None
	The QT template updated time displays at the bottom of the screen.	
Hide Baseline	Hides the reference baseline.	None

* The factory default settings are in bold.

12.8.6 QT Display

When [QT Analysis] is enabled, the QT digital area displays:

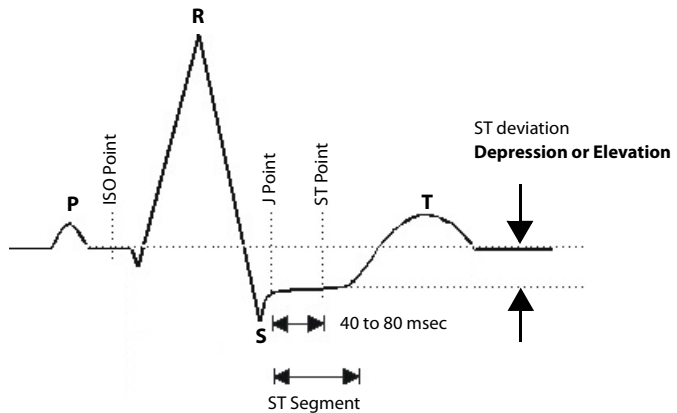
1. Parameter label
2. QTc value
3. Δ QTc value
4. QT value
5. QTc alarm limit (if QTc alarm is off, the alarm off symbol is displayed)



NOTE

- The display of the QT digital area differs as related settings change.

12.9 ST Monitoring



A normal ECG waveform (for ST monitoring)

The ST segment of an ECG waveform (as shown in the above figure) represents the period from the end of ventricular de-polarization, to the beginning of ventricular re-polarization, or the end of the QRS complex (the J point) and the beginning of the T-wave. ST Segment analysis is used to monitor the oxygen supply and the viability of the heart muscle.

ST deviation is the vertical distance between the isoelectric (ISO) point level and signal level at ST point.

The ISO point is located between the end of the P-wave and the onset of the QRS complex. The ISO point provides the baseline for this measurement.

The ST point is a fixed distance from the J point at the end of the QRS complex. The ST point can be configured to 40, 60, or 80 milliseconds past the J-point, independent of the heart rate. By default, the ST point is positioned as follows:

- at 80 milliseconds for heart rates less than or equal to 120 beats per minute
- at 60 milliseconds for heart rates greater than 120 beats per minute

All available ECG leads are analyzed to measure deviations in the ST segment.

Selecting leads that contain the least amount of baseline flutter will improve measurement accuracy, but accurate ST deviation measurement is dependent on the correct location of the ISO and ST points.

- ST segment analysis calculates ST segment elevations and depressions for individual leads and then displays them as numerics in the ST digital area.
- A positive value indicates ST segment elevation; a negative value indicates ST segment depression.



WARNING

- **The ST algorithm has been tested for accuracy of the ST segment data. The significance of the ST segment changes need to be determined by a clinician.**
-
-

12.9.1 Measurement Limitations

- ST values may be affected by such factors as some drugs or metabolic and conduction disturbances.
- Since ST is often calculated with a fixed delay from the J point, changes in heart rate may affect ST.
- The ST algorithm has been tested for accuracy of the ST segment data. The significance of the ST segment changes needs to be determined by a physician.

12.9.2 Entering the ST Tab

1. Select the ECG digital area or waveform area to enter the **[ECG]** menu on the ViewBed screen of the CMS.
2. Select the **[ST]** tab.

12.9.3 Changing ST Alarm Properties

1. From the **[ST]** tab, select the **[Alarm]** section.
2. Set the desired alarm properties.

For the default alarm properties, See **"Factory Default Parameter Alarm Settings" on page 12 - 3.**

12.9.4 Changing ST Settings

1. From the **[ST]** tab, select the **[Setup]** section.
2. Set the desired items.

Options or Buttons	Description	Default Setting
ST Analysis	Enables or disables ST analysis.	Off
ST Segment	Select whether or not to display the ST segments in the waveform area.	Auto
Show Markers	Select whether or not to display the ISO point, J point, and ST point mark do not display on the ST segments.	Off
Define ST Point	Select to display the [Define ST Point] menu.	See "Adjusting ST Measurement Points" on page 12 - 18 for details.
	This button is only available when [ST Analysis] is set to [On] .	

* *The factory default settings are in bold.*

12.9.5 Adjusting ST Measurement Points

The ISO and ST points need to be adjusted when you start monitoring and if the patient's heart rate or ECG morphology changes significantly. Exceptional QRS complexes are not considered for ST-segment analysis.

WARNING

- **Always make sure that the ST measurement points are appropriate for your patient.**
-

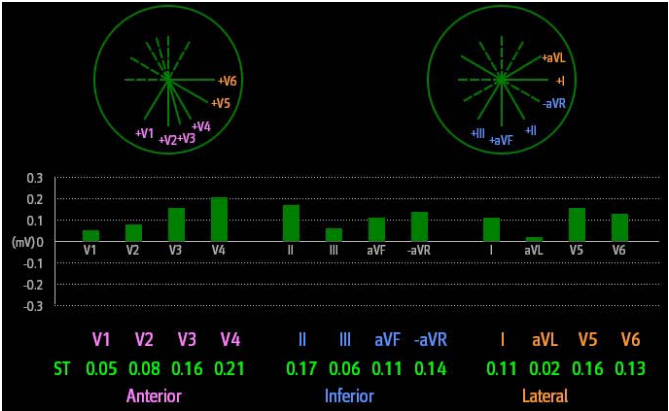
To adjust ST measurement points, follow this procedure.

1. From the **[ST]** tab, select the **[Adjust]** section.
2. Set **[ST Point]**.
3. Enable or disable **[Auto Adjust]**. This option defines the method of adjusting the ISO point and J point.
 - ◆ Enabled: It is enabled by default. In this case, positions of ISO point and J point are automatically adjusted accordingly.
 - ◆ Disabled: you need to manually adjust the position of ISO point and J point by selecting the arrows at the right sides of ISO and J.

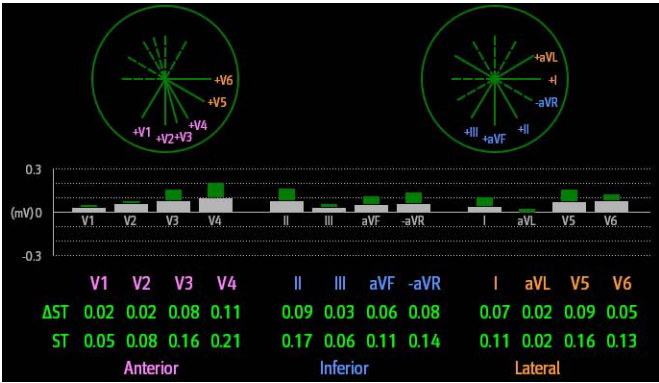
12.9.6 Entering the ST Graphic Window

1. Select the ECG digital area or waveform area to enter the **[ECG]** menu on the ViewBed screen of the CMS.
2. Select the **[ST]** tab to enter the **[ST]** menu.
3. From the bottom of the ST menu, select **[ST Graphic]**.

The height of the bar indicates the ST value of corresponding ST lead. The color of the bar indicates ST alarm status: green indicates that corresponding ST value is within alarm limits; cyan, yellow and red indicate that the ST value exceeds the alarm limits. The color matches ST alarm priority.



The height of grey bar indicates the baseline ST value and the green bar (cyan, yellow or red if an alarm occurs) indicates Δ ST.



12.9.7 Entering the ST View

The ST View shows a complete QRS segment for each ST lead. The color of current ST segments and ST values is consistent with the color of ECG waveforms, normally green. The color of baseline ST segments and ST values is white.

To enter the ST View, follow this procedure:

1. Select the ECG digital area or waveform area to enter the **[ECG]** menu on the ViewBed screen of the CMS.
2. Select the **[ST]** tab to enter the **[ST]** menu.
3. From the bottom of the menu, select **[ST View]**.

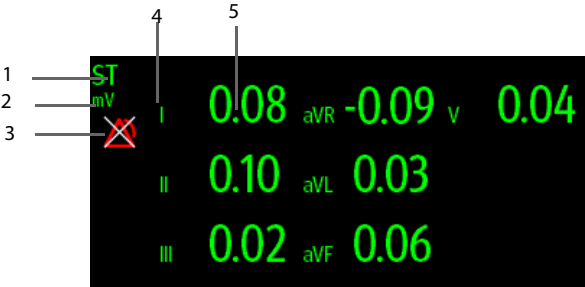
4. Set the desired items.

Buttons	Description	Settings*
Set Baseline	Set an ST baseline when ST values become stable.	None
	The QT template updated time displays at the bottom of the screen.	
Display/Hide Baseline	Displays or hides the reference baseline.	None
Display/Hide Marker	Displays or hides the position of ISO point, J point and ST point.	

12.9.8 ST Display

When [ST Analysis] is enabled, the ST digital area displays:

- 1. Parameter label
- 2. ST unit
- 3. ST alarm off symbol
- 4. Lead labels
- 5. ST numerics: a positive value indicates ST segment elevation, and a negative value indicates ST segment depression.



Example 5-lead ST digital area

12.9.9 ST Segment Display

The ST segments display in the waveform area:

- 1. Lead labels
- 2. ST markers (ISO, J/ST)
- 3. Current ST value

4. Baseline ST value
5. ST unit



5-lead ST segments

12.10 Arrhythmia Monitoring

12.10.1 Entering the Arrhythmia Tab

To enter the **[Arrhythmia]** tab, follow this procedure:

1. Select the ECG digital area or waveform area to enter the **[ECG]** menu on the ViewBed screen of the CMS.
2. Select the **[Arrhythmia]** tab.

12.10.2 Measurement Limitations

- Since the arrhythmia detection algorithm sensitivity and specificity is less than 100%, sometimes there may be some false arrhythmias detected and also some true arrhythmia events may not be detected. This is especially true when the signal is noisy.
- The ECG size and QRS width settings affect arrhythmia detection and heart rate calculation sensitivity.
- If QRS amplitude is low, the monitor might not be able to calculate HR and false asystole may occur.
- At the algorithm learning phase, arrhythmia detection may not be available. Therefore, closely monitor the patient's condition during the learning phase after the learning phase to allow the algorithm to reach optimal detection performance.

12.10.3 Understanding the Arrhythmia Events

For description about arrhythmia events, see *"Arrhythmia Events" on page 7 - 25*.

12.10.4 Setting Arrhythmia Alarm Properties

1. From the [Arrhythmia] tab, select the [Alarm] section.
2. Set the desired alarm properties.

For the default alarm properties, See *"Factory Default Parameter Alarm Settings" on page 12 - 3*.

12.10.5 Changing Arrhythmia Alarm Threshold Settings

You can change threshold settings for some arrhythmia alarms. When an arrhythmia violates its threshold, an alarm will be triggered. To do so, follow this procedure:

To change arrhythmia settings, follow this procedure:

1. From the [Arrhythmia] tab, select the [Threshold] section.
2. Set the desired items.

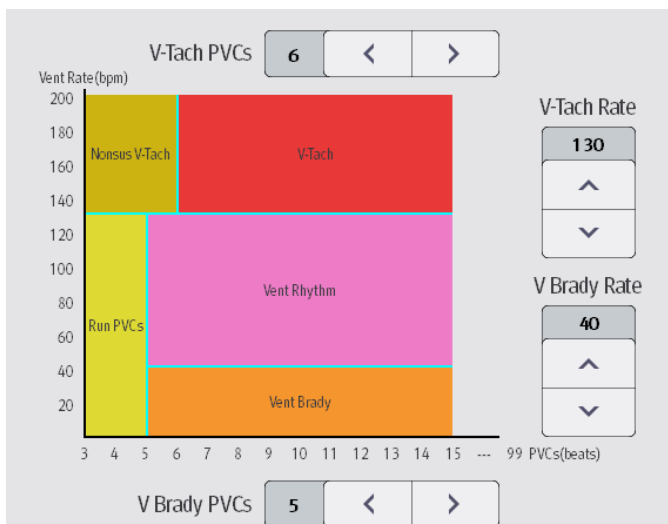
12.10.6 Setting PVC-Related Alarms Threshold

PVC-related alarms are detected on the basis of the current ventricular heart rate and the number of consecutive PVCs.

To set the threshold of PVC-related alarm threshold, follow this procedure:

1. From the [Arrhythmia] tab, select the [More Threshold] section.
2. Set the desired items using the right or left arrow.

The following figure illustrates the conditions under which PVC alarms will be generated if [V-Tach PVCs] is set to 6, [V-Tach Rate] is set to 130, [V Brady PVCs] is set to 5, and [V Brady Rate] is set to 40.



If both V-Tach PVCs and V-Tach Rate are greater than or equal to the limits, a V-Tach alarm is generated.

- If consecutive PVCs is lower than the V-Tach PVCs limit (6) but greater than 2, and the Vent rate is greater or equal to the V-Tach Rate limit (130), a Nonsus V-Tach alarm is generated.
- If consecutive PVCs is greater than or equal to the V Brady PVCs limit (5), and the Vent rate is lower than the V Brady limit (40), a Vent Brady alarm is generated.
- If both the V Brady PVCs and V Brady Rate are lower than the limits, but V Brady PVCs is greater than 2, a Run PVCs alarm is generated.
- If the V Brady PVCs and V Brady Rate are greater than or equal to limits, but the Vent rate is lower than V-Tach Rate (130), a Vent Rhythm alarm is generated.

12.10.7 Configuring the Arrhythmia Shield Time

To set arrhythmia shield time, follow this procedure:

1. Select the system menu area  in the upper left corner of the screen and then select **[System Setup]** to access the **[System Setup]** menu.
2. Select the **[Telemetry]** tab.
3. Select the **[Alarm]** Tab.
4. Set **[Arrhy Shield Time]**. When it is set to **[0]**, it indicates that the alarm shield function is disabled.

12.10.8 Arrhythmia Display

When **[Arrhythmia]** is selected to display in the **[Tile Layout]**, the arrhythmia digital area displays:

1. Parameter label
2. Measurement unit
3. Arrhythmia alarm off symbol
4. PVCs per minute label
5. Pauses per minute label
6. PVCs per minute value
7. Pauses per minute value



12.10.9 Relearning

For details about relearning, see **"Relearning" on page 7 - 34**.

12.11 Resp Monitoring

At the CMS, you can view and change Resp settings in the **[Resp]** menu.

Select the Resp digital area or waveform area on the ViewBed screen of the CMS to enter the **[Resp]** menu.

12.11.1 Changing Resp Alarm Properties

1. In the **[Resp]** menu, select the **[Alarm]** tab and **[PR Alarm]** tab respectively.
2. Set the desired alarm properties.

For the default alarm properties, See **"Factory Default Parameter Alarm Settings" on page 12 - 3**.

12.11.2 Changing Resp Settings

1. In the **[Resp]** menu, select the **[Setup]** tab.
2. Set the desired items.

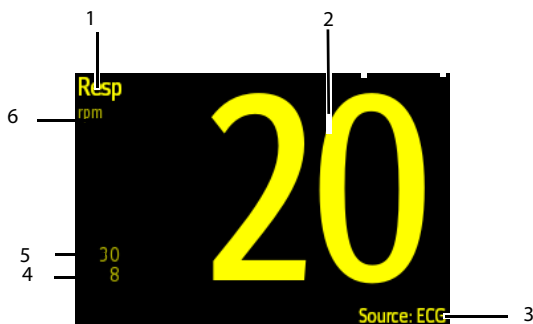
Options	Description	Default Setting
Gain	Configures the Resp waveform size.	x2
Speed	Configures the Resp wave speed.	6.25mm/s

12.11.3 Resp Display

Resp Digital Area

The Resp digital area displays:

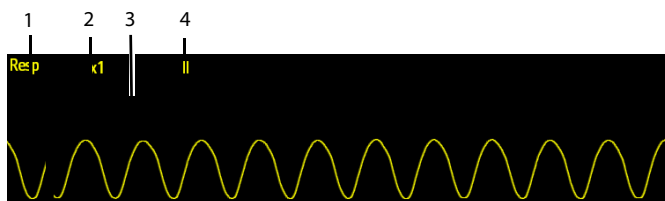
1. Parameter label
2. RR value
3. RR source
4. Low RR alarm limit
5. High RR alarm limit
6. RR unit



Resp Waveform Area

The Resp waveform area displays:

1. Parameter label
2. Resp size
3. Resp waveform
4. Resp lead



12.12 SpO₂ Monitoring

At the CMS, you can view and change the SpO₂ settings in the [SpO₂] menu.

Select the SpO₂ digital area or waveform area on the ViewBed screen of the CMS to enter the [SpO₂] menu.

12.12.1 Measurement Limitations

See "*Measurement Limitations*" on *page 8 - 2* for details.

12.12.2 Changing SpO₂ Alarm Properties

To change ECG alarm properties, follow this procedure:

1. In the [SpO₂] menu, select the [Alarm] tab and [PR Alarm] tab respectively.
2. Set the desired alarm properties.

For the default alarm properties, See *"Factory Default Parameter Alarm Settings" on page 12 - 3*.

12.12.3 Changing SpO₂ Settings

1. In the [SpO₂] menu, select the [SpO₂ Setup] tab.
2. Set the desired items.

Options	Description	Settings*
Sensitivity (Masimo only)	The option is not configurable. The option setting is synchronous with the setting at the TM80/TM70. See <i>"Configuring the SpO₂ Setup" on page 8 - 6</i> .	None
Display PI		
Speed	Configures the Pleth wave speed.	25 mm/s
Averaging (Masimo only)	The option is not configurable. The option setting is synchronous with the setting at the TM80/TM70. See <i>"Configuring the SpO₂ Setup" on page 8 - 6</i> for details.	

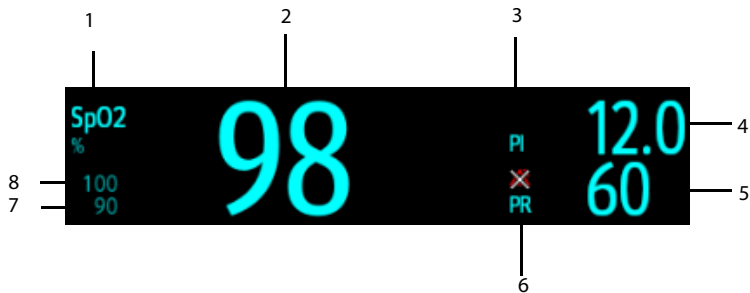
12.12.4 SpO₂ Display

SpO₂ Digital Area

The SpO₂ digital area displays:

1. Parameter name
2. High SpO₂ alarm limit
3. PR label
4. PR value
5. High PR alarm limit
6. SpO₂ unit of measure
7. Low PR alarm limit
8. Masimo perfusion index value
9. PI label

- 10. Low SpO₂ alarm limit
- 11. SpO₂ value



Masimo SpO₂ digital area



Nonin SpO₂ digital area

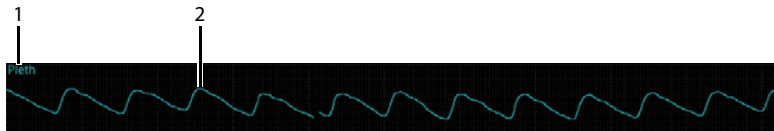


Nellcor SpO₂ digital area

12.12.5 SpO₂ Waveform Area

The SpO₂ waveform area displays:

- 1. Parameter label
- 2. Pleth waveform



SpO₂ waveform area

12.13 NIBP Monitoring

At the CMS, you can view and change NIBP settings in the **[NIBP]** menu.

Select the NIBP digital area on the ViewBed screen of the CMS to enter the **[NIBP]** menu.

12.13.1 Measurement Limitations

See **BP10 NIBP Module Operator's Manual (P/N 046-011008-00)** for details.

12.13.2 Changing NIBP Alarm Properties

1. In the **[NIBP]** menu, select the **[Alarm]** tab.
2. Set the desired alarm properties.

For the default alarm properties, See **"Factory Default Parameter Alarm Settings" on page 12 - 3.**

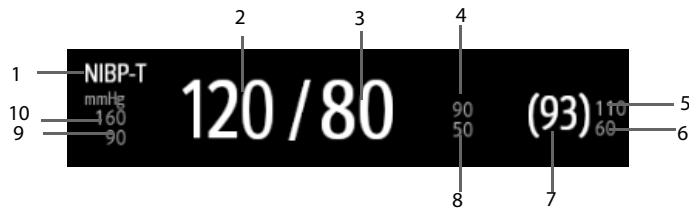
12.13.3 Changing NIBP Settings

1. In the **[NIBP]** menu, select the **[Setup]** tab.
2. Set **[Interval]**.

12.13.4 NIBP Display

The NIBP area displays numerics, as shown below:

1. Parameter label
2. Systolic pressure
3. Diastolic pressure
4. Diastolic pressure high limit
5. Mean pressure high limit
6. Mean pressure low limit
7. Mean pressure obtained after the measurement and cuff pressure obtained during the measurement
8. Diastolic pressure low limit
9. Systolic pressure low limit
10. Systolic pressure high limit



12.13.5 NIBP List

When[NIBP List] is selected to display in the [Tile Layout], the NIBP list area displays multiple sets of most recent NIBP measurements. The displayed PR is derived from NIBP.

NIBP List				PR	Time
mmHg	117/79	(87)	)	79	18:15
	115/80	(87)	)	79	18:00
	115/80	(87)	)	79	17:44

NOTE

- NIBP List cannot be displayed on some screens such as the big numerics screen.

12.14 Locating the TM80/TM70

If the AP information of the TM80/TM70 has been imported into the CentralStation, you can view device location information for wireless devices. For details on how to import AP information, see *BeneVision Central Monitoring System Operator’s Manual*.

To view device location, follow this procedure:

1. Select the  symbol at the top of the ViewBed screen. The [Device Location] menu is displayed.
2. View the AP switch time in the Time column and the current location of devices in the [Location] column.

If you wish to locate a TM80/TM70 telemetry device, select the [Find Device] button. The TM80/TM70 will generate a continuous audible tone until it is acknowledged at the TM80/TM70.

NOTE

- **Find Device requires that the TM80/TM70 has sufficient battery power and is within the coverage area.**
-

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13

Configuring the TM80/TM70

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Maintenance Menu	13-2

13.1 Introduction

The **[Maintenance]** menu provides access to the system settings such as location, device name, alarm settings, quick keys, screen lock, and password updates. Entering this menu **requires** a passcode.

13.2 Maintenance Menu

The **[Maintenance]** menu contains the following submenus:

- General
- Alarms
- Quick Keys
- Network
- Defaults
- Screen Lock
- Edit Passwords
- Device Name
- Demo Mode
- CMS Disconnect Alarm
- Service

13.2.1 Entering the Maintenance menu

1. In the main menu, tap **[Maintenance]**.
2. Input the maintenance passcode.
3. Tap **[Accept]** to enter the **[Maintenance]** menu.

13.2.2 Configuring the General Menu

Select **[General]** to configure the display auto off, language, location, notch filter, ECG lead labeling, SpO₂ module, SpO₂ tone, and enable or disable ECG calibration.

1. In the **[Maintenance]** menu, tap **[General]**.
The current setting displays to the right of the option.
2. Select the options described in the following table.

Options	Description	Settings*
Display Auto Off	Configures the time for display auto off.	1 min , 2 min, 5 min, 15 min 30 min, Off
Language	Configures the system language.	ENGLISH , FRENCH
Device Location	Changes the hospital ,department name, room number, and bed number. Refer to "Configuring Device Location" on page 13 - 4 for details.	N/A
Notch Filter	Configures the ECG Notch filter. This option is used to filter out AC line noise from the ECG waveform.	50 Hz, 60 Hz , Off The default is 50 Hz when the monitor is not configured for the US.
ECG Lead Labeling	Changes the ECG lead labeling.	AHA , IEC
Calibrate ECG	Enables or disables the ECG verification.	On, Off Refer to "Verifying the ECG" on page 17 - 5 for details.
SpO ₂ Module	Changes the SpO ₂ module.	Masimo SpO ₂ , Nonin SpO ₂ , Nellcor SpO ₂
SpO ₂ Tone	Configures the SpO ₂ tone.	Mode 1 , Mode 2
Set Time/Date	Set time and date for the TM80/TM70.	Date & Time: 12Hr, 24 Hr Date Format: DD/MM/YY, YY/MM/DD , MM/DD/YY
Resp	This option is available only when the Resp functionality is supported. When it is supported and [Resp] is enabled, Resp numeric and waveform are displayed on the screen.	On, Off

* The factory default settings are in bold.

3. Tap  to exit the **[General]** menu.

NOTE

- **Mindray recommends the same SpO₂ tone mode be used for the device within a monitoring area.**

13.2.2.1 Configuring Device Location

You can change the hospital name and set whether to allow modifying a department name, room number, and bed number in the **[Patient Info]** menu. To do so, follow this procedure:

1. In the **[Maintenance]** menu, tap **[General]**.
2. Tap **[Device Location]**.
3. Tap **[Facility]**.
4. Enter the desired name.
5. Tap **[Department]**.
6. Select the desired option.
 - ◆ **[Fixed]**: you cannot modify **[Department]** in the **[Patient Info]** menu. **[Department]** is the one entered in the **[Department]** field of the **[Device Location]** menu.
 - ◆ **[Unfixed]**: you can modify **[Department]** in the **[Patient Info]** menu.
7. Tap **[Bed No./Room No.]**.
8. Select the desired option.
 - ◆ **[Fixed]**: you cannot modify **[Room No.]** and **[Bed No.]** in the **[Patient Info]** menu. **[Room No.]** and **[Bed No.]** are the ones entered in the **[Room No.]** and **[Bed No.]** fields of the **[Device Location]** menu.
 - ◆ **[Unfixed]**: you can modify **[Room No.]** and **[Bed No.]** in the **[Patient Info]** menu.

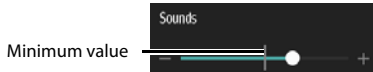
NOTE

- If **[Department]** and **[Bed No./Room No.]** are set to **[Unfixed]**, **Department name, Room No., and Bed No. are cleared each time you discharge a patient.**

13.2.3 Configuring the Alarms Menu

Select **[Alarms]** to configure the alarm tone, reminder tone, reminder interval, minimum alarm volume, and technical alarm priority.

1. In the **[Maintenance]** menu, tap **[Alarms]**.
The current setting displays to the right of the option.
2. Select the options described in the following table.

Section & Options	Description	Settings*
Sounds		
Style	Allows an authorized user to set the alarm tone pattern.	ISO, Mode 1, Mode 2
Minimum Alarm Volume	Allows an authorized user to configure the minimum alarm volume. The minimum alarm volume defines the minimum value you can set for the alarm volume. For example: If the minimum alarm volume is set to [5], the minimum value you can set for the alarm volume in the [Audio Volume] menu is 5 (as shown in the following figure).  If the minimum alarm volume is set to [Off] and the [Sounds] is set to 0, the alarm sound is turned off and the  symbol appears on the screen.	Off, 1, 2, 3, 4, 5, 6, 7, 8, 9, 10
Timeout		
Reminder Tone	Allows an authorized user to enable or disable the reminder tone.	On, Off
Reminder Interval	Allows an authorized user to configure the intervals between the alarm tones.	1 min, 2 min, 3 min, 5 min, 10 min
Technical Alarm Priority		
ECG Lead Off	Allows an authorized user to configure the alarm priority.	Low, Medium, High
SpO ₂ Sensor Off	Allows an authorized user to configure the alarm priority.	Low, Medium, High

* The factory default settings are in bold.

3. Tap  to exit the [Alarms] menu.



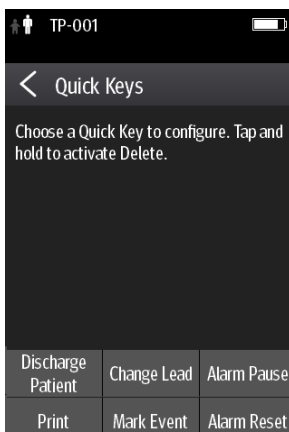
WARNING

- When [Minimum Alarm Volume] is set to [Off] and [Sounds] is set to 0, alarm sound is turned off, the TM80/TM70 will not enunciate alarms when they occur. Be careful when turning off the alarm sound.
 - Do not rely exclusively on the audible alarm system for monitoring. Adjustment of alarm volume to a low level may result in a hazard to the patient. Always keep the patient under close surveillance.
-
-

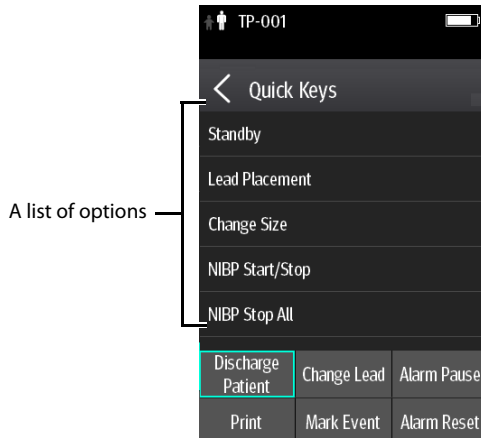
13.2.4 Quick Keys Menu

13.2.4.1 Changing the Quick Keys

1. In the [Maintenance] menu, tap [Quick Keys].
The [Quick Keys] configuration menu displays.



2. From the quick keys area at the bottom of the screen, tap a quick key you want to configure.
A list of option displays.



3. Tap the desired option from the list of options to configure the selected quick key.
4. Repeat steps 2 to 3 to configure other quick keys, if needed.
5. Tap  to exit the **[Quick Keys]** menu.

13.2.4.2 Deleting a Quick Key

1. From the quick keys area at the bottom of the **[Quick Keys]** menu, press and hold the desired quick key for two seconds, and then release it.
The quick key background turns to red and displays **[Delete]**.
2. Tap **[Delete]**.
The quick key is removed from the quick keys area, and the area displays **[Not Used]**.
3. Tap  to exit the **[Quick Keys]** menu.

13.2.5 Configuring the Network Menu

In the **[Network]** menu, you can configure network settings and connect the TM80/TM70 to the BeneVision Central Monitoring System via the wireless network.

1. In the **[Maintenance]** menu, tap **[Network]**.
2. Select the options described in the following table.

Options	Action	Description	Applicable model
IP Address Setup	Select to access the IP Setting menu.	Refer to "Configuring IP Settings" on page 13 - 8 for details.	TM80
WLAN Setup	Select to access the WLAN Setting menu.	Refer to "Configuring WLAN Settings" on page 13 - 9 for details.	TM80
Connect CMS	Select to access the Connect CMS menu.		TM80&TM70
Wireless Setup	Select the desired wireless band.	Refer to "Selecting a WiFi Band" on page 13 - 11 for details.	TM80(for TM70, refer to "Configuring WMTS Setting" on page 13 - 16"
EAP Certificate	Import desired certificates and delete certificates from the TM80.	Refer to "EAP Certificate Management" on page 13 - 12 for details.	TM80

3. Tap  to exit the [Network] menu.

NOTE

- **The design, installation, reconstruction and maintenance of the wireless network's distribution shall be performed by authorized service personnel of Mindray.**
- **The existence of obstacles (such as wall) will exert impact on data transferring or even cause network interruption.**
- **The Central Monitoring System is capable of connecting up to 32 Telemetry Monitors via the wireless network.**

13.2.5.1 Configuring IP Settings

The TM80 provides two ways to get IP address: Dynamic Host Configuration Protocol (DHCP) and Static IP address.

To configure IP settings:

1. In the [Network] menu, tap [IP Address Setup].
2. Select the options described in the following table.

Options	Description	Settings*
DHCP	Allows an authorized user to select the way to get the IP address. When enabled, the IP address is automatically assigned.	On , Off
The following three options are only enabled when [DHCP] is set to Off.		
IP Address	Select to input the IP address.	Range: 1 to 255 Factory default: 192.168.0.100
Subnet Mask	Select to input the subnet mask.	Range: 1 to 255 Factory default: 255.255.255.0
IP Gateway	Select to input the IP gateway address.	Range: 1 to 255 Factory default: 192.168.0.254

* The factory default settings are in bold.

3. Tap **[Confirm]** to apply the settings and exit the **[IP Address Setup]** menu.

13.2.5.2 Configuring WLAN Settings

1. In the **[Network]** menu, tap **[WLAN Setup]**.
2. Select the options described in the following table.

Options	Description	Settings*
Network Name	Select to input the name for the desired wireless network.	N/A
Security Type	Configure the wireless network security type. If [WPA2-PSK] is selected, you need to configure [Network Password] . The [WPA/WPA2 EAP] option is displayed only when [WiFi Band] is set to [5G] . If [WPA/WPA2 EAP] is selected, you need to configure [Network Password] and additional items such as [EAP Method] and [Authentication] . You also need to import the desired certificate into the TM80 before you can select a certificate. For how to manage certificates, refer to "EAP Certificate Management" on page 13 - 12.	WPA2-PSK, WPA/WPA2 EAP

* The factory default settings are in bold.

3. Tap **[Confirm]** to apply the settings and exit the **[WLAN Setup]** menu.

NOTE

- **We recommend that the latest WPA2-PSK security encryption mode be used when the TM80 is in use. It provides a strong method of security when used with rotating strong passwords. Besides, it can provide optimal mobility and connectivity performance.**
 - **WPA/WPA2 EAP may be used but should be carefully considered, because it may TM80 roam more slowly.**
-
-

13.2.5.3 Configuring Connection to the CMS

You can connect a TM80/TM70 to a CMS in unicast or multicast mode.

Connecting a CMS in Multicast Mode

1. In the **[Network]** menu, tap **[Connect CMS]**.
2. Tap **[Connection Mode]**.
3. Select **[Multicast]**.
4. Configure the desired options.

Options	Description	Settings*
Multicast Address	Select to input the multicast address.	Range: 1 to 255 Factory default: 225.0.0.8
Port	It is a public port to communicate with the Central Monitoring System.	6678, grayed and unchangeable
	This option is not configurable.	
Multicast TTL	Select to input the Multicast Time to Live (TTL).	Range: 1 to 255 Factory default: 1
QOS	Configure the quality of service mode for the wireless network.	High , Normal

* *The factory default settings are in bold.*

5. Tap **[Confirm]** to apply the settings and exit the **[Connect CMS]** menu.

Connecting a CMS in Unicast Mode

1. In the **[Network]** menu, tap **[Connect CMS]**.
2. Tap **[Connection Mode]** .
3. Select **[Unicast]**.
4. Configure the desired options.

Options	Description	Settings*
Edit CMS	Configure the name and IP of the CMS you want to connect.	/
Select CMS	Select the CMS you want to connect.	/
QOS	Configure the quality of service mode for the wireless network.	High , Normal

* The factory default settings are in bold.

5. Tap **[Confirm]** to apply the settings and exit the **[Connect CMS]** menu.

13.2.5.4 Selecting a CMS

When you connect a TM80/TM70 to a CMS in unicast mode, you can select a CMS by one of the following ways:

- Select **[Select CMS]** from the **[Connect CMS]** menu. For details, refer to **"Connecting a CMS in Unicast Mode" on page 13 - 10**.
- Press  to enter the main menu → in the **[Central Monitoring System]** section, tap **[Select CMS]** → select the desired CMS.

13.2.5.5 Selecting a WiFi Band

The TM80 supports both 2.4G and 5G WiFi bands.

To select a WiFi band:

1. In the **[Network]** menu, tap **[Wireless Setup]**.
2. Tap **[WiFi Band]**.
3. Select the desired band. 5G is recommended, if available. Because there is much more wireless interference in the 2.4GHz band.

13.2.5.6 EAP Certificate Management

You can import up to 10 certificates from a USB drive or delete certificates from the TM80.

Importing Certificates

1. Insert a USB drive to the USB port of your computer.
2. Create the folder named "Cert" in the USB drive.
3. Copy the desired certificates to the "Cert" folder.
4. Remove the battery for the TM80's battery compartment and find the MicroUSB socket inside the battery compartment.
5. Connect the MicroUSB end of the USB upgrade cable (P/N; 009-00549-00) to the MicroUSB socket. Insert the prepared upgrade USB drive on the USB female connector of the upgrade cable, and connect the USB male connector of the upgrade cable to the USB power adapter.
6. Power on the TM80.
7. Press  to enter the main menu → tap **[Maintenance]** → enter the required password → tap **[Network]** → tap **[EAP Certificate]**.
8. Tap **[USB]** and then select the desired certificate.
9. Tap **[Import]**.

Deleting Certificates

1. Press  to enter the main menu → tap **[Maintenance]** → enter the required password → tap **[Network]** → tap **[EAP Certificate]**.
2. Tap **[Local]**.
3. Select the desired certificate.
4. Tap **[Delete]**.

13.2.6 Configuring the Defaults Menu

The **[Defaults]** menu allows an authorized user to manage the system configurations.

1. In the **[Maintenance]** menu, tap **[Defaults]**.
2. Select the options described in the following table.

Options	Description
Save Departmental Defaults	Allows an authorized user to save the current device settings for the selected patient category.

* The factory default settings are in bold.

Options	Description
Export Device Settings	Copies the current settings to the external device.
Import Device Settings	Copies the settings from the external device to the TM80/TM70 unit. Refer to "Transferring a Configuration" on page 13 - 13 for details.
Restore Factory Defaults	Allows an authorized user to reestablish the original database power up settings to factory default values.

* The factory default settings are in bold.

3. Tap  to exit the **[Defaults]** menu.

13.2.7 Transferring a Configuration

The TM80/TM70 is capable of configuring multiple devices through one export operation via a wireless interface.

To transfer the configuration from the TM80/TM70 to an external device:

1. In the **[Maintenance]** menu of an external device, tap **[Defaults]** → **[Import Device Settings]** to enter the settings import mode.
2. In the **[Maintenance]** menu of the TM80/TM70 unit, tap **[Defaults]** → **[Export Device Settings]** to enter the **[Export Device Settings]** menu.
The discovered external devices are listed in the **[Export Device Settings]** menu.
3. Select the desired external devices by tapping the check box.
4. Tap **[Export]** to start exporting the TM80's configuration.
The selected external devices screen will shortly display the "Downloading device settings" message.



WARNING

- **Do not power off the devices during the download process.**
- **Configurations can only be transferred between telemetry devices of the same model. You cannot transfer configuration from TM80 to TM70, or vice versa.**

- On the external devices if an import is successful, the external device will display the "Download complete." message, and after 10 seconds return to the **[Defaults]**

menu. On the TM80/TM70, the status for the external device will display the “Complete” message.

- On the external device if the import fails, the external device will display the “Import attempt failed.” message. On the TM80/TM70, the status for the failed external device will display the “Failure” message and remain in the list.

The user has two options when a failure occurs:

- ◆ To stop the import from the external device, tap the  icon to exit the [Import Device Settings].
- ◆ To retry the import from the TM80/TM70 tap the external device which is displaying the [Failure] message, tap the [Retry] button to restart the transfer.
You may need to repeat the retry operation several times until the transfer is successful.

13.2.8 Screen Lock Menu

13.2.8.1 Understanding the Screen Lock Mode

There are two modes of being able to lock the screen to assist in preventing unauthorized use. Each mode allows the user access to certain features of the product without entering a passcode. When the correct passcode is entered, all features are available.

- Locked Mode Features:
 - ◆ Main screen and main menu are not accessible without passcode entry.
 - ◆ The message area is still viewable.
 - ◆ Hardkeys are enabled.
- View Only Features:
 - ◆ Upon powering up, the main screen will be displayed after the new patient choice is made.
 - ◆ Main Screen is accessible without passcode entry.
 - ◆ The [System Info] menu is accessible by tapping the battery symbol on the main screen.
 - ◆ The [Lead Placement] menu is accessible by tapping an “ECG Sensor Off” message in the alarm area.
 - ◆ Ability to change display orientation.
 - ◆ Hardkeys are enabled.

13.2.8.2 Setting the Screen Lock

The initial enabling of screen lock mode requires a passcode to be entered immediately as follows:

1. In the **[Maintenance]** menu, tap **[Screen Lock]** to select a screen lock mode.
2. Enter a new passcode for the screen lock.

After the passcode is entered, the screen exits the passcode setup menu. The selected lock mode displays to the right of **[Screen Lock]**.

13.2.8.3 Changing the Current Screen Lock Passcode

1. In the **[Maintenance]** menu, tap **[Screen Lock]**.
2. Tap **[Screen Lock Passcode]**.
3. Input the current password.
4. Input and verify the new password

13.2.9 Changing the Passwords

1. In the **[Maintenance]** menu, tap **[Edit Passwords]**.
 - ◆ Tap **[Maintenance Password]** and follow the on-screen instructions to change the maintenance password.
 - ◆ Tap **[Service Password]** and follow the on-screen instructions to change the service password.
2. Tap the  icon to exit the **[Edit Password]** menu.

13.2.10 Changing the Device Name

1. In the **[Maintenance]** menu, tap **[Device Name]**.
2. Use the on-screen keyboard to input the device name.
3. Tap **[Accept]** to save the setting and exit the **[Device Name]** menu.

NOTE

- **Do not set the same device name for the TM80s.**
-

13.3 Setting CMS Disconnect Alarm

In the **[Maintenance]** menu, you can set whether to enable **[CMS Disconnect Alarm]**. This option is enabled by default.

- When it is enabled, after the TM80/TM70 is disconnected from the CMS:
 - ◆ The TM80/TM70's display is turned on automatically.
 - ◆ The TM80/TM70 issues a low-pitched beep, its alarm light indicator flashes in cyan, and the "No CMS" message is displayed in the prompt message area of the TM80/TM70.
- When it is disabled, after the TM80/TM70 is disconnected from the CMS:
 - ◆ The TM80/TM70's display is not turned on automatically. But you can turn on the display manually.
 - ◆ The TM80/TM70 does not issue a low-pitched beep and its alarm light indicator does not flash. But the "No CMS" message is still displayed in the prompt message area of the TM80/TM70.

WARNING

- **When [CMS Disconnect Alarm] is disabled, the medical staff should pay more attention to the patient's status and check the TM80/TM70's network connection status at the CMS. When the offline alarm is displayed on the CMS, medical staff should check the patient's status immediately.**
-

13.3.1 Demo Mode

Allows an authorized user to choose a demonstration mode for in-servicing staff or testing product features.

13.3.2 Service Menu

Allows an authorized user access to the passcode protected Service menu.

13.4 Configuring WMTS Setting

You can set up AP Code and WMTS AP Band for TM70 in the **[WMTS Setting]** menu. Follow this procedure:

1. In the **[Maintenance]** menu, tap **[Service]**.
2. Input the password and tap **[Accept]**.
3. Tap **[WMTS Setting]** and select the options described in the following table:.

Options	Description	Settings*
AP Code	Select the AP Code of the AP TM70 connects to. AP Code is the unique attribute of an AP.	0 ,1,2,3,4,5,6,7
WMTS AP Band	Select the WMTS AP band TM70 works on.	Auto ,1.4G Wide, 608M, 1.4G Narrow

* *The factory default settings are in bold.*

14 Battery

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14.1 Introduction

The TM80/TM70 can be powered by a lithium-ion rechargeable battery or AA batteries. This chapter provides instructions on how to use, maintain, and dispose of the batteries.

14.2 Safety



WARNING

- **Keep the batteries out of children's reach.**
 - **Keep the batteries in their original package until you are ready to use them.**
 - **Do not install the lithium-ion battery pack or the AA battery frame to close the battery compartment during defibrillation.**
 - **Only use specified AA batteries or rechargeable lithium-ion battery to power the TM80/TM70. Other power supply may cause damage to the equipment or lead to body injury.**
 - **While installing AA batteries, do not apply reverse polarity.**
 - **Only use specified fresh AA batteries. Using other AA batteries can give unacceptable performance.**
 - **Do not mix old and new AA batteries.**
 - **Only use specified rechargeable lithium-ion battery. Unspecified lithium-ion battery can give unacceptable performance.**
 - **Use caution when handling the rechargeable lithium-ion battery. Misuse or abuse may cause bodily injury or device damage.**
 - ◆ **Do not short circuit. Take care that the terminals do not contact metal or other conductive materials during transport and storage.**
 - ◆ **Do not crush, drop or puncture the battery. Mechanical abuse can lead to internal damage and internal short circuits. If a battery has been dropped or banged against a hard surface, whether damage is externally visible or not, remove the battery from use and dispose of it properly.**
 - ◆ **Do not incinerate batteries or expose them to temperatures above 60°C (140°F).**
-
-



WARNING

- The rechargeable lithium-ion batteries should be charged in the specified central charger.
 - If a battery shows signs of damage or signs of leakage, replace it immediately. Use caution in removing the battery. Avoid contact with skin. Refer to qualified service personnel.
 - Some failure conditions, such as short circuits, can cause a battery to overheat during using. High temperature can cause burns to the patient or user. If the device becomes too hot to the touch, remove it from the patient and place aside until it cools. Then remove the battery from the device, and contact your service personnel to identify the cause of overheating.
 - Replace the battery immediately once the “Critically Low Battery” alarm message displays. Replace the battery in time once the “Low Battery” alarm message displays. If those conditions are not corrected, device shutdown and cessation of monitoring will result.
 - To eliminate the risk of electrical shock or burn, do not carry loose batteries on your person, such as placing the battery in clothing pockets.
-
-



CAUTION

- Remove the battery before transporting the device or if the device is not in use or is being stored.
 - AA batteries should be removed from the device at the end of the battery’s useful life to prevent leakage. In case of battery leakage, use caution to remove the batteries and clean the battery compartment. Install fresh AA batteries and check if the TM80/TM70 can power on properly. If the TM80/TM70 fails to power on, contact your service personnel.
-

14.3 Installing the Battery

Refer to *“Installing the Batteries” on page 3 - 5* for details.

14.4 Checking the Battery Charge Status

The battery symbol displaying on the top of main screen indicates the battery charge status. The white part () indicates the remaining battery charge.

NOTE

- If the “Low Battery” or “Critically Low Battery” alarm occurs, the TM80/TM70 turns off the audio, the screen display the “Local Audio Off” message, and the screen brightness turns dimmer.
-

14.5 Removing the Battery



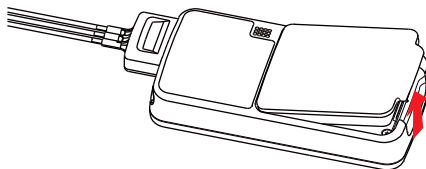
CAUTION

- Some failure conditions, such as short circuits, can cause a battery to overheat during using. High temperature can cause burns to the patient or user. If the device becomes too hot to the touch, remove it from the patient and place aside until it cools. Then remove the battery from the device, and contact your service personnel to identify the cause of overheating.
 - Avoid scraping the metal contactor in the battery compartment while removing the lithium-ion battery pack or AA battery frame. Otherwise, the broken contact will affect the power supply performance.
 - Remove the battery before transporting the device or if the device is not in use or is being stored.
-

NOTE

- Retain the ECG cable and SpO₂ module with the device while removing the battery.
-

1. Lift up the lithium-ion battery pack or AA battery tray at the bottom of the TM80/TM70.



2. Remove the lithium-ion battery pack or AA battery tray from the TM80/TM70.

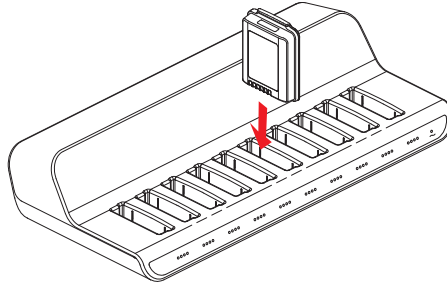
14.6 Charging the Rechargeable Lithium-ion Battery



WARNING

- Only use the specified central charger to charge the lithium-ion batteries designated by Mindray.
- Only use the approved power cord with the grounded mains plug to firmly connect the central charger to a grounded AC mains socket. Never refit the mains plug to fit an ungrounded AC mains socket.
- Do not use the Multiple Portable Socket Outlets (MPSO) or AC mains extension cords. Use an IEC 60601-1 approved isolation / separation transformer, otherwise, it may result in leakage current. Insure that the sum of the individual ground leakage currents does not exceed the allowable limits.
- Do not place any shield object (such as cloth or paper) to cover the central charger or batteries, and keep ventilated while charging the lithium-ion batteries.
- Do not connect other devices to the power supply system.
- Do not use the central charger to charge the lithium-ion batteries in high temperature above 40°C.

Use the central charger to charge the lithium-ion batteries. The central charger can charge 10 lithium-ion batteries at one time. For details about the central charger, refer to the *BeneVision Central Charger Operator's Manual (P/N 046-007059-00)*.



14.7 Storing the Batteries

14.7.1 Storing Rechargeable Lithium-ion Battery

When storing batteries, make sure that the battery terminals do not come into contact with metallic objects.

If you need to store the batteries for an extended period of time, place the batteries in a cool, dry place (ideally at 15°C or 60°F) with a partial charge of about 50% capacity (two LEDs illuminated). Storing batteries in a cool place can slow the aging process.

Stored batteries should be charged to about 50% of their capacity every six months. The battery should be fully charged prior to first use.

NOTE

- **Remove the lithium-ion battery from the device if the device is not used for a prolonged time (for example, several weeks), and keep the device in clean place to avoid the dust or liquid entering the battery compartment.**
- **Storing batteries at high temperatures for an extended period of time will significantly shorten their life expectancy.**
- **Do not store the batteries in an environment above 60°C (122°F) or lower than -20°C (4°F).**

14.7.2 Storing AA Batteries

If you remove undepleted AA batteries from the TM80/TM70 and need to store the batteries, keep the batteries together as a set for later re-use so that all batteries will have the same level of remaining power.

Do not store disposable AA batteries by leaving the batteries in the incorrect polarity position in the TM80/TM70.

NOTE

- **Replace the AA battery frame on the battery compartment after removing the AA batteries.**

14.8 Maintaining the Rechargeable Lithium-ion Battery

Take care of the rechargeable lithium-ion battery once you receive a new battery for use. The following table describes the battery maintenance activities and recommended frequency.

Activity	Recommended Frequency
Visual inspection	Before installing a battery in the TM80/TM70.
Charge the battery	Upon receipt, after use, a “Low Battery” or “Critically Low Battery” alarm occurs. To optimize performance, a fully or almost fully discharged battery must be charged immediately.
Clean the battery	At each patient discharge, or in case that the battery is exposed to contaminants. Do not clean the battery connector during the cleaning.
Charge stored battery to at least 40% of the battery capacity.	Every six months if the TM80/TM70 is not in use for an extended period of time.
Dispose of the battery	When the “Battery Maintenance Required” alarm message displays on the TM80/TM70.

The lifetime of a lithium-ion battery depends on the frequency and duration of use. With good maintenance, the useful life is approximately 500 complete charge-discharge cycles. Experience indicates that the incidence of failure may increase with battery service life due to the accumulated stresses of daily use. Therefore, Mindray strongly recommend that lithium-ion battery should be replaced after two years or 500 complete charge-discharge cycles. Using the outdated battery may cause the device abnormality and unacceptable performance.

The age of a lithium-ion battery begins at the date of manufacture. The date of manufacture is listed on the rear of the battery.

NOTE

- **The battery capacity degrades as using time and number of recharge cycles. Toward the end of its useful life, the battery capacity may be reduced by 20% to 25%. If the reduced battery life is unacceptable for your device, Mindray recommends the battery be replaced.**
-

14.9 Disposing of the Batteries

14.9.1 Disposing of the Rechargeable Lithium-ion Battery

Discard the lithium-ion battery in the following situations:

- The battery has visual signs of damage.
- The battery fails.
- The battery is aged and its runtime significantly less than the specification.
- The battery has been used for more than two years or 500 complete charge-discharge circles.

Discharge the battery and insulate the terminals with tape before disposal. Properly dispose of the batteries according to local regulations.

14.9.2 Disposing of the AA Batteries

The batteries may be subject to local regulations regarding disposal. Dispose of batteries in approved containers. Follow local regulations, if any, to recycle the batteries.

15 Troubleshooting

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15.1 General Problems

The following table lists the problems that are likely to occur. If the problem persists after corrective actions have been taken, contact your service personnel.

Symptom	Possible cause	Solution
ECG Signal Saturated	The TM80/TM70 detected ECG signal saturation or overload.	Check the ECG leadwires. Check if the electrodes are in good contact with the skin.

15.2 Physiological Alarm Messages at the TM80/TM70

The following table lists the major physiological alarm messages displayed in the message area of the TM80/TM70.

Measurement	Alarm message	Alarm level	Possible cause	Solution
ECG	HR Too High	Medium*	HR value has risen above the high alarm limit or fallen below the low alarm limit.	Check the patient's condition and make sure that the patient category and alarm limit settings are correct.
	HR Too Low			

* The asterisk (*) means the alarm level is configurable.

Measurement	Alarm message	Alarm level	Possible cause	Solution		
ECG	Asystole	High	The patient is in arrhythmia.	Check the patient's condition and the ECG connections.		
	V-Fib/V-Tac					
	V-Tac					
	Vent Brady					
	Extreme Tachy					
	Extreme Brady					
	R on T	Med*				
	Run PVCs	Low*				
	Couplet	Message*				
	Multif. PVC	Med*				
	PVC	Message*				
	Bigeminy	Med*				
	Trigeminy					
	Tachy					
	Brady					
	Missed Beat	Message*				
	Nonsus V-Tach	Med*				
	Vent Rhythm					
	Pause	Low*				
	Irr Rhythm	Message*				
	A-Fib					
	PVCs/min	Med*				
	Pauses/min					
	Pacer Not Capture	Message*			The pacer appears abnormal.	Check the pacer.
	Pacer Not Pacing					

* The asterisk (*) means the alarm level is configurable.

Measurement	Alarm message	Alarm level	Possible cause	Solution
Resp	RR Too High	Medium*	RR value has risen above the high alarm limit or fallen below the low alarm limit.	Check the patient's condition and make sure that the patient category and alarm limit settings are correct.
	RR Too Low			
	No Chest Movement	High	The respiration signal was so weak that the monitor cannot perform respiration analysis.	Check the patient's condition, module and patient connections.
	Resp Artifact		The patient's heartbeat has interfered with his respiration.	
SpO ₂	SpO ₂ Too High	Medium*	SpO ₂ value has risen above the high alarm limit or fallen below the low alarm limit.	Check the patient's condition and make sure that the patient category and alarm limit settings are correct.
	SpO ₂ Too Low			
	SpO ₂ Desat	High	The SpO ₂ value has fallen below the desaturation alarm limit.	
	PR Too High	Medium*	PR value has risen above the high alarm limit or fallen below the low alarm limit.	
	PR Too Low			
	No Pulse (for Nonin SpO ₂ module only)	High	The pulse signal was so weak that the monitor cannot perform pulse analysis.	Check the patient's condition, SpO ₂ sensor and measurement site.
NIBP	NIBP-Sys Too High	Medium*	The NIBP systolic pressure has risen above the high alarm limit or fallen below the low alarm limit.	Check the patient's condition and check if the alarm limit settings and patient category are correct.
	NIBP-Sys Too Low			
	NIBP-Mean Too High		The NIBP mean pressure has risen above the high alarm limit or fallen below the low alarm limit.	
	NIBP-Mean Too Low			
	NIBP-Dia Too High		The NIBP diastolic pressure has risen above the high alarm limit or fallen below the low alarm limit.	
	NIBP-Dia Too Low			

* The asterisk (*) means the alarm level is configurable.

Measurement	Alarm message	Alarm level	Possible cause	Solution
NIBP	NIBP-Sys Extremely High	High	The NIBP systolic pressure has risen above the SYS Desat alarm high limit or fallen below the SYS Desat alarm low limit.	Check the patient's condition and check if the alarm limit settings are correct.
	NIBP-Sys Extremely Low			
	NIBP-Mean Extremely High		The NIBP mean pressure has risen above the MAP Desat alarm high limit or fallen below the MAP Desat alarm low limit.	
	NIBP-Mean Extremely Low			
	NIBP-Dia Extremely High		The NIBP diastolic pressure has risen above the DIA Desat alarm high limit or fallen below the DIA Desat alarm low limit.	
	NIBP-Dia Extremely Low			

* The asterisk (*) means the alarm level is configurable.

15.3 Technical Alarm Messages at the TM80/TM70

The following table lists the major technical alarm messages displayed in the message area of the TM80/TM70.

The Alarm Indication column in the table below is capable of three different indication types: A, B, C.

- A: The alarm sound will be silenced, the alarm light will continue to indicate the alarm, a ✓ will appear before the alarm message. The  symbol appears on the top of the main screen.
- B: The technical alarm will be changed to the prompt message, it will not longer make sound or be indicated by the alarm light.
- C: The technical alarms are cleared, there will be no alarm indications.

Measurement	Alarm message	Alarm level	Alarm Indication	Possible cause	Solution
ECG	ECG Lead Off	Low*	B	The electrode has become detached from the patient or the lead wire has become disconnected from the adapter cable.	Check the connections of the electrodes and leadwires.
	ECG XX** Lead Off	Low*	B		
	ECG Module Error	High	A	An error occurred to the ECG module. There is a problem with the communications between the module and the TM80/TM70.	Restart the TM80/TM70. If the problem persists, contact your service personnel.
	ECG Noisy	Low	A	The ECG signal is noisy.	Check for any possible sources of signal noise around the cable and electrode, and check the patient for great motion.
	ECG Cable Type Error	Low	C	Connect wrong ECG leadwire.	Reconnect the 3 or 5 lead ECG leadwire.
	HR Over-range	Low	A	HR exceeds the measurement limit.	Contact Mindray or your service personnel.
	ECG Learning	Message	/	ECG learning is manually or automatically triggered.	/
	Cannot Analyze QT	Message	/	/	/
	Check Leads	Message	/	ECG original sampling exceeds signal saturation threshold.	/

* The asterisk (*) means the alarm level is configurable.

** XX is the ECG lead name.

Measurement	Alarm message	Alarm level	Alarm Indication	Possible cause	Solution
SpO ₂	SpO ₂ Sensor Off	Low*	B	The SpO₂ sensor has become detached from the patient or the module. There is a fault with the SpO₂ sensor. An unspecified SpO₂ sensor has been used.	Check the sensor application site and the sensor type, and make sure the sensor is not damaged.
	SpO ₂ Sensor Fault	Low	C		Reconnect the sensor or use a new sensor.
	SpO ₂ No Sensor	Low	B		
	SpO ₂ Module Error	High	A		
	SpO ₂ Too Much Light	Low	A	There is too much light on the SpO ₂ sensor.	Move the sensor to a place with lower level of ambient light or cover the sensor to minimize the ambient light.
	SpO ₂ No Pulse	Low	A	SpO ₂ sensor failed to obtain pulse signal.	Move the sensor to a site with better perfusion.
	SpO ₂ Unplugged	Low	C	SpO ₂ module connector is disconnected from the TM80/TM70.	Reconnect the SpO ₂ module to the TM80/TM70.
	PR Over-range	Low	A	The measured PR value exceeds the measurement range.	Contact Mindray or your service personnel.
NIBP	MPAN Disconnected	Medium	C	The MAPN is disconnected.	Enable the MPAN switch.
	NIBP Clock Needs To Be Set	Low	C	The button cell does not have sufficient charge.	Reset the system time for the BP10.

* The asterisk (*) means the alarm level is configurable.

** XX is the ECG lead name.

Measurement	Alarm message	Alarm level	Alarm Indication	Possible cause	Solution
NIBP	NIBP Error	High	A	■ An error occurred to the NIBP module. ■ There is a problem with communication between the TM80/TM70 and BP10.	Restart the BP10.
	NIBP Cuff Loose	Low	C	■ The NIBP cuff is not properly connected. ■ There is a leak in the airway.	1. Check the patient's condition and verify patient category. 2. Replace with an appropriate cuff and connect it correctly.
	NIBP Airway Error	Low	C	An airway error occurs.	Check the airway.
	NIBP Weak Signal	Low	C	The patient's pulse is weak or the cuff is loose.	Check the patient's condition and change the cuff application site. If the error persists, replace the cuff.
	NIBP Over-range	Low	C	The measured NIBP value is not within the specified range.	Contact your service personnel.
	NIBP Excessive Motion	Low	C	Patient's arm moves too much.	Check the patient's condition and reduce the patient motion.
	NIBP Cuff Over-pressure	Low	C	The NIBP airway may be occluded.	Check the airway and measure again.

* The asterisk (*) means the alarm level is configurable.

** XX is the ECG lead name.

Measurement	Alarm message	Alarm level	Alarm Indication	Possible cause	Solution
NIBP	NIBP Cuff or Airway Leak	Low	C	The NIBP airway may leak air.	1. Verify that the cuff is properly connected. 2. Verify that the airway does not leak air.
	NIBP Timeout	Low	C	- Time is out. - The measurement time is over 120 seconds.	1. Check the patient's condition and NIBP connections. 2. Replace the cuff.
	NIBP Cuff and Patient Mismatch	Low	C	The cuff type applied mismatches the patient category.	1. Check the patient's category. 2. Replace the cuff.
	Intervals Not Set	Low	C	The interval in Sequence mode is not set.	Set the intervals.
	NIBP-S Over-range	Low	A	The measured NIBP value is not within the measurement range.	Contact your service personnel.
	NIBP-Dia Over-range	Low	A		
	NIBP-M Over-range	Low	A		

* The asterisk (*) means the alarm level is configurable.

** XX is the ECG lead name.

Measurement	Alarm message	Alarm level	Alarm Indication	Possible cause	Solution
Power	Low Battery	Medium	A	The battery charge is low.	Replace with new batteries.
	Critically Low Battery	High	A	The battery charge is almost depleted.	
	Battery Maintenance Required	Medium	A	The lithium-ion battery is aging.	
	Battery Error	Medium	A	The lithium-ion battery communication is error.	
	Battery Type Error	Medium	A	The battery contacts are in bad contact.	
System	Device Error	High	A	The self-test of the main board is error. The self-test of the parameter module or bluetooth module are error. The parameter module communication is error or initialization is error.	Restart the TM80/TM70. If the problem persists, contact your service personnel.
	Real Time Clock Error	High	A	The real time clock initialization is error.	
	Restoring Last Defaults Failed	Low	C	Restoring the last default configuration is error.	
	Loading Defaults Failed	Low	C	Loading the default configuration is error.	

* The asterisk (*) means the alarm level is configurable.

** XX is the ECG lead name.

16

Cleaning and Disinfecting

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16.1 Introduction

Only use the substances approved by Mindray and methods listed in this chapter to clean or disinfect your device. Our warranty does not cover damage caused by unapproved substances or methods.

Mindray makes no claims regarding the efficacy of the listed chemicals or methods as a means for controlling infection. For the method to control infection, consult your hospital's Infection Control Officer or Epidemiologist.

16.2 Safety Information

CAUTION

- **The responsible hospital or institution shall carry out all cleaning and disinfection procedures specified in this chapter.**
 - **Be sure to shut down the TM80/TM70 before cleaning the equipment.**
 - **Non-medical equipment does not provide the same level of protection against electrical shock. Do not touch the patient and any part of nonmedical equipment at the same time. Some examples of non-medical equipment are laser printers and nonmedical computers.**
 - **Avoid use of cleaners, materials or chemicals that may damage equipment surfaces, labels, or cause equipment failures.**
 - **During cleaning and disinfection, using a wrong disinfectant in the wrong disinfection method will damage accessories after cleaning and disinfection, which will result measurement failure.**
 - **Do not pour or spray any liquid directly on the equipment or accessories or permit fluid to seep into connections or openings.**
 - **Keep your equipment and accessories free of dust and dirt. To avoid damage to the equipment, follow these guidelines:**
 - ◆ **Always dilute according to the manufacturer's instructions or use lowest possible concentration.**
 - ◆ **Do not immerse any part of the equipment or accessories into liquid. Do not pour liquid onto the equipment or accessories.**
 - ◆ **Do not allow liquid to enter the case and the equipment interior.**
 - ◆ **Never use abrasive materials (such as steel wool or silver polish), or erosive cleaners (such as acetone or acetone-based cleaners).**
-

CAUTION

- **If liquid has accidentally entered the equipment or its parts, shut down the equipment and have the device serviced by authorized service personnel.**
 - **Remove the equipment from use if liquid is spilled on the equipment or accessories. Contact your service personnel.**
 - **When cleaning, avoid the ECG leadwire connector and other connectors.**
-

16.3 Cleaning the TM80/TM70

CAUTION

- **Only use the following approved cleaning solutions. The equipment may become inoperable or halted because of contamination or damage caused by use of unapproved cleaning solution.**
-

Clean your equipment on a regular basis. Before cleaning the equipment, consult your hospital's regulations for cleaning the equipment.

Recommended cleaning agents are:

- Water
- Mild soap

Before cleaning your device, do as follows:

- Install the lithium-ion battery or AA battery tray into the battery compartment and close the battery compartment door.
 - Insert the SpO₂ cap into the SpO₂ connector when SpO₂ is not in use.
 - Insert the ECG leadwire plug into the ECG connector.
-

WARNING

- **Never allow the cleaning solutions to spill or enter the plug, connector or battery compartment.**
-

To clean your TM80/TM70, follow this procedure:

1. Shut down the equipment.
2. Dilute the mild soap in water to make a cleaning solution.
3. Soak a clean and soft cloth in the solution and wring out excess solution.
4. Thoroughly wipe the display screen and the exterior surface of the equipment with the damp cloth, avoiding the connectors.
5. Wipe off all the cleaning solution with a dry cloth if necessary.
6. Dry your equipment in a ventilated, cool place.

16.4 Cleaning the Reusable ECG Leadwires, SpO₂ Modules and Sensors

- Check reusable sensors and cables daily for signs of damage. Replace as required.
- Clean the SpO₂ sensor before and after each new patient.
- Wipe sensors and cables using a soft cloth with mild soap and water solution.
- Allow the cables and sensors to completely dry before using.

Refer to the cleaning procedure described in the **ECG Cable and Lead Set Instructions for Use** and **SpO₂ Sensor Instructions for Use** to clean the reusable ECG leadwires and SpO₂ sensor.

Follow this procedure to clean the SpO₂ module.

Recommended cleaning agents are:

- Water
 - Mild soap
1. Dilute the mild soap in water to make a cleaning solution.
 2. Soak a clean and soft cloth in the solution to wipe the SpO₂ module cable.
 3. Wipe off all the excess cleaning solution with a dry cloth if necessary.
 4. Dry the SpO₂ module in a ventilated, cool place.



CAUTION

- **Never immerse cables and sensors in any fluids. Do not clean them with harsh chemicals such as acetone or non-diluted bleach.**
-



CAUTION

- **Clean the cables carefully to avoid breaking internal wires by excessive bending, strain, or flexing.**
 - **Do not autoclave, radiation or steam sterilize the cables and sensors.**
 - **Extended exposure to Ethylene Oxide gas may shorten life of the cables, leading to poor signal quality.**
-

NOTE

- **Refer to the individual instruction sheets that are packaged with the accessories for additional information.**
-

16.5 Cleaning the Battery and Battery Compartment

- Clean the exterior surface of the lithium-ion battery and AA battery tray before and after each new patient.
 - Wipe the lithium-ion battery, AA battery tray and the battery compartment using a soft cloth with mild soap and water solution. Use caution to avoid the battery contacts.
 - Wipe off all the cleaning solution with a dry cloth if necessary.
 - Allow the lithium-ion battery, AA battery tray and the battery compartment completely dry before using.
-

CAUTION

- **Never immerse the lithium-ion battery, AA battery tray and AA batteries in any fluids. Do not clean them with harsh chemicals such as acetone or diluted bleach.**
 - **As the battery compartment is not water proof, do not contact the battery contacts when cleaning the battery compartment.**
 - **Do not hook the battery contacts in the battery compartment with other objects. Otherwise, the battery contacts may be distorted.**
 - **Keep the battery compartment free away from any foreign objects.**
-

16.6 Disinfection

Disinfect the TM80/TM70 and accessories as required in your hospital's servicing schedule. Cleaning before disinfection is recommended.

Refer to the instructions for use delivered with the accessory to disinfect reusable ECG leadwires and SpO₂ sensors.

The following table lists recommended disinfectants for disinfecting the TM80/TM70.

Product Name	Product Type	Active Ingredients
Isopropanol*	Liquid	Isopropanol 70%
1-Propanol*		1-Propanol 50%
CIDEX® OPA Solution		Ortho-Phthalaldehyde 0.55%
Metrex CaviCide ¹ ™		Diisobutylphenoxyethoxyethyl dimethyl benzyl ammonium chloride 0.28%, Isopropanol 17.2%
Virex® II 256		Didecyl dimethyl ammonium chloride 8.704%, n-Alkydimethyl benzyl ammonium chloride 8.190%
Virex® TB		n-Alkyl dimethyl benzyl ammonium chlorides 0.105%, n-Alkyl dimethyl ethylbenzyl ammonium chlorides 0.105%
*Ethanol, 70%		/
Hydrogen peroxide, 3%		/
Sodium hypochloride (bleach) solution, 10%		/
Isopropyl alcohol, 70%		/
50% propyl alcohol (1-propyl alcohol)		/
Super Sani-cloth		0.5% Quaternary ammonium chloride and 55% Isopropyl alcohol
Rely+On™ Virkon® Powder * (Used as 1% solution)	Powder	Used as 1% solution Biocidal active: Pentapotassium bis (peroxymonosulphate) bis (sulphate)(500g/kg), Contains dipotassium peroxodisulphate.

Product Name	Product Type	Active Ingredients
Alpet® D2 Surface Sanitizing Wipes	Wipes	Isopropyl Alcohol 58.6000%? Octyl Decyl Dimethyl Ammonium chloride 0.0075%, Dioctyl Dimethyl Ammonium Chloride 0.0030%
Clorox Dispatch® Hospital Cleaner Disinfectant Towels with Bleach		Sodium Hypochlorite 0.65%
Clorox Healthcare® Bleach Germicidal Wipes		Sodium Hypochlorite 0.55%
Clorox Healthcare® Hydrogen Peroxide Cleaner Disinfectant Wipes		Hydrogen Peroxide 1.4%
Diversey Oxivir® TB Wipes		Hydrogen Peroxide 0.5%
Metrex CaviWipes™		Diisobutylphenoxyethoxyethyl dimethyl benzyl ammonium chloride 0.28%, Isopropanol 17.2%
PDI Sani-Cloth® AF3 Germicidal Disposable Wipe		n-Alkyl dimethyl ethylbenzyl ammonium chlorides 0.14%, n-Alkyl dimethyl benzyl ammonium chlorides 0.14%
PDI Sani-Cloth® Bleach Germicidal Disposable Wipe		Sodium Hypochlorite 0.63%,other ingredients 99.37%
PDI Sani-Cloth® HB Germicidal Disposable Wipe		n-Alkyl dimethyl ethylbenzyl ammonium chlorides 0.07%, n-Alkyl dimethyl benzyl ammonium chlorides 0.07%
PDI Sani-Cloth® Plus Germicidal Disposable Cloth		n-Alkyl dimethyl ethylbenzyl ammonium chlorides 0.125%, n-Alky dimethyl benzyl ammonium chlorides 0.125%
PDI Super Sani-Cloth® Germicidal Disposable Wipe *		n-Alkyl dimethyl ethylbenzyl ammonium chlorides 0.25%, n-Alkyl dimethyl benzyl ammonium chlorides 0.25%, Isopropyl Alcohol 55.0%,
VIRAGUARD Hospital Surface Disinfectants		Isopropanol 70%,Other ingredients 30%

16.7 Sterilization

Sterilization is not recommended for this equipment, related products, accessories or supplies unless otherwise indicated in the Operating Instructions that accompany the accessories or supplies.

17 Maintenance

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17.1 Introduction

The chapter outlines the routine maintenance guidelines.

The TM80/TM70 is designed for stable operation over long periods of time. Under normal circumstances, the devices should not require technical maintenance beyond that described in this chapter. However, routine maintenance, calibration and safety checks are recommended at least once a year or more often as required by local statutory or hospital administration practice.

17.2 Safety



WARNING

- **Failure on the part of the responsible individual hospital employing the use of this equipment to implement a satisfactory maintenance schedule may cause undue equipment failure and possible health hazards.**
 - **The safety checks or maintenance involving any disassembly of the equipment should be performed by service personnel. Otherwise, undue equipment failure and possible health hazards could result.**
 - **No modification of this equipment is allowed.**
 - **Do not open the equipment housings. All servicing and future upgrades must be carried out by the service personnel.**
 - **All replaced components and accessories as well as consumables are provided or qualified by Mindray.**
 - **If you discover a problem with any of the equipment, contact your service personnel or Mindray.**
 - **The service personnel must be properly qualified and thoroughly familiar with the equipment operation.**
-

17.3 Regular Check

Perform a visual inspection before the equipment is first used every day. Verify that the equipment meets the following requirements:

- The housing and display screen are free from cracks or other damages.
- All keys function properly.
- Connectors are not loose, cracked, or bent and cables have no cuts, nicks, or fraying.
- ECG leadwires are securely connected with the equipment
- Battery pack is installed and has sufficient charge.
- Chest electrodes are free from cracks and limb electrodes can properly clamp.

After your equipment has been used for 6 to 12 months, or whenever your equipment is repaired or upgraded, a thorough inspection should be performed by qualified service personnel to ensure the reliability.

Follow these guidelines when inspecting the devices:

- Make sure that the environment and power supply meet the requirements.
- Inspect the devices and their accessories for mechanical damage.
- Inspect all plugs, connectors, leadwires for damage, and make sure that their insulation is in good condition.
- Make sure that only specified accessories are applied.
- Make sure that the alarm system functions correctly.
- Make sure that the battery meet the performance requirements.
- Make sure that the devices are in good working condition.

In case of any damage or abnormality, do not use the devices. Contact the hospital's bio-medical engineers or your service personnel immediately.

17.3.1 Power-on Test

The TM80/TM70 performs a self-test during startup. You can refer to **"Powering On the Unit" on page 3 - 8** for details.

17.3.2 Battery Check

For details about the battery charge check and maintenance, refer to **"Maintaining the Rechargeable Lithium-ion Battery" on page 14 - 7**.

17.4 Maintenance and Testing Schedule

The following maintenance and tests, except for visual inspection, power on test, and battery check, shall be carried out by the service personnel only. Contact your service personnel if any maintenance is required. Make sure to clean and disinfect the equipment before any test and maintenance.

Check/Maintenance Item		Recommended Frequency
Visual inspection		When first installed or reinstalled.
ECG test and verification	Performance test	1. If the user suspects that the measurement is incorrect. 2. Following any repairs or replacement of relevant module. 3. Once every two years. Note: NIBP test should be performed at least twice a year.
	Verification	
SpO ₂ test		
Resp test	Performance test	
NIBP test	Pressure check	
	Leakage test	
Nurse call test		If the user suspects that the nurse call functionality does not work properly.
Power on test		1. When first installed or reinstalled. 2. Following any maintenance or the replacement of any main unit parts.
Battery check	Functionality test	1. When first installed. 2. Whenever the battery is replaced.
	Performance test	When the battery run time reduced significantly.

17.5 Checking the System Information

To view the information about the device, radio frequency (RF), battery, MPAN, and system statistics, Press the  key to enter the main menu and then select **[System Info]**.

17.6 Verifying the ECG

The ECG signal may be inaccurate due to hardware or software problems. As a result, the ECG wave amplitude becomes greater or smaller.

To verify the ECG waveform amplitude:

1. In the main menu, tap **[Maintenance]**.
2. Input the maintenance passcode.
3. Tap **[Accept]**.
4. In the **[Maintenance]** menu, tap **[General]**.
5. Enable **[Calibrate ECG]**.
A square wave appears on the screen and the message **[ECG Calibrating]** is displayed.
6. Compare the amplitude of the square wave with the wave scale. The difference should be within 5%.
7. After completing the verification, disable **[Calibrate ECG]**.

17.6.1 NIBP Accuracy Test

The NIBP accuracy test is required at least twice a year or when you doubt the measured NIBP result. Contact your service personnel to perform NIBP accuracy test.

17.6.2 NIBP Leakage Test

The NIBP leakage test checks the integrity of the system and of the valve. It is required at least twice a year or when you doubt the measured NIBP result. Contact your service personnel to perform NIBP leakage test.

17.6.3 Nurse Call Test

The nurse call test checks whether this functionality can work properly. Contact your service personnel to perform the nurse call test.

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18

Accessories

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The accessories listed in this chapter comply with the requirements of IEC 60601-1-2 when in use with the device. The accessory material that contacts the patients has undertaken the bio-compatibility test and is verified to be in compliance with ISO 10993-1. For details about the accessories, refer to the instructions for use provided with the accessory.



WARNING

- **Use accessories specified in this chapter. Using other accessories may cause damage to the TM80/TM70 or not meet the claimed specifications.**
- **Single-use accessories are not designed to be reused. Reuse may cause a risk of contamination and affect the measurement accuracy.**
- **Check the accessories and their packages for any sign of damage. Do not use them if any damage is detected.**
- **Use the accessories before the expiry date if indicated.**
- **The disposable accessories shall be disposed of according to the hospital's regulations.**

18.1 ECG Accessories

18.1.1 ECG Electrodes

PN	Description	Applicable property	Applicable patient
0010-10-12304	Adult Electrode (Kendall, package of 10)	Disposable	Adult
9000-10-07469	Pediatric ECG electrode (3M, package of 50)	Disposable	Pediatric

18.1.2 ECG Leadsets

3-Lead

PN	Description	Applicable property	Applicable patient
009-004765-00	3-Lead, New Telemetry, AHA, Snap, 24"	Reusable	Adult, Pediatric
009-004766-00	3-Lead, New Telemetry, AHA, Snap, 36"		
009-004771-00	3-Lead, New Telemetry, AHA, Pinch, 24"		
009-004772-00	3-Lead, New Telemetry, AHA, Pinch, 36"		
009-004777-00	3-Lead, New Telemetry, Disp, AHA, Snap, 24"	Disposable	

5-Lead

PN	Description	Applicable property	Applicable patient
009-004782-00	5-Lead, New Telemetry, AHA, Snap, 24"	Reusable	Adult, Pediatric
009-004783-00	5-Lead, New Telemetry, AHA, Snap, 36"		
009-004786-00	5-Lead, New Telemetry, AHA, Pinch, 24"		
009-004787-00	5-Lead, New Telemetry, AHA, Pinch, 36"		
009-004790-00	5-Lead, New Telemetry, AHA, Snap, 24"	Disposable	

6-Lead

PN	Description	Applicable property	Applicable patient
009-004794-00	6-Lead, New Telemetry, AHA, Snap, 24"	Reusable	Adult, Pediatric
009-004795-00	6-Lead, New Telemetry, AHA, Snap, 36"		
009-004798-00	6-Lead, New Telemetry, AHA, Pinch, 24"		
009-004799-00	6-Lead, New Telemetry, AHA, Pinch, 36"		

18.2 SpO₂ Accessories

The SpO₂ sensor material that contacts patients or other staff has undertaken the bio-compatibility test and is verified to be in compliance with ISO 10993-1.

18.2.1 Masimo SpO₂ Module

PN	Description	Applicable property	Applicable patient
009-004936-00	Masimo SpO ₂ module (SET uSpO ₂)	Reusable	Adult, Pediatric

18.2.2 Masimo SpO₂ Sensor

PN	Description	Applicable property	Applicable patient
0600-00-0121	LNCS Aadx-Adult Single Patient Adhesive Sensors, >30 kg (20/box)	Disposable	Adult
0600-00-0122	LNCS Pdx-Pediatric Single Patient Adhesive Sensors, 10-50 kg (20/box)		Pediatric
0600-00-0126	LNCS DCI Adult Reusable Finger Sensor, >30 kg	Reusable	Adult
0600-00-0127	LNCS DCIP Pediatric Reusable Finger Sensor, 10-50 kg		Pediatric

Wavelength emitted by the sensors is between 600 nm and 1000 nm. The maximum photic output consumption of the sensor is less than 18 mW.

The information about the wavelength range and maximum photic output consumption can be especially useful to clinicians (for example, when photodynamic therapy is performed).

18.2.3 Nonin SpO₂ Module

PN	Description	Applicable property	Applicable patient
009-004935-00	Nonin SpO ₂ module (XPOD 3012LP)	Reusable	Adult, Pediatric

18.2.4 Nonin SpO₂ Sensor

PN	Description	Applicable property	Applicable patient
0600-00-0139-24	Sensor, SpO ₂ (Nonin), Disp (24)	Disposable	Adult
100-000077-00	Nonin 8000AA Reusable SpO ₂ Sensor	Reusable	
100-000134-00	standard pediatric clip sensor	Reusable	Pediatric
100-000135-00	pediatric disp. sensor 24 pcs/box	Disposable	

18.2.5 Nellcor SpO₂ Module

PN	Description	Applicable property	Applicable patient
115-054978-00	Nellcor SpO ₂ module	Reusable	Adult, Pediatric

18.2.6 Nellcor SpO₂ Sensor

PN	Description	Applicable property	Applicable patient
9000-10-05161	Reusable SpO ₂ sensor, finger-clip	Reusable	Adult
9000-10-07308	Reusable Pediatric-Infant SpO ₂ sensor with wraps, Ped/Infant	Reusable	Pediatric
0010-10-12476	Nellcor reusable D-YS SpO ₂ sensor with wraps	Reusable	Adult, Pediatric

18.3 Miscellaneous

PN	Description
022-000196-00	Li-ion battery 3.8V 3800mAh
0000-10-10902	Alkaline 1.5 V AA battery
0146-00-0077-10	L91 AA battery
045-001699-00	TP-3AA battery frame
048-005247-00	Disposable pouch
048-005246-00	Reusable pouch
DA8K-10-14452	US power cord
009-005409-00	USB upgrade cable
115-026852-00	Main unit of the charger

18.4 NIBP Accessories

Refer to **BP10 NIBP Module Operator's Manual (P/N 046-008269-00)** for accessories for BP10 modules.

A

Product Specifications

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This chapter provides specifications of the TM80, TM70, AP70, SYNC70 and central charger. For specifications of BP10, refer to **BP10 NIBP Module Operator's Manual (P/N 046-008269-00)**.

A.1 Classifications

The device is classified as follows according to IEC60601-1:

Type of protection against electrical shock	TM80/TM70: Class I, energized from an internal electrical power source. Central Charger: Class I. AP70: Class II. SYNC70: Class I.
Degree of protection against electrical shock for the TM80/TM70	Type CF defibrillation proof for ECG and SpO ₂ .
Mode of operation	Continuous
Degree of protection against harmful ingress of water	TM80/TM70: IPX7 Central Charger: IPX0 AP70: IPX1 SYNC70: IPX0 AC70: IPX0
Degree of protection against hazards of explosion	Not suitable: Equipment not suitable for use in the presence of a flammable anesthetic mixture with air with oxygen or nitrous oxide.
Degree of protection against hazard of dropping	No damage by dropping from a height of 1.5 m for the TM80/TM70

A.2 Environmental Specifications



WARNING

- The devices may not meet the performance specifications if stored or used outside the specified temperature and humidity ranges.

Item	Operating conditions	Storage conditions
Temperature	0 °C to 40 °C	-20 °C to 60 °C
Relative humidity (noncondensing)	15% to 95%	10% to 95%
Barometric	427.5 mmHg to 805.5 mmHg, or 57.0 kPa to 107.4 kPa	120 mmHg to 805.5 mmHg, or 16.0 kPa to 107.4 kPa

A.3 Power Supply Specifications

A.3.1 TM80/TM70

The TM80/TM70 is powered by batteries.

The battery life listed below may be shortened by the following factors:

- Wireless signal interference
- Aging battery
- Frequent operation of turning on/off the display
- Wireless network coverage which does not meet the technical specifications in *"Wireless Specification" on page A - 7.*

Battery type	AA batteries (three) Rechargeable lithium-ion battery (one)		
Capacity for lithium-ion battery	≥ 3500 mAh		
Charge time for lithium-ion battery	At the room temperature: ≤ 5 hours to 90% charge		
Safety and authentication for lithium-ion battery	UL2054, IEC62133, UN38.3		
Battery run time (at 25 °C ±5 °C, with display off, no sound and light as default, no alarms, display lit for one minute every two hours, using L91 AA batteries (PN 0146-00-0077-10))		Three AA batteries	Lithium-ion battery
	5-lead ECG	≥30 hours	≥30 hours
	5-lead ECG+SpO ₂	≥24 hours	≥24 hours
Shutdown delay	At least 10 minutes after the low battery alarm first occurs. At least five minutes after the critically low battery alarm first occurs.		

A.3.2 Central Charger

The central charger is powered by external AC power.

Input voltage	100 VAC to 240 VAC (± 10%)
Frequency	50 Hz/60 Hz (±3 Hz)
Input current	1.5 A to 0.75 A
Charge time	At the room temperature: ≤ 5 hours to 90% charge
Overcharge protection function	The charger automatically stops charging when the lithium-ion battery charge is full.

A.4 Physical Specifications

Item	Size	Weight
TM80/ TM70	126 mm × 64 mm × 23 mm	< 140 g (without batteries, SpO ₂ module, ECG lead-wires, or accessories)
AP70	≤300mm×300mm×≤60mm(without wall-mount bracket and antennas)	≤1kg(without wall-mount bracket)
SYNC70	465mm×241mm×44mm(without wall-mount bracket)	<3kg
Central charger	365 mm × 171 mm × 78 mm (without batteries and wall-mount bracket)	1130 g (without batteries and wall-mount bracket)

A.5 Hardware Specifications

A.5.1 TM80/TM70

Display	
Screen type	Color TFT LCD screen
Screen size	3.5"
Resolution	480 pixels × 320 pixels

Display Activation (Power On/Off) key	The switch time is less than or equal to two seconds.
LED	
Alarm lamp	1 (three colors: red, yellow, and cyan)
Audio Indicator	
Speaker	1
Sound Pressure Range	45 dBA to 85 dBA
Keys	
Nurse call	1
Power On/Off	1
Main menu	1
External Connectors	
ECG connector	1
SpO₂ connector	1

A.5.2 AP70

LED	
Power lamp	1(one color: green)
Run lamp	1(three colors: red, green, blue)
RF lamp	1(two colors: red and green)
Port	
Network port	one RJ45 port, compatible with 100BASE-TX standard, supporting POE

USB port	1micro USB port, USB2.0 standard
Button	
Reset button	1

A.5.3 AC70

System requirements for computers running AC70 management software:

Hardware	≥1T
Network port	1
Network adapter	≥1GB
CPU	≥2.1GHz;; ≥6 cores
Memory	≥ 12GB
Operating system	windows 10 or windows server 2016

A.5.4 SYNC70

LED	
Power lamp	1(one color: green)
Run lamp	1(two colors: red and green)
CLK(MAIN-BACKUP) lamp	1(one color: green)
Port	
Network port	two RJ45 ports, compatible with 100BASE-TX standard
USB port	1micro USB port, USB2.0 standard

AC power input port	1,supporting voltage input:100~240VAC(±10%),frequency input: 50Hz(±3Hz) or 60Hz(±3Hz)
Button	
Reset button	1

A.5.5 Central Charger

Charger slot	10
LED	10, which indicates the battery charge status.
AC power indicator	1
Installation mode	Place on the desktop, or mount on GCX® wall channel.

A.6 Wireless Specification

A.6.1 TM80 wifi specification

A.6.1.1 Technical Specifications

Protocol	IEEE 802.11a/b/g/n/ac
Modulation mode	DSSS and OFDM
Operating frequency	FCC: 2412 MHz to 2462 MHz 5180 MHz to 5240 MHz 5745 MHz to 5825 MHz ETSI: 2412 MHz to 2472 MHz 5180 MHz to 5240 MHz
Channel spacing	IEEE 802.11 b/g/n (at 2.4G): 5 MHz IEEE802.11 a/n/ac (at 5G): 20 MHz

Wireless baud rate	IEEE 802.11b: 1~11M Mbps IEEE 802.11a/g: 6~54M Mbps IEEE 802.11n: MCS0~7 IEEE 802.11ac: MCS0~8
Output power	< 20 dBm (CE requirement: detection mode – RMS); < 30 dBm (FCC requirement: detection mode – peak power)
Operating mode	Infrastructure
Data security	Standard: WPA/ WPA2 PSK, WPA/WPA2 EAP, WPA/WPA2 CCKM EAP method:LEAP,TLS,TLS,FAST,PEAP-MSChapV2,PEAP-GTC, PEAP-TLS; Encryption : TKIP and AES
QoS	QoS setting supported

A.6.1.2 Implemented Functions

The TM80 transmits waveforms, parameters, status and alarms of ECG, SpO₂, RESP; and parameters, status and alarms of NIBP to the central monitoring system. The waveforms, parameters, status and alarms displayed on the central monitoring system are consistent with that of the TM80.

The TM80 can work well with APs which support POE (e.g. AIR-CAP2802I-C-K9, working with AC: AIR-CT2504-15-K9), if the RSSI from APs is higher than -65 dbm.

A.6.1.3 Function Specifications

WARNING

- **Do perform all network functions of data communication within an enclosed network.**

Data integrity	The probability for loss of application data within wireless network should be less than 1000ppm(0.1%).
Data latency	Total delay of data transmission from the TM80 Telemetry Monitor to the Central Station: ≤ 3 seconds.

Priority	All communication data types shall have the same priority.
Transmission distance	Distinct vision distance between the TM80 and the AP is no less than 50 m.
Roaming	The network switchover is automatically implemented when the TM80 moves from the coverage area of AP1 to the coverage area of AP2, no network interruption alarm event will occur.
System capacity	Number of the TM80s supported by a single AP: ≤ 16 ; Each TM80 can communicate with the Central Station.
Dynamic networking stability	When a TM80 is moving at the rate of no more than 3.75 m/s within a 15m non-blocking linear distance, it does not encounter a network interruption alarm event.
Resistance to wireless interference	When the distance between the interfering devices and the TM80 is greater than 20 cm, and a co-channel interference Wi-Fi network (should be no greater than -85dBm) and an adjacent-channel Wi-Fi network (should be no greater than -50 dBm) synchronously exist, the TM80 does not encounter a network interruption alarm event. Note: the interfering devices includes: • Cellular communication devices • Microwave ovens • Intercoms • Cordless phones • Bluetooth devices
Network interruption alarm	1. When the network interruption occurs, the Central Station issues related alarms in 12 seconds. 2. When the network is reconnected, wireless connection recovers automatically.
Wireless networking stability	The ratio of the communication data lost on the center station from the TM80 is less than 0.1% in 24 hours under the following circumstances: ■ When 16 TM80s are connected to one AP, ■ Each of the 16 TM80s roam 30 times, and At least 3 TM80s roam simultaneously

A.6.2 TM70 and AP70 WMTS Specifications

A.6.2.1 Technical Specification

Specifications	608M	1.4G
Modulation mode	GFSK	
Operating frequency	608MHz(608~614MHz)	1.4GHz(1395~1400MHz and 1427~1432MHz)
Channel spacing	600kHz	800kHz or 600kHz
Wireless baud rate (data rate)	Max 400kbps	Max 433kbps for 800kHz channel spacing; Max 400kbps for 600kHz channel spacing.
Max. Output power	10 dBm	
Receiver sensitivity	≤-90 dBm for AP70 ≤-87 dBm for TM70	
Data security	authentication: based on TLS ; encryption : AES-128bit	
Radio Frequency Accuracy during normal operation	(-50,+50) KHz relative to channel frequency	
Occupied bandwidth as defined by power in 99% bandwidth	(-300,+300) KHz	(-400,+400) KHz

A.6.2.2 Implemented Function

TM70 transmits waveforms, parameters, status and alarms of ECG, SPO2, RESP and parameters, status and alarms of NIBP to the central station. The waveforms, parameters, status and alarms displayed on central station are consistent with TM70.

TM70 can work well with APs which support POE, if the RSSI from APs is higher than -70 dBm.

A.6.2.3 Function Specifications

WARNING

- Do perform all network functions of data communication within an enclosed network.

Specifications	608M	1.4G
Data integrity	The time percentage when a TM70 fails to transmit data to the central station shall not exceed 0.1% over a 24-hour period.	
Data latency	Total delay of data transmitted from the TM70 to the central station: ≤ 3 s.	
Transmission distance	Distinct vision distance from the TM70 to the AP shall be no less than 50 m for LOS.	
Roaming	The network switchover is automatically implemented when TM70 moves from the coverage area of AP1 to the coverage area of AP2.	
System capacity	Number of TM70s supported by a single AP: 14 for 5-lead ECG and 12 for 6-lead ECG. Every TM70 can communicate with the central station.	Number of TM70s supported by a single AP: ■ 16 for 800kHz channel spacing & 5-lead ECG ■ 14 for 800kHz channel spacing & 6-lead ECG ■ 14 for 600kHz channel spacing & 5-lead ECG ■ 12 for 600kHz channel spacing & 6-lead ECG Each TM70 can communicate with the central station.
Resistance to wireless interference	When the distance between interfering devices and TM70 transmitter is farther than 20cm and the co-channel interference WMTS network (should be no greater than -85dBm) and an adjacent-channel WMTS network (adjacent-channel power should be no greater than -40dBm@1.2MHz) also exist, the TM70 does not encounter network interruption alarm event. Note: the interfering devices includes: • Wireless equipment operated at 2.4GHz • Cellular communication devices • Microwave ovens • Cordless phones	
Dynamic networking stability	When TM70 is moving at the rate of no more than 3.75 m/s within a 15m non-blocking linear distance, it does not encounter network interruption alarm event.	
Network interruption alarm	When the network interruption occurs, the central station initiates the related alarms in 8s. When the network is reconnected, wireless connection recovers automatically.	

Wireless networking stability	The ratio of the communication data lost on the center station from the TM70 is less than 0.1% in 24 hours under the following circumstances: Each of the TM70 roams 30 times and at least 3 TM80s roam simultaneously.
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A.7 Bluetooth Specification

A.7.1 Technical Specification

Protocol standard	Bluetooth low energy 4.0
Modulation mode	GFSK
Operating frequency	2402 MHz to 2480 MHz
Channel spacing	2 MHz
Wireless baud rate	1 Mbps
Output power	≤ 2.5 mW
Data Security	Private protocol

A.7.2 Implemented Function

The function implemented via bluetooth is as follows:

- Transmits configuration information between TM80s or between TM70s.
- BP10 transmits NIBP parameters, status and prompt messages to TM80/TM70.
- TM80/TM70 transmits control information and settings to BP10.

A.7.3 Function Specification

Data integrity	Code error rate ≤ 1%
Data latency	Total delay of data transmission from BP10 to TM80/TM70 or from TM80/TM70 to BP10: ≤ 3 second Total delay of data transmission from TM80/TM70 to the central station: ≤ 3 second

Priority	All communication data type shall have the same priority.
Transmission distance	■ Distinct vision distance between the TM80s or between the TM70s is no less than 3 m. ■ Distinct vision distance between TM80 and BP10 or between TM70 and BP10 is no less than 3 m.
System capacity	■ One TM80 can synchronously transport the device configuration to at least other five TM80s in a 10 m² space. Five pairs of TM80 and BP10s can communicate in a 10 m² space, with TM80 communicating with the central station. ■ One TM70 can synchronously transport the device configuration to at least other five TM70s in a 10 m² space. Five pairs of TM70 and BP10s can communicate in a 10 m² space, with TM70 communicating with the central station.
Resistance to wireless interference	The bluetooth function is normal when the distance between the following interfering devices and TM80/TM70 or BP10 are as follows: ■ > 1 m for microwave ovens. ■ > 0.2 m for cellular communication devices, wireless devices, intercoms, and cordless phones.
Communication interruption message	When the bluetooth communication is interrupted, TM80/TM70 displays prompt message.

A.8 Measurement Specifications

A.8.1 ECG

ECG	
Standard	Meet standards of IEC60601-2-27
Leadset	3-lead: I, II, III 5-lead: I, II, III, aVR, aVL, aVF, V 6-lead: I, II, III, aVR, aVL, aVF, Va, Vb Automatic 3/5/6- lead recognition
ECG standard	AHA, IEC
Sweep speed	6.25 mm/s, 12.5 mm/s, 25 mm/s Accuracy: ± 10%

Display Sensitivity	1.25 mm/mV (×0.125), 2.5 mm/mV (×0.25), 5 mm/mV (×0.5), 10 mm/mV (×1), 20 mm/mV (×2), 40 mm/mV (×4) Accuracy: ± 5%
Input signal range	±8 mV (peak-to-peak value)
Calibration signal	1 mV (peak-to-peak value) Accuracy: ± 5%
Differential input impedance	≥ 5 MΩ
Bandwidth (-3dB)	Monitor mode: 0.5 Hz to 40 Hz ST mode: 0.05 Hz to 40 Hz
Common mode rejection ratio (with Notch off)	> 105 dB
Notch	50/60 Hz, rejection capacity ≥ 20 dB
Polarizing voltage scope	± 500 mV
Noise	≤ 30 μV (p-v RTI)
Baseline recovery time	< 5 s (after defibrillation)
Direct current leakage	Input electrode: < 0.1 μA Drive electrode: <1 μA
Electrode polarization recovery time	< 10 s
Defibrillation energy absorption	≤ 10% (100 Ω load)
Pace Pulse	
Pace pulse markers	Pace pulses meeting the following conditions are labelled with a PACE marker: Amplitude: ±2 mV to ±700 mV Width: 0.1 ms to 2 ms Rise time: 10 μs to 100 μs Amplitude: ≥ 0.2mV RTI

Pace pulse rejection	When tested in accordance with the IEC60601-2-27: 201.12.1.101.13, the heart rate meter rejects all pulses meeting the following conditions. Amplitude: ± 2 mV to ± 700 mV Width: 0.1 ms to 2 ms Rise time: 10 μs to 100 μs No overshoot About 50% pulse of ANSI/AAMI EC13 (5d) can trigger the pulse detector, the least changing rate is 20 V/s RTI.
HR	
Measurement range	Adult: 15 bpm to 300 bpm Pediatric: 15 bpm to 350 bpm
Resolution	1 bpm
Accuracy	± 1 bpm or $\pm 1\%$, whichever is greater.
Sensitivity	200 μ V
HR averaging method	In compliance with the requirements in Clause 201.7.9.2.9.101 b) 3) of IEC60601-2-27, the following method is used: If the last 3 consecutive RR intervals are greater than 1200 ms, the 4 most recent RR intervals are averaged to compute the HR. Otherwise, heart rate is computed by subtracting the maximum and minimum ones from the most recent 12 RR intervals and then averaging them. The HR value displayed on the monitor screen is updated every second.
Tall T-wave rejection capability	When the test is performed based on Clause 201.7.9.2.9.101 b) 2) of IEC60601-2-27, the heart rate meter will reject all 100 ms QRS complexes with less than 1.2 mV of amplitude, and T waves with T-wave interval of 180 ms and those with Q-T interval of 350 ms.
Response time to heart rate change	Meets the requirements of IEC60601-2-27: Clause 201.7.9.2.9.101 b) 5). From 80 bpm to 120 bpm: less than 11 s From 80 bpm to 40 bpm: less than 11 s
Response to irregular rhythm	In compliance with the requirements in Clause 201.7.9.2.9.101 b) 4) of IEC60601-2-27, the heart rate after 20 seconds of stabilization is displayed as follows: Ventricular bigeminy (3a): 80 ± 1 bpm Slow alternating ventricular bigeminy (3b): 60 ± 1 bpm Rapid alternating ventricular bigeminy (3c): 120 ± 1 bpm Bidirectional systoles (3d): 90 ± 2 bpm

Time to alarm for tachycardia	Meets the requirements of IEC60601-2-27: Clause 201.7.9.2.9.101 b) 6). Waveform B1h - range: < 11 s B1- range: < 11 s B1d - range: < 11 s B2h - range: < 11 s B2- range: < 11 s B2d- range: < 11 s
ST Segment Analysis	
Measurement range	-2.0 mV to +2.0 mV RTI
Resolution	0.01 mV
Accuracy	-0.8 mV to +0.8 mV: ± 0.02 mV or $\pm 10\%$, whichever is greater Beyond this range: Not specified
Arrhythmia Analysis	
Arrhythmia analysis classifications	Asystole, VFib/VTac, Vtac, Vent. Brady, Extreme Tachy, Extreme Brady, PVCs/min, Pauses/min, R on T, Run PVCs, Couplet, Multif. PVC, PVC, Bigeminy, Trigeminy, Tachy, Brady, Pacer Not Pacing, Pacer Not Capture, Missed Beat, Nonsus. Vtac, Vent. Rhythm, Pause, Irr.Rhythm, Afib
QT Analysis	
QTc formula	Bazett, Fridericia, Framingham, and Hodges
QT measurement range	[200, 800] ms
QT accuracy	[200, 800] ms: ± 30 ms Beyond this range: Not specified
QT resolution	[200, 800] ms: 4 ms Beyond this range: Not specified
QTc measurement range	[200, 800] ms
QTc resolution	[200, 800] ms: 1 ms Beyond this range: Not specified
QT-HR measurement range	Adult: [15, 150] bpm Pediatric: [15, 180] bpm

A.8.2 SpO₂

NOTE

- **A functional tester or SpO₂ simulator can be used to determine the pulse rate accuracy.**

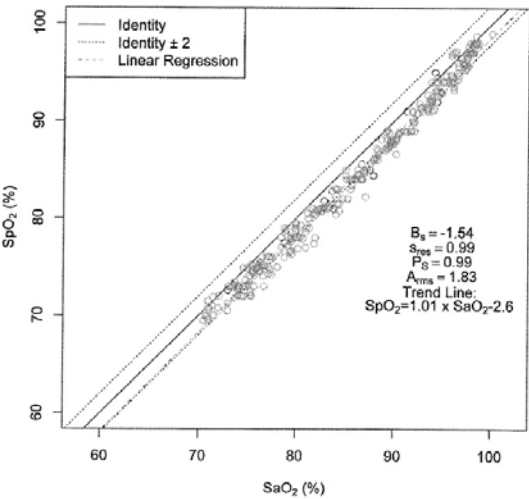
A.8.2.1 Nonin SpO₂ Module

SpO ₂	
Measurement range	0% to 100%
Resolution	1%
Accuracy	70-100%: ±3 digits 0-69%: Not specified
Data update rate	≤2s
*Studies were performed to validate the accuracy of Pulse Oximeter with Nonin SpO₂ sensors by contrast with a CO-Oximeter. In total, 12 adults (7 male & 5 female) aged from 19 to 35 years old were voluntarily involved in this study. Five are Caucasian, two are Indian, three are Asian, and two are African-American. All of them conform the clinical study requirements for age, gender, skin and health.	
The following table shows the accuracy (A_{rms}) for the SpO₂ sensors in four kinds of SaO₂ ranges. For the Fitting Curve of the SpO₂ sensors, refer to the "Fitting Curve for Nonin SpO₂ Sensors" on page A - 17.	
SaO ₂ range	Measured A_{rms} Value (7000A, 7000P, 8000AA, 8000AP)
70% to 100%	1.54
70% to 80%	1.41
80% to 90%	1.97
90% to 100%	1.28
PR	
Measurement range	20 bpm to 300 pm
Resolution	1 bpm
Accuracy	±3 bpm

Response Time	
■	≤ 25 s (PR 75 bpm, average time 4 heart beats, no disturbance, SpO ₂ value rises from 70% to 100%)
■	≤ 35 s (SpO ₂ value 98%, average time 4 heart beats, no disturbance, PR value rises from 60 bpm to 150 bpm)

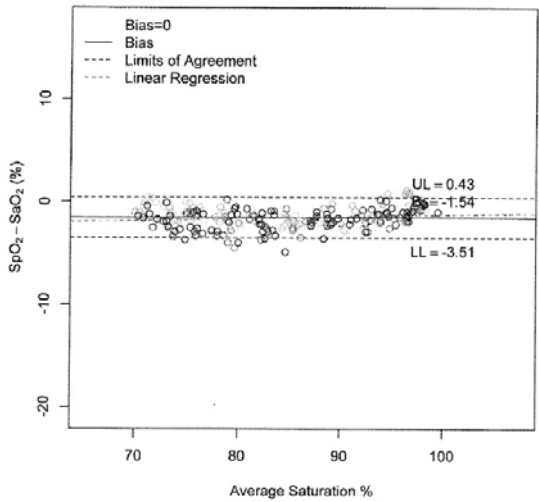
A.8.2.2 Fitting Curve for Nonin SpO₂ Sensors

7000A, 7000P, 8000AA, 8000AP



$SpO_2 = 1.01 \times SaO_2 - 2.6$

Scatter Plot of the SpO₂ versus the SaO₂



Bland-Altman Plots of the Bias versus the Mean

A.8.2.3 Masimo SpO₂ Module

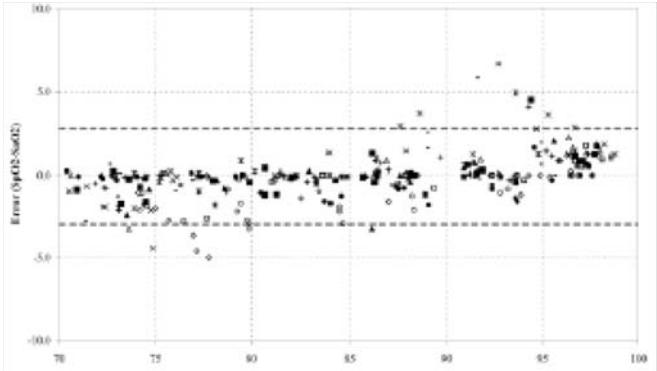
SpO ₂	
Measurement range	1% to 100%
Resolution	1%
Accuracy*	70-100%: ±2.0% (measured without motion) 70-100%: ±3.0% (measured with motion) 1-69%: Not specified
Low Perfusion Conditions	Pulse amplitude: > 0.02% Light penetration: > 5% Accuracy: ±2%
Data update rate	≤2s
*SpO ₂ accuracy was determined by testing on healthy adult volunteers in the range of 60% to 100% SpO ₂ against a laboratory CO-Oximeter. SpO ₂ accuracy was determined on 16 neonatal NICU patients ranging in age from 7-135 days old and weighing between 0.5-4.25 kg. Seventy-nine (79) data samples were collected over range of 70-100% SaO ₂ with a resultant accuracy of 2.9% SpO ₂ .	
The following table shows the accuracy (A _{rms}) for the SpO ₂ sensors in four kinds of SaO ₂ ranges. For the Fitting Curve of the SpO ₂ sensors, refer to the "Fitting Curve for Masimo SpO2 Sensors" on page A - 20.	

SaO ₂ range	Measured A _{rms} Values	
	LNCS Adtx, LNCS Pdtx	LNCS DCI, LNCS DCIP
70% to 100%	± 2%	2%
70% to 80%	1.55%	0.60%
80% to 90%	1.07%	0.54%
90% to 100%	1.64%	0.60%
PR		
Measurement range	25 bpm to 240 bpm	
Resolution	1 bpm	
Accuracy	±3.0 bpm(measured without motion) ±5.0 bpm (measured with motion)	
PI		
Measurement range	0.02% to 20%	
Least resolution	0.01, use three valid digits	
Response Time		
■	≤ 25 s (PR 75 bpm, average time 8 s, no disturbance, SpO ₂ value rises from 50% to 100%)	
■	≤ 20 s (SpO ₂ value 98%, average time 8 s, no disturbance, PR value rises from 60 bpm to 150 bpm)	

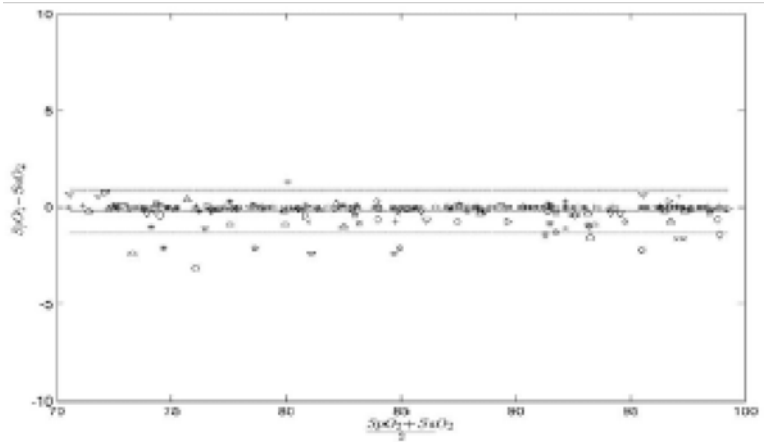
A.8.2.4 Fitting Curve for Masimo SpO₂ Sensors

Table information for the plots below show ARMS values measured with Masimo SET Oximetry Technology in a clinical study.

Adtx/Pdtx



DCI/DCIP



A.8.2.5 Nellcor SpO₂ Module

SpO ₂	
Measurement range	0% to 100%
Resolution	1%

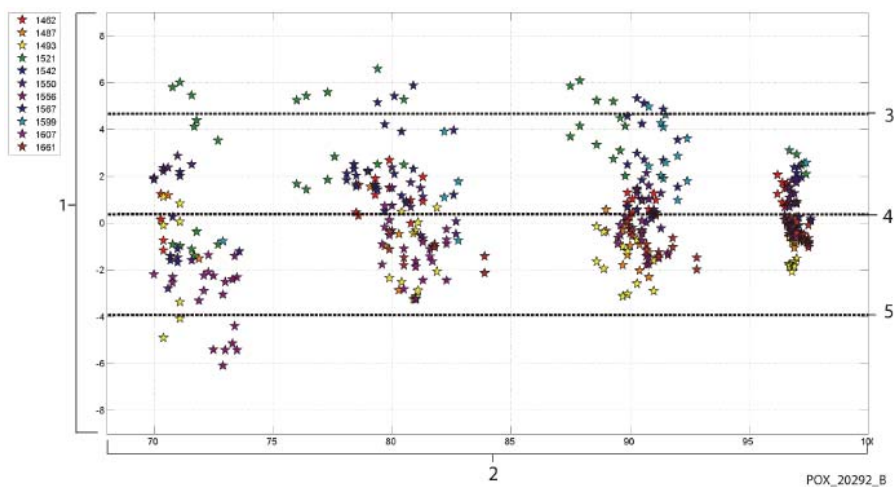
Accuracy	70% to 100%: $\pm 2\%$ ABS 60-80%: ± 3 ABS 0-59%: Not specified
PR	
Measurement range	20 bpm to 300 pm
Accuracy	20 bpm to 250 bpm: ± 3 bpm 251 bpm to 300 bpm: Not specified

A.8.2.6 Fitting Curve for Nellcor SpO₂ Sensors

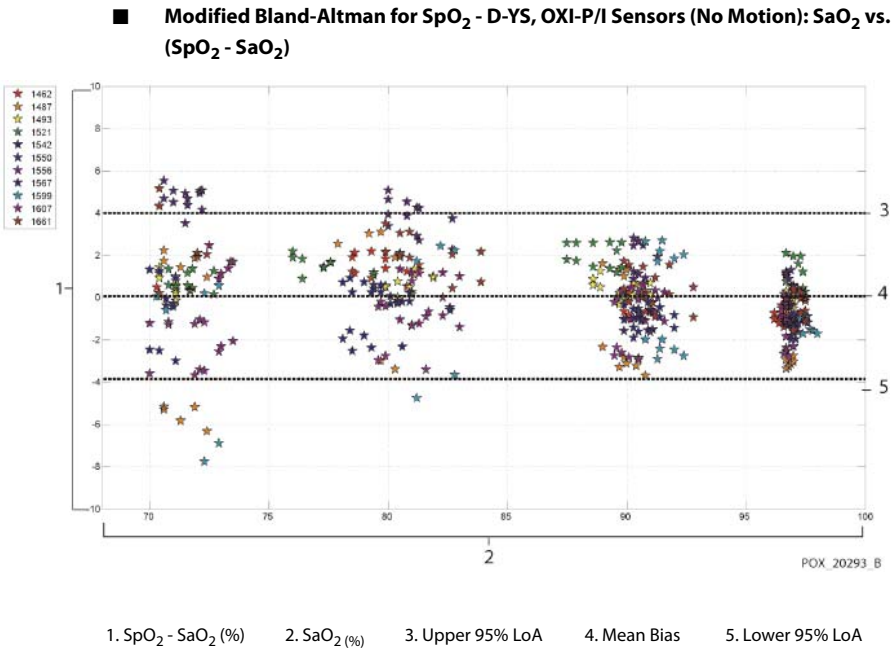
■ The accuracy of Nellcor SpO₂ Sensors

Sensor	Motion	# of Data Points	A _{RMS} (%)	SpO ₂ Acceptance Criteria 70% - 100% (%)	Pass/Fail
DS-100A (PN:9000-10-05161)	No	411	2.16	≤3.0	Pass
D-YS (PN: 0010-10-12476), OXI-P/I (PN: 9000-10-07308)	No	458	1.96	≤3.5	Pass

■ Modified Bland-Altman for SpO₂ - DS-100A Sensor (No Motion): SaO₂ vs. (SpO₂ - SaO₂)



1. SpO₂ - SaO₂ (%) 2. SaO₂ (%) 3. Upper 95% LoA 4. Mean Bias 5. Lower 95% LoA



A.8.3 Resp

Technique	Trans-thoracic impedance
Lead	Lead II
Respiration Rate	
Measurement range	Adult: 0 to 120 rpm Pediatric: 0 to 150 rpm
Resolution	1 rpm
Accuracy	0 to 6 rpm: not specified 7 to 150 rpm: ±2 rpm or ±2% whichever is greater

B

EMC and Radio Regulatory Compliance

B.1 EMC

The device meets the requirements of IEC 60601-1-2: 2014.



WARNING

- **Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this device could result in increased electromagnetic emissions or decreased electromagnetic immunity of this device and result in improper operation.**
- **Use of this device adjacent to or stacked with other device should be avoided because it could result in improper operation. If such use is necessary, this device and the other device should be observed to verify that they are operating normally.**
- **Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the this device, including cables specified by the manufacturer. Otherwise, degradation of the performance of this device could result.**
- **The non-ME EQUIPMENT (e.g. ITE) that is a part of an ME SYSTEM may be disrupted by the electromagnetic interference of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the non-ME EQUIPMENT or shielding the location.**
- **This device is intended for use in professional healthcare facility environment. If it is used in special environment, such as magnetic resonance imaging environment, the equipment/system may be disrupted by the operation of nearby equipment.**

Guidance and Declaration - Electromagnetic Emissions		
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment — guidance
RF emissions CISPR 11	Group 1	The system uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.

RF emissions CISPR 11	Class B*	Only TM80/TM70 Telemetry Monitor and BP10 (subpart) compliance. The devices are suitable for use in all establishments, including domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes.
RF emissions CISPR 11	Class A	
Harmonic distortion IEC 61000-3-2	Class A	
Voltage fluctuations and flicker IEC 61000-3-3	Compliance	
Note: The TM80/TM70 Telemetry Monitoring System and BP10 (subpart) are classified by their using environment or intended function.		

NOTE

- **The device needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided below.**
- **Other devices may affect this device even though they meet the requirements of CISPR.**
- **When the inputted signal is below the minimum amplitude provided in technical specifications, erroneous measurements could result.**
- **The EMISSIONS characteristics of this device make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this device might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the device.**
- **If the essential performance is lost or degraded, it may be necessary to take mitigation measures, such as re-orienting or relocating the ME EQUIPMENT or ME SYSTEM or shielding the location or stopping using the monitor and contact the service personnel.**

If the system is operated within the electromagnetic environment listed in Table Guidance and declaration — electromagnetic immunity, the system will remain safe and provide the following essential performance:

- Operating mode

- Accuracy
- Function
- Accessories identification
- Data stored
- Alarm
- Detect for connection

Guidance and Declaration - Electromagnetic Immunity			
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.			
Immunity test	IEC 60601 Test level	Compliance level	Electromagnetic environment - guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	±8 kV contact ±15kV air	±8 kV contact ±15kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines (length greater than 3 m)	±2 kV for power supply lines ±1 kV for input/output lines (length greater than 3 m)	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	±1 kV line(s) to line(s) ±2 kV line(s) to earth	
Voltage dips and Voltage interruptions IEC 61000-4-11	0 % U_T for 0,5 cycle 0 % U_T for 1 cycle and 70 % U_T for 25/30 cycles 0 % U_T for 250/300 cycle	0 % U_T for 0,5 cycle 0 % U_T for 1 cycle and 70 % U_T for 25/30 cycles 0 % U_T for 250/300 cycle	Mains power quality should be that of a typical commercial or hospital environment. If the user of our product requires continued operation during power mains interruptions, it is recommended that our product be powered from an uninterruptible power supply or a battery.
RATED power frequency magnetic fields IEC 61000-4-8	30 A/m 50 Hz / 60 Hz	30 A/m 50 Hz / 60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: U_T is the A.C. mains voltage prior to application of the test level.			

Guidance and Declaration - Electromagnetic Immunity			
The device is intended for use in the specified electromagnetic environment. The customer or the user of the device should assure that it is used in such an environment as described below.			
Immunity test	IEC 60601 Test level	Compliance level	Electromagnetic environment - guidance
Conducted disturbances induced by RF fields IEC61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d = \left[\frac{3.5}{V} \right] \sqrt{P}$ 150kHz to 80 MHz
	6 Vrms in ISM bands and amateur radio bands between 0,15 MHz and 80 MHz	6 Vrms	
Radiated RF EM fields IEC61000-4-3	10V/m 80 MHz to 2.7 GHz	10V/m(TM80/ TM70 and BP10)	$d = \left[\frac{3.5}{E} \right] \sqrt{P}$ 80 MHz to 800 MHz
Radiated RF EM fields IEC61000-4-3	3V/m 80 MHz to 2.7 GHz	3V/m(TM80/ TM70 System)	$d = \left[\frac{7}{E} \right] \sqrt{P}$ 800 MHz to 2.7 GHz
Proximity fields from RF wireless communications equipment IEC61000-4-3	27 V/m 380–390 MHz	27 V/m	where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).
	28 V/m 430–470 MHz, 800–960 MHz, 1700–1990 MHz, 2400–2570 MHz	28 V/m	Field strengths from fixed RF transmitters, as determined by an electromagnetic site surveyb, should be less than the compliance level in each frequency range.
	9 V/m 704–787 MHz, 5100–5800 MHz	9 V/m	Interference may occur in the vicinity of equipment marked with the following symbol: 
Note 1: At 80 MHz and 800 MHz, the higher frequency range applies. Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

- a The ISM (industrial, scientific, and medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz. The amateur radio bands between 0,15 MHz and 80 MHz are 1,8 MHz to 2,0 MHz, 3,5 MHz to 4,0 MHz, 5,3 MHz to 5,4 MHz, 7 MHz to 7,3 MHz, 10,1 MHz to 10,15 MHz, 14 MHz to 14,2 MHz, 18,07 MHz to 18,17 MHz, 21,0 MHz to 21,4 MHz, 24,89 MHz to 24,99 MHz, 28,0 MHz to 29,7 MHz and 50,0 MHz to 54,0 MHz.
- b Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the device.
- c Over the frequency ranges 150 kHz to 80 MHz, field strengths should be less than 3V/m.

Recommended Separation Distances between Portable and Mobile RF, Communications Equipment and This Equipment

The equipment is intended for use in an electromagnetic environment in which radiated RF disturbance are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the device as recommended below, according to the maximum output power of the communication equipment.

Rated Maximum Output power of Transmitter Watts (W)	Separation Distance According to Frequency of Transmitter (m)		
	150kHz -80MHz $d = \left[\frac{3.5}{V} \right] \sqrt{P}$	80MHz to 800MHz $d = \left[\frac{3.5}{E} \right] \sqrt{P}$	800MHz to 2.7GHz $d = \left[\frac{7}{E} \right] \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For telemetry monitors at a maximum output power not listed above, the recommended separation distanced in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

B.2 Radio Regulatory Compliance

The TM80/TM70 telemetry monitor complies with the requirements of FCC Part 95:

Radio frequency Radiation Exposure Information

For body worn operation, this equipment has been tested and meets the FCC and CE RF exposure guidelines when used with the accessories supplied or those approved for use with this product. Use of other accessories may not ensure compliance with FCC and CE RF exposure guidelines within 32 kilometers of the National Radio Astronomy Observatory centered on:

Very long baseline array stations	Latitude (north)	Longitude (west)
Pie Town, NM	34°18'	108°07'
Kitt Peak, AZ	31°57'	111°37'
Los Alamos, NM	35°47'	106°15'
Fort Davis, TX	30°38'	103°57'
North Liberty, IA	41°46'	91°34'
Brewster, WA	48°08'	119°41'
Owens Valley, CA	37°14'	118°17'
Saint Croix, VI	17°46'	64°35'
Mauna Kea, HI	19°49'	155°28'
Hancock, NH	42°56'	71°59'

If the installation distance is not enough, obtain the written concurrence of the Director of the affected radio astronomy station before the equipment can be installed or operated.

RF parameter (Bluetooth Module)

Protocol	Bluetooth low energy 4.0
Operating frequency band	2402 MHz to 2480 MHz
Modulation mode	GFSK
Output power	≤2.5 mW

RF parameter (Wi-Fi Module) for TM80

Protocol	IEEE 802.11a/b/g/n
Operating frequency band	FCC: 2412 MHz to 2462 MHz 5180 MHz to 5240 MHz 5745 MHz to 5825 MHz ETSI: 2412 MHz to 2472 MHz 5180 MHz to 5240 MHz
Modulation mode	DSSS and OFDM
Output Power	<30 dbm (peak power)

RF parameter (WMTS Module) for TM70 and AP70

Operation of this equipment requires the prior coordination with a frequency coordina-

Operating frequency band	■ 608~614MHz ■ 1395~1400MHz and 1427~1432MHz
Modulation mode	GFSK
Output Power	<10 dBm (peak power)

tor designated by the FCC for the Wireless Medical Telemetry Service. This equipment here refers to TM70 or AP70.

The device including Wireless module complies with part 15 of the FCC Rules. Operation is subject to the condition that this device does not cause harmful interference.



The radio devices used in TM80 telemetry monitoring systemis in compliance with the essential requirements and other relevant provisions of Directive 2014/53/EU. (Radio Equipment and Telecommunications Terminal Equipment Directive).

C

Symbols and Abbreviations

Units.....	C-2
Symbols	C-3
Abbreviations	C-3

C.1 Units

A	ampere
Ah	ampere hour
bpm	beats per minute
°C	centigrade
cc	cubic centimeter
cm	centimeter
dB	decibel
DS	dyne. second
°F	fahrenheit
g	gram
hr	hour
hPa	hundred pascal
Hz	hertz
in	inch
k	kilo
kg	kilogram
kPa	kilopascal
l	litre
lb	pound
m	meter
mg	milligrams
min	minute
ml	milliliter
mm	millimeters
ms	millisecond
mV	millivolt
mW	milliwatt
nm	nanometer
ppm	part per million
s	second
V	volt
VA	volt ampere
Ω	ohm
μ A	microampere
μ m	micron

μV	microvolt
W	watt

C.2 Symbols

-	minus
%	percent
/	per; divide; or
$\wedge$	power
+	plus
=	equal to
<	less than
>	greater than
$\leq$	less than or equal to
$\geq$	greater than or equal to
$\pm$	plus or minus
$\times$	multiply
©	copyright

C.3 Abbreviations

AAMI	Association for Advancement of Medical Instrumentation
AC	alternating current
AHA	American Heart Association
ANSI	American National Standard Institute
ARR	arrhythmia
ART	arterial
AUX	Auxiliary output
aVF	left foot augmented lead
aVL	left arm augmented lead
aVR	right arm augmented lead
CH	channel
CISPR	International Special Committee on Radio Interference
CMS	central monitoring system
CS	central station

ECG	electrocardiograph
EMC	electromagnetic compatibility
err	error
ES	electrosurgical
ESU	electrosurgical unit
HR	heart rate
HT	height
IEC	International Electrotechnical Commission
ISO	International organization for standardization
MRI	magnetic resonance imaging
LA(L)	left arm
LAP	left atria pressure
LED	light emitting diode
LL(F)	left leg
Loop	loop read-write test fail
M, MEAN	mean pressure
O ₂	oxygen
P	power
PR	pulse rate
QRS	interval of ventricular depolarization (QRS complex)
RA(R)	right arm
RL(N)	right leg
ROM	read-only memory
SpO ₂	arterial oxygen saturation from pulse oximetry
VGA	Video Graphics Array
WMTS	Wireless Medical Telemetry Service

Caution:

This device complies with Part 15 of the FCC rules and Industry Canada license-exempt RSS standard(s). Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

The manufacturer is not responsible for any radio or TV interference caused by unauthorized modifications or change to this equipment. Such modifications or change could void the user's authority to operate the equipment.

This radio transmitter (identify the device by certification number or model number if Category II) has been approved by Industry Canada to operate with the antenna types listed below with the maximum permissible gain indicated. Antenna types not included in this list, having a gain greater than the maximum gain indicated for that type, are strictly prohibited for use with this device.

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

The device has been evaluated to meet general RF exposure requirement.

To maintain compliance with FCC's RF exposure guidelines, this equipment should be installed and operated with a minimum distance of 5mm between the radiator and your body.