

CE 2764



Dynamic ECG Monitor Instruction Manual

Model: MCT-H1

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Chapter One Foreword

1.1 Precautions

1.1.1 Prior to application

In order to ensure safety&security operation and steady performance of the device, please read this manual carefully before your use so as to equip yourself with full knowledge about its functions, operations and maintenance.


Safety:


- (1)Do not drop but handle it with care. Otherwise damages or measuring errors will occur.
- (2)Damage to the device or personal injury might occur due to improper operation or user' s failure to follow the instructions from the manufacturer or its agent.
- (3)Please start charging the unit (2 hours or so for full charge) before your first use.
- (4)Please do not apply this device to ECG monitoring of children, newborns etc., otherwise the monitoring figures might be irresponsible.
- (5)All warning symbols and illustrations contained in the manual are for user to operate system of this device safely and rightly hence to prevent any injury to the user along or others. The warning symbols, illustrations & explanations are as follows.

(6) Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

(7) 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 equipment and result in improper operation.

(8) 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 device, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Warning /Symbol	Interpretation
	If used incorrectly, it may cause casualties.
	Do not dismantle, repair or temper with the components of the device, it gets rise to inaccurate testing result and device breakdown.
	Charging only with charging dock supplied by our company for charging the device.
	Adapter with national accreditation is recommended as DC 5V charging accessory.

	Never throw the device into the fire, or battery will explode, even a consequence of casualties.
	Do not store it in or near water heaters, microwave ovens, cooking equipment or high pressure containers so as to guard against fire and battery explosion out of overheating.
	Do not pull and plug charging dock with wet hand, otherwise it may get electric shocked or injured.
	Adapter with national accreditation is recommended as DC 5V charging accessory.
	The measuring result from this system is for your reference only. If any measuring result is beyond the normal range, please go to hospital for further examination and diagnosis, or it may delay and deteriorate the disease.
	This system is intended for use only in ECG measuring and recording other than that it will lead to an unknown event or accident.
	Do not store any of its parts in a space with too heat or too cold so as to avoid any accidents.
	Do not dispose this device&accessories in a manner of usual domestic garbage,Do not discard it randomly but dispose it according to medical appliance on its final expiry.
	CF equipment.

Security:

- (1) Before using the application, please choose the appropriate device and deploy network configuration for security.
- (2) The phone with the application installed is recommended to install anti-virus software, and open the system automatic patch upgrade.
- (3) In order to ensure data security, the phone with the application installed is recommended to set the access password.
- (4) When using the application, please pay attention to the privacy protection.
- (5) When sending or sharing ECG data, please pay attention to the protection of private data and ensure the facticity of the person.
- (6) When not using the application anymore, please delete the sensitive data stored in the idle or scrapped application device.

1.1.2 When ECG monitor is running

- (1) This product must be assembled with compatible disposable ECG electrode with medical appliance registration number
- (2) While in use, please wear it strictly as instructed in this manual.
- (3) If abnormal heating is found available with this device while in use, please shut it at once and place it in the storage box and contact us.
- (4) The device is not suitable for use in water.
- (5) Do not exert strong impact on this device and its accessories to avoid malfunctions.

- (6) Do not use with defibrillator at the same time so as to avoid damage to the device and injury to people.
- (7) During measurement, the electrode should not be in contact with other conductive components, including the ground.
- (8) Stay as much calm as possible during measuring to have steady monitoring and reliable record data.
- (9) Please do not uninstall, reinstall the software or replace the mobile phone before the monitoring record data is uploaded, otherwise the record data may be lost;
- (10) Please charge it first before your use when the PC APP software reads “ battery too low, device disconnected, please charge it in time”, it shows that the battery is poor for less than 10% content. It is time you charged the device before use.
- (11) Please use only new electrodes other than recycled ones which may result in unreliable measurements and even bacterial transmission.
- (12) Do not treat this product and its consumable parts as ordinary daily waste. It shall be disposed in compliance with medical appliance standard, Please do not discard it at will but hand to local environmental bureau for disposal collectively.

1.1.3 Charging with charging dock

- (1) DC. 5 V power supply shall have a national certification within validity for applying adaptor.
- (2) Before charging, firstly buckle the unit on the charging dock then plug its USB connector into the port of adaptor.

(3) During the battery charging, please do not apply it for ECG monitoring .

(4) After charging, cut the power off the adaptor then plug off the charging dock USB connector before taking out the ECG monitor from the dock.

(5) During the battery charging, when this device is found heating abnormally, stop the operation and turn off the unit and place it in the storage box then contact our company.

1.1.4 Applying smart APP software:

(1) Before using this product, please ensure your phone to installed with the APP software properly with setting reference to 2.5.1 basic parameters in the manual while to have sufficient storage space.

(2) Please do not uninstall, reinstall this APP arbitrary, otherwise it may lead to loss of historic data.

(3) During the monitoring process, the software will automatically store the testing data of users.

(4) Before unbinding the product to the APP application, the software will only function with one device.

(5) During the application, if there occurs any crash of phone system etc, please restart the software or mobile phone for continual monitor service.

(6) If the software memory alters, it may cause the program not to run normally or the monitoring data loss.

(7) The signal of same range will be slightly different displayed on

the different smart phone terminals selected by users accordingly, However, the corresponding relationship between the signal range and the background grid is consistent with any mobile phone, and the relation between the voltage and the display format can be referred to the scale displayed by the mobile phone.

(8) This software is free to use so is its inquiry and its system upgrade. If you have any comments or suggestions arising from your application, please contact our customer service department directly.

1.1.5 Transportation & storage











(1) Please store the product away from water, high temperature and moisture.

(2) Please do not place the product in direct sunlight or strong ultraviolet ray etc for a long time, otherwise it may lead to poor appearance.






(3) Do not store with disinfection gas or active gas which may cause corrosion and damage to the device.

(4) Please fix this product in a relatively sturdy position during the transportation so as to save equipment from collision and damage.

Symbols & Identifications

	Attention! referring to attached paper		Attention
	CF application		Non-ionizing radiation
	II equipment		DC
	Bluetooth		Recycle
	Do not discard trash		Stop use while in defibrillation

shipping warning marks

	Fragile -do not drop
	This side up
	Stacking limit
	Keep dry
	Keep from sunlight

Chapter Two Product Description

2.1 Intended use:

The device is intended for the use in ECG monitoring at home or healthcare environment on human over 18 years old.

Contraindications:

It should not be used in such cases:

- Pediatric use

People with cardiac pacemakers are forbidden

Side effects: There are no known side effects

- Patient Profile

More than 18 years old persons who meet indications but do not meet contraindications.

- User profile

The device is intended to be used by Cardiologist and Cardiac Surgeons on adult patient over 18 years old. The operator must be able to read English.

2.2 Main structure

The dynamic ECG monitor consists of ① acquisition unit (including battery, communication system, signal processing system and so on). ② charging unit (charging dock, USB cable), ③ client APP software.

2.3 Application range :

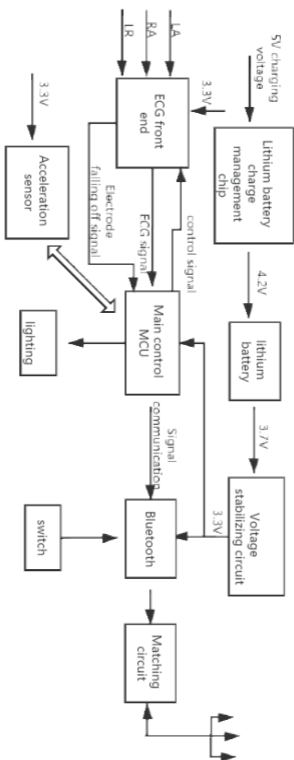
Heart function monitoring (monitoring items: ECG waveform ECG, heart rate, heart rate alarm)

2.4 Model Designation

MCT-H1 indicator status description

Operation	LED	Status
Short press	No response	Low battery
	Red	Off
	Blue	On
Long Press	Red	Power on
	Blue	Power off
No operation	Blue solid	Bluetooth connected
	Red pulse	Charging
	Green solid	Charging completed

2.5 Electric schematic diagram



Warning

The user or operator of this dynamic ECG monitor shall read and follow the manual instructions carefully before use.

The user shall assume all consequences arising from their own dismantle of this unit which could only be opened and overhauled each part inside by our authorized engineer.

The user shall apply this device to procure testing results for reference only. When the testing results turn out abnormal, please consult with a professional doctor or go to hospital for check-up, diagnosis and treatment.

This product is not suitable for use neither in the presence of FLAMABLE ANESTHTICS. Do not use this device during a MRI or CT scan.

This device may pose a safety threat to the cardiac pacemaker. Please avoid using them both at the same time.

Do not use this device with a defibrillator for the results may be inaccurate , please try not to use them both at the same time.

This device is compatible with a battery charger certified for safety application by local relevant authority.

Do not apply this device while charging.

This device is not intended for use in neonatal ECG monitoring.

【Contraindication】

1. People with cardiac pacemakers are forbidden;
2. Person with serious heart disease during the period of frequent occurrence should be prudent;
3. Person with allergy to a disposable ECG electrode is forbidden.

Chapter three Product Maintenance & Trouble Shooting

3.1: Introduction

Please refer any problem available in your application to the trouble shooting table.

Although the device is tested strictly and fully functional, its normal operation might be disrupted due to abrupt changes in ambience or unfinished installing on App.

Most obstacles, roots and solutions are available in the trouble shooting table list in this chapter.

Should any problem occur which comes within one of their obstacles in the list, you may fix it accordingly unless otherwise it is beyond the obstacles listed, please contact our customer services department for our technical support.

If there is any need of circuit diagram, component list or any other information regarding your application and installation of this device, please contact our customer service department for our supply and support.

3.2 Trouble Shooting

No	Occurrence	Fault Type	Solutions
1	indicator off while power turned on	battery exhausted	to charge
2	Indicator in red	Poor battery	to charge
3	Indicator in blue	charging	normal
4	Indicator in green	full battery	to plug off charging dock

3.3 Maintenance

- 1.Cleaning: Make sure you turn off the device and do not charge before you are cleaning the device and recommend to use cotton swabs to clean the surface.
- 2.If any obstacle occurs to the device in use, please take it off at once and cut power off and check out the trouble, shooting table for solutions and when you find no such a solution , please contact with the manufacturer or your distributor for more support.
- 3.If the product is in no use for a long time, it is recommended to be charged every 3 months to have good performance.
- 4.Environmental protection: When the life cycle of dynamic ECG scanner runs out, it has to be sent for local environmental protection bureau and any disposal by individual privately is not permitted.

3.4 Cleaning and Disinfection.

Frequently cleaning once a week: The product surface with medical alcohol and application of the device shall come after the alcohol is completely evaporated.

3.5 Safety Inspection

Inspection prior to application :

Check if any damage or stains exist and contact our customer service for any malfunction;

Check if the electrode is used for the first time and ensure it is applicable within warranty period.

Appendix A Equipment Parameters and Specifications

A.1 Major technical parameters

A.1.1 Basic parameter

- 1.Size: 54mm (Length)*61mm(Width)*9.0 mm(Height)
- 2.Shell material: ABS+antibacterial plastics
- 3.Net weight: 20g
- 4.Battery capacity: $\geq 170\text{mAh}$
- 5.Indicator light status: Flashing, Steady Internal
- 6.power supply: DC 3.7V
- 7.Sample rate: 500Hz 8.Charging time: <2 hour 9.Standby time: $\geq 60\text{days}$
- 10.Continuous monitoring time: $\geq 13\text{h}$
- 11.Charging voltage: DC 5.0V-0.2A
- 12.Operating Current: $\leq 20\text{mA}$
- 13.Data transmission: Bluetooth 4.0
- 14.Channel number: Single channel
- 15.IP protection class: Acquisition unit IPX5, charging unit IPX0;
- 16.Application(APP) Software Software name: MCT-H1 Software
Software version: 1.1
17. APP software configuration requirements:
 - Application system: Smart phone, tablet PC
 - Processor: Dual Core 1.0GHz and above

- Capacity: 4G and above
- Memory size: 1G and above
- Display Screen: 1280*720 and above
- Operation system: Android 4.4 and above, IOS 8.0 and above
- Data transmission: Bluetooth 4.0

A.1.2 Database

The standard database applied for analysis & evaluation in this device is contributed by:

MIT Database: Massachusetts Institute of Technology- Beth Israel hospital database of arrhythmias
(48 records, 30 minutes each record)

1. Major Technical Parameters

- (1)Input dynamic range: The output signal relative input signal discontinuous scale for no larger than 30 μV .
- (2)Input impedance: within full range of frequency single-end input impedance is no less than 2.5M Ω .
- (3)System noise: No higher than 30 μV p-v) RTI.
- (4)Gain control and stability: No more than $\pm 10\%$ of fix gain of the device .
- (5)The input signal rebuild accuracy range: 1.25mm~15mm by frequency response when the input is 200ms.
- (6)Common-mode rejection: For within 60s duration the output signal ranges no higher than 1 mGV p-vn RTI.

(7)Minimum detection signal: Apparent deflection occurs once a sinusoidal signal 10Hz / 50uV (peak value) is applied at a speed of 25mm / s for scanning and recording and with gain 10mm / mV.

(8)Monitoring time: No less than 13 h for continuous monitoring.

2.Heart rate calculation formula

For calculating the heart rate, we need filter ECG data by LPF, then apply LPF datum for curve integral to obtain the ECG vector whose peak value is further examined, then evaluate RR interval validity to have recent heart rates for an average before reaching the final heart rate.

3.Environmental Conditions

(1)Operating environment Ambient temperature: 5°C~40°C;

Relative humidity: 25%~95%RH;

Atmospheric pressure: 860hPa~1060hPa;

Acquisition unit voltage & current: DC5.0V 0.2A; Built-in battery operating voltage: DC 3.7V;

Charging unit power: USB supply, DC 5V

Reminder: This device shall be applied free of strong electromagnetic field interference.

(2)Storage and transportation environment Ambient temperature : -20°C~45°C; Relative humidity: 10%RH~95%RH; Atmospheric pressure: 860hPa~1060hPa;

Reminder :

Store the device out of strong sunlight or any substances which causes corrosion and in a good ventilated space.

The acquisition unit built-in battery: DC 3.7V

Appendix B

Guidance and manufacturer's declaration – electromagnetic emission

The model MCT-H1 is intended for use in the electromagnetic environment specified below. The customer or the user of the model MCT-H1 should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The Model MCT-H1 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	The Model MCT-H1 is 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.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Not applicable	

Guidance and manufacturer's declaration – electromagnetic immunity

The Model MCT-H1 is intended for use in the electromagnetic environment specified below. The customer or the user of the Model MCT-H1 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 ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV ai	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrostatic transient / burst IEC 61000-4-4	± 2 kV for power supply lines 100 kHz repetition frequency ± 1 kV for input/output lines	N/A	N/A

Surge IEC 61000-4-5	± 0.5 kV, ± 1 kV differential mode line-line	N/A	N/A
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<p>0 % UT (100 % dip in UT) for 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315°</p> <p>0 % UT (100 % dip in UT) for 1 cycle at 0°</p> <p>70 % UT (30 % dip in UT) for 25/30 cycles at 0°</p> <p>0 % UT (100 % dip in UT) for 250/300 cycle at 0</p>	N/A	N/A

Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m, 50/60Hz	30 A/m, 50/60Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: UT is the a. c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity

The MCT-H1 is intended for use in the electromagnetic environment specified below. The customer or the user of the MCT-H1 should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
<p>Conducted RF IEC 61000-4-6</p> <p>Radiated RF IEC 61000-4-3</p>	<p>3 Vrms 150 kHz to 80 MHz</p> <p>6 Vrms 150 kHz to 80 MHz outside ISM bands</p> <p>10 V/m 80 MHz to 2.7 GHz</p>	<p>N/A</p> <p>10 V/m</p>	<p>Portable and mobile RF communications equipment should be used no closer to any part of the Models MCT-H1, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance</p> $d = \left[\frac{3.5}{V_1} \right] \sqrt{P}$ $d = \left[\frac{3.5}{E_1} \right] \sqrt{P} \quad 80\text{MHz to } 800\text{MHz}$ $d = \frac{7}{E_1} \sqrt{P} \quad 800\text{MHz to } 2.7\text{GHz}$

			<p>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 metres(m).</p>
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Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, ^a should be less than the compliance level in each frequency range b

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 0,15 MHz 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 The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2,7 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 has been incorporated into the formulae used in calculating the recommended separation distance for transmitters in these frequency ranges.

c 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 MCT-H1 is used exceeds the applicable RF compliance level above, the MCT-H1 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the MCT-H1.

d Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between
portable and mobile RF communications
equipment and the model MCT-H1

The Model MCT-H1 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Model MCT-H1 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Model MCT-H1 as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d = \left[\frac{3.5}{V_1} \right] \sqrt{P}$	80 MHz to 800 MHz $d = \left[\frac{3.5}{E_1} \right] \sqrt{P}$	800 MHz to 2.7GHz $d = \frac{7}{E_1} \sqrt{P}$
0.01	0.12	0.04	0.07
0.1	0.37	0.12	0.23
1	1.17	0.35	0.7
10	3.7	1.11	2.22
100	11.7	3.5	7.0

For transmitters rated at a maximum output power not listed above the recommended separation distance d in metres (m) can be estimated 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 separation distance for 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.

Recommended separation distances between RF wireless communications equipment

The device MCT-H1 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between RF wireless communications equipment and the device as recommended below, according to the maximum output power of the communications equipment.

Frequency MHz	Maximum Power W	Distance	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
385	1.8	0.3	27	27	RF wireless 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
450	2	0.3	28	28	
710	0.2	0.3	9	9	
745					
780					

					<p>frequency of the transmitter.</p> <p>Recommended separation distance</p> $E = \frac{6}{d} \sqrt{P}$ <p>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). Field strengths from fixed RF transmitter, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range.</p> <p>Interference may occur in the vicinity of equipment</p>
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					marked with the following symbol: 
810	2	0.3	28	28	
870					
930					
1720	2	0.3	28	28	
1845					
1970					
2450	2	0.3	28	28	
5240	0.2	0.3	9	9	
5500					
5785					
<p>Note 1: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p>					

WARNINGS!

This device should not be used in the vicinity or on the top of other electronic equipment such as cell phone, transceiver or radio control products. If you have to do so, the device should be observed to verify normal operation.

The use of accessories and power cord other than those specified, with the exception of cables sold by the manufacturer of the equipment or system as replacement parts for internal components, may result in increased emissions or decreased immunity of the equipment or system.

Appendix C Electronic Information Equipment Pollution Control

C.1 Electronic information equipment pollution control

The Measures for the Administration of Pollution Control of Electronic Information Equipment (No. 39) was implemented on March 1, 2007. According to the Electronic Information Equipment Classification Notes, this equipment belongs to the medical electronic information equipment in the electronic application equipment category. According to the "Administrative Measures for Pollution Control of Electronic Information Equipment" (No. 39), the toxic substances or elements contained in the pollution control signs and equipment are described as follows:

1. Lead;
2. mercury;
3. Cadmium;
4. Hexavalent chromium;
5. Polybrominated biphenyls (pbb);
6. Polybrominated diphenyl ether (pbde);
7. Other toxic and hazardous substances or elements

prescribed by the state.



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