



Optimizing Pain Management and Rehabilitation

CTM Controller® 1600

Operating Manual

Important product information. Do not throw away or destroy.

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 Swiss Made

We are grateful that we have been able to convince you of the benefits of CTM Therapy® and that you have bought the CTM Controller® 1600.

The CTM Controller® 1600 is a very light, mobile cold and heat therapy device for using CTM Therapy®, which supports improved rehabilitation and pain management. The CTM Controller® 1600 enables controlled cold treatment in a constant therapeutic temperature range of 8 to 18°C (46 to 64°F) and controlled heat treatment in a constant therapeutic temperature range of 38 to 42°C (100 to 108°F).

Please read this operating manual through thoroughly, so as to guarantee the maximum safety and benefits of the CTM Controller® 1600.

The CTM Controller® 1600 is intended to be used by physicians and patients.

Patients can operate the device after an adequate training by qualified clinicians, no restrictions in functions described in this User Manual are applied.

The CTM Controller® 1600 is designed to be used for a period of 10 years when subjected to regular maintenance.

The CTM Exchanger® shall be used for one patient only for the extension of the treatment.



CTM Controller® 1600 specifications and data

Weight (net)	5.0 kg (control unit)
Dimensions	300 mm x 260 mm x 184 mm
Input	230 V, 50 Hz, 260 W
Water temperature	8 °C – 42 °C (normal tap water)
Operating temperature	5 °C – 35 °C (optimal room temperature below 25 °C) *
Transport and storage temperature	5 °C – 50 °C *

* Relative humidity 10% to 90%

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A. Important safety information

Warning

The CTM Controller® 1600 supplies beneficial cold and heat to support rehabilitation and pain reduction. If you have a serious illness or injury, always ask your doctor or another qualified medical specialist before using the CTM Controller® 1600.

NEVER use the CTM Controller® 1600 on people who are sensitive to heat or cold, on people with a reduced state of consciousness or on children under 12 years of age.

NEVER sleep while using the CTM Controller® 1600.

NEVER use the CTM Controller® 1600 for cold therapy under one of the following conditions:

- Cold allergies (cold urticaria) or cold intolerance
- Raynaud's syndrome or phenomenon
- Cryoglobulinemia
- Paroxysmal cold haemoglobinuria
- Clear reaction to the cold pressor test
- On areas with regenerating peripheral nerves
- On areas with circulatory problems or peripheral vascular diseases
- Pregnancy

NEVER use the CTM Controller® 1600 for heat therapy under one of the following conditions:

- Diabetes mellitus
- Multiple sclerosis
- Peripheral vascular diseases
- Spinal cord injuries
- Rheumatic disorders
- Pregnancy

NOTE: In case of haematomas the heat treatment might not be indicated

NOTE: Some products can cause early degradation of the CTM Exchangers® which may lead to material failure or leaks. This is not covered by the warranty.

WARNING: The CTM Controller®1600 is not waterproof. Protect the device from water at any time! Always protect the device with the plastic zip-bag provided with the package, for transport and storage. If water or any other liquid is spilled on it wipe it off immediately with a damp cloth. Do not use the CTM Controller® 1600 if wet, or connect it to a power outlet with wet hands.

B. General safety and usage instructions

Do not use the CTM Controller® 1600 and CTM Exchanger® with other devices unless described in this User Manual.

The CTM Controller® 1600 is intended for indoor use in a dry and well-ventilated environment. A distance of at least 30 cm (12") should be left free on all sides of the device in order to ensure sufficient air circulation.

The CTM Controller® 1600 must be filled with water prior to use. See "CTM Controller® 1600 setup" for the instructions for setting up and filling the appliance.

Before filling with water or emptying, the device must always be switched off and disconnected from the power supply.

Never use caustic or flammable liquids in the CTM Controller® 1600. Only use clean tap water for the device.

Make sure that the tubes and CTM Exchangers® are properly connected before you switch on the device.

Empty the CTM Controller® 1600 before it is transported and/or stored at temperatures around freezing point.

Transport the CTM Controller® 1600 with care. Shocks or tilting may result in damage to the device components.

Keep the CTM Controller®1600 and the CTM Exchanger® out of the reach of unsupervised infants and children.

Do not clean the CTM Controller® 1600 with solvents, but only with a damp cloth.

Do not disassemble or attempt to repair the CTM Controller® 1600. Leave all maintenance work and repairs to a qualified technician.

In case of maintenance, repair or changes in the performance contact Ener-C. Contact information is provided on the last page of the manual or on www.ener-c.com.

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 other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation.

The device is intended for use in orthopedic centers, therapy clinics, athletic training facilities, hospitals, nursing facilities, medical centers, as well as in patient homes. The device should not be used in an environment where the intensity of electromagnetic disturbance is high.

NOTE: do not store the device in direct sunlight. Keep dry.

NOTE: Do not operate the device in direct sunlight.

C. Components

The components of the CTM Controller® 1600

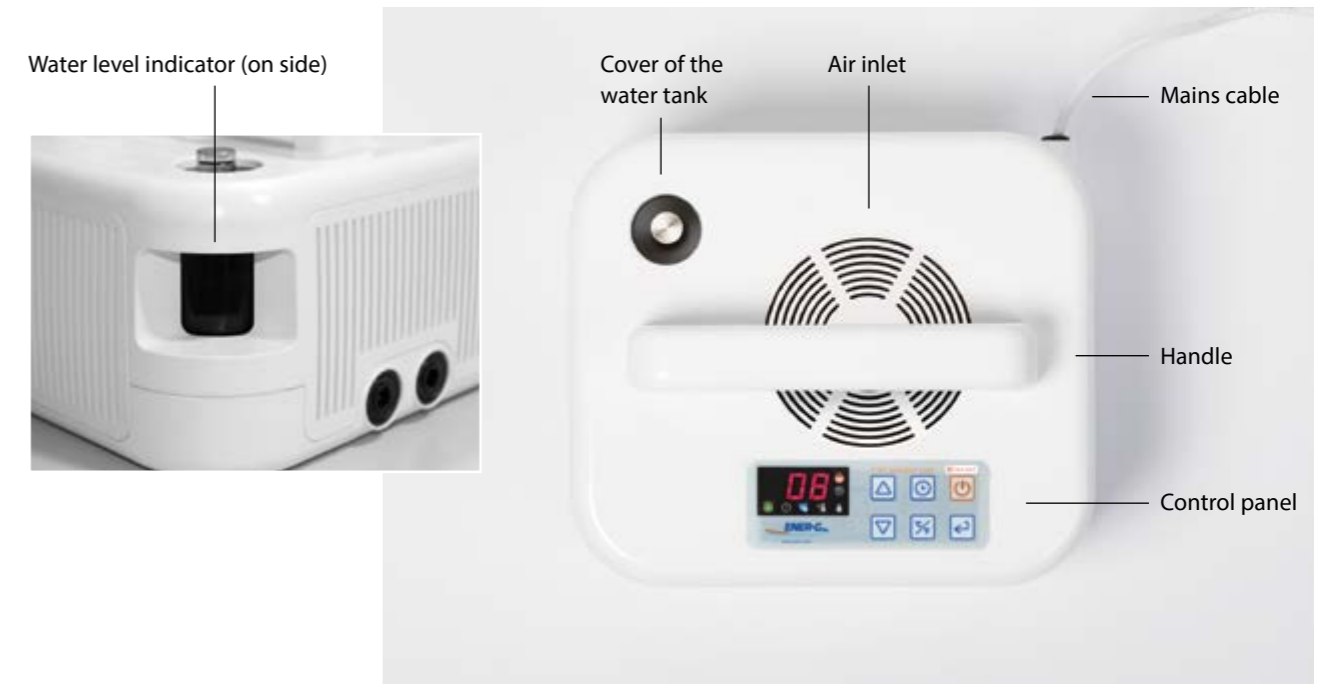
- 1 Control unit
- 1 Set of tubes
- 1 CTM Exchanger®

There are a large number of CTM Exchanger® available for use with the CTM Controller® 1600 (see section H. CTM Exchanger®).

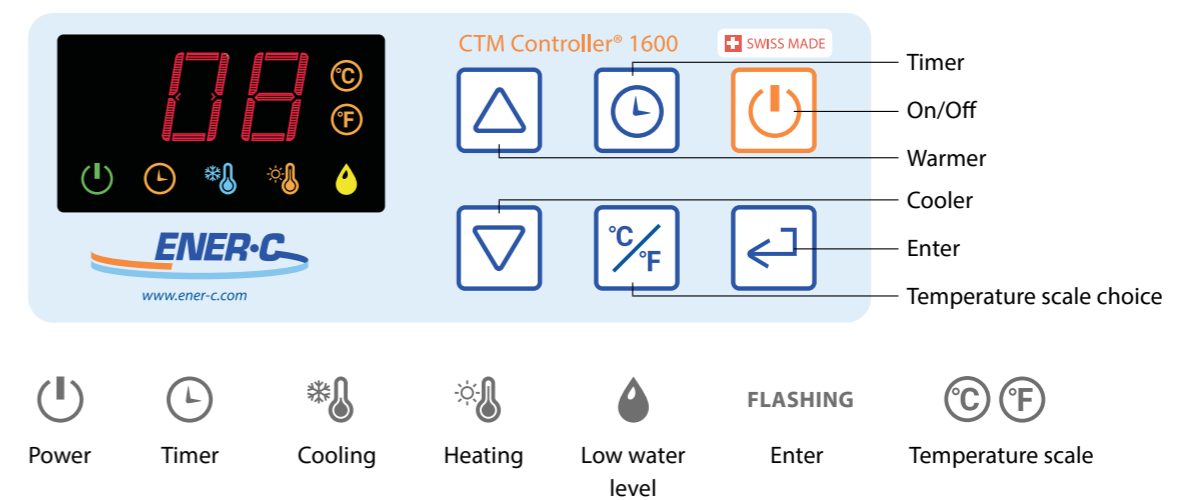


NOTE: The tube may be different in appearance from the above example.

The control unit



The control panel / display symbols



Warning: User interface keys are very sensitive to touch, inadvertently touching could modify the parameters.

D. CTM Controller® 1600 setup

Connecting the tube and the CTM Exchanger®

The CTM Controller® 1600 is supplied with a tube set and a CTM Exchanger® is needed for its use. Connect the two black plastic plugs of the tube set to the control unit, as shown below. You hear a click when the plug has properly locked into place. To remove the tube, hold the black plug and pull it out. Please do not disconnect the plug with pulling the white tube.



Then connect the CTM Exchanger® to the tube by inserting both the CTM Exchanger® plugs into the two sockets of the tube. Twist both halves of the connection to lock it.



A large number of specific, anatomically shaped CTM Exchangers® are available. See section H. for further information or visit:

www.ener-c.com/ctm-exchanger

Fill the control unit of the CTM Controller® 1600 with water

Before use, the control unit must be filled with clean tap water. In order to fill the device completely, remove the cover of the water tank and fill the tank with approx. 300 ml of water with a funnel. The water level in the tank can be read out through the window of the water tank on the side of the device. Avoid the tank overflowing (2/3 to 3/4 full is ideal). When the tank is full, close it again using the cover.



As soon as the tank has been filled, connect the mains cable to a suitable socket and press the ON/OFF button to switch the device on. The control unit then pumps the water through the tube and the CTM Exchanger®, which may lead to the water level in the tank falling, while the tube and CTM Exchanger® are filling with liquid. If the water level drops below half, remove the cover and slowly fill with water until the level is again between half-full and full. Then fasten the cover again.

NOTE: The device does not function when the “Low water level” light is on. When this indicator lights up, add more water as described above and then press the ON/OFF button to restart the device.


⚠ Caution



Do NOT immerse the control unit in water to fill the tank.
Do NOT pour or spill any water into the control unit's ventilation openings.
Do NOT drink any water from the control unit.


Before using the device, make sure that the cover is closed so as to prevent the water from overflowing. If the CTM Exchanger® is located in a higher position than the control unit, this may lead to the tank overflowing.

E. Operation


The following sections contain the recommended procedures for optimum therapeutic cooling and heating. The control unit can be set to temperatures between 8 °C (46 °F) and 42 °C (108 °F).

 **To switch the device on or off: press ON/OFF button.**
NOTE: The Power symbol on the display blinks until the set temperature is reached.

 **To set the temperature: press the COOLER or WARMER**
 **button on the control panel until the required temperature is shown.**


 **To select °C or °F: press the TEMPERATURE SCALE button.**

For optimum efficiency, the control unit should be located at about the same height as the CTM Exchanger®. Please also note that the system is designed for operation at normal ambient temperatures below 25°C (77°F). The cooling performance is reduced at ambient temperatures above this value. For cooling, the control unit's fan runs at 55% output in the standard setting. Proceed as follows if you would like to increase the output manually to 75%:

 **Press and hold the button for 3 seconds with the device switched on**

The fan stops automatically when the set target temperature is reached. To switch off manually, please press and hold the ENTER button again for 3 seconds.

Control unit operation in low-noise SILENT mode (40% output) as follows:

 **Press and hold the button for 6 seconds with the device switched on**

NOTE: The device does NOT stop automatically in silent mode. It is only possible to switch off manually by pressing and holding the ENTER button for 3 seconds again. After changing the temperature > 5 Kelvin, the control unit's fan starts to run with the standard settings until the new set temperature is reached.

Recommended procedure for therapeutic cooling

NOTE: always follow the therapy temperature and exposure time given by the treating physician.

To isolate the device from the supply mains disconnect the power cord. Please ensure the power cord is easily accessible and could be unplugged at any time. It is advisable to disconnect the device after each use.

Set the device to 8°C (46°F) and let it cool down until the display shows 12°C (54°F) or less. Apply the CTM Exchanger® to the required part of the body without the tube kinking, because this impairs the flow of water.

When the CTM Exchanger® is applied to the body, the temperature displayed on the control panel goes up by a few degrees. This is normal and means that the CTM Exchanger® is removing heat from the body.

NOTE: If the temperature rises further to above 20°C (68°F), it is likely that the flow of water has been restricted. In this case, the cooling phase must be restarted. In order to re-establish the flow, remove the CTM Exchanger® from the body and set the temperature to 42°C (108°F) for about 7 to 10 minutes. The flow of water should then be re-established and you can restart the cold therapy.

WARNING: Too long application of cold can lead to frostbites and to local skin damages up to tissue necrosis.

Recommended procedure for therapeutic heating

NOTE: always follow the therapy temperature and exposure time given by the treating physician.

Set the device to 42°C (108°F) and let it heat up until the display shows 40°C (104°F) or more. Apply the CTM Exchanger® to the required part of the body without the tube kinking, because this impairs the flow of water.

When the CTM Exchanger® is applied to the body, the temperature displayed on the control panel falls by a few degrees. This is normal and means that the CTM Exchanger® is supplying heat to the body.

Warning

Regularly monitor the temperature of the device and stop the treatment if the temperature drops below 8°C (46°F) or exceeds 43°C (109°F) or if discomfort occurs. If these temperatures are applied to the skin over a long period of time, this may lead to serious injuries.

Contact the treating physician to discuss the discomfort symptoms.

Display current temperature

Only the set temperature is shown on the display during operation. The current temperature can be shown as follows:


 **Press the TEMPERATURE SCALE button and hold for 2 seconds**

The target temperature setting does not change in the process. The indication of the current temperature appears for 3 seconds on the display and then disappears again.

NOTE: If the water temperature drops below 4°C or higher 47°C, the device automatically switches off. The device can only be restarted after disconnection from the mains.

Timer function

The timer programs the device to switch off within 6 minutes to 4 hours according to the setting. This can be set in steps of 0.1 hours. For example, a timer setting of 1 means that the device will be switched off in 1 hour. A timer setting of 4 means that the device will be switched off in 4 hours.

 **When the TIMER button is pressed, the standard setting is 00.**
Press the TIMER button repeatedly to set the desired time.

So that the device switches OFF at a defined time: make sure that the control unit is switched ON. Repeatedly press the TIMER button until the desired number of 0.1 hour steps is achieved. Press the ENTER button. The indicator light above the TIMER remains switched on. The control unit will end the heating or cooling at the desired time.

After 4 hours without any action on the CTM Controller® 1600, the system will be automatically switched off.

F. Maintenance

Cleaning the control unit

Switch the device off and pull out the mains plug. Use a clean, damp cloth to clean the outside of the control unit. Only use mild soap when necessary. Make sure that no water gets into the device. The CTM Controller® 1600 may be cleaned in this way as often as you like.

NEVER immerse the control unit in water and avoid any water getting into the vent openings.

Emptying the control unit

To empty the device, remove the cover of the water tank and tilt the control unit so that the water can flow out of the tank opening. Then close the cover again.

NOTE: Always empty the control unit prior to transport or storage to prevent accidental leakage.

Storage of the device

If the device is not used for a long period of time, take the tube off the control unit. Let the water out of the control unit as described above. Use the water drain key to let any residual water out of the control unit, tube and CTM Exchanger®. For complete emptying, the CTM Exchanger® must be inverted so that the tube points downwards.

Coil the cable up loosely for storage to avoid damage.

Maintenance

Ener-C recommends to perform an yearly check of the CTM Controller® 1600. Please get in contact with Ener-C or your distributor to arrange the maintenance. The equipment needs to be sent back with the original packaging.

G. Troubleshooting

The following section provides tips and instructions in case of difficulties in using the CTM Controller® 1600. In case the information is not sufficient to solve the issue, unexpected events or changes in the performance of the device please contact Ener-C or the authorized distributor in your country.

Contact information are provided at the end of this user manual or on www.ener-c.com.

The device does not switch on	No power	Check if the device is plugged in. If the mains cable is damaged, disconnect the device from the mains and call customer service.
	Not connected to the power grid	Connect the mains cable to the power source
	Little water in the tank	Fill the water tank and press the ON/OFF button to reset the device
	Water on the control panel	Make sure that the control panel is dry
Poor cooling or heating performance	Little water in the tank	Fill the tank as described in section D. CTM Controller® 1600 setup
	Incorrect temperature set	Set the temperature and press the ENTER button

Poor cooling or heating performance	Kinked tube	Make sure that the tube and CTM Exchanger® are not kinked or folded. See section E. Operation
	Reduced cooling performance at ambient temperatures over 25 °C	Move the device into a cooler room
Error message on the control unit display	The device is equipped with several automatic switch-off functions to protect the system; an error message shows that one of these situations has occurred (E1, E10, E11, E2, E3)	Switch the device off and pull out the mains plug. Wait for 15 minutes, switch the device back on and enter the desired temperature. If the problem occurs again, note the error message, pull out the mains plug and call customer service

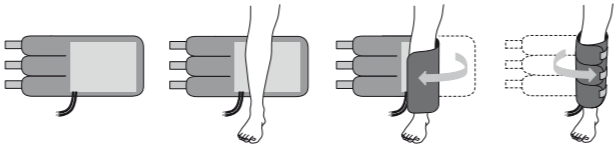
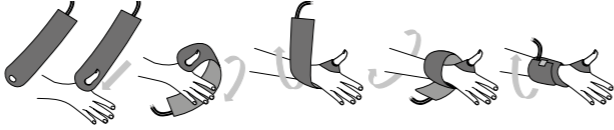
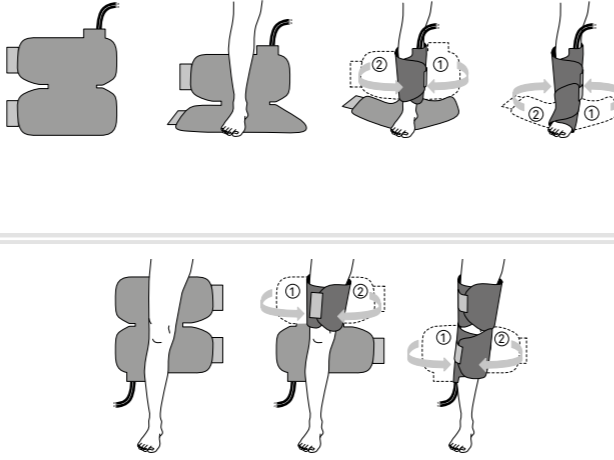
Message	What it means	What to do
"---	Water level to low	Water refill
"E1"	Water temperature < 4 °C Equipment off	Switch the device off and pull out the mains plug. Wait for 15 minutes, switch the device back on and enter the desired temperature. If the Problem occurs again, note the error message, pull out the mains plug and call customer service
"E10"	Water temperature Sensor Disconnected Equipment off	Contact Ener-C for repair
"E11"	Water temperature Sensor short circuit Equipment off	Contact Ener-C for repair
"E2"	Water temperature > 47 °C Equipment off	Switch the device off and pull out the mains plug. Wait for 15 minutes, switch the device back on and enter the desired temperature. If the Problem occurs again, note the error message, pull out the mains plug and call customer service
"E3"	Heat sink temperature > 55 °C Equipment off	Switch the device off and pull out the mains plug. Wait for 15 minutes, switch the device back on and enter the desired temperature. If the Problem occurs again, note the error message, pull out the mains plug and call customer service

If this equipment does cause harmful interference to other devices, 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 device
- Increase the separation between the equipment. Connect the equipment into an outlet on a circuit different from that to which the other device(s) are connected
- Consult the manufacturer or field service technician for help

In the event the device experiences a loss of performance or degradation due to electromagnetic disturbance, the device is expected to continue to operate safely. The device should not be used less than 30 cm (12 inches) away from any portable and mobile RF communications equipment.

H. CTM Exchanger®

Cat. no.	Description	Size	Application
MMM-01	Multi-purpose	small, medium	
MML-03	Multi-purpose	large, x-large	
CWX-03	Wrist	one size	
CAX-03	Ankle	one size	
CES-03*	Elbow	small, medium	
CEL-03*	Elbow	large, x-large	
CKX-03	Knee	one size	

NOTE: Choose the correct size of the exchanger to completely cover the area to treat with the pad where water circulates.

*The elbow exchanger is applied in the same manner as the ankle exchanger.
















Cleaning the CTM Exchanger®

The CTM Exchanger® can be cleaned by wiping the plastic surface with a mild washing-up liquid in water. Then wipe off the residual washing-up liquid with clean water. Allow to dry before using. The CTM Exchanger® may be cleaned in this way as often as you like. It is recommended to clean the CTM Exchanger® between uses.

NOTE: Do not under any circumstances use alcohol, aggressive cleaning agents or disinfectants to clean the CTM Exchanger®.

NOTE: The exchangers shall be used only for one patient. In case more than one patient is treated a new CTM Exchanger® must be used.

Appendix A – Explanation of symbols

	Manufacturer	CE0426	The device complies with European Directive MDD 93/42 EEC
	Type BF Applied Part. Classification required for medical devices that come in direct contact with the patient	REF	Catalogue Number
	Consult Instructions for use	LOT	Batch code
	Refer to instruction manual/ booklet		Caution / Warning
	Keep away from sunlight		Keep dry
	Do not use if package is damaged		Fragile, handle with care
SN	Serial Number	IP 21	Protection against harmful ingress of water or particulate matter (Achieved with transport water proof bag)
	Indoor use only		Alternating current
5 °C  40 °C	Storage temperature limits		Waste Electrical and Electronic Equipment (WEEE) Symbol Product owners should refer to their specific state and government regulatory guidelines for proper disposal.
10%  90%	Storage relative humidity limits		
UDI	Unique device identifier	EC REP	Authorized representative in the European Union
MD	Medical Device		Importer

Appendix B – Manufacturer's declaration

This equipment has been tested and found to comply with the limits for medical devices in EN 60601-1-2:2015. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation.

Guidance and Manufacturer's declaration – Electromagnetic emissions

The CTM Controller® 1600 is suitable for use in the electromagnetic environment specified below. The customer or the user of the CTM Controller® 1600 should assure that it is used in an environment as described below.

Table 1 for Emissions

Emission Test	Compliance
RF emission CISPR 11	Group 1
RF Emission	Class B
Harmonic Emissions EN 61000-3-2	Class A
Flicker emissions EN 61000-3-3	Complies

Guidance and Manufacturer's declaration – Electromagnetic immunity

The CTM Controller® 1600 is suitable for use in the electromagnetic environment specified below. The customer or the user of the CTM Controller® 1600 should assure that it is used in an environment as described below.

Table 2 for Transient Electromagnetic Immunity

Immunity Test	IEC 60601 Test Level	Compliance – Level	Electromagnetic Environment Guidance
Electrostatic Discharge (ESD) EN 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air	
Radiated RF EN 61000-4-3	10 V/m 80 MHz to 3 GHz	10 V/m 80 MHz to 3 GHz	
Electrical Fast transient EN 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	
Surge EN61000-4-5	± 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	
Conduct disturbances EN 61000-4-6	10 Vrms	10 Vrms	
Power frequency magnetic field (50Hz/60Hz) EN 61000-4-8	3 A/m	30 A/m	
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	$U_T = 0\% 0,5p$ $0^\circ, 45^\circ, \dots, 315^\circ$ $U_T = 0\% 1p$ 0° $U_T = 70\% 25/30p$ 0°	$U_T = 0\% 0,5p$ $0^\circ, 45^\circ, \dots, 315^\circ$ $U_T = 0\% 1p$ 0° $U_T = 70\% 25/30p$ 0°	
	$U_T = 0\% 250/300p$	$U_T = 0\% 250/300p$	Interrupt

NOTE: U_T is the AC mains voltage prior to application of the test level.

Table 3 for RF Electromagnetic Immunity

The CTM Controller® 1600 is intended for use in the electromagnetic environment specified below. The customer or the user of the CTM Controller® 1600 should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance – Level	Recommended Separation distance
Conducted RF IEC 61000-4-6	10 Vrms 150 kHz to 80 MHz	V1 = 10 Vrms 150 kHz to 80 MHz	Portable and mobile RF communications equipment should be used no closer to any part of the CTM Controller® 1600, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz $d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz $d = 2.3 \sqrt{P}$ 800 MHz to 2.5 GHz Where <i>P</i> is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and <i>d</i> is the recommended separation distance in meters (<i>m</i>). 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:
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 800 MHz	E1 = 10 V/m 80 MHz to 800 MHz	
	10 V/m 800 MHz to 2.5 GHz	E2 = 10 V/m 800 MHz to 2.5 GHz	



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 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 CTM Controller® 1600 is used exceeds the applicable RF compliance level above, the CTM Controller® 1600 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the CTM Controller® 1600.

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



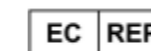
Dispose of the unit and pads in a manner that is consistent with your federal, state, and local laws and regulations.

CE 0426



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