

## Battle Creek Equipment Company

September 15, 2016

### **URGENT: MEDICAL DEVICE RECALL**

#### **Thermophore® Classic Moist Heat Pads Manufactured between July 2012 and July 2014**

Dear Consumer,

The purpose of this letter is to advise you that Battle Creek Equipment Company is voluntarily recalling certain model numbers of **Thermophore® Classic Moist Heat Pads** with July 2012 through July 2014 dates of manufacture. Instructions are provided to help you identify the model numbers and lot codes involved in this recall. No other Thermophore® models or lot codes are affected by this recall.

We are aware that the electrical cord for the affected Thermophore® Classic units can, in some rare situations, fail prematurely when the user over-stresses the cord in a particular way that is warned against in the user manual and on the labels.

If the electrical cord is over-stressed by wrapping the cord tightly around the pad or bent sharply during use, the cord may wear or potentially crack open at specific points shown in the image below. Consumers have reported sparking, smoke, fire and mild shock when the failure occurs.



**If your product is included in the recall, please stop using it immediately!**

Out of an abundance of caution, BCE is voluntarily recalling these units. No serious injuries have occurred due to the failure mode associated with this recall.

The rates of occurrence associated with this failure mode is less than 0.06% or less than one unit for every 1,800 in use, and less than 0.03% or less than one for every 3,400 units used in accordance with the user manual and labels. Over a period of three years, we are aware of 337 total failures.

No serious injuries have been reported and the likelihood of injury to the user or damage to property is extremely remote. However, since it is a failure of the electrical cord which could cause a brief spark in some situations, we would rather proactively address the situation.

**Battle Creek Equipment CO. 702 S. Reed Road, PO Box 629, Fremont, IN 46737**  
**The Original Drug-Free Pain Relief Company™ ...since 1931!**

Product manufactured after July 2014 is not affected by this recall. The electrical cord associated with this failure mode was discontinued from manufacturing by mid-2014

Please follow the instructions below to support our efforts to address the issue with the heating pads that were manufactured with this cord.

### **What should you do?**

Find your model number \_\_\_\_\_ (listed on a label on the pad)

Find your lot code \_\_\_\_\_ (location varies by size, see below)

**How to find your lot code:** The Lot Code is stamped on the heating pad. Locations of the lot code vary by model, see instruction on following pages.

### **Check your model number and lot code against the attached lists.**

**If your Thermophore® Classic moist heat pad is included in this recall, stop using it immediately.** Directions on finding the lot code and model number are below. If you are having difficulty call us at 269-924-0946. Once we verify that your product is included in the recall, we will ask you to discard it as you would normally. If your product is still within the warranty period, we will replace it.

**If you have a Thermophore® Classic moist heat pad that has a “round cord” rather than a flat, two-wire cord** shown in the picture, your unit is NOT part of this recall effort.

**If you have a Thermophore® moist heat pad that is not a Classic or Classic Plus model** then your product is NOT involved in this recall.

**How to contact us:** 269-924-0946 between the hours of 8am and 5pm Eastern Time, M-F.

If you reach the number during non-business hours or while assisting other customers, please leave your name, your reference number (top right hand corner of the first page of this letter), and a telephone number where we can reach you back during business hours.

If you prefer, you may contact us by email at [Recall@BattleCreekEquipment.com](mailto:Recall@BattleCreekEquipment.com). Please include your name, your reference number (top right hand corner of the first page of this letter), and any questions that you may have.

**DO NOT return your pad to Battle Creek Equipment! There is no need for you to do this. Call us and we will explain how the recall will be processed. Thank you!**

**MEDICAL DEVICE RECALL RETURN RESPONSE**  
**Acknowledgement and Receipt Form**  
Response is Requested

**Customer Information:**

Reference # (top right hand corner of the first page) \_\_\_\_\_

Customer Name \_\_\_\_\_

Street Address \_\_\_\_\_

Town, State, Zip Code \_\_\_\_\_

Telephone \_\_\_\_\_

Email \_\_\_\_\_

## Thermophore® Classic Moist Heat Pad

**Model number:** \_\_\_\_\_ **Lot number:** \_\_\_\_\_

I have read and understand the recall instructions provided in the 9-1-2016 letter. Yes \_\_\_ No \_\_\_

Any adverse events associated with recalled product? Yes \_\_\_ No \_\_\_

If yes, please explain:

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Send via email to: [Recall@BattleCreekEquipment.com](mailto:Recall@BattleCreekEquipment.com)

or by mail to: BCE Recall PO Box 629, Fremont, IN 46737

DO NOT return your heating pad to this address. Call us or we will contact you.

Thank you for your help in this matter!

## Finding your Lot Code number



### **Models 055, 255 or 095**

- Remove the cover
- Turn the pad so that the label is facing up
- Rotate the pad so that the cord is at the top
- The LOT CODE will be stamped at the bottom edge of the pad (see image)

**CHECK YOUR LOT CODE AGAINST THE LIST BELOW**

<b>F00055 055 Standard Thermophore® Classic Moist Heat Pad</b>			<b>F00255 255 Standard Thermophore® Classic Plus Moist Heat Pad</b>			<b>F80095 095 Standard CSA Thermophore® Classic Moist Heat Pad</b>		
0552712	0550513	0553513	2552712	2550513	2553513	0952712	0950513	0953513
0552812	0550613	0553613	2552812	2550613	2553613	0952812	0950613	0953613
0552912	0550713	0553713	2552912	2550713	2553713	0952912	0950713	0953713
0553012	0550813	0553813	2553012	2550813	2553813	0953012	0950813	0953813
0553112	0550913	0553913	2553112	2550913	2553913	0953112	0950913	0953913
0553212	0551013	0554013	2553212	2551013	2554013	0953212	0951013	0954013
0553312	0551113	0554113	2553312	2551113	2554113	0953312	0951113	0954113
0553412	0551213	0554213	2553412	2551213	2554213	0953412	0951213	0954213
0553512	0551313	0554313	2553512	2551313	2554313	0953512	0951313	0954313
0553612	0551413	0554413	2553612	2551413	2554413	0953612	0951413	0954413
0553712	0551513	0554513	2553712	2551513	2554513	0953712	0951513	0954513
0553812	0551613	0554613	2553812	2551613	2554613	0953812	0951613	0954613
0553912	0551713	0554713	2553912	2551713	2554713	0953912	0951713	0954713
0554012	0551813	0554813	2554012	2551813	2554813	0954012	0951813	0954813
0554112	0551913	0554913	2554112	2551913	2554913	0954112	0951913	0954913
0554212	0552013	0555013	2554212	2552013	2555013	0954212	0952013	0955013
0554312	0552113	0555113	2554312	2552113	2555113	0954312	0952113	0955113
0554412	0552213	0555213	2554412	2552213	2555213	0954412	0952213	0955213
0554512	0552313	0550113	2554512	2552313	2550113	0954512	0952313	0950113
0554612	0552413	0550214	2554612	2552413	2550214	0954612	0952413	0950214
0554712	0552513	0550314	2554712	2552513	2550314	0954712	0952513	0950314
0554812	0552613	0550414	2554812	2552613	2550414	0954812	0952613	0950414
0554912	0552713	0550514	2554912	2552713	2550514	0954912	0952713	0950514
0555012	0552813	0550614	2555012	2552813	2550614	0955012	0952813	0950614
0555112	0552913	0550714	2555112	2552913	2550714	0955112	0952913	0950714
0555212	0553013	0550814	2555212	2553013	2550814	0955212	0953013	0950814
0550112	0553113	0550914	2550112	2553113	2550914	0950112	0953113	0950914
0550213	0553213	0551014	2550213	2553213	2551014	0950213	0953213	0951014
0550313	0553313	0551114	2550313	2553313	2551114	0950313	0953313	0951114
0550413	0553413		2550413	2553413		0950413	0953413	

## Finding your Lot Code number



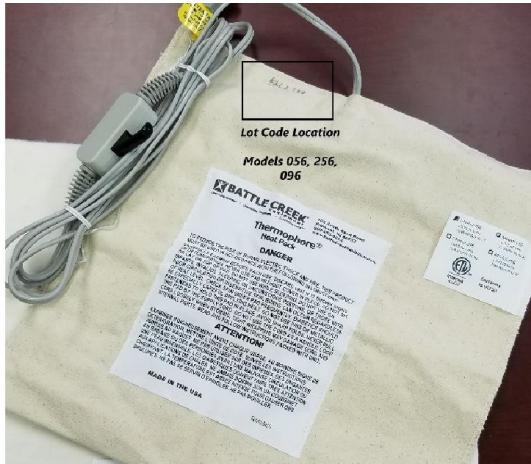
## Models 077, 277 or 097

- Remove the cover
- Turn the pad so that the label is facing up
- Rotate the pad so that the cord is at the top
- The LOT CODE will be stamped at the bottom edge of the pad (see image)

**CHECK YOUR LOT CODE AGAINST THE LIST BELOW**

F00077 077 Petite Thermophore® Classic Moist Heat Pad			F00277 277 Petite Thermophore® Classic Plus Moist Heat Pad			F80097 097 Petite CSA Thermophore® Classic Moist Heat Pad		
0772712	0771013	0774513	2772712	2771013	2774513	0972712	0971013	0974513
0772812	0771113	0774613	2772812	2771113	2774613	0972812	0971113	0974613
0772912	0771213	0774713	2772912	2771213	2774713	0972912	0971213	0974713
0773012	0771313	0774813	2773012	2771313	2774813	0973012	0971313	0974813
0773112	0771413	0774913	2773112	2771413	2774913	0973112	0971413	0974913
0773212	0771513	0775013	2773212	2771513	2775013	0973212	0971513	0975013
0773312	0771613	0775113	2773312	2771613	2775113	0973312	0971613	0975113
0773412	0771713	0775213	2773412	2771713	2775213	0973412	0971713	0975213
0773512	0771813	0770113	2773512	2771813	2770113	0973512	0971813	0970113
0773612	0771913	0770214	2773612	2771913	2770214	0973612	0971913	0970214
0773712	0772013	0770314	2773712	2772013	2770314	0973712	0972013	0970314
0773812	0772113	0770414	2773812	2772113	2770414	0973812	0972113	0970414
0773912	0772213	0770514	2773912	2772213	2770514	0973912	0972213	0970514
0774012	0772313	0770614	2774012	2772313	2770614	0974012	0972313	0970614
0774112	0772413	0770714	2774112	2772413	2770714	0974112	0972413	0970714
0774212	0772513	0770814	2774212	2772513	2770814	0974212	0972513	0970814
0774312	0772613	0770914	2774312	2772613	2770914	0974312	0972613	0970914
0774412	0772713	0771014	2774412	2772713	2771014	0974412	0972713	0971014
0774512	0772813	0771114	2774512	2772813	2771114	0974512	0972813	0971114
0774612	0772913	0771214	2774612	2772913	2771214	0974612	0972913	0971214
0774712	0773013	0771314	2774712	2773013	2771314	0974712	0973013	0971314
0774812	0773113	0771414	2774812	2773113	2771414	0974812	0973113	0971414
0774912	0773213	0771514	2774912	2773213	2771514	0974912	0973213	0971514
0775012	0773313	0771614	2775012	2773313	2771614	0975012	0973313	0971614
0775112	0773413	0771714	2775112	2773413	2771714	0975112	0973413	0971714
0775212	0773513	0771814	2775212	2773513	2771814	0975212	0973513	0971814
0770112	0773613	0771914	2770112	2773613	2771914	0970112	0973613	0971914
0770213	0773713	0772014	2770213	2773713	2772014	0970213	0973713	0972014
0770313	0773813	0772114	2770313	2773813	2772114	0970313	0973813	0972114
0770413	0773913	0772214	2770413	2773913	2772214	0970413	0973913	0972214
0770513	0774013	0772314	2770513	2774013	2772314	0970513	0974013	0972314
0770613	0774113	0772414	2770613	2774113	2772414	0970613	0974113	0972414
0770713	0774213	0772514	2770713	2774213	2772514	0970713	0974213	0972514
0770813	0774313	0772614	2770813	2774313	2772614	0970813	0974313	0972614
0770913	0774413	0772714	2770913	2774413	2772714	0970913	0974413	0972714

## Finding your Lot Code number



## Models 056, 256 or 096

- Remove the cover
- Turn the pad so that the label is facing up
- Rotate the pad so that the cord is at the top
- The LOT CODE will be stamped at the TOP edge of the pad (see image)

**CHECK YOUR LOT CODE AGAINST THE LIST BELOW**

F00056 056 Medium Thermophore® Classic Heat Pad			F00256 256 Medium Thermophore® Classic Plus Moist Heat Pad			F80096 096 Medium CSA Thermophore® Classic Moist Heat Pad		
0562712	0561113	0564713	2562712	2561113	2564713	0962712	0961113	0964713
0562812	0561213	0564813	2562812	2561213	2564813	0962812	0961213	0964813
0562912	0561313	0564913	2562912	2561313	2564913	0962912	0961313	0964913
0563012	0561413	0565013	2563012	2561413	2565013	0963012	0961413	0965013
0563112	0561513	0565113	2563112	2561513	2565113	0963112	0961513	0965113
0563212	0561613	0565213	2563212	2561613	2565213	0963212	0961613	0965213
0563312	0561713	0560113	2563312	2561713	2560113	0963312	0961713	0960113
0563412	0561813	0560214	2563412	2561813	2560214	0963412	0961813	0960214
0563512	0561913	0560314	2563512	2561913	2560314	0963512	0961913	0960314
0563612	0562013	0560414	2563612	2562013	2560414	0963612	0962013	0960414
0563712	0562113	0560514	2563712	2562113	2560514	0963712	0962113	0960514
0563812	0562213	0560614	2563812	2562213	2560614	0963812	0962213	0960614
0563912	0562313	0560714	2563912	2562313	2560714	0963912	0962313	0960714
0564012	0562413	0560814	2564012	2562413	2560814	0964012	0962413	0960814
0564112	0562513	0560914	2564112	2562513	2560914	0964112	0962513	0960914
0564212	0562613	0561014	2564212	2562613	2561014	0964212	0962613	0961014
0564312	0562713	0561114	2564312	2562713	2561114	0964312	0962713	0961114
0564412	0562813	0561214	2564412	2562813	2561214	0964412	0962813	0961214
0564512	0562913	0561314	2564512	2562913	2561314	0964512	0962913	0961314
0564612	0563013	0561414	2564612	2563013	2561414	0964612	0963013	0961414
0564712	0563113	0561514	2564712	2563113	2561514	0964712	0963113	0961514
0564812	0563213	0561614	2564812	2563213	2561614	0964812	0963213	0961614
0564912	0563313	0561714	2564912	2563313	2561714	0964912	0963313	0961714
0565012	0563413	0561814	2565012	2563413	2561814	0965012	0963413	0961814
0565112	0563513	0561914	2565112	2563513	2561914	0965112	0963513	0961914
0565212	0563613	0562014	2565212	2563613	2562014	0965212	0963613	0962014
0560112	0563713	0562114	2560112	2563713	2562114	0960112	0963713	0962114
0560213	0563813	0562214	2560213	2563813	2562214	0960213	0963813	0962214
0560313	0563913	0562314	2560313	2563913	2562314	0960313	0963913	0962314
0560413	0564013	0562414	2560413	2564013	2562414	0960413	0964013	0962414
0560513	0564113	0562514	2560513	2564113	2562514	0960513	0964113	0962514
0560613	0564213	0562614	2560613	2564213	2562614	0960613	0964213	0962614
0560713	0564313	0562714	2560713	2564313	2562714	0960713	0964313	0962714
0560813	0564413	0562814	2560813	2564413	2562814	0960813	0964413	0962814
0560913	0564513	0562914	2560913	2564513	2562914	0960913	0964513	0962914
0561013	0564613		2561013	2564613		0961013	0964613	