Digital Heat Corporation
5626 S. Captain Kidd Ct. Unit B
Tempe, AZ 85283

DIGITAL HEAT

K142228

FDA CDRH DMC

AUG 13 2014

Received

August 11, 2014

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

RE: 510(k) Premarket Notification for Digital Heat Corporation, Heated Eye Pad

Dear FDA:

Enclosed is the 510(k) Premarket Notification for the proposed product "Heated Eye Pad." Intended for an application that provides dry heat therapy for the eyelid. The eCopy is an exact duplicate of the paper copy.

The Heated Eye Pad is recommended for any eyelid treatment whereby the current medical community would suggest applying a warm compress to the eyelids. Current indications for use would include anyone diagnosed with Meibomian Gland Dysfunction (MGD), dry eye, Blepharitis, Stye, or Chalazia.

510(k) notification submitted under premarket notification procedures described in 21 Code of Federal Regulations (CFR) Part 807, Subpart E for the new device of substantial equivalence to predicate devices includes:

21 CFR 890.5740 (Powered Heating Pad)
21 CFR 890.5720 (Water Circulating Hot or Cold Pack)
21 CFR 890.5710 (Chemical Hot/Cold Pack) Class

Gel packs and warm compress intended for the Meibomian gland fluids have been classified as Class I devices, under Product Code IME, according to section 890-5710.

A summary of 510(k) is included in this notification.

Contact information is provided below for any additional requirements or further correspondence on this 510(k) submission.

Sincerely,

John Devine

John Devine
President and CEO

Telephone: (512) 560-7184
Email: john.devine@digitalheat911.com

1-CD

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John Devine

John Devine
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Telephone: (512) 560-7184
Email: john.devine@digitalheat911.com

Table of Contents

0.0 GUIDANCE DOCUMENT USED FOR THIS 510(K) APPLICATION

Guidance Document for the Preparation of Premarket Notification [510(k)] Applications for Heating and Cooling Devices

This guidance was written prior to the February 27, 1997 implementation of FDA's Good Guidance Practices, GGP's. It does not create or confer rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both. This guidance will be updated in the next revision to include the standard elements of GGP's.

July 26, 1995
(reformatted 12/18/97)

This guidance document may contain references to addresses and telephone numbers that are now obsolete. The following contact information is to be used instead:

- **While this guidance document represents a final document, comments and suggestions may be submitted at any time for Agency consideration to the Restorative Devices Branch, 9200 Corporate Blvd., HFZ-410, Rockville, MD 20850.**
- **For questions regarding the use or interpretation of this guidance, contact the Restorative Devices Branch at 301-594-1296.**
- **To contact the Division of Small Manufacturers Assistance (DSMA), call 800-638-2041 or 301-443-6597; fax 301-443-8818; email dsmo@cdrh.fda.gov; or write to DSMA (HFZ-200), Food and Drug Administration, 1350 Piccard Drive, Rockville, Maryland 20850-4307. FACTS-ON-DEMAND (800-899-0381 or 301-827-0111) and the World Wide Web (CDRH home page: http://www.fda.gov/cdrh/index.html) also provide easy access to the latest information and operating policies and procedures.**

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
Center for Devices and Radiological Health
Rockville, MD 20850

PREFACE

The purpose of this document is to provide guidance to the sponsors of premarket notifications [510(k)'s] for restorative devices. This document is intended to assist the sponsors in organizing and providing the essential information that should be submitted to the Food and Drug Administration (FDA) for review.

This guidance is based on the Restorative Devices Branch's (REDB's) identification of specific criteria necessary to conduct an adequate evaluation of a 510(k) for the purpose of determining substantial equivalence for physical medicine/restorative devices. The objective of this document is to delineate to the device manufacturer important administrative, descriptive, and scientific information that should be included in a 510(k) for a restorative device. Individual 510(k) submissions may require additional information pertinent to each specific device. The suggestions and recommendations included in the guidance reflect the minimal requirements that would allow an evaluation of the device as determined by REDB. While the use of this document in the preparation of a 510(k) premarket notification will not ensure FDA clearance of a device, following the guidance will ensure that sufficient basic information is available to initiate a substantive review.

Note that the guidance document is a living document. It will be periodically revised as scientific knowledge and regulations change.

INTRODUCTION

Any 510(k) notification submitted under premarket notification procedures described in 21 Code of Federal Regulations (CFR) Part 807, Subpart E, for FDA's determination that a new device is substantially equivalent to a predicate (existing) device in 21 CFR 890.5950 (Powered Heating Unit), 21 CFR 890.5740 (Powered Heating Pad), 21 CFR 890.5500 (Infrared Lamp), 21 CFR 890.5720 (Water Circulating Hot or Cold Pack), or Class I by 21 CFR 890.5710 (Chemical Hot/Cold Pack) should follow the format below and must contain all specified information that is pertinent to the device.

ADMINISTRATIVE INFORMATION

1. Provide the name and address of the manufacturer and sponsor of the 510(k) submission.
2. Provide the FDA registration number (if available) of the manufacturer of the new device.
3. Identify the official contact person for all correspondence.

DEVICE IDENTIFICATION

1. As stated in 21 CFR 807.90(d), a 510(k) shall be submitted separately for each product the manufacturer intends to market. Therefore, a submission can describe no more than one new device.

   A submission can describe more than one component of, or attachment to, a single device. The submission must compare each such component or attachment with that of a predicate device, or must state that the predicate device lacks such a component or attachment.

2. The following information must be provided:

a. The proprietary name of the new device;
b. The generic name of the device;
c. The classification of the predicate device e.g., Class II. Refer to 21 CFR and section 513 of the Food, Drug, and Cosmetic Act;
d. The proposed regulatory class for the new device, e.g., Class II. (21 CFR 862-892 contains the regulatory classifications for medical devices); and
e. The panel code(s) for the device. [If the product is not classified under the physical medicine devices panel, identify the panel under which it is classified and provide the panel identification code (e.g., 89 is the code for the physical medicine devices panel)].

3. Specify whether this device:

a. Has been previously submitted to the FDA for identical or different indications;
b. Is currently being reviewed for different indications by the same or different branch within ODE; or
c. Has been previously cleared by the FDA for different indications.

DEVICE DESCRIPTIVE INFORMATION

Intended Use

Identify the specific intended use(s), including the specific therapeutic indications, for the subject device and the predicate device.

The new device must have the same intended medical uses as those specified for the predicate device, to the extent that the changes do not alter the therapeutic or diagnostic effect and do not affect the safety and effectiveness.

These intended uses must be consistent with the descriptions of intended medical uses contained within the CFR section that is applicable to the device and must identify the specific medical conditions for which the device is indicated.

If the indication differs, you must provide a justification as to how the change(s) do not affect safety and effectiveness. If special labeling claims are sought, information must be provided to support these claims.

It is not necessary to notify FDA of an intent to market a device if it will not be labeled or promoted for medical uses. However, FDA will regulate the equipment and may require premarket notification if any promotional material appears which makes medical claims after marketing begins.

Device Description

1. Provide a written description of the device, including all device components, instruments, and any new features of the device.
2. Identify all sizes, configurations, and functions of each device component.
3. Describe how the device works and interconnects with other components.
4. Engineering drawings and/or photographs and complete written descriptions of the new and predicate devices. The document must contain illustrations of all internal and external features of both devices. Engineering drawings must provide the lengths, widths, and heights of the devices and their major component parts.
5. Provide the temperature range of the device.
6. Provide the temperature range at the skin surface where device is applied.

Materials

Identify the specific materials for each component, any additional processing that may affect the material properties, and the voluntary standards with which the device materials will conform. In the case of powered heating pads, the material of the heating pad cover must be specified. Similarly, the chemicals and activator(s) used in hot/cold packs must be described.

Labeling

1. Provide draft or sample package labeling, package inserts, including complete operator's instructions for the new device.
2. Include copies of promotional materials for the new and predicate devices.
3. The following warning statement must be included in the labeling for all devices:

   "WARNING: Use carefully. May cause serious burns. Do not use over sensitive skin areas or in the presence of poor circulation. The unattended use of ..... by children or incapacitated persons may be dangerous."

Additional Information

1. The distance of the device from the area of application must be provided for infrared lamps.
2. The leakage current must be specified for powered heating pads, infrared lamps, and water circulating hot/cold packs.
3. The flow rate, pressure, and the liquid to be used must be specified for water circulating hot/cold packs.

SUBSTANTIAL EQUIVALENCE INFORMATION

1. The legally marketed predicate device with which the subject device is to be compared for the determination of substantial equivalence must be identified.
2. Evidence must be provided that the device was placed into interstate commerce for other than research uses or as part of a plant-to-plant transfer and was actually labeled and promoted for the intended use to which the submitter of the premarket notification is claiming substantial equivalence. This may be accomplished by providing copies of the firm's advertisements, catalog pages, or other promotional material dated prior to May 28, 1976 and shipping documents such as invoices, bills of lading, receipts showing the interstate transit of the device (for other information which can be used to prove Pre-Amendment status contact DSMA).

   Alternatively, the 510(k) number(s) of the predicate device(s) may be identified.

   The 510(k) number may be obtained from the Electronic Docket (ED), an automated retrieval system of the Division of Small Manufacturers Assistance (DSMA), which provides medical device regulations, FDA talk papers and press releases, device evaluation guidance, and the listing of all approved 510(k)s sorted by applicant name.

   This 510(k) information is located under the Product Clearance Main Menu Item # 12. Dial (301) 594-4802 or (800) 252-1366. For more guidance on how to assess this information, contact DSMA. Call toll free (800) 638-2041, (301) 443-6597, or fax (301) 443-8818.
3. The submission should include a description of all significant similarities and differences between the new and predicate device.
4. To facilitate the review, the submission should contain a table which compares the
   1. intended medical uses and
   2. the physical characteristics and
   3. functions of the two devices.

510(K) SUMMARY OR STATEMENT

1. Provide a 510(k) summary of safety and effectiveness information in the premarket notification submission upon which an equivalence determination could be based, written in accordance with the content and format requirements that are specified in 21 CFR 807.92 **or**
2. Provide a 510(k) statement that safety and effectiveness information will be made available to interested persons upon request. This statement must follow the format and contain the wording as specified in 21 CFR 807.93.

TRUTHFUL AND ACCURATE STATEMENT

Provide a statement that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted, as required by 21 CFR 807.87(j).

1.0 ADMINISTRATIVE INFORMATION

Applicant, Sponsor:	Digital Heat Corporation
Address:	5626 S. Captain Kidd Ct., Unit B Tempe, AZ 85283
FDA Registration Number:	
Contact Person:	John Devine (CEO)
Telephone Number:	(512) 560-7184

2.0 DEVICE IDENTIFICATION

The proprietary name of the new device:	Heated Eye Pad
The generic name of the device:	Powered Heating Pad
Classification of the predicate device:	Title 21 C.F.R. § 890.5740 Powered heating pad Regulatory Class II (special controls) Exempt subject to § 890.9
The proposed regulatory class for the new device:	Title 21 C.F.R. § 890.5740 Powered heating pad Regulatory Class II (special controls) Exempt subject to § 890.9
Panel Code:	Physical Medicine Devices panel 89
Has been previously submitted to the FDA for identical or different indications?	No Prior Submission
Is currently being reviewed for different indications by the same or different branch within ODE?	No
Has been previously cleared by the FDA for different indications?	No

3.0 DEVICE DESCRIPTIVE INFORMATION

3.1 Intended Used:

The proposed device use is for treatment where the current medical community recommends the application of a warm compress to the eyelids. Such applications would include Meibomian Gland Dysfunction (MGD), dry eye, Blepharitis, Stye, or Chalazia.

The Digital Heat (Heated Eye Pad) makes contact with the exterior eyelid tissue. Users typically apply the device 5-10 minutes, twice per day. This device is targeted for over the counter distribution. Patients' use of the proposed device can be at home, on travel, or at the office.

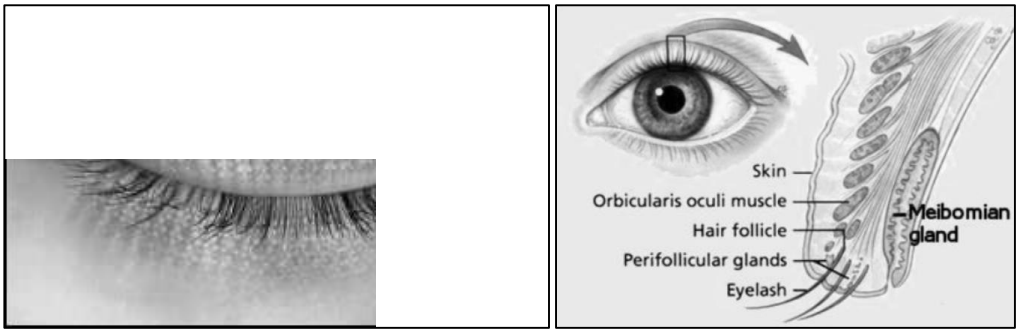
The meibomian glands supply lipids or oily substances that help to prevent or minimize tear evaporation. There are 50 on the upper eyelid, 25 on the lower eyelid (Figure 1). The medical community recognizes meibomian gland dysfunction as presenting several problems to the eyelid:

- Dry eye: Either poor quality or poor quantity of lipid secretion from the meibomian glands.
- Chalazion (meibomian gland lipogranuloma): Is a cyst in the eye lid caused by inflammation of a blocked meibomian gland.
- Blepharitis: Chronic inflammation of eye lid
- Sty(e): Infection of glands caused by bacteria; Caused by blocking of an oil gland

For all four stages of Meibomian gland dysfunction, the medical community recommends a warm compress for treatment, whereby heating the lipid will decrease the meibomian gland viscosity, liquefy any clog in the oil gland, and increase the flow of lipids to the eye. (Mori, 2003, Foulks, 2012).

Figure 1: Meibomian Gland

(A) External Eyelid **(B) Internal Eyelid Structure**



In terms of thermal therapy for the treatment, the medical community would like an elevated temperature, but not such that it will inflame or burn the skin. The skin starts to feel pain at 44 centigrade and 1st degree burns occur at 48 centigrade (NIST, 2013).

The proposed new device provides (b)(4)

1. Heat only where needed
2. A more precise temperature
3. Constant temperature over time.

Several prior predicate devices as noted in Table-1 provide the basis for comparison to the proposed device.

- Theratherm Electric Heating Pad
- EyeFeel™ Ophthalmic Warmer
- ThermalOn Ophthalmic Warmer

The proposed device will not alter the therapeutic effect as applicable to the predicate devices. In addition to improved thermal performance, the proposed device provides additional safety not currently embodied in the prior predicate devices (details provided in device description).

Table-1 Proposed and Predicate Device Summary

Device	**Proposed Device (Ophthalmic Warmer)**	**Theratherm (Electric Heating Pad)**	**EyeFeel™ (Ophthalmic Warmer)**	**ThermalOn (Ophthalmic Warmer)**
510(k):	New	K770686	K021843, K082087	Not Applicable
Title 21 CFR	§890.5740	§890.5740	§890.5710	§890.5730
Classification:	Class II (Special Controls) Exempt	Class II (Special Controls) Exempt	Class I	Class I
Generic Name:	Powered Heating Pad	Powered Heating Pad	Chemical Hot Pack	Moist Heat Pack

3.2 Device Description:

3.2.1 Written Description

(b)(4)

The proposed new device provides heating of the eyelid with three factors of improved heat treatment as compared to predicates; 1) heat only where needed, 2) a more precise temperature, and 3) constant temperature over time.

3.2.2 Sizes, Configurations, and functions of each device component

The design of the heater is a one size fits all. There is only 1 configuration.

A complete list (Table 2) of components, their functions, and sizes are as follows:

Table 2: A complete list of components, their functions, and sizes (Not to Scale)

Picture	Part	Function	Size
	Heater	(b)(4)	b)(4)
	Foam		
	Frame		
	Fuse		
	USB Connector		
	Power Cable		
	Band		

3.2.3 Describe how the device works and interconnects with other components:

(b)(4)

3.2.4 Drawings and Photographs

Photographs and complete written descriptions of the new and predicate devices are presented below. In addition, Figures 3-6 are drawings and overall dimensions of the proposed product and predicate devices.

3.2.4.1 Digital Heat Proposed Device: Figure 2

(b)(4)

[redacted]

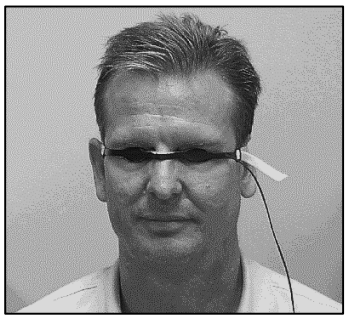
Figure 3: Digital Heat Eye Pad (Product Packaging and User Wear)

(A) Heating Element

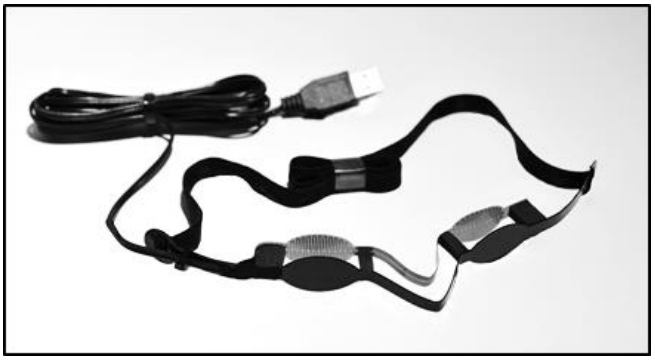
(b)(4) Schematic Drawings

[redacted]

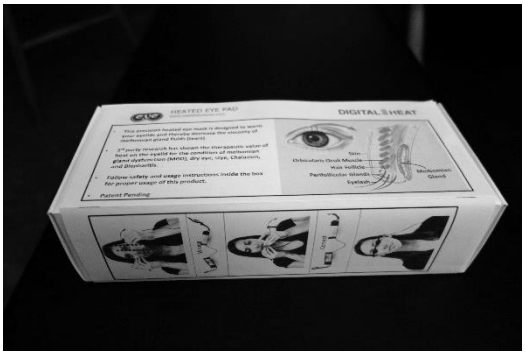
(B) User Configuration



(C) Digital Heat Elastic Band



(D) Box/Labeling



3.2.4.2 Theratherm: Figure-3

This device consists of an inner sealed liner with a powered heater along with a thermal couple and control electronics for the user (Figure 4A). The packaging for the device (Figure 4B)

shows the user application which is normally for large area usage on the human body. The user positions the product (Figure 4C) on facial features for heat treatment of eyes. This predicate is a large area application of a heated surface as noted in dimensions of Figure 4A, 4B, and 4C.

Figure 4: Theratherm Powered Heating Pad (Product Packaging and User Wear)

(A) Heated Pad (B) Box/Labeling (C) User Configuration

(Reference:www.dme-direct.com/theratherm-moist-heatting-pack)
D = 15mm // W = 370mm // L = 700mm

3.2.4.3 Kao (Chemically Activated Heated Eye Pad): Figure 5

The Kao product (Figure 5) is an embodiment (Chemical Heat Generation Eye Pad) to the "EyeFeel" predicate device (K021843, K082087) of like function. The EyeFeel is not currently on the open market for representative packaging and labeling. The Kao device uses a chemically activated air reaction to produce heat.

The Kao eye pad (Figure 5A) consists of two eye pads with interior sealed chemical packets that are activated by air when the seal pouch is opened. Labeling and packaging is noted in Figure 5B) and written in Japanese. Translation of the labeling includes opening of the package and positioning the product on the eyes. Dimensions of this product are provided in Figure 5A.

Figure 5: Kao Heat Eye Pad (Product Packaging and User Wear)

(A) Chemical Eye Pad (B) Box/Labeling (C) User Configuration

(Reference:.www.amazon.com/Kao-Megurhythm-Steam-Mask-Sheets/product-reviews/B0012R23UK)
D = 3 mm // W = 80 mm // L = 180 mm (Non Activated Condition)

3.2.4.4 Thermalon (Microwave Heated Eye Pad): Figure-6

The Theramalon product is a facemask (Figure 6A) with inner materials (silicone gel beads) for heat activation in a microwave. The user places the mask on the face for thermal heat transfer

treatment. Packaging (Figure 6B) is a plastic sealed container along with instructions and safety documentation. The user control of the temperature is dependent on time placed in the microwave along with power of the appliance. The outer structure of the facemask is cloth along with a band of material used to secure the facemask to the users' face (Figure 6C). Dimensions of the Thermalon product is noted in Figure 6A.

Figure 6: Thermalon Heat Eye Pad (Product Packaging and User Wear)

(A) Microwave Eye Pad (B) Box/Labeling (C) User Configuration

(Reference: www.walmart.com/ip/Thermalon-Dry-Eye-Compress-1ct/16608834)
D = 15mm // W = 80 mm // L = 210 mm

3.2.5 Temperature Range of the Device

Digital Heat claims the proposed new device provides heating of the eyelid with three factors of improved heat treatment as compared to predicates:

1. Heat only where needed
2. A more precise temperature
3. Constant temperature over time.

The data in this section supports claim number 2) A more precise temperature, and 3) Constant temperature over time. Data to support claim 1) Heat only where needed is provided in Section 3.2.6 Temperature Range at the skin surface where applied.

(b)(4)

- Theratherm: A powered heating pad, but it uses feedback control to adjust the voltage sent to the heater based on a thermocouple measurement, the heating element is widely dispersed and unfocused within the heater. In addition, the heater contains a cloth cover, creating an unpredictable thermal profile based on ambient humidity, and compression on the heater.
- Kao: Uses chemical activation to heats up, peaks, and begins too cool
- Thermalon: Uses a microwave to heat up, it starts off hot and cools over time. Actual starting temperature will vary based on the power of the microwave and the duration of time in the microwave.

(b)(4) Drawing

3.2.6 Temperature Range at the skin surface where applied:

The proposed new device provides heating of the eyelid with three factors of improved heat treatment as compared to predicates:

1. Heat only where needed
2. A more precise temperature
3. Constant temperature over time.

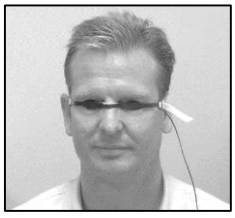
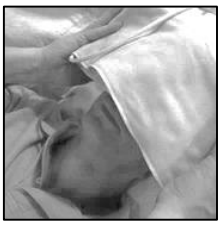
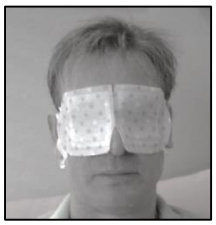
Data in this section supports the assertion that Digital Heat provides improved heat treatment as compared to predicates by providing heat only where needed.

(b)(4)

Figure 8: Meibomian Gland and Localized Heat

(A) Eye Lid Meibomian Gland (B) Proposed Product

Table 3: Heated Products versus Eyelid Coverage

Digital Heat	Theratherm	Kao	Thermalon
			

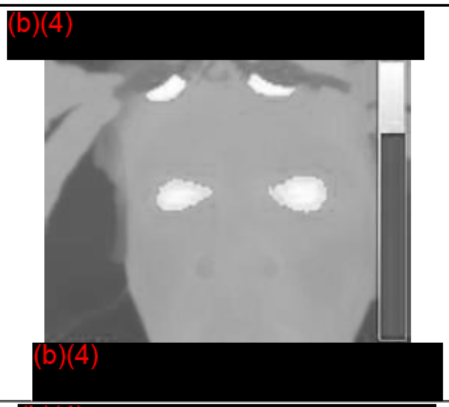
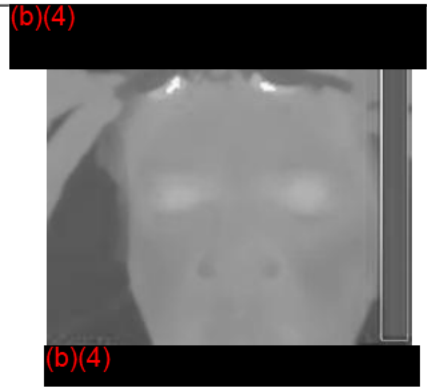
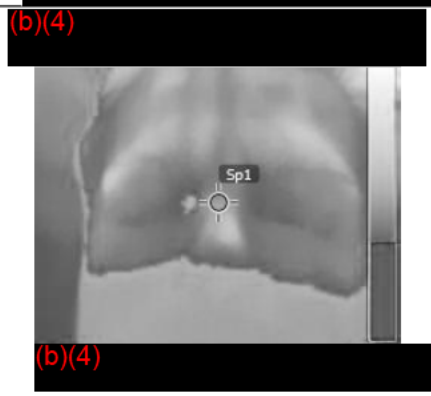
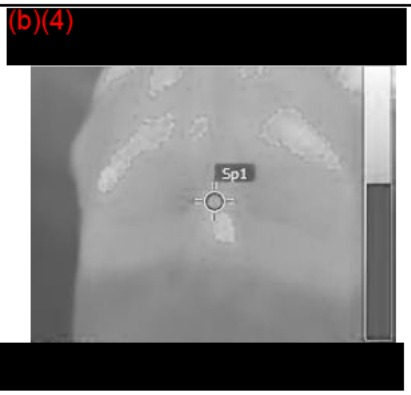
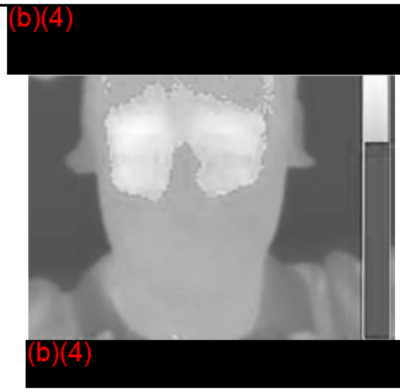
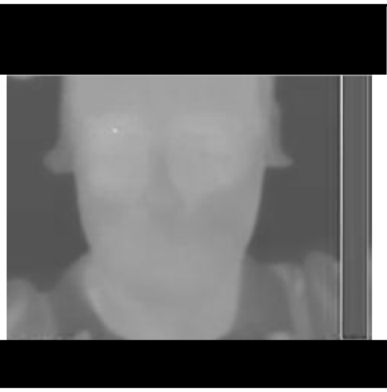
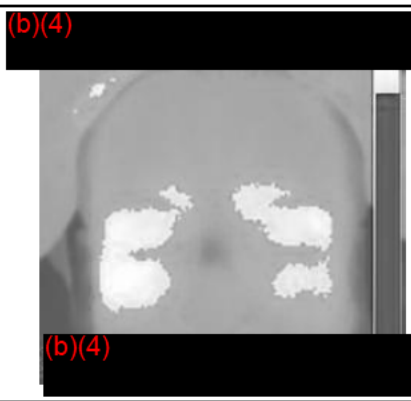
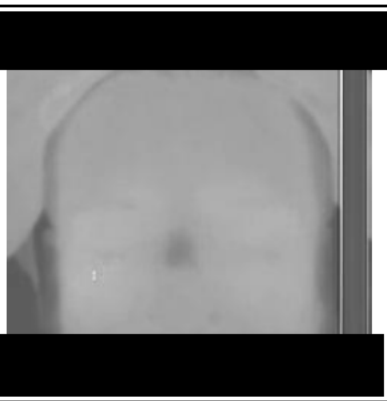
(b)(4)

(b)(4)

In summary, the proposed new device provides heating of the eyelid with three factors of improved heat treatment as compared to predicates:

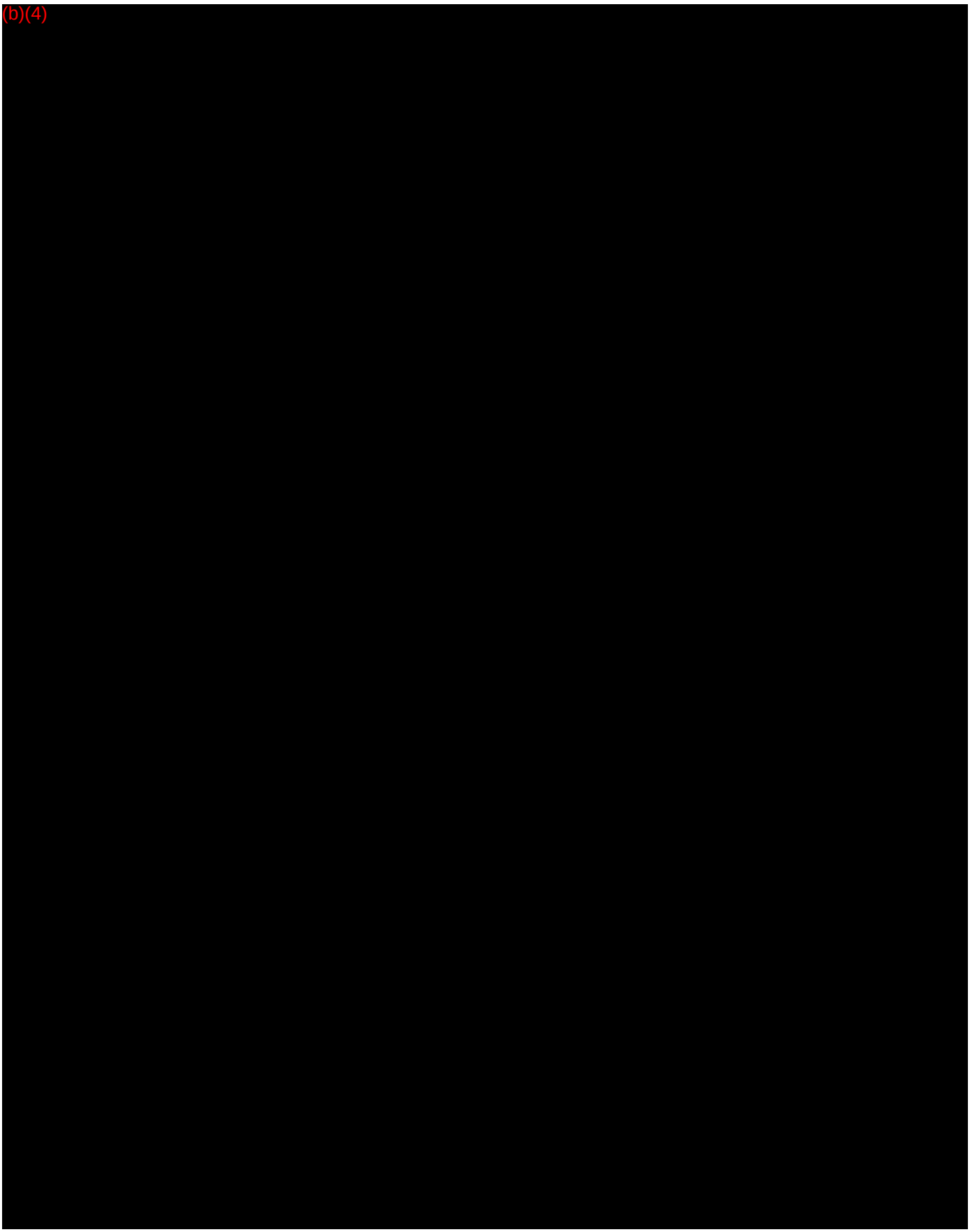
1. Heat only where needed
2. A more precise temperature
3. Constant temperature over time.

Figure 9: Facial Product Spatial Temperature Measurements

	Temperature above 38 C	Temperature above 43 C
(A) Digital Heat		
(B) Theratherm		
(C) Kao		
(D) Thermalon		

3.3 Materials

(b)(4)



3.4 Labeling:

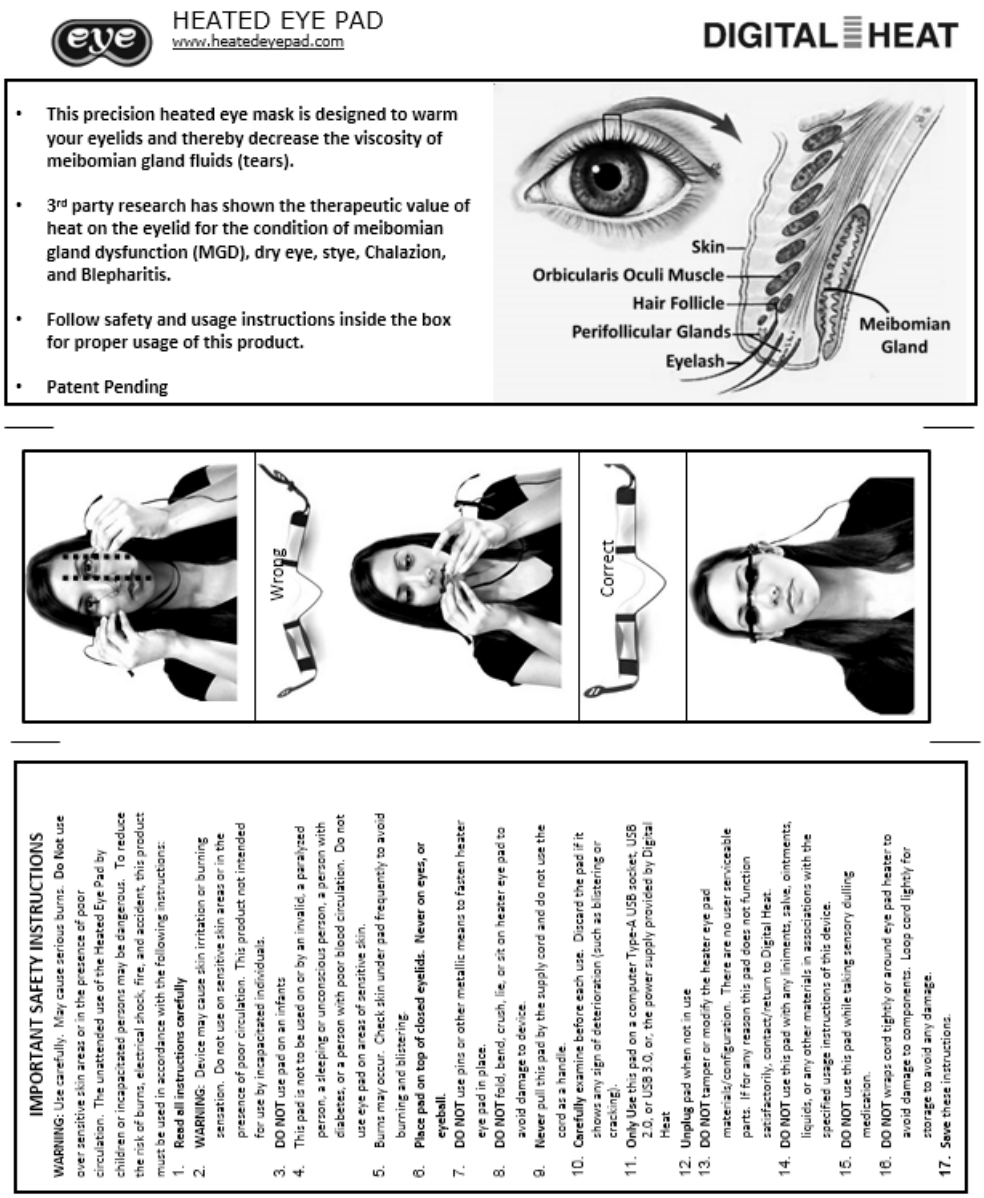
3.4.1 Digital Heat Labeling

Digital Heat makes no medical claims, and refers users to third party medical research for the efficacy of heating the Meibomian gland fluid. For all four stages of Meibomian gland dysfunction, the medical community recommends a warm compress for treatment (Foulks 2012).

The next several pages include photographs of Digital Heat labels and predicate device labels.

The Digital Heat device box will include labeling as seen in Figure 10: Heated Eye Pad, Box Labeling (not to scale).

Figure 10: Heated Eye Pad, Box Labeling (not to scale)



The Digital Heat, Heated Eye Pad package inserts will include user instructions font size 11, Calibri, and safety instructions at font size 12, Calibri (Figures 11, 12).

Figure 11: Package Insert User Instructions (not to scale)

HEATED EYE PAD eye
www.heatedeyepad.com

by DIGITAL HEAT
5626 S. Captain Kidd Ct., Unit B
Tempe, AZ 85283
(512) 517-6649

Instructions on how to use the Heated Eye Pad
Read ALL Safety Precautions before use.

Look in the mirror. Fold or expand the nose part of the Heated Eye Pad to fit your face and eyes.

The round section of the Heated Eye Pad should line up with your eyes, as shown in between the dashed lines.

As you fold the nose bridge, the Heated Eye Pad might go out of alignment. This is incorrect

Slightly bend the frame as needed to make it straight to your face.

This is correct. You are ready to wear.

1. Setup a timer (Watch, Clock, Phone, Etc.) if you wish to time your session.
2. Plug the heater into the power supply furnished by Digital Heat, or, a computer Type-A USB socket, USB 2.0, or USB 3.0. Do not use other power supplies.
3. Gently place the Heated Eye Pad on your CLOSED eyelids and position the elastic strap behind ears.
4. Adjust the tightness of the elastic strap for comfort, and place the electrical cord behind an ear.
5. DO NOT apply excessive pressure on your eyelids by over tightening the elastic strap.
6. Repeat steps 1 through 6 as needed for comfort.
7. If timed, after timer has expired remove the Heated Eye Pad from your eyelids and face.

Figure 12: Heated Eye Pad User Safety Instructions (not to scale)

HEATED EYE PAD eye
www.heatedeyepad.com

by DIGITAL HEAT
5626 S. Captain Kidd Ct., Unit B
Tempe, AZ 85283
(512) 517-6649

IMPORTANT SAFETY INSTRUCTIONS

WARNING: Use carefully. May cause serious burns. **Do Not** use over sensitive skin areas or in the presence of poor circulation. The unattended use of the Heated Eye Pad by children or incapacitated persons may be dangerous. To reduce the risk of burns, electrical shock, fire, and accident, this product must be used in accordance with the following instructions:

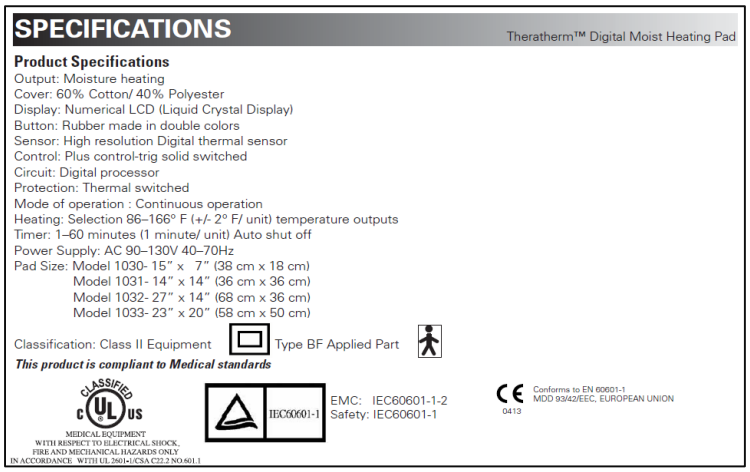
1. **Read all instructions carefully**
2. **WARNING:** Device may cause skin irritation or burning sensation. Do not use on sensitive skin areas or in the presence of poor circulation. This product not intended for use by incapacitated individuals.
3. **DO NOT** use pad on an infants
4. This pad is not to be used on or by an invalid, a paralyzed person, a sleeping or unconscious person, a person with diabetes, or a person with poor blood circulation. Do not use eye pad on areas of sensitive skin.
5. Burns may occur. Check skin under pad frequently to avoid burning and blistering.
6. **Place pad on top of closed eyelids. Never on eyes, or eyeball.**
7. **DO NOT** use pins or other metallic means to fasten heater eye pad in place.
8. **DO NOT** fold, bend, crush, lie, or sit on heater eye pad to avoid damage to device.
9. **Never** pull this pad by the supply cord and do not use the cord as a handle.
10. **Carefully** examine before each use. Discard the pad if it shows any sign of deterioration (such as blistering or cracking).
11. **Only Use** this pad on a computer Type-A USB socket, USB 2.0, or USB 3.0, or, the power supply provided by Digital Heat
12. **Unplug** pad when not in use
13. **DO NOT** tamper or modify the heater eye pad materials/configuration. There are no user serviceable parts. If for any reason this pad does not function satisfactorily, contact/return to Digital Heat.
14. **DO NOT** use this pad with any liniments, salve, ointments, liquids, or any other materials in associations with the specified usage instructions of this device.
15. **DO NOT** use this pad while taking sensory dulling medication.
16. **DO NOT** wraps cord tightly or around eye pad heater to avoid damage to components. Loop cord lightly for storage to avoid any damage.
17. **Save** these instructions.

Contact Information:

Web:	www.heatedeyepad.com
Email:	Info@digitalheat911.com
Technical Support:	(512) 517-6649

3.4.2 Theratherm Labeling

Figure 13 Theratherm User Instructions and Safety Labeling



SPECIFICATIONS Theratherm™ Digital Moist Heating Pad

Product Specifications

Output: Moisture heating
Cover: 60% Cotton/ 40% Polyester
Display: Numerical LCD (Liquid Crystal Display)
Button: Rubber made in double colors
Sensor: High resolution Digital thermal sensor
Control: Plus control-trig solid switched
Circuit: Digital processor
Protection: Thermal switched
Mode of operation : Continuous operation
Heating: Selection 86–166° F (+/- 2° F/ unit) temperature outputs
Timer: 1–60 minutes (1 minute/ unit) Auto shut off
Power Supply: AC 90–130V 40–70Hz
Pad Size: Model 1030- 15" x 7" (38 cm x 18 cm)
Model 1031- 14" x 14" (36 cm x 36 cm)
Model 1032- 27" x 14" (68 cm x 36 cm)
Model 1033- 23" x 20" (58 cm x 50 cm)

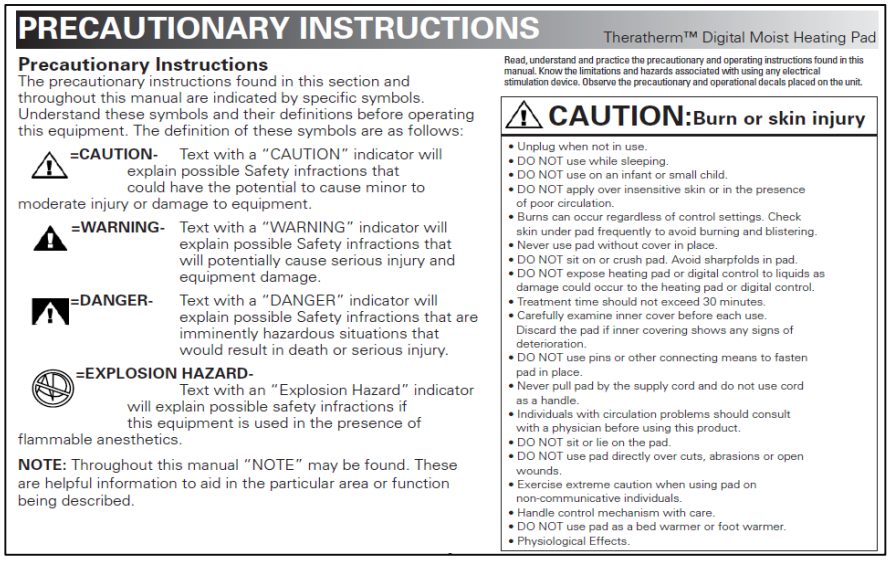
Classification: Class II Equipment Type BF Applied Part

This product is compliant to Medical standards

CLASSIFIED UL US
MEDICAL EQUIPMENT
WITH RESPECT TO ELECTRICAL SHOCK,
FIRE AND MECHANICAL HAZARDS ONLY
IN ACCORDANCE WITH UL 2601-1/CSA C22.2 NO.601.1

IEC60601-1 EMC: IEC60601-1-2
Safety: IEC60601-1

CE 0413 Conforms to EN 60601-1
MDD 93/42/EEC, EUROPEAN UNION



PRECAUTIONARY INSTRUCTIONS Theratherm™ Digital Moist Heating Pad

Precautionary Instructions

The precautionary instructions found in this section and throughout this manual are indicated by specific symbols. Understand these symbols and their definitions before operating this equipment. The definition of these symbols are as follows:

=CAUTION- Text with a "CAUTION" indicator will explain possible Safety infractions that could have the potential to cause minor to moderate injury or damage to equipment.

=WARNING- Text with a "WARNING" indicator will explain possible Safety infractions that will potentially cause serious injury and equipment damage.

=DANGER- Text with a "DANGER" indicator will explain possible Safety infractions that are imminently hazardous situations that would result in death or serious injury.

=EXPLOSION HAZARD- Text with an "Explosion Hazard" indicator will explain possible safety infractions if this equipment is used in the presence of flammable anesthetics.

NOTE: Throughout this manual "NOTE" may be found. These are helpful information to aid in the particular area or function being described.

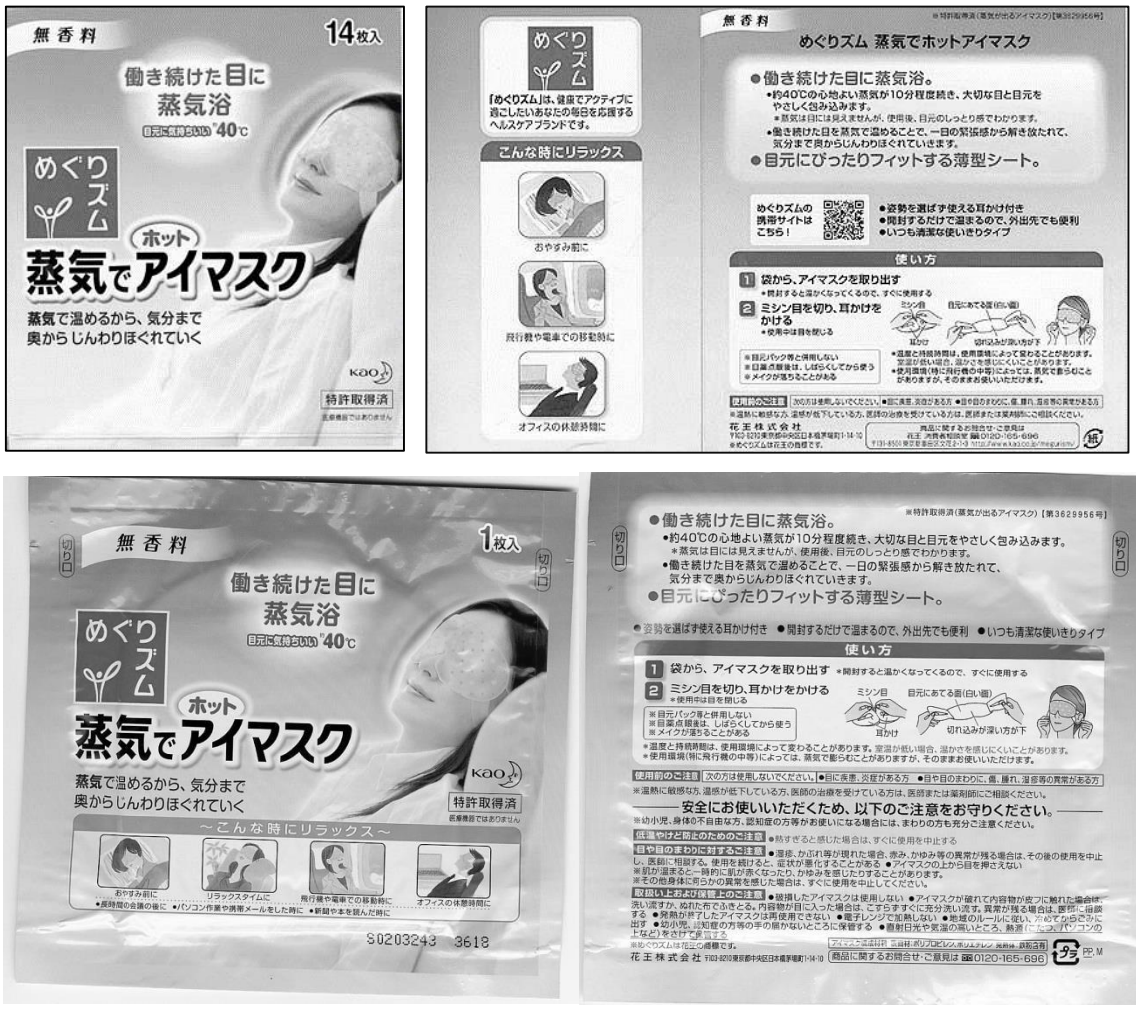
Read, understand and practice the precautionary and operating instructions found in this manual. Know the limitations and hazards associated with using any electrical stimulation device. Observe the precautionary and operational decals placed on the unit.

CAUTION: Burn or skin injury

- Unplug when not in use.
- DO NOT use while sleeping.
- DO NOT use on an infant or small child.
- DO NOT apply over insensitive skin or in the presence of poor circulation.
- Burns can occur regardless of control settings. Check skin under pad frequently to avoid burning and blistering.
- Never use pad without cover in place.
- DO NOT sit on or crush pad. Avoid sharpfolds in pad.
- DO NOT expose heating pad or digital control to liquids as damage could occur to the heating pad or digital control.
- Treatment time should not exceed 30 minutes.
- Carefully examine inner cover before each use. Discard the pad if inner covering shows any signs of deterioration.
- DO NOT use pins or other connecting means to fasten pad in place.
- Never pull pad by the supply cord and do not use cord as a handle.
- Individuals with circulation problems should consult with a physician before using this product.
- DO NOT sit or lie on the pad.
- DO NOT use pad directly over cuts, abrasions or open wounds.
- Exercise extreme caution when using pad on non-communicative individuals.
- Handle control mechanism with care.
- DO NOT use pad as a bed warmer or foot warmer.
- Physiological Effects.

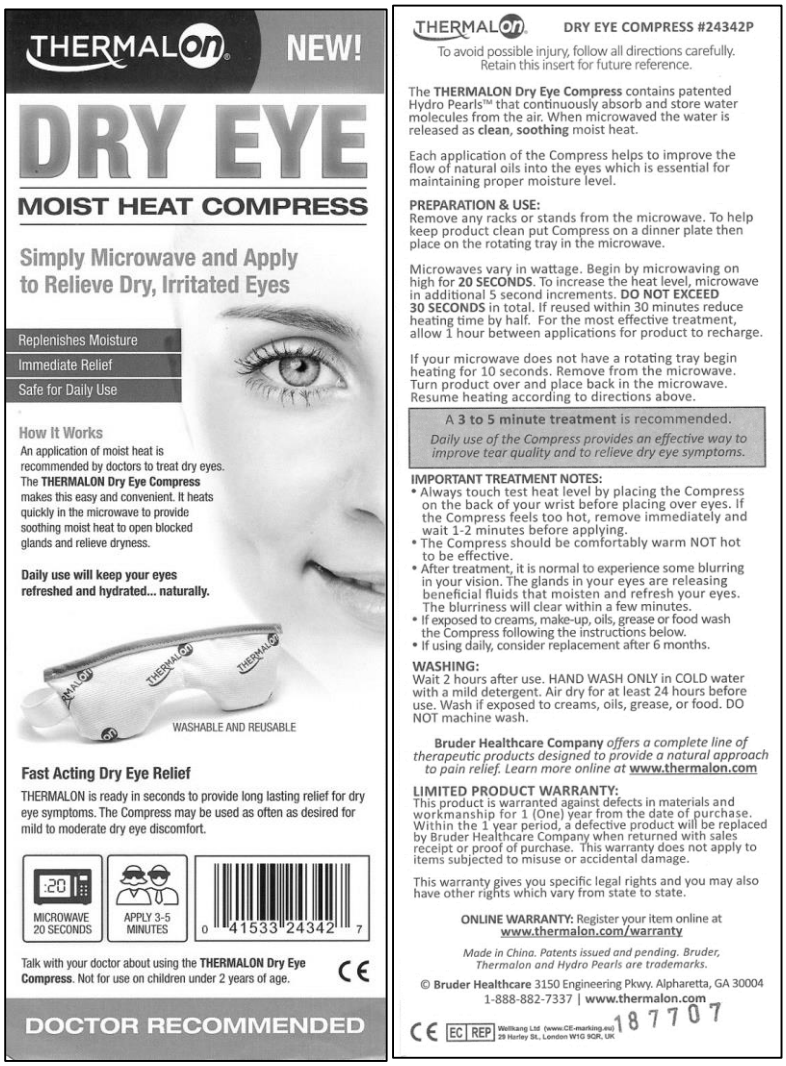
3.4.3 Kao Labeling

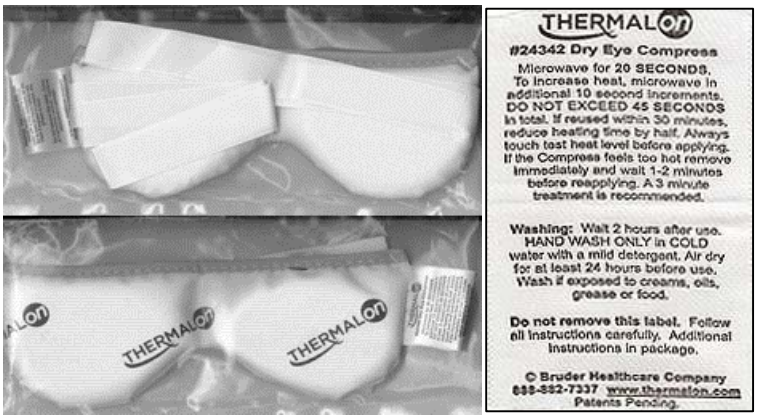
Figure 14 Kao Box, User Instructions and Safety Labeling



3.4.4 ThermalOn Labeling

Figure 15 ThermalOn User Instructions and Safety Labeling





3.5 Additional Information:

(b)(4) [redacted]. The device has two power states, plugged in and "ON," or unplugged and "OFF."

4.0 SUBSTANTIAL EQUIVALENCE INFORMATION:

The Digital Heat's "Heated Eye Pad" is designed for us on the outer eyelids. The user does not apply heat to undesired sections of the human body or facial area.

(b)(4)

Table 4 a brief summary of the Digital Heat proposed device substantial equivalency to Sec. 890.5710 Hot or cold disposable pack and sec. 890.5740 Powered Heating Pad.

Table 5: Substantial Equivalency Summary

Category Of Equivalence	Powered Heating Pad	Powered Heating Pad	Chemical Hot Disposable Pack	Microwave Heated Beads
FDA CFT Title 21 Section	(890.5740)	(890.5740)	(890.5710)	(890.5730)
Warm Compress	Digital Heat's "Heated Eye Pad"	Theratherm	Bio-Lipid, EyeFeel	Thermalon
510(k)	Submission	K770686	K021843, K082087	Not Applicable
Mechanism for Heat Generation	Electricity	Electricity	Chemical reaction	Microwave Energy
Maximum Unit Surface Temperature (Thermal Couple)	(b)(4) [redacted]			
Power Usage				
Mechanism for Heat Control				
Software				
Control Mechanism for Safety				
Specific Therapeutic Indications	Ophthalmic Warmer	Electric Heating Pad	Ophthalmic Warmer	Ophthalmic Warmer

5.0 510(K) SUMMARY OR STATEMENT:

The proposed device use is for treatment where the current medical community recommends the application of a warm compress to the eyelids. Such applications would include Meibomian Gland Dysfunction (MGD), dry eye, Blepharitis, Stye, or Chalazia.

The Digital Heat (Heated Eye Pad) makes contact with the exterior eyelid tissue. Users typically apply the device 5-10 minutes, twice per day. This device is targeted for over the counter distribution. Patients' use of the proposed device can be at home, on travel, or at the office.

6.0 TRUTHFUL AND ACCURATE STATEMENT:

All data and information submitted in the premarket notification are truthful and accurate and no material fact has been omitted, as required by 21 CFR 807.87(j).

7.0 REFERENCES:

1. Mori Asako, et al. Disposable Eyelid-Warming Device for the Treatment of Meibomian Gland Dysfunction, Japan Journal Ophthalmological Society 47, p578–586 (2003).

2. Foulks GN, Nichols KK. Gary N. Meibomian Gland Dysfunction, COPE Course ID: 34224-AS, State University of New York College of Optometry, (May 2012).

(b)(4)

5. NIST, Fire Dynamics, Dan Madrzykowski, Fire Research Division, www.nist.gov/fire/fire_behavior.cfm, July 16, 2013

K142228/S1

September 22, 2014

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

142228

RE: 510(k) #K~~14228~~, Premarket Notification for Digital Heat Corporation, Heated Eye Pad

Dear Kelliann Wachrathit:

Enclosed is the revised 510(k) Premarket Notification for the proposed product "Heated Eye Pad." Intended for an application that provides dry heat therapy for the eyelid. The eCopy is an exact duplicate of the paper copy.

The Heated Eye Pad is recommended for any eyelid treatment whereby the current medical community would suggest applying a warm compress to the eyelids. Current indications for use would include anyone diagnosed with Meibomian Gland Dysfunction (MGD), dry eye, Blepharitis, Stye, or Chalazia.

510(k) notification submitted under premarket notification procedures described in 21 Code of Federal Regulations (CFR) Part 807, Subpart E for the new device of substantial equivalence to predicate devices includes:

21 CFR 890.5740	(Powered Heating Pad)
21 CFR 890.5720	(Water Circulating Hot or Cold Pack)
21 CFR 890.5710	(Chemical Hot/Cold Pack) Class

Gel packs and warm compress intended for the Meibomian gland fluids have been classified as Class I devices, under Product Code IME, according to section 890-5710.

A summary of 510(k) is included in this notification.

Contact information is provided below for any additional requirements or further correspondence on this 510(k) submission.

Sincerely,

John Devine
President and CEO
Telephone: (512) 560-7184
Email: john.devine@digitalheat911.com

5

September 22, 2014

U.S. Food and Drug Administration
Center for Devices and Radiological Health
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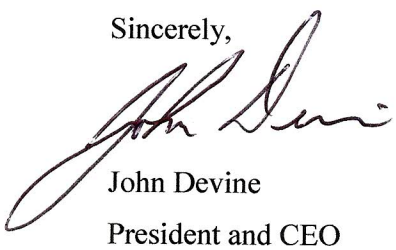


John Devine
President and CEO
Telephone: (512) 560-7184
Email: john.devine@digitalheat911.com

Table of Contents

0.0 GUIDANCE DOCUMENT USED FOR THIS 510(K) APPLICATION

Guidance Document for the Preparation of Premarket Notification [510(k)] Applications for Heating and Cooling Devices

This guidance was written prior to the February 27, 1997 implementation of FDA's Good Guidance Practices, GGP's. It does not create or confer rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both. This guidance will be updated in the next revision to include the standard elements of GGP's.

July 26, 1995
(reformatted 12/18/97)

This guidance document may contain references to addresses and telephone numbers that are now obsolete. The following contact information is to be used instead:

- **While this guidance document represents a final document, comments and suggestions may be submitted at any time for Agency consideration to the Restorative Devices Branch, 9200 Corporate Blvd., HFZ-410, Rockville, MD 20850.**
- **For questions regarding the use or interpretation of this guidance, contact the Restorative Devices Branch at 301-594-1296.**
- **To contact the Division of Small Manufacturers Assistance (DSMA), call 800-638-2041 or 301-443-6597; fax 301-443-8818; email dsmo@cdrh.fda.gov; or write to DSMA (HFZ-200), Food and Drug Administration, 1350 Piccard Drive, Rockville, Maryland 20850-4307. FACTS-ON-DEMAND (800-899-0381 or 301-827-0111) and the World Wide Web (CDRH home page: http://www.fda.gov/cdrh/index.html) also provide easy access to the latest information and operating policies and procedures.**

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
Center for Devices and Radiological Health
Rockville, MD 20850

PREFACE

The purpose of this document is to provide guidance to the sponsors of premarket notifications [510(k)'s] for restorative devices. This document is intended to assist the sponsors in organizing and providing the essential information that should be submitted to the Food and Drug Administration (FDA) for review.

This guidance is based on the Restorative Devices Branch's (REDB's) identification of specific criteria necessary to conduct an adequate evaluation of a 510(k) for the purpose of determining substantial equivalence for physical medicine/restorative devices. The objective of this document is to delineate to the device manufacturer important administrative, descriptive, and scientific information that should be included in a 510(k) for a restorative device. Individual 510(k) submissions may require additional information pertinent to each specific device. The suggestions and recommendations included in the guidance reflect the minimal requirements that would allow an evaluation of the device as determined by REDB. While the use of this document in the preparation of a 510(k) premarket notification will not ensure FDA clearance of a device, following the guidance will ensure that sufficient basic information is available to initiate a substantive review.

Note that the guidance document is a living document. It will be periodically revised as scientific knowledge and regulations change.

INTRODUCTION

Any 510(k) notification submitted under premarket notification procedures described in 21 Code of Federal Regulations (CFR) Part 807, Subpart E, for FDA's determination that a new device is substantially equivalent to a predicate (existing) device in 21 CFR 890.5950 (Powered Heating Unit), 21 CFR 890.5740 (Powered Heating Pad), 21 CFR 890.5500 (Infrared Lamp), 21 CFR 890.5720 (Water Circulating Hot or Cold Pack), or Class I by 21 CFR 890.5710 (Chemical Hot/Cold Pack) should follow the format below and must contain all specified information that is pertinent to the device.

ADMINISTRATIVE INFORMATION

1. Provide the name and address of the manufacturer and sponsor of the 510(k) submission.
2. Provide the FDA registration number (if available) of the manufacturer of the new device.
3. Identify the official contact person for all correspondence.

DEVICE IDENTIFICATION

1. As stated in 21 CFR 807.90(d), a 510(k) shall be submitted separately for each product the manufacturer intends to market. Therefore, a submission can describe no more than one new device.

   A submission can describe more than one component of, or attachment to, a single device. The submission must compare each such component or attachment with that of a predicate device, or must state that the predicate device lacks such a component or attachment.

2. The following information must be provided:

a. The proprietary name of the new device;
b. The generic name of the device;
c. The classification of the predicate device e.g., Class II. Refer to 21 CFR and section 513 of the Food, Drug, and Cosmetic Act;
d. The proposed regulatory class for the new device, e.g., Class II. (21 CFR 862-892 contains the regulatory classifications for medical devices); and
e. The panel code(s) for the device. [If the product is not classified under the physical medicine devices panel, identify the panel under which it is classified and provide the panel identification code (e.g., 89 is the code for the physical medicine devices panel)].

3. Specify whether this device:

a. Has been previously submitted to the FDA for identical or different indications;
b. Is currently being reviewed for different indications by the same or different branch within ODE; or
c. Has been previously cleared by the FDA for different indications.

DEVICE DESCRIPTIVE INFORMATION

Intended Use

Identify the specific intended use(s), including the specific therapeutic indications, for the subject device and the predicate device.

The new device must have the same intended medical uses as those specified for the predicate device, to the extent that the changes do not alter the therapeutic or diagnostic effect and do not affect the safety and effectiveness.

These intended uses must be consistent with the descriptions of intended medical uses contained within the CFR section that is applicable to the device and must identify the specific medical conditions for which the device is indicated.

If the indication differs, you must provide a justification as to how the change(s) do not affect safety and effectiveness. If special labeling claims are sought, information must be provided to support these claims.

It is not necessary to notify FDA of an intent to market a device if it will not be labeled or promoted for medical uses. However, FDA will regulate the equipment and may require premarket notification if any promotional material appears which makes medical claims after marketing begins.

Device Description

1. Provide a written description of the device, including all device components, instruments, and any new features of the device.
2. Identify all sizes, configurations, and functions of each device component.
3. Describe how the device works and interconnects with other components.
4. Engineering drawings and/or photographs and complete written descriptions of the new and predicate devices. The document must contain illustrations of all internal and external features of both devices. Engineering drawings must provide the lengths, widths, and heights of the devices and their major component parts.
5. Provide the temperature range of the device.

6. Provide the temperature range at the skin surface where device is applied.

Materials

Identify the specific materials for each component, any additional processing that may affect the material properties, and the voluntary standards with which the device materials will conform. In the case of powered heating pads, the material of the heating pad cover must be specified. Similarly, the chemicals and activator(s) used in hot/cold packs must be described.

Labeling

1. Provide draft or sample package labeling, package inserts, including complete operator's instructions for the new device.
2. Include copies of promotional materials for the new and predicate devices.
3. The following warning statement must be included in the labeling for all devices:

   "WARNING: Use carefully. May cause serious burns. Do not use over sensitive skin areas or in the presence of poor circulation. The unattended use of ..... by children or incapacitated persons may be dangerous."

Additional Information

1. The distance of the device from the area of application must be provided for infrared lamps.
2. The leakage current must be specified for powered heating pads, infrared lamps, and water circulating hot/cold packs.
3. The flow rate, pressure, and the liquid to be used must be specified for water circulating hot/cold packs.

SUBSTANTIAL EQUIVALENCE INFORMATION

1. The legally marketed predicate device with which the subject device is to be compared for the determination of substantial equivalence must be identified.
2. Evidence must be provided that the device was placed into interstate commerce for other than research uses or as part of a plant-to-plant transfer and was actually labeled and promoted for the intended use to which the submitter of the premarket notification is claiming substantial equivalence. This may be accomplished by providing copies of the firm's advertisements, catalog pages, or other promotional material dated prior to May 28, 1976 and shipping documents such as invoices, bills of lading, receipts showing the interstate transit of the device (for other information which can be used to prove Pre-Amendment status contact DSMA).

   Alternatively, the 510(k) number(s) of the predicate device(s) may be identified.

   The 510(k) number may be obtained from the Electronic Docket (ED), an automated retrieval system of the Division of Small Manufacturers Assistance (DSMA), which provides medical device regulations, FDA talk papers and press releases, device evaluation guidance, and the listing of all approved 510(k)s sorted by applicant name.

   This 510(k) information is located under the Product Clearance Main Menu Item # 12. Dial (301) 594-4802 or (800) 252-1366. For more guidance on how to assess this information, contact DSMA. Call toll free (800) 638-2041, (301) 443-6597, or fax (301) 443-8818.
3. The submission should include a description of all significant similarities and differences between the new and predicate device.
4. To facilitate the review, the submission should contain a table which compares the
   1. intended medical uses and
   2. the physical characteristics and
   3. functions of the two devices.

510(K) SUMMARY OR STATEMENT

1. Provide a 510(k) summary of safety and effectiveness information in the premarket notification submission upon which an equivalence determination could be based, written in accordance with the content and format requirements that are specified in 21 CFR 807.92 **or**
2. Provide a 510(k) statement that safety and effectiveness information will be made available to interested persons upon request. This statement must follow the format and contain the wording as specified in 21 CFR 807.93.

TRUTHFUL AND ACCURATE STATEMENT

Provide a statement that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted, as required by 21 CFR 807.87(j).

1.0 ADMINISTRATIVE INFORMATION

Applicant, Sponsor:	Digital Heat Corporation
Address:	5626 S. Captain Kidd Ct., Unit B Tempe, AZ 85283
FDA Registration Number:	
Contact Person:	John Devine (CEO)
Telephone Number:	(512) 560-7184

2.0 DEVICE IDENTIFICATION

The proprietary name of the new device:	Heated Eye Pad
The generic name of the device:	Powered Heating Pad
Classification of the predicate device:	Title 21 C.F.R. § 890.5740 Powered heating pad Regulatory Class II (special controls) Exempt subject to § 890.9
The proposed regulatory class for the new device:	Title 21 C.F.R. § 890.5740 Powered heating pad Regulatory Class II (special controls) Exempt subject to § 890.9
Panel Code:	Physical Medicine Devices panel 89
Has been previously submitted to the FDA for identical or different indications?	Yes, on August 11, 2014.
Is currently being reviewed for different indications by the same or different branch within ODE?	No
Has been previously cleared by the FDA for different indications?	No

3.0 DEVICE DESCRIPTIVE INFORMATION

3.1 Intended Used:

The proposed device use is for treatment where the current medical community recommends the application of a warm compress to the eyelids. Such applications would include Meibomian Gland Dysfunction (MGD), dry eye, Blepharitis, Stye, or Chalazia.

The Digital Heat (Heated Eye Pad) makes contact with the exterior eyelid tissue. Users typically apply the device 5-10 minutes, twice per day. This device is targeted for over the counter distribution. Patients' use of the proposed device can be at home, on travel, or at the office.

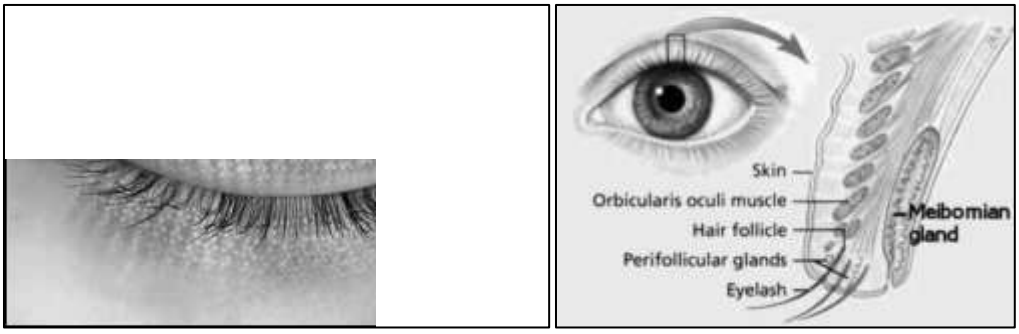
The meibomian glands supply lipids or oily substances that help to prevent or minimize tear evaporation. There are 50 on the upper eyelid, 25 on the lower eyelid (Figure 1). The medical community recognizes meibomian gland dysfunction as presenting several problems to the eyelid:

- Dry eye: Either poor quality or poor quantity of lipid secretion from the meibomian glands.
- Chalazion (meibomian gland lipogranuloma): Is a cyst in the eye lid caused by inflammation of a blocked meibomian gland.
- Blepharitis: Chronic inflammation of eye lid
- Sty(e): Infection of glands caused by bacteria; Caused by blocking of an oil gland

For all four stages of Meibomian gland dysfunction, the medical community recommends a warm compress for treatment, whereby heating the lipid will decrease the meibomian gland viscosity, liquefy any clog in the oil gland, and increase the flow of lipids to the eye. (EU Regulatory Workshop: Meibomian Gland Dysfunction, Kelly K. Nichols, OD, MPH, PhD, FERV Professor, University of Houston College of Optometry Chair, TFOS International Meibomian Gland Workshop, slide 23, March 2010.)

Figure 1: Meibomian Gland

(A) External Eyelid **(B) Internal Eyelid Structure**



In terms of thermal therapy for the treatment, the medical community would like an elevated temperature, but not such that it will inflame or burn the skin. The skin starts to feel pain at 44 centigrade and 1st degree burns occur at 48 centigrade. (Fire Dynamics, Dan Madrzykowski, Fire Research Division, www.nist.gov/fire/fire_behavior.cfm, July 16, 2013).

(b)(4) [redacted]

1. Heat only where needed
2. A more precise temperature
3. Constant temperature over time.

Several prior predicate devices as noted in Table-1 provide the basis for comparison to the proposed device.

- Theratherm Electric Heating Pad
- EyeFeel™ Ophthalmic Warmer
- ThermalOn Ophthalmic Warmer

The proposed device will not alter the therapeutic effect as applicable to the predicate devices. In addition to improved thermal performance, the proposed device provides additional safety not currently embodied in the prior predicate devices (details provided in device description).

Table-1 Proposed and Predicate Device Summary

Device	**Proposed Device (Ophthalmic Warmer)**	**Theratherm (Electric Heating Pad)**	**EyeFeel™ (Ophthalmic Warmer)**	**ThermalOn (Ophthalmic Warmer)**
510(k):	New	K770686	K021843, K082087	Not Applicable
Title 21 CFR	§890.5740	§890.5740	§890.5710	§890.5730
Classification:	Class II (Special Controls) Exempt	Class II (Special Controls) Exempt	Class I	Class I
Generic Name:	Powered Heating Pad	Powered Heating Pad	Chemical Hot Pack	Moist Heat Pack

Proposed and Predicate Device Intended Use Comparison

Intended Use, Proposed Device, Heated Eye Pad

The Heated Eye Pad ophthalmic warmer is a powered heating pad for the application of localized heat therapy. Use for treatment when the current medical community recommends the application of a warm compress to the eyelids. Such applications would include Meibomian Gland Dysfunction (MGD), Dry Eye, Blepharitis, Stye, or Chalazia.

The Heated Eye Pad makes contact with the exterior eyelid tissue. Users typically apply the device 5-10 minutes, twice per day. Patients' use of the Heated Eye Pad can be at home, on travel, or at the office.

Theratherm (Electric Heating Pad) K770686

For fast pain relief, use Theratherm moist heat therapy

- Moist heat therapy is routinely prescribed for temporary pain relief associated with muscle strains and spasms
- Use the Theratherm Digital Moist Heating Pad for treatment of pain caused by muscle spasm or inflammation from exercise, sports or everyday household activities.

The application of moist heat is a routinely prescribed therapy in today's medical field. The body's physiological response to moist heat is dilation of the blood vessels, causing an increase in the blood flow to the area under treatment. Increased local circulation enhances recovery by flushing away the waste products and bringing in fresh blood cells to the treatment area. Moist heat is exceptionally useful in treating back pain caused by muscle spasms from strain and tension. The pain of arthritic and muscleskeletal conditions can be temporarily alleviated with the use of moist heat therapy. The increased blood flow can help relax muscles in spasm and help maintain joint and muscle flexibility. Along with rest, the Theratherm Digital Moist Heating Pad will gradually relieve pain by relaxing a muscle in spasm. Theratherm treatment is also efficient in relieving pain caused by muscle spasm or inflammation after a day of recreation, gardening, jogging or household activities.

Intended Use / Indications for Use EyeFeel ophthalmic warmer K021843

The EyeFeel is a hot disposable pack for the application of localized heat therapy in cases of chronic inflammatory and cystic conditions of the eye lids, including meibomian gland dysfunction and chalazia.

Intended Use / Indications for Use EyeFeel ophthalmic warmer K082087

The EyeFeel ophthalmic warmer is a hot disposable pack for the application of localized heat therapy in cases of chronic inflammatory and cystic conditions of the eyelids, including meibomian gland dysfunction (MGD), also known as evaporative dry eye or lipid deficiency dry eye, and chalazia. The EyeFeel Ophthalmic Warmer also may relieve accommodative fatigue

and may help recover baseline visual acuity levels after prolonged work on visual display terminals.

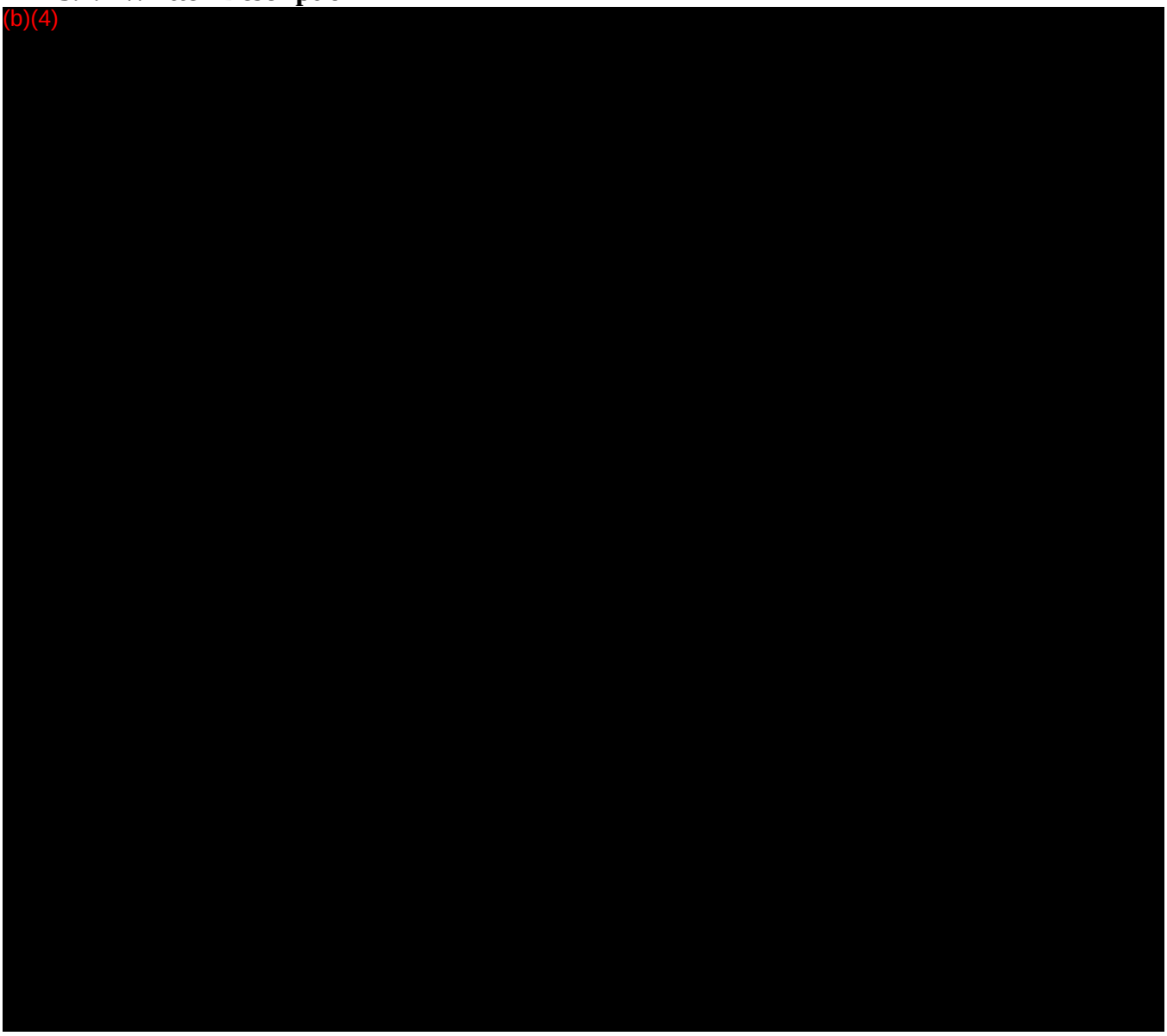
Intended Use / Indications for Use ThermalOn ophthalmic warmer K N/A

A 3 to 5 minute treatment is recommended. Daily use of the compress provides an effective way to improve tear quality and to relieve dry eye symptoms. The compress may be used as often as desired for mild to moderate dry eye discomfort.

3.2 Device Description:

3.2.1 Written Description

(b)(4)



3.2.2 Sizes, Configurations, and functions of each device component

The design of the heater is a one size fits all. There is only 1 configuration.

A complete list (Table 2) of components, their functions, and sizes are as follows:

Table 2: A complete list of components, their functions, and sizes (Not to Scale)

Picture	Part	Function	Size
	Heater	(b)(4)	(b)(4)
	Foam		
	Frame		
	Fuse		
	USB Connector		
	Power Cable		
	Band		

3.2.3 Describe how the device works and interconnects with other components:

(b)(4)

(b)(4)

3.2.4 Drawings and Photographs

Photographs and complete written descriptions of the new and predicate devices are presented below. In addition, Figures 3-6 are drawings and overall dimensions of the proposed product and predicate devices.

3.2.4.1 Digital Heat Proposed Device: Figure 2

(b)(4)

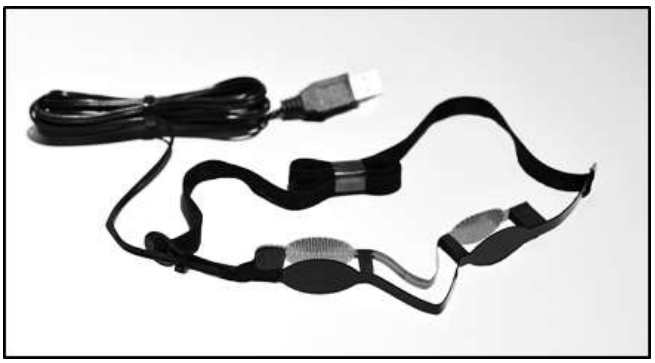
Figure 3: Digital Heat Eye Pad (Product Packaging and User Wear)

(A) Heating Element

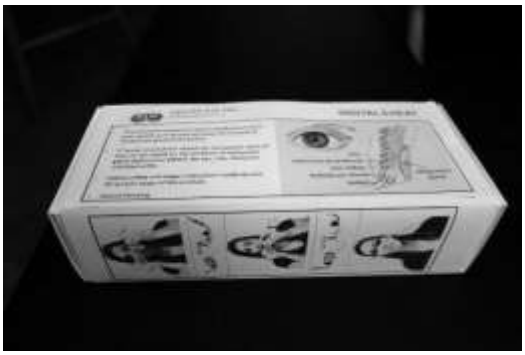
(b)(4) Schematic Drawings

(B) User Configuration

(C) Digital Heat Elastic Band



(D) Box/Labeling



3.2.4.2 Theratherm: Figure-3

This device consists of an inner sealed liner with a powered heater along with a thermal couple and control electronics for the user (Figure 4A). The packaging for the device (Figure 4B) shows the user application which is normally for large area usage on the human body. The user positions the product (Figure 4C) on facial features for heat treatment of eyes. This predicate is a large area application of a heated surface as noted in dimensions of Figure 4A, 4B, and 4C.

Figure 4: Theratherm Powered Heating Pad (Product Packaging and User Wear)

(A) Heated Pad (B) Box/Labeling (C) User Configuration

(Reference:www.dme-direct.com/theratherm-moist-heatting-pack)
D = 15mm // W = 370mm // L = 700mm

3.2.4.3 Kao (Chemically Activated Heated Eye Pad): Figure 5

The Kao product (Figure 5) is an embodiment (Chemical Heat Generation Eye Pad) to the "EyeFeel" predicate device (K021843, K082087) of like function. The EyeFeel is not currently on the open market for representative packaging and labeling. The Kao device uses a chemically activated air reaction to produce heat.

The Kao eye pad (Figure 5A) consists of two eye pads with interior sealed chemical packets that are activated by air when the seal pouch is opened. Labeling and packaging is noted in Figure 5B) and written in Japanese. Translation of the labeling includes opening of the package and positioning the product on the eyes. Dimensions of this product are provided in Figure 5A.

Figure 5: Kao Heat Eye Pad (Product Packaging and User Wear)

(A) Chemical Eye Pad (B) Box/Labeling (C) User Configuration


(Reference:.www.amazon.com/Kao-Megurhythm-Steam-Mask-Sheets/product-reviews/B0012R23UK)
D = 3 mm // W = 80 mm // L = 180 mm (Non Activated Condition)

3.2.4.4 Thermalon (Microwave Heated Eye Pad): Figure-6

The Theramalon product is a facemask (Figure 6A) with inner materials (silicone gel beads) for heat activation in a microwave. The user places the mask on the face for thermal heat transfer treatment. Packaging (Figure 6B) is a plastic sealed container along with instructions and safety documentation. The user control of the temperature is dependent on time placed in the microwave along with power of the appliance. The outer structure of the facemask is cloth along with a band of material used to secure the facemask to the users' face (Figure 6C). Dimensions of the Thermalon product is noted in Figure 6A.

Figure 6: Thermalon Heat Eye Pad (Product Packaging and User Wear)

(A) Microwave Eye Pad (B) Box/Labeling (C) User Configuration


(Reference: www.walmart.com/ip/Thermalon-Dry-Eye-Compress-1ct/16608834)
D = 15mm // W = 80 mm // L = 210 mm

3.2.5 Temperature Range of the Device

Digital Heat claims the proposed new device provides heating of the eyelid with three factors of improved heat treatment as compared to predicates:

1. Heat only where needed
2. A more precise temperature
3. Constant temperature over time.

The data in this section supports claim number 2) A more precise temperature, and 3) Constant temperature over time. Data to support claim 1) Heat only where needed is provided in Section 3.2.6 Temperature Range at the skin surface where applied.

(b)(4)

- Theratherm: A powered heating pad, but it uses feedback control to adjust the voltage sent to the heater based on a thermocouple measurement, the heating element is widely dispersed and unfocused within the heater. In addition, the heater contains a cloth cover, creating an unpredictable thermal profile based on ambient humidity, and compression on the heater.
- Kao: Uses chemical activation to heats up, peaks, and begins too cool
- Thermalon: Uses a microwave to heat up, it starts off hot and cools over time. Actual starting temperature will vary based on the power of the microwave and the duration of time in the microwave.

(b)(4)

3.2.6 Temperature Range at the skin surface where applied:

The proposed new device provides heating of the eyelid with three factors of improved heat treatment as compared to predicates:

1. Heat only where needed
2. A more precise temperature
3. Constant temperature over time.

Data in this section supports the assertion that Digital Heat provides improved heat treatment as compared to predicates by providing heat only where needed.

(b)(4)

Figure 8: Meibomian Gland and Localized Heat

(A) Eye Lid Meibomian Gland (B) Proposed Product

Table 3: Heated Products versus Eyelid Coverage

Digital Heat	Theratherm	Kao	Thermalon
			

(b)(4)

(b)(4)

In summary, the proposed new device provides heating of the eyelid with three factors of improved heat treatment as compared to predicates:

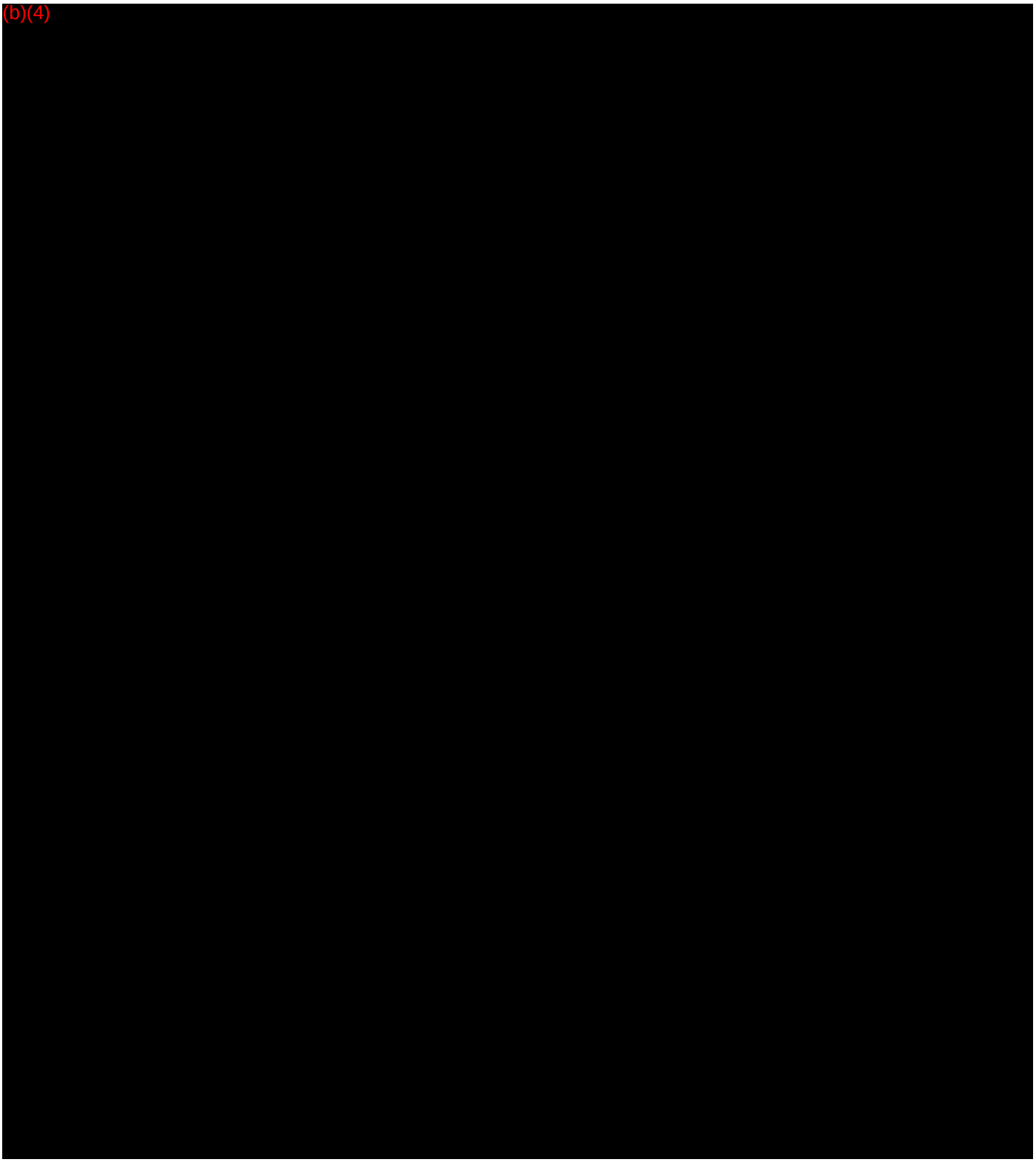
1. Heat only where needed
2. A more precise temperature
3. Constant temperature over time.

Figure 9: Spatial Temperature Measurements of Heated Eye Pad and Predicates

	Temperature above 38 C	Temperature above 43 C
(A) Digital Heat	(b)(4)	
(B) Theratherm	(b)(4)	
(C) Kao	(b)(4)	
(D) Thermalon	(b)(4)	

3.3 Materials

(b)(4)



3.3.2 Sterilization

The Heated Eye Pad and all predicate devices are sold as non-sterile devices.

3.3.3 Biocompatibility

(b)(4)

[redacted]

3.3.4 Shelf Life

Digital Heat does not specify a time based shelf life. Prior to each use, Digital Heat requests users to examine the Heated Eye Pad. Step #10 of the Heated Eye Pad Safety Instructions states:

> **Carefully** examine before each use. Discard the pad if it shows any sign of deterioration (such as blistering or cracking).

Storage conditions are not expected to affect device safety or effectiveness. The product consists of blended materials of (b)(4). The storage of the product will be within a box, ambient room temperature of (20C-25C), and not under any mechanical, temperature, or humidity conditions that would alter the properties of the base materials.

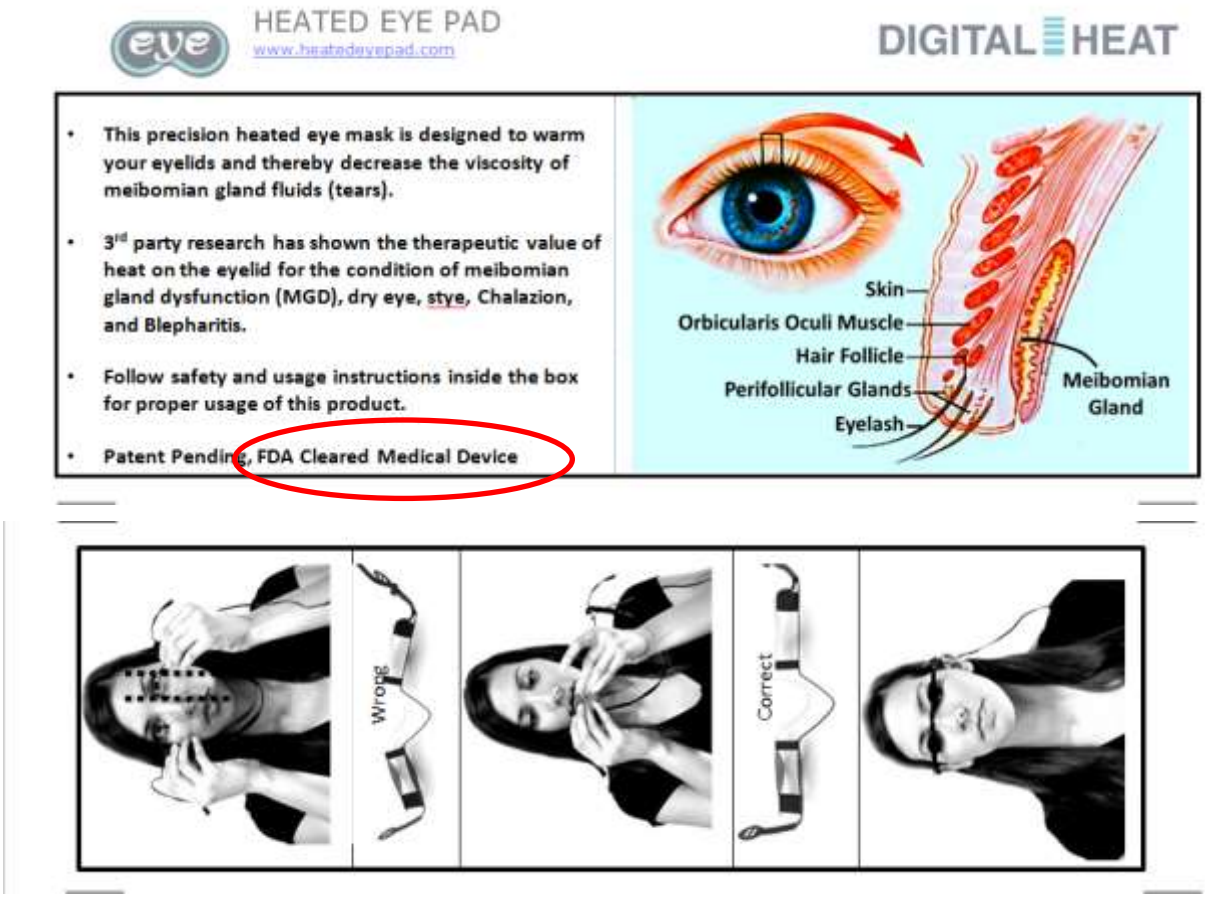
3.4 Labeling:

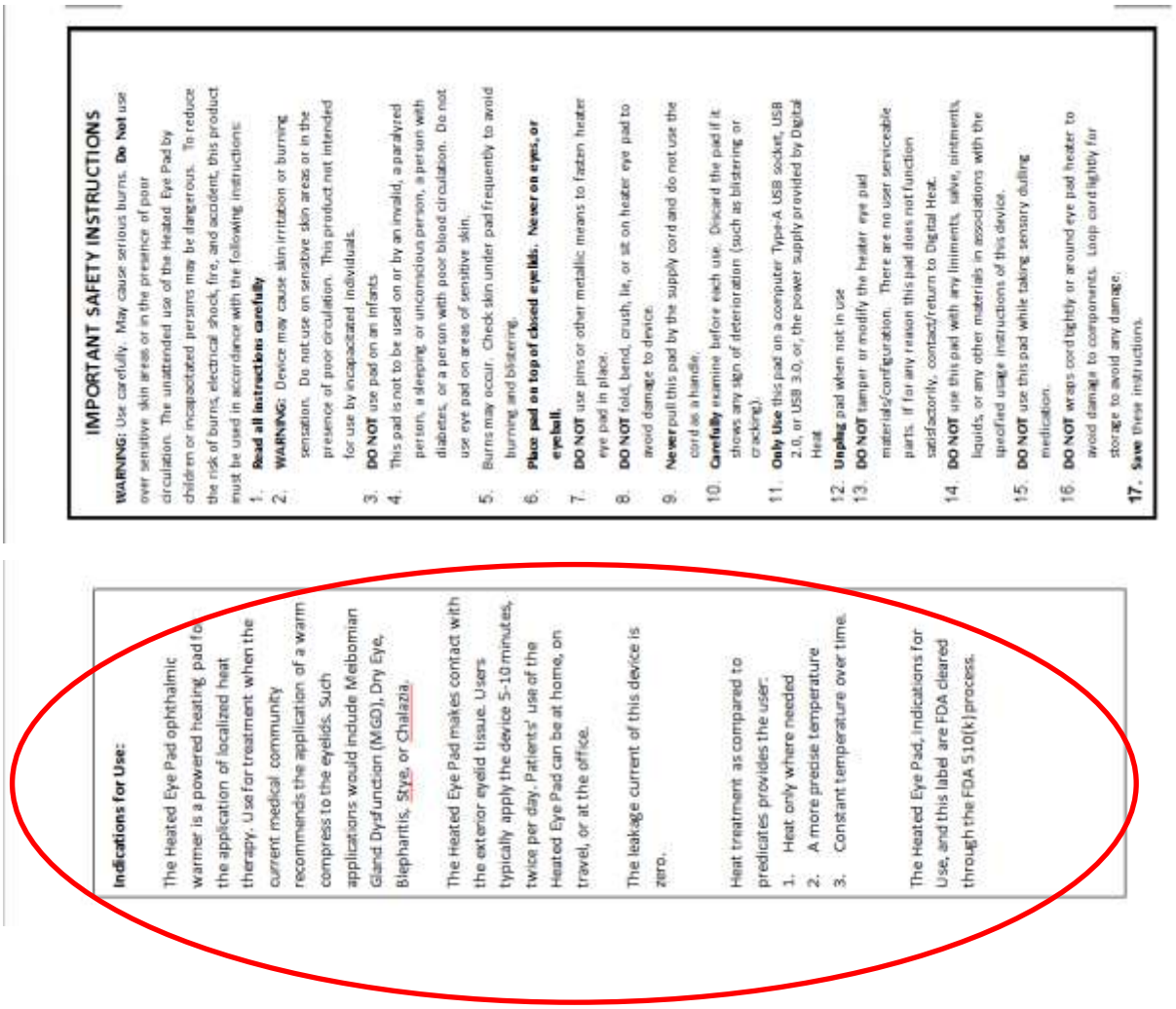
3.4.1 Digital Heat Labeling

Digital Heat makes no medical claims, and refers users to third party medical research for the efficacy of heating the Meibomian gland fluid. For all four stages of Meibomian gland dysfunction, the medical community recommends a warm compress for treatment (EU Regulatory Workshop: Meibomian Gland Dysfunction, Kelly K. Nichols, OD, MPH, PhD, FERV Professor, University of Houston College of Optometry Chair, TFOS International Meibomian Gland Workshop, slide 23, March 2010.)The next several pages include photographs of Digital Heat labels and predicate device labels.

The Digital Heat device box will include labeling as seen in Figure 10: Heated Eye Pad, Box Labeling (not to scale).

Figure 10: Heated Eye Pad, Box Labeling (not to scale)





IMPORTANT SAFETY INSTRUCTIONS

WARNING: Use carefully. May cause serious burns. **Do Not** use over sensitive skin areas or in the presence of poor circulation. The unattended use of the Heated Eye Pad by children or incapacitated persons may be dangerous. To reduce the risk of burns, electrical shock, fire, and accident, this product must be used in accordance with the following instructions:

1. **Read all instructions carefully**
2. **WARNING:** Device may cause skin irritation or burning sensation. Do not use on sensitive skin areas or in the presence of poor circulation. This product not intended for use by incapacitated individuals.
3. **DO NOT** use pad on an infants
4. This pad is not to be used on or by an invalid, a paralyzed person, a sleeping or unconscious person, a person with diabetes, or a person with poor blood circulation. Do not use eye pad on areas of sensitive skin.
5. Burns may occur. Check skin under pad frequently to avoid burning and blistering.
6. **Place pad on top of closed eyelids. Never on eyes, or eyeball.**
7. **DO NOT** use pins or other metallic means to fasten heater eye pad in place.
8. **DO NOT** fold, bend, crush, lie, or sit on heater eye pad to avoid damage to device.
9. **Never** pull this pad by the supply cord and do not use the cord as a handle.
10. **Carefully** examine before each use. Discard the pad if it shows any sign of deterioration (such as blistering or cracking).
11. **Only Use** this pad on a computer Type-A USB socket, USB 2.0, or USB 3.0, or, the power supply provided by Digital Heat
12. **Unplug** pad when not in use
13. **DO NOT** tamper or modify the heater eye pad materials/configuration. There are no user serviceable parts. If for any reason this pad does not function satisfactorily, contact/return to Digital Heat.
14. **DO NOT** use this pad with any liniments, salve, ointments, liquids, or any other materials in associations with the specified usage instructions of this device.
15. **DO NOT** use this pad while taking sensory dulling medication.
16. **DO NOT** wraps cord tightly or around eye pad heater to avoid damage to components. Loop cord lightly for storage to avoid any damage.
17. **Save** these instructions.

Indications for Use:

The Heated Eye Pad ophthalmic warmer is a powered heating pad for the application of localized heat therapy. Use for treatment when the current medical community recommends the application of a warm compress to the eyelids. Such applications would include Meibomian Gland Dysfunction (MGD), Dry Eye, Blepharitis, Stye, or Chalazia.

The Heated Eye Pad makes contact with the exterior eyelid tissue. Users typically apply the device 5-10 minutes, twice per day. Patients' use of the Heated Eye Pad can be at home, on travel, or at the office.

The leakage current of this device is zero.

Heat treatment as compared to predicates provides the user:

1. Heat only where needed
2. A more precise temperature
3. Constant temperature over time.

The Heated Eye Pad, indications for Use, and this label are FDA cleared through the FDA 510(k) process.

The Digital Heat, Heated Eye Pad package inserts will include user instructions font size 11, Calibri, and safety instructions at font size 12, Calibri (Figures 11, 12).

Figure 11: Package Insert User Instructions (not to scale)

HEATED EYE PAD eye
www.heatedeyepad.com

by DIGITAL HEAT
5626 S. Captain Kidd Ct., Unit B
Tempe, AZ 85283
(512) 517-6649

Instructions on how to use the Heated Eye Pad
Read ALL Safety Precautions before use.

Look in the mirror. Fold or expand the nose part of the Heated Eye Pad to fit your face and eyes.

The round section of the Heated Eye Pad should line up with your eyes, as shown in between the dashed lines.

As you fold the nose bridge, the Heated Eye Pad might go out of alignment. This is incorrect

Slightly bend the frame as needed to make it straight to your face.

This is correct. You are ready to wear.

1. Setup a timer (Watch, Clock, Phone, Etc.) if you wish to time your session.
2. Plug the heater into the power supply furnished by Digital Heat, or, a computer Type-A USB socket, USB 2.0, or USB 3.0. Do not use other power supplies.
3. Gently place the Heated Eye Pad on your CLOSED eyelids and position the elastic strap behind ears.
4. Adjust the tightness of the elastic strap for comfort, and place the electrical cord behind an ear.
5. DO NOT apply excessive pressure on your eyelids by over tightening the elastic strap.
6. Repeat steps 1 through 6 as needed for comfort.
7. If timed, after timer has expired remove the Heated Eye Pad from your eyelids and face.

Figure 12: Heated Eye Pad User Safety Instructions (not to scale)

HEATED EYE PAD
www.heatedeyepad.com

by DIGITAL HEAT
5626 S. Captain Kidd Ct., Unit B
Tempe, AZ 85283
(512) 517-6649

IMPORTANT SAFETY INSTRUCTIONS

WARNING: Use carefully. May cause serious burns. **Do Not** use over sensitive skin areas or in the presence of poor circulation. The unattended use of the Heated Eye Pad by children or incapacitated persons may be dangerous. To reduce the risk of burns, electrical shock, fire, and accident, this product must be used in accordance with the following instructions:

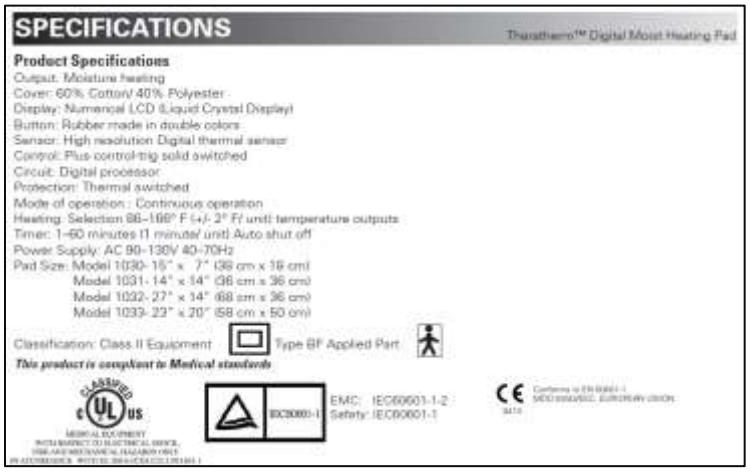
1. **Read all instructions carefully**
2. **WARNING:** Device may cause skin irritation or burning sensation. Do not use on sensitive skin areas or in the presence of poor circulation. This product not intended for use by incapacitated individuals.
3. **DO NOT** use pad on an infants
4. This pad is not to be used on or by an invalid, a paralyzed person, a sleeping or unconscious person, a person with diabetes, or a person with poor blood circulation. Do not use eye pad on areas of sensitive skin.
5. Burns may occur. Check skin under pad frequently to avoid burning and blistering.
6. **Place pad on top of closed eyelids. Never on eyes, or eyeball.**
7. **DO NOT** use pins or other metallic means to fasten heater eye pad in place.
8. **DO NOT** fold, bend, crush, lie, or sit on heater eye pad to avoid damage to device.
9. **Never** pull this pad by the supply cord and do not use the cord as a handle.
10. **Carefully** examine before each use. Discard the pad if it shows any sign of deterioration (such as blistering or cracking).
11. **Only Use** this pad on a computer Type-A USB socket, USB 2.0, or USB 3.0, or, the power supply provided by Digital Heat
12. **Unplug** pad when not in use
13. **DO NOT** tamper or modify the heater eye pad materials/configuration. There are no user serviceable parts. If for any reason this pad does not function satisfactorily, contact/return to Digital Heat.
14. **DO NOT** use this pad with any liniments, salve, ointments, liquids, or any other materials in associations with the specified usage instructions of this device.
15. **DO NOT** use this pad while taking sensory dulling medication.
16. **DO NOT** wraps cord tightly or around eye pad heater to avoid damage to components. Loop cord lightly for storage to avoid any damage.
17. **Save** these instructions.

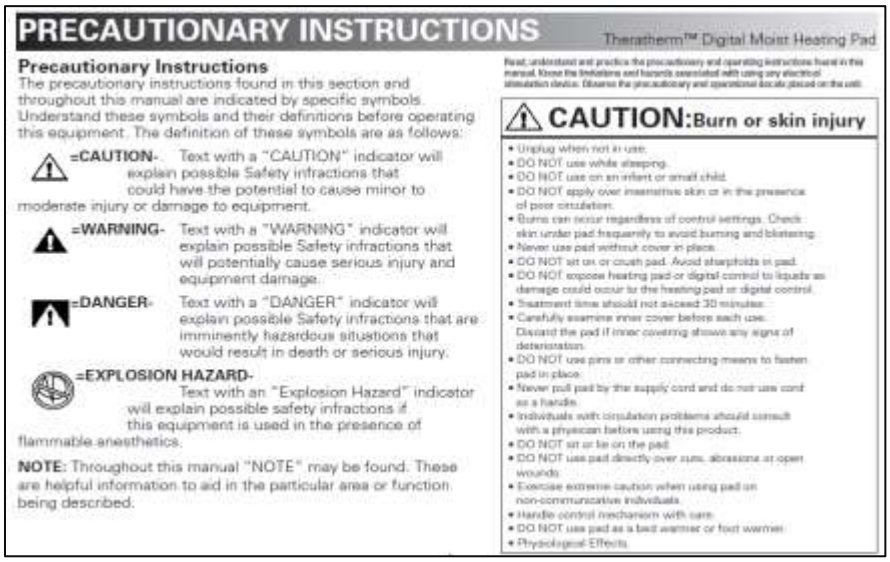
Contact Information:

Web:	www.heatedeyepad.com
Email:	Info@digitalheat911.com
Technical Support:	(512) 517-6649

3.4.2 Theratherm Labeling

Figure 13 Theratherm User Instructions and Safety Labeling





3.4.3 Kao Labeling

Figure 14 Kao Box, User Instructions and Safety Labeling

3.4.4 ThermalOn Labeling

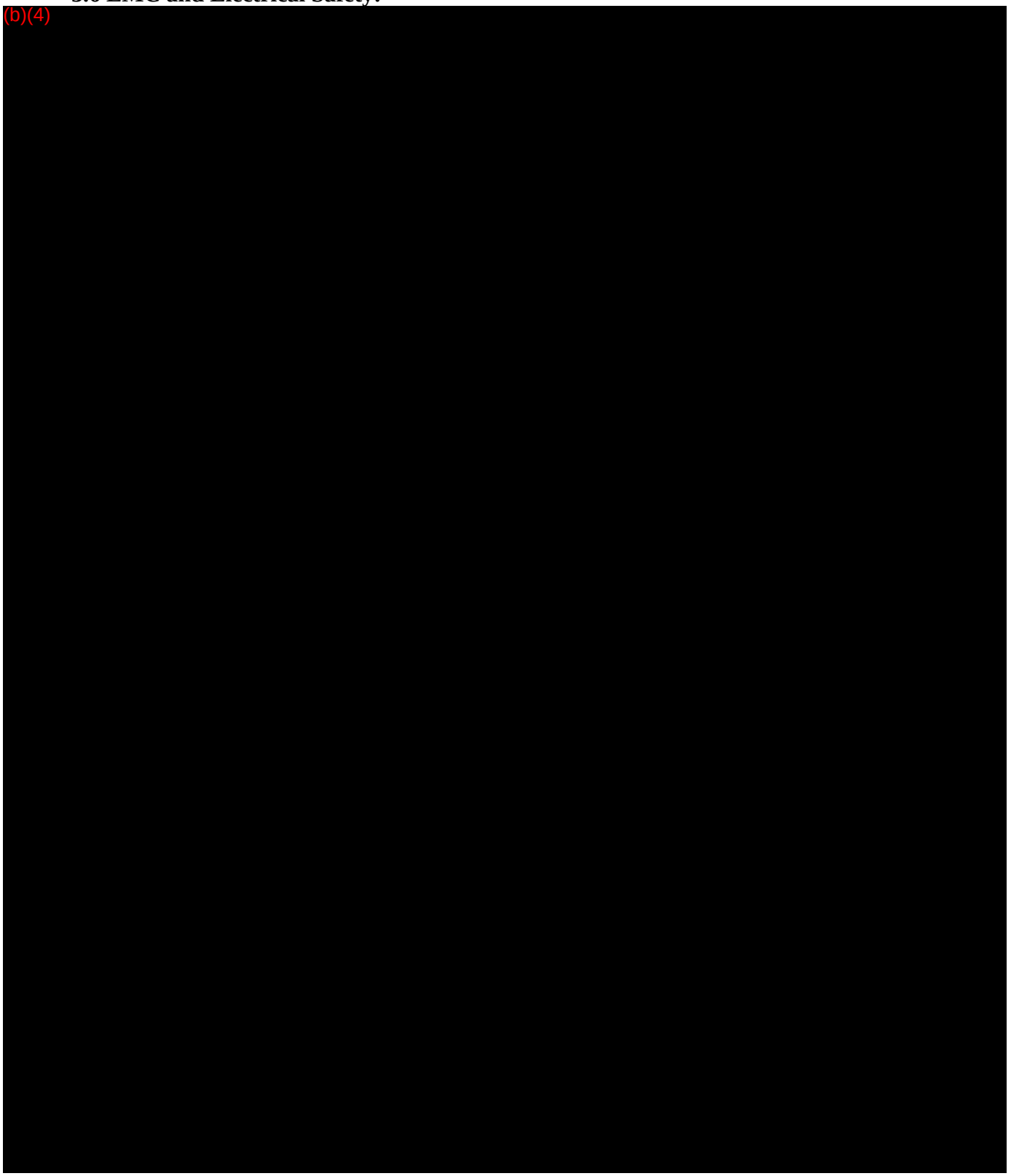
Figure 15 ThermalOn User Instructions and Safety Labeling

3.5 Additional Information:

(b)(4) [redacted]. The device has two power states, plugged in and "ON," or unplugged and "OFF."

3.6 EMC and Electrical Safety:

(b)(4)



(b)(4) EMC and Electrical Safety

(b)(4) EMC and Electrical Safety

(b)(4) EMC and Electrical Safety

3.7 Performance Data - General

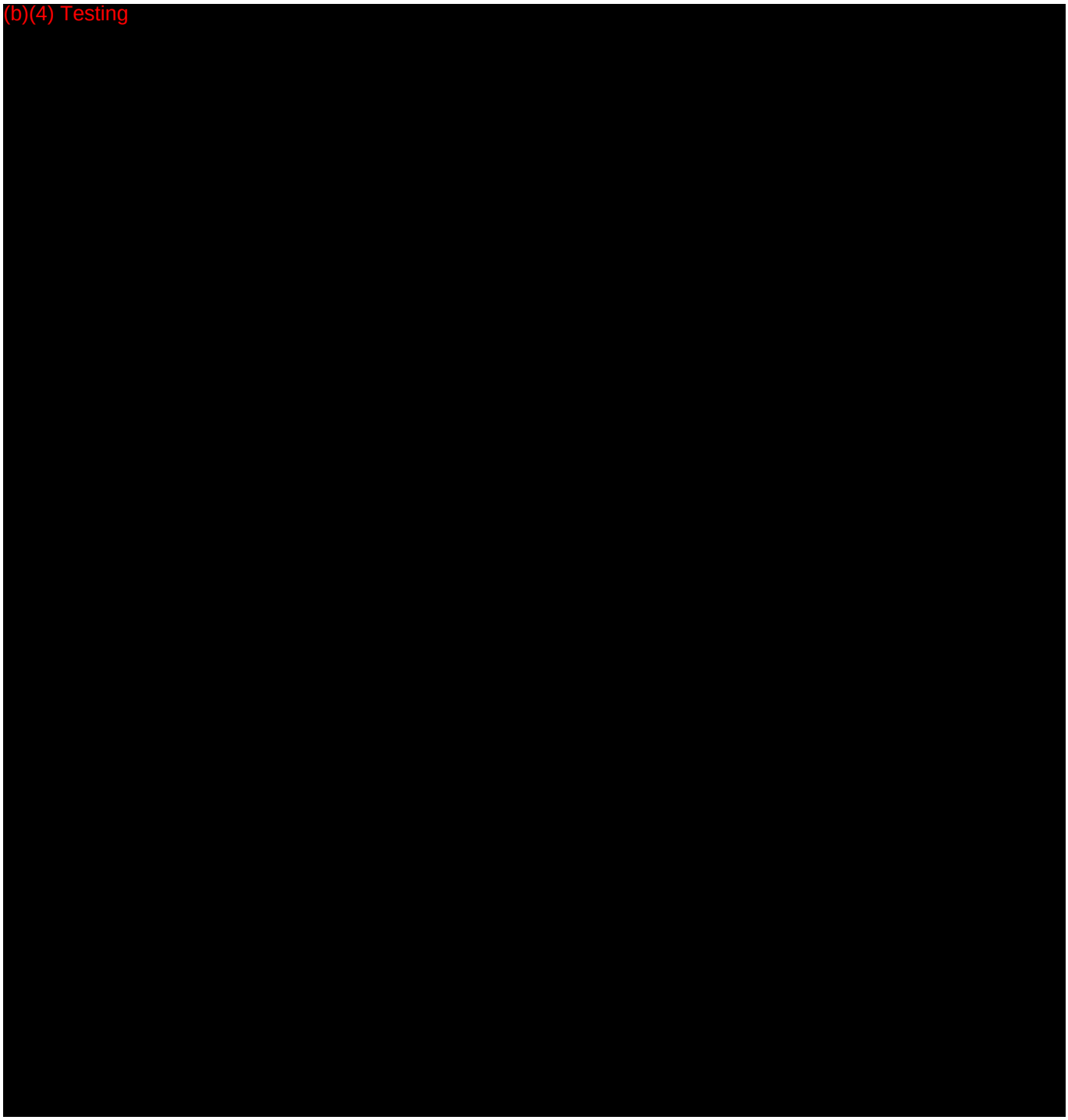
3.7.1 Temperature versus Voltage Range

(b)(4) Testing

(b)(4) Testing

3.7.2 Meibomian Gland Temperature versus Predicate Devices

(b)(4) Testing



(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

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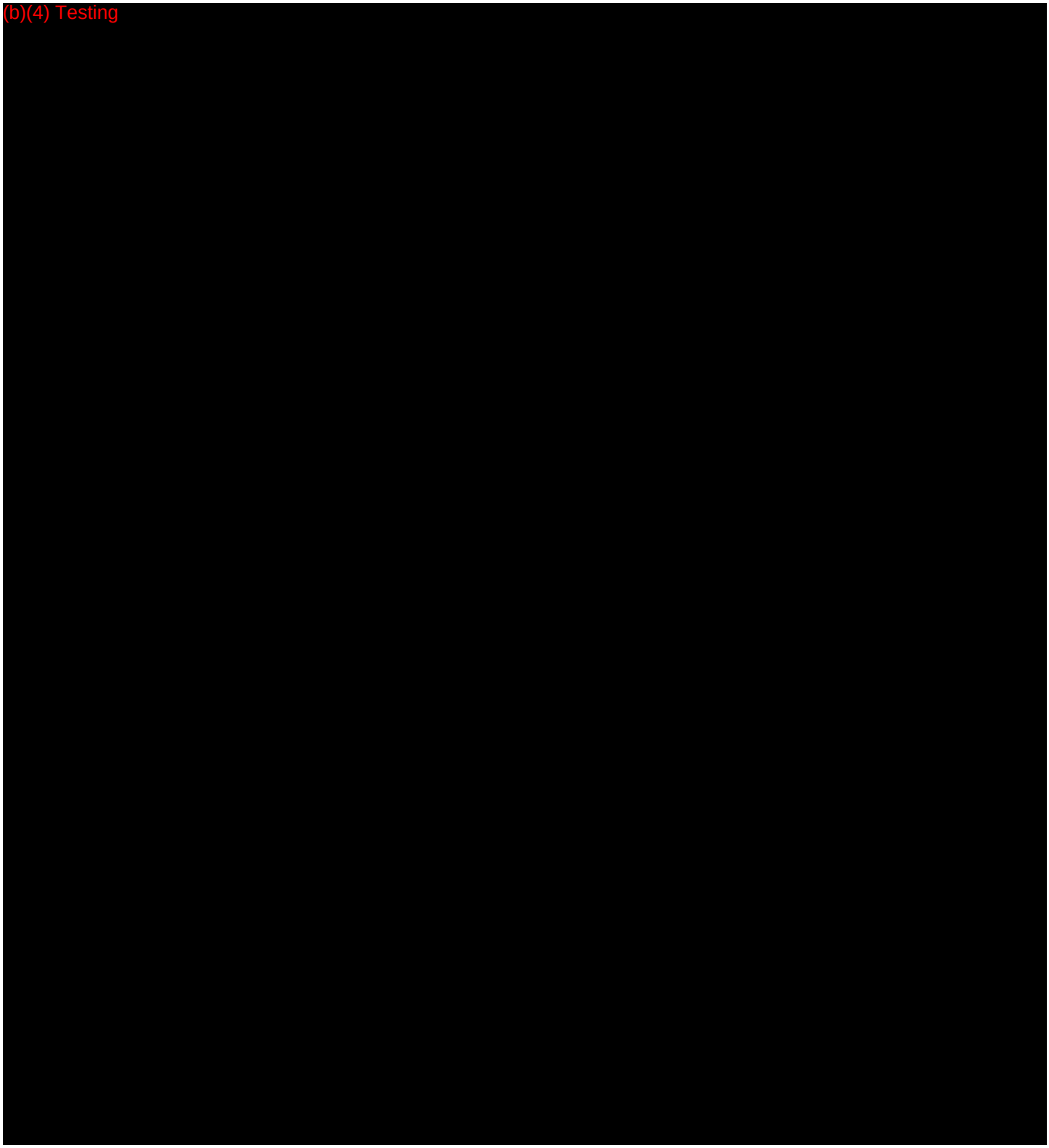
(b)(4) Testing

(b)(4) Testing

3.7.3 Temperature over Time versus Predicates

(b)(4) Testing



(b)(4) Testing

4.0 SUBSTANTIAL EQUIVALENCE INFORMATION:

The Digital Heat's "Heated Eye Pad" is designed for us on the outer eyelids. The user does not apply heat to undesired sections of the human body or facial area.

(b)(4)

Table 6 a brief summary of the Digital Heat proposed device substantial equivalency to Sec. 890.5710 Hot or cold disposable pack and sec. 890.5740 Powered Heating Pad.

Table 6: Substantial Equivalency Summary

Category Of Equivalence	Powered Heating Pad	Powered Heating Pad	Chemical Hot Disposable Pack	Microwave Heated Beads
FDA CFR Title 21 S	(890.5740)	(890.5740)	(890.5710)	(890.5730)
Warm Compress	Digital Heat's "Heated Eye Pad"	Theratherm	Bio-Lipid, EyeFeel	Thermalon
510(k)	Submission	K770686	K021843, K082087	Not Applicable
Intended for OTC?	Yes	Yes	Yes	Yes
Sterility	Non-sterile when used	Non-sterile when used	Non-sterile when used	Non-sterile when used
Biocompatible?	Yes	unknown	unknown	unknown
Software	(b)(4) [redacted]			
Mechanism for Heat Generation				
Maximum Surface Temperature (using Thermocouple)				
Power Usage				
Mechanism for Heat Control				
Control Mechanism for Safety				
Specific Therapeutic Indications	Ophthalmic Warmer	Electric Heating Pad	Ophthalmic Warmer	Ophthalmic Warmer

5.0 510(K) Statement:

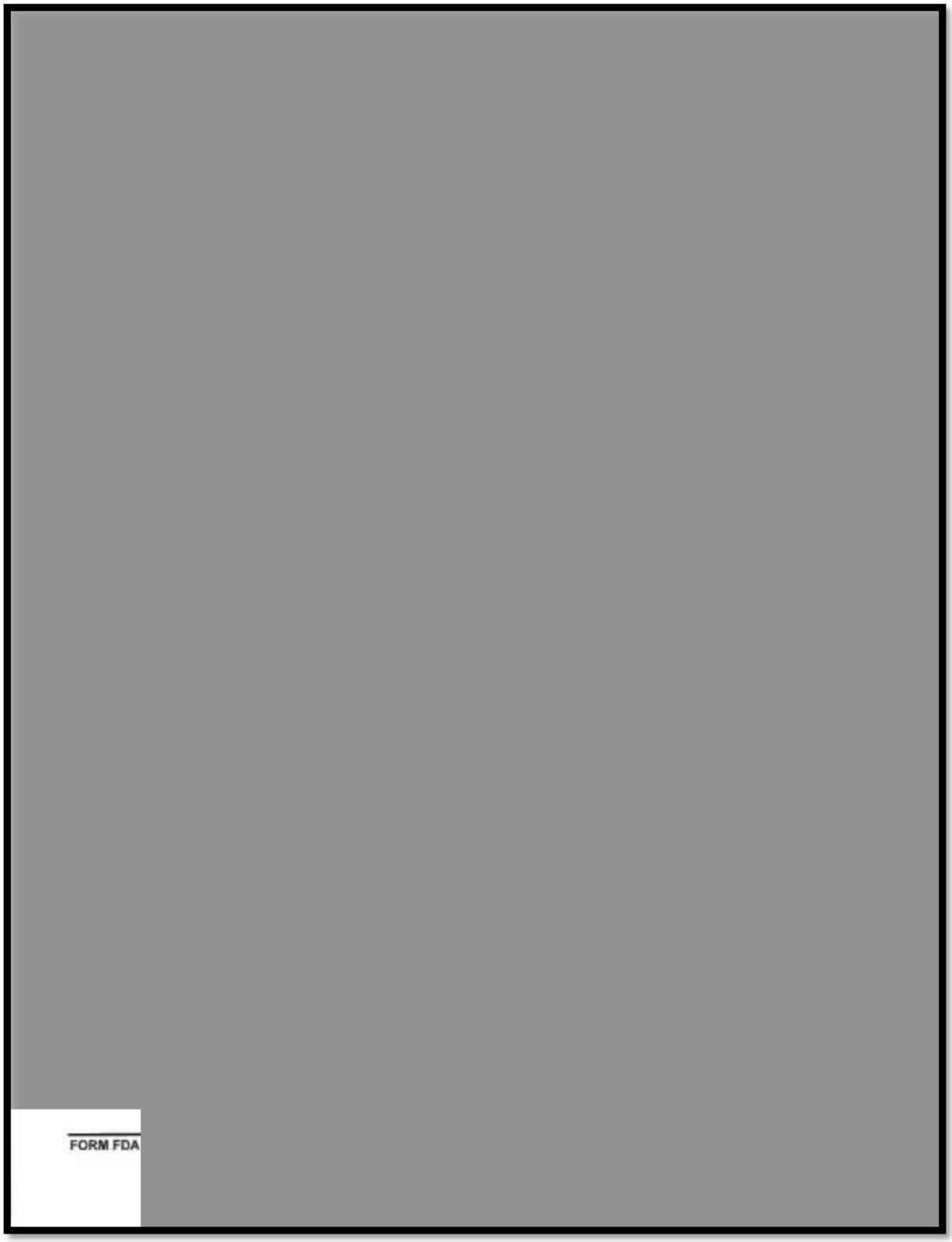
I certify that, in my capacity as President and Chief Executive Officer, of Digital Heat Corporation, I will make available all information included in this premarket notification on safety and effectiveness within 30 days of request by any person if the device described in the premarket notification submission is determined to be substantially equivalent. The information I agree to make available will be a duplicate of the premarket notification submission, including any adverse safety and effectiveness information, but excluding all patient identifiers, and trade secret and confidential commercial information, as defined in 21 CFR 20.61.

6.0 TRUTHFUL AND ACCURATE STATEMENT:

All data and information submitted in the premarket notification are truthful and accurate and no material fact has been omitted, as required by 21 CFR 807.87(j).

7.0 Appendix:

Indications for Use, Form 3881



References:

Copies of references in the order they appear are in the subsequent pages.

EU Regulatory Workshop: Meibomian Gland Dysfunction, Kelly K. Nichols, OD, MPH, PhD, FERV Professor, University of Houston College of Optometry Chair, TFOS International Meibomian Gland Workshop, slide 23, March 2010.)

- This reference is relevant because it supports the assertion that a warm compress is the recommended treatment for all four stages of meibomian gland dysfunction. Predicate devices recommend heat therapy, as does the Heated Eye Pad.

NIST, Fire Dynamics, Dan Madrzykowski, Fire Research Division, www.nist.gov/fire/fire_behavior.cfm, July 16, 2013

- This reference is relevant because it supports the assertion that a warm compress temperature below 44 centigrade is the recommended temperature to avoid patient pain. The Heated Eye Pad versus all predicates is contained in the performance reports attached to this 510(k) application.

(b)(4)

EU Regulatory Workshop: Meibomian Gland Dysfunction

Kelly K. Nichols, OD, MPH, PhD
FERV Professor
University of Houston College of Optometry
Chair, TFOS International Meibomian Gland Workshop

Disclosures

- K. Nichols
  - Paid consultant to:
    - Alcon
    - Allergan
    - Celtic/ Resolvyx
    - Eleven Biotherapeutics
    - InSite
    - Ista
    - SARcode
    - TearLab
- Research support
  - CL Tear Film Lab (OSU)
    - Alcon
    - CIBA
    - Inspire
    - TearLab
    - Pfizer
    - Vistakon
  - National Eye Institute
    - R01 EY015519 (PI)
    - R01 EY017951 (Co-I)
    - R34 EY017626 (Co-I)

MGD Contributes to Dry Eye

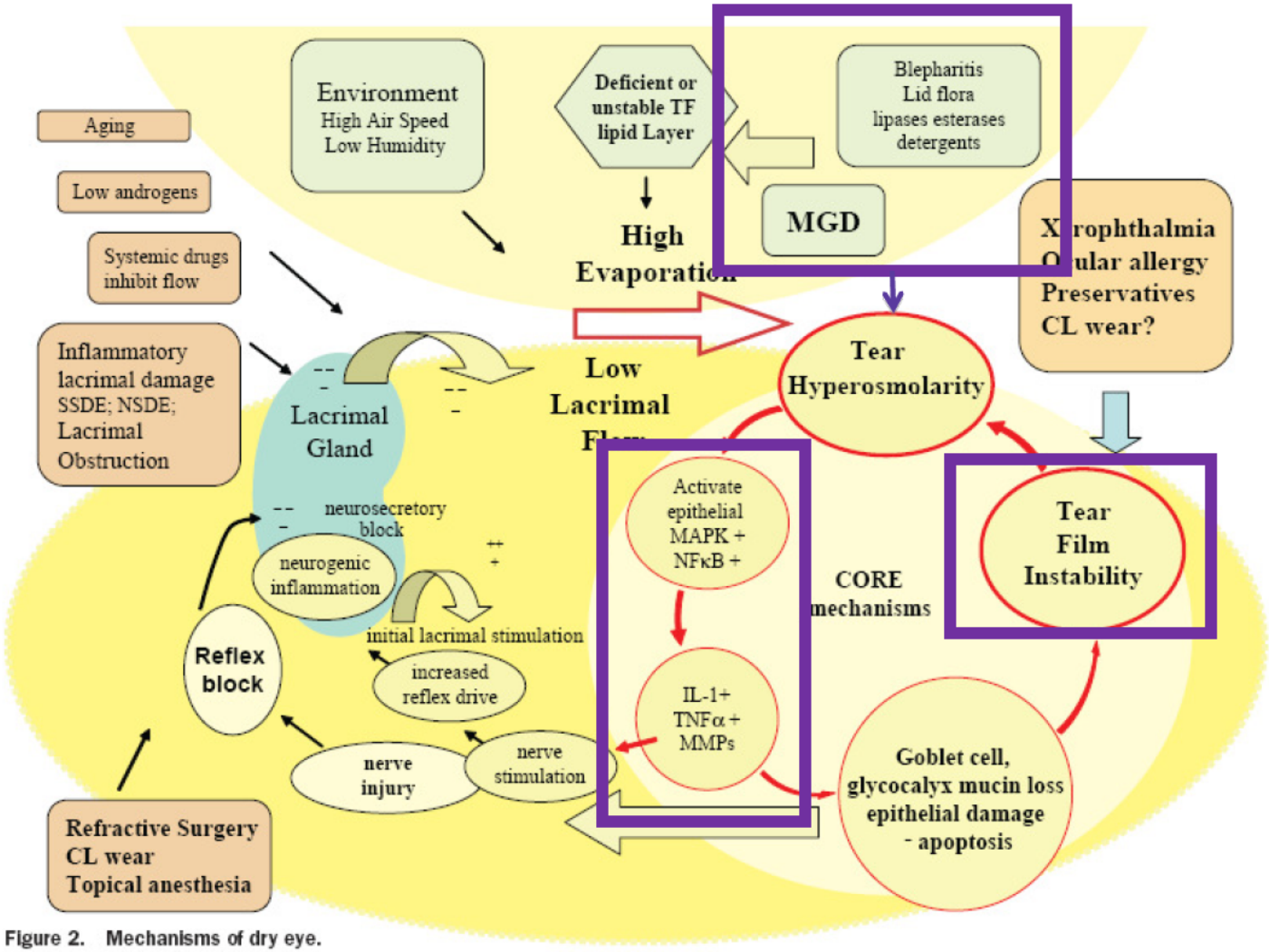


Figure 2. Mechanisms of dry eye.

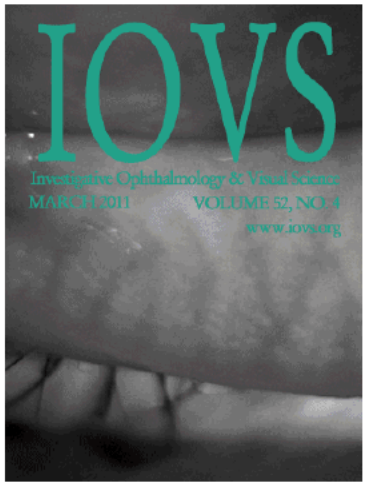
DEWS Definition and classification report. *Ocular Surface* 2007

Table 2. Dry eye severity grading scheme

Dry Eye Severity Level	1	2	3	4*
Discomfort, severity & frequency	Mild and/or episodic occurs under environ stress	Moderate episodic or chronic, stress or no stress	Severe frequent or constant without stress	Severe and/or disabling and constant
Visual symptoms	None or episodic mild fatigue	Annoying and/or activity limiting episodic	Annoying, chronic and/or constant limiting activity	Constant and/or possibly disabling
Conjunctival injection	None to mild	None to mild	+/–	+/++
Conjunctival staining	None to mild	Variable	Moderate to marked	Marked
Corneal staining (severity/location)	None to mild	Variable	Marked central	Severe punctate erosions
Corneal/tear signs	None to mild	Mild debris, ↓ meniscus	Filamentary keratitis, mucus clumping, ↑ tear debris	Filamentary keratitis, mucus clumping, ↑ tear debris, ulceration
Lid/meibomian glands	MGD variably present	MGD variably present	Frequent	Trichiasis, keratinization, symblepharon
TFBUT (sec)	Variable	≤ 10	≤ 5	Immediate
Schirmer score (mm/5 min)	Variable	≤ 10	≤ 5	≤ 2

*Must have signs AND symptoms. TBUT: fluorescein tear break-up time. MGD: meibomian gland disease

Reprinted with permission from Behrens A, Doyle JJ, Stern L, et al. Dysfunctional tear syndrome. A Delphi approach to treatment recommendations. *Cornea* 2006;25:90-7



TFOS International MGD Workshop

Special Issue

The International Workshop on Meibomian Gland Dysfunction: Executive Summary

Kelly K. Nichols,[1] Gary N. Foulks,[2] Anthony J. Bron,[3] Ben J. Glasgow,[4,5] Murat Dogru,[6] Kazuo Tsubota,[6] Michael A. Lemp,[7] and David A. Sullivan[8,9]

- Over 65 International clinicians, scientists, and industry participants
- 2+ year process
- Published in March 2011, *IOVS*
- #1 Most downloaded *IOVS* article for the last 12 months
- Downloaded over 5500 times
- All MGD workshop reports are in the "top 10"
- Translation into 12 languages
- www.tearfilm.org

The 65 Most-Frequently Read Articles
in Invest. Ophthalmol. Vis. Sci. during **October 2010 thru September 2011** -- updated monthly

Most-read rankings are recalculated at the beginning of the month and are based on full-text and pdf views.

1. Kelly K. Nichols, Gary N. Foulks, Anthony J. Bron, Ben J. Glasgow, Murat Dogru, Kazuo Tsubota, Michael A. Lemp, David A. Sullivan
The International Workshop on Meibomian Gland Dysfunction: Executive Summary
Invest Ophthalmol Vis Sci Mar 30, 2011; 52: 1922-1929.
(In "Special Issue") [Full Text] [PDF]
(Read 5554 times)

2. Kelly K. Nichols
The International Workshop on Meibomian Gland Dysfunction: Introduction
Invest Ophthalmol Vis Sci Mar 30, 2011; 52: 1917-1921.
(In "Special Issue") [Full Text] [PDF]
(Read 5318 times)

3. Erich Knop, Nadja Knop, Thomas Millar, Hiroto Obata, David A. Sullivan
The International Workshop on Meibomian Gland Dysfunction: Report of the Subcommittee on Anatomy, Physiology, and Pathophysiology of the Meibomian Gland
Invest Ophthalmol Vis Sci Mar 30, 2011; 52: 1938-1978.
(In "Special Issue") [Full Text] [PDF]
(Read 4663 times)

4. Alan Tomlinson, Anthony J. Bron, Donald R. Korb, Shiro Amano, Jerry R. Paugh, E. Ian Pearce, Richard Yee, Norihiko Yokoi, Reiko Arita, Murat Dogru
The International Workshop on Meibomian Gland Dysfunction: Report of the Diagnosis Subcommittee
Invest Ophthalmol Vis Sci Mar 30, 2011; 52: 2006-2049.
(In "Special Issue") [Full Text] [PDF]
(Read 4074 times)

5. Gerd Geerling, Joseph Tauber, Christophe Baudouin, Eiki Goto, Yukihiro Matsumoto, Terrence O'Brien, Maurizio Rolando, Kazuo Tsubota, Kelly K. Nichols
The International Workshop on Meibomian Gland Dysfunction: Report of the Subcommittee on Management and Treatment of Meibomian Gland Dysfunction
Invest Ophthalmol Vis Sci Mar 30, 2011; 52: 2050-2064.
(In "Special Issue") [Full Text] [PDF]
(Read 4027 times)

6. J. Daniel Nelson, Jun Shimazaki, Jose M. Benitez-del-Castillo, Jennifer P. Craig, James P. McCulley, Seika Den, Gary N. Foulks
The International Workshop on Meibomian Gland Dysfunction: Report of the Definition and Classification Subcommittee
Invest Ophthalmol Vis Sci Mar 30, 2011; 52: 1930-1937.
(In "Special Issue") [Full Text] [PDF]
(Read 3221 times)

7. Penny A. Asbell, Fiona J. Stapleton, Kerstin Wickström, Esen K. Akpek, Pasquale Aragona, Reza Dana, Michael A. Lemp, Kelly K. Nichols
The International Workshop on Meibomian Gland Dysfunction: Report of the Clinical Trials Subcommittee
Invest Ophthalmol Vis Sci Mar 30, 2011; 52: 2065-2085.
(In "Special Issue") [Full Text] [PDF]
(Read 2580 times)

8. Kari B. Green-Church, Igor Butovich, Mark Willcox, Douglas Borchman, Friedrich Paulsen, Stefano Barabino, Ben J. Glasgow
The International Workshop on Meibomian Gland Dysfunction: Report of the Subcommittee on Tear Film Lipids and Lipid–Protein Interactions in Health and Disease
Invest Ophthalmol Vis Sci Mar 30, 2011; 52: 1979-1993.
(In "Special Issue") [Full Text] [PDF]
(Read 2546 times)

9. Debra A. Schaumberg, Jason J. Nichols, Eric B. Papas, Louis Tong, Miki Uchino, Kelly K. Nichols
The International Workshop on Meibomian Gland Dysfunction: Report of the Subcommittee on the Epidemiology of, and Associated Risk Factors for, MGD
Invest Ophthalmol Vis Sci Mar 30, 2011; 52: 1994-2005.
(In "Special Issue") [Full Text] [PDF]
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TFOS REPORTS

Tfos Scientific Reports

MGD REDEFINED: INTERNATIONAL WORKSHOP ON MEIBOMIAN GLAND DYSFUNCTION REPORT AVAILABLE

Report Overview, Link to Full Report & Press Release

BOSTON, MA, March 31, 2011-

The Tear Film & Ocular Surface Society (TFOS) reported the conclusions and recommendations of the International Workshop on Meibomian Gland Dysfunction (MGD).

The MGD Workshop, sponsored by TFOS, was conducted to provide an evidence-based evaluation of meibomian gland structure and function in health and disease. MGD is an extremely important condition, conceivably underestimated, and very likely the most frequent cause of dry eye disease.

The Report required over 2 years to complete and involved the efforts of more than 50 leading clinical and basic research experts from around the world.

- Report Overview
- Link to full Report (IOVS)

search TFOS

NEWS & EVENTS

- **Dry Eye Review Blog:. Industry Experts blogging about Dry Eye Disease**

subscribe now!or view entries!

- **TFOS Meibomian Gland Dysfunction Report online**

TFOS MGD Report available now

- **The 6th International Conference on the Tear Film & Ocular Surface**

Basic Science and Clinical Relevance
Abstract Book, Highlights & Historical Perspective

Anatomy, Physiology and Pathophysiology of the Meibomian Gland

Tear Film & Ocular Surface Society presents MGD Workshop 2010

A Report from the International Workshop on Meibomian Gland Dysfunction

Erich Knop, M.D., Ph.D. (Chair)
Nadja Knop, M.D., Ph.D.
Thomas J. Millar, Ph.D.
Hiroto Obata, M.D.
David A. Sullivan, Ph.D.

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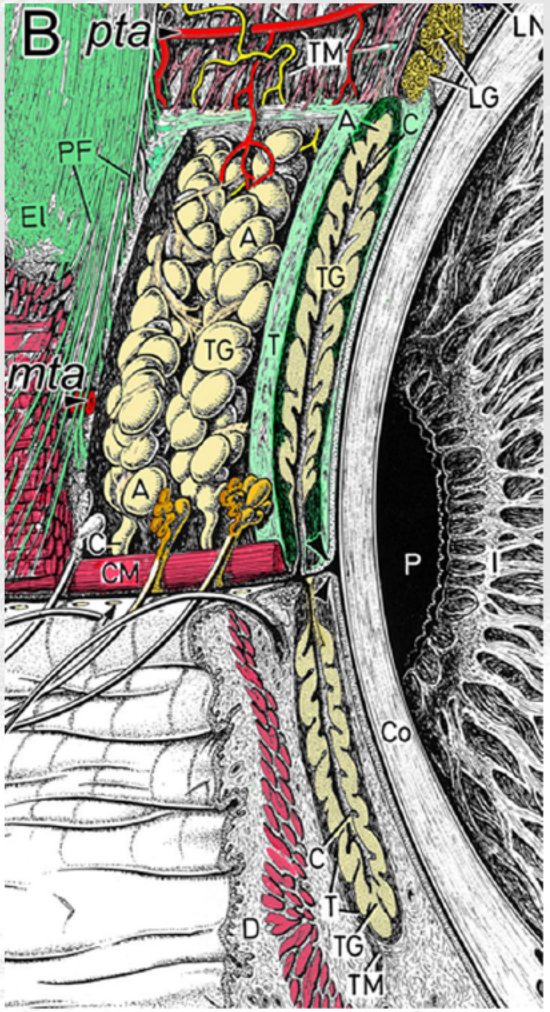
Meibomian Gland - ANATOMY

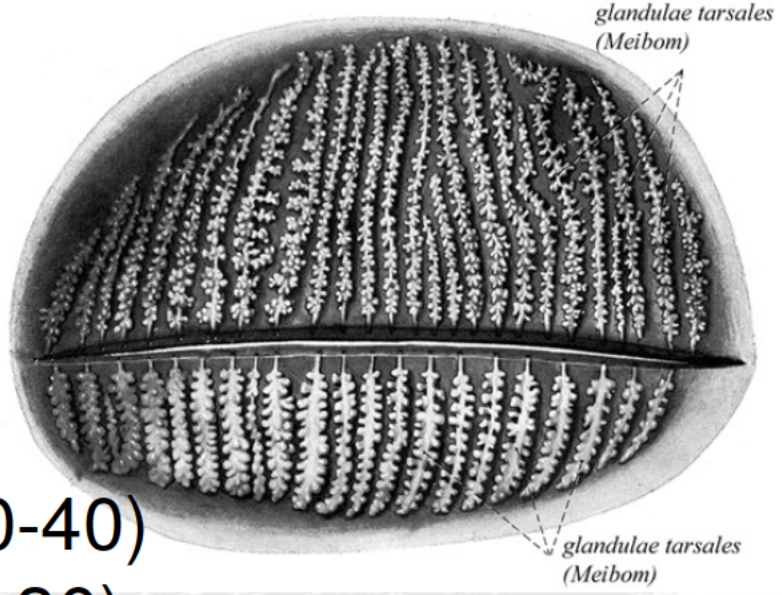
- Large sebaceous glands
- No direct contact to hair follicles
- Located in the tarsal plates
  - Upper and lower eye lids



Modified and colored from Krstic H. Human microscopic anatomy. Springer Medizin Verlag 1991, (reproduced from Knop N & Knop E Ophthalmologe 2009; 106:872–883)

Meibomian Gland - ANATOMY

- **Length**
  - Follows the tarsus
- **Number**
  - More in upper lid (30-40)
  - Less in lower lid (20-30)
- **Volume**
  - Higher in upper lid (26µl vs. 13µl)
- Relative functional contribution (upper vs. lower) to the tear film lipid layer is unknown



Modified from Sobotta Atlas der Anatomie des Menschen. Urban & Schwarzenberg Verlag 1982, (reproduced from Knop N & Knop E. Ophthalmologe 2009; 106:872–883)

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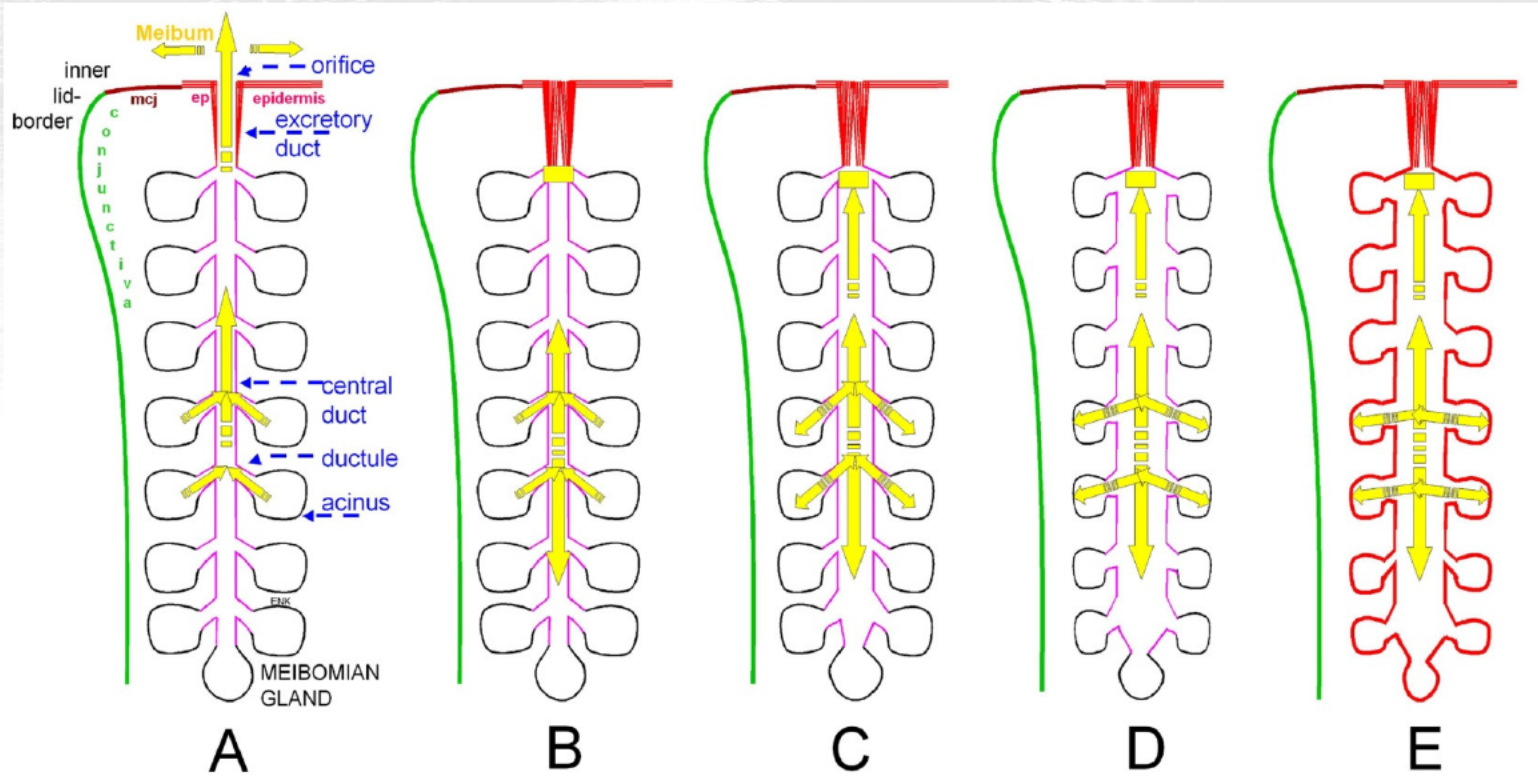
Meibomian Gland – PATHOLOGY

- Obstructive PATHOLOGY leads to a progressive ductal DILATATION and acinar ATROPHY



Fom Knop E & Knop N. Meibom-Drüsen Teil IV. Funktionelle Interaktionen in der Pathogenese der Dysfunktion (MGD). Ophthalmologe.2009;106:980–987

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Interacting Pathways in

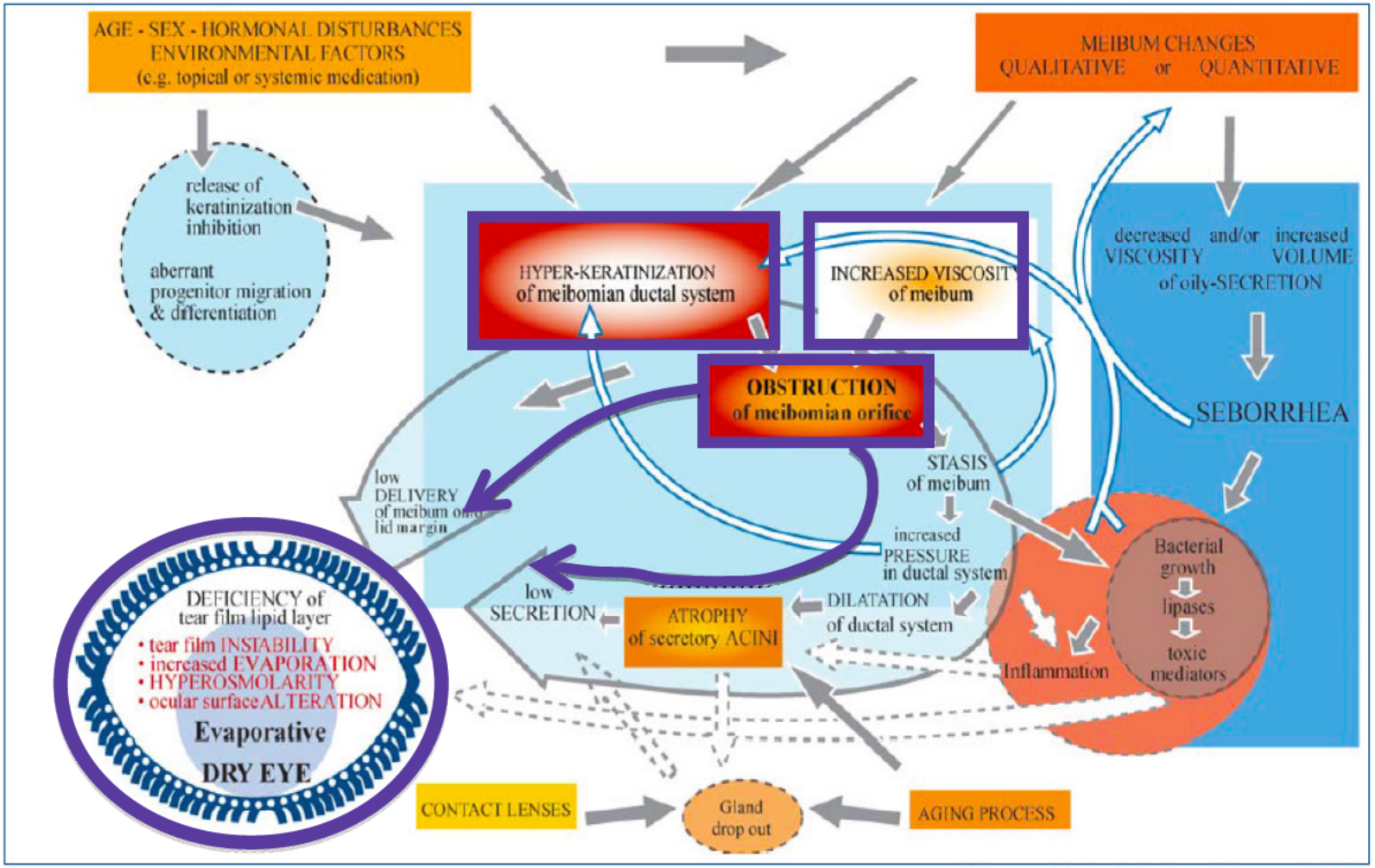

Figure 2. *Pathophysiology of obstructive MGD*

Modified from Knop E & Knop N. Meibom-Drüsen Teil IV. Funktionelle Interaktionen in der Pathogenese der Dysfunktion (MGD). Ophthalmologe.2009;106:980–987

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Meibomian Gland Dysfunction Definition & Classification

Tear Film & Ocular Surface Society presents MGD Workshop 2010

A Report from the International Workshop on Meibomian Gland Dysfunction

J. Daniel Nelson, M.D. (Co-Chair)
Jun Shimazaki, M.D., Ph.D. (Co-Chair)
Jose M. Benitez-del-Castillo, M.D., Ph.D.
Jennifer Craig, Ph.D., MCOptom
James P. McCulley, M.D.
Seika Den, M.D., Ph.D.
Gary N. Foulks, M.D.

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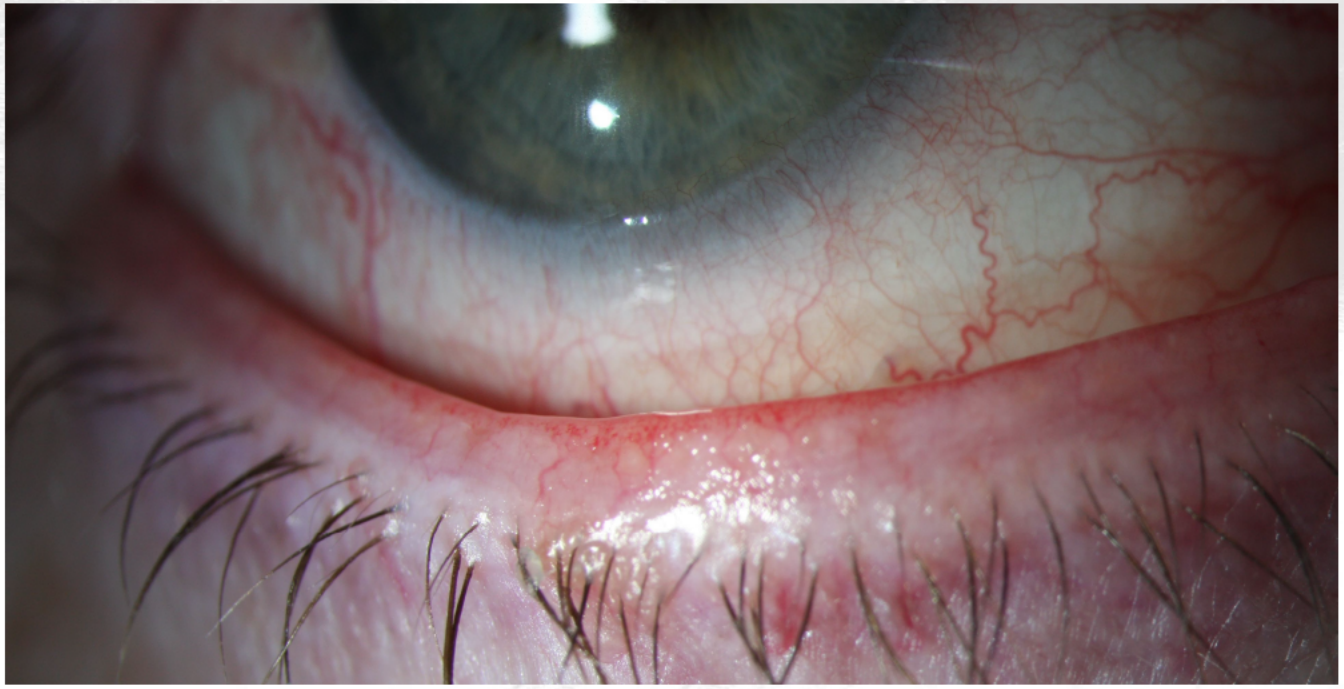
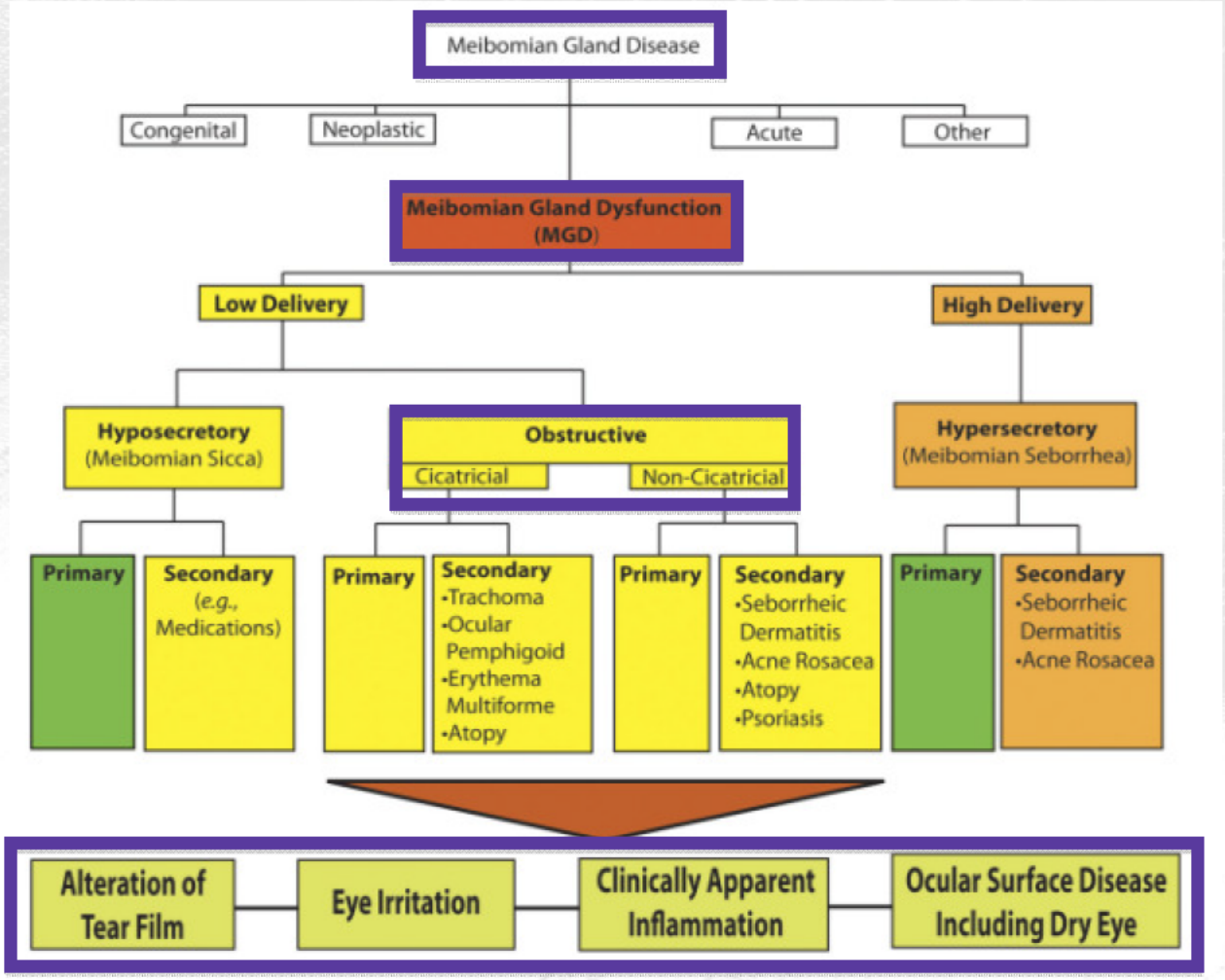
What is MGD?

The Workshop defined MGD as follows:

Meibomian gland dysfunction (MGD) is a chronic, diffuse abnormality of the meibomian glands, commonly characterized by terminal duct obstruction and/or qualitative/quantitative changes in the glandular secretion. This may result in alteration of the tear film, symptoms of eye irritation, clinically apparent inflammation, and ocular surface disease.



Classification of MGD



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Epidemiology and Associated Risk Factors of Meibomian Gland Dysfunction

Tear Film & Ocular Surface Society presents MGD Workshop 2010

A Report from the International Workshop on Meibomian Gland Dysfunction

Debra A. Schaumberg, Sc.D., O.D., M.P.H. (Chair)
Jason J. Nichols, O.D., M.P.H., Ph.D.
Eric B. Papas, M.Sc., O.D., Ph.D.
Louis Tong, F.R.C.S., M.B.B.S.
Miki Uchino, M.D.
Kelly K. Nichols, O.D., M.P.H., Ph.D.

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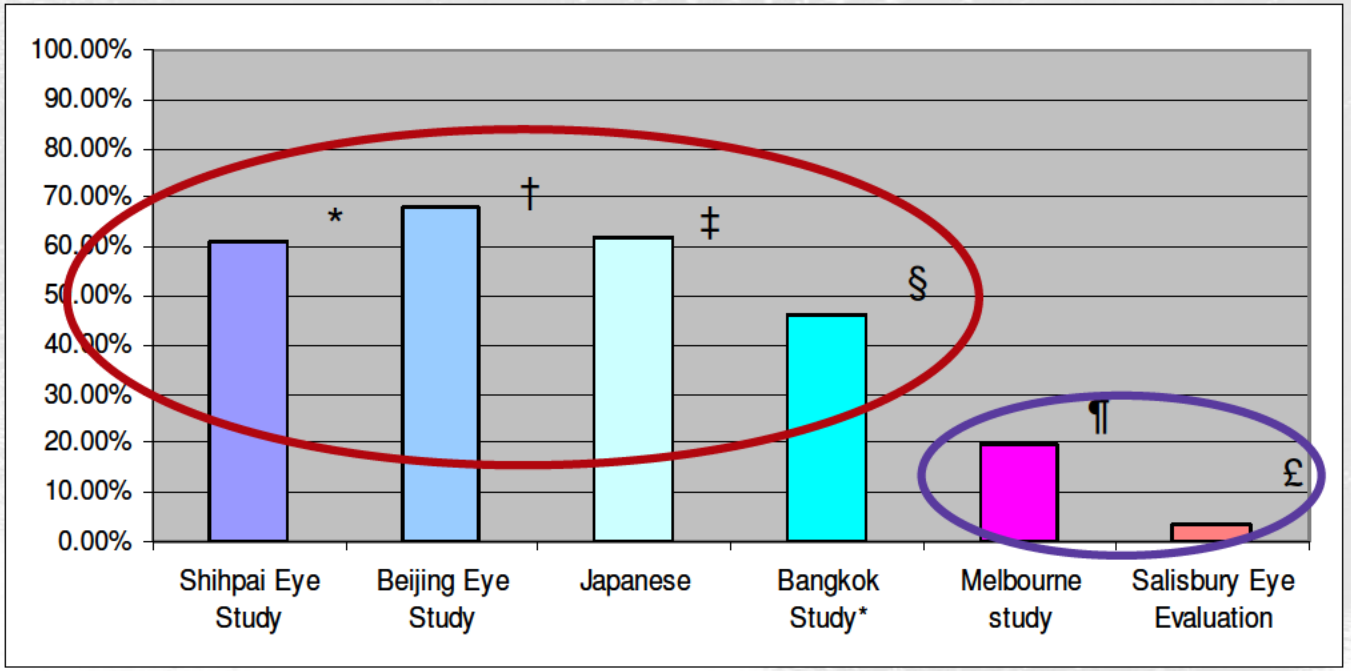
Prevalence of MGD



* Telangiectasia or Meibomian gland orifice plugging

† Telangiectasia

‡ Gland dropout, expressibility and nature of Meibum secretion

§ Telangiectasia or Meibomian gland orifice plugging OR collarettes

¶ Tear break up time < 1SD (10 sec)

£ Meibomian gland plugging OR collarettes (grade 2-3)

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Factors Associated with MGD

Special Issue

The International Workshop on Meibomian Gland Dysfunction: Report of the Subcommittee on the Epidemiology of, and Associated Risk Factors for, MGD

Debra A. Schaumberg,[1] Jason J. Nichols,[2] Eric B. Papas,[3] Louis Tong,[4] Miki Uchino,[5] and Kelly K. Nichols[2]

Factor	Reference
Aniridia	Jastaneiah and Al-Rajhi[48]
Chronic blepharitis (anterior or posterior)	Auw-Haedrich and Reinhard[40] Jackson[38] Mathers et al.[37] McCulley et al.[39] McCulley and Shine[49]
Contact lens wear	Arita et al.[36] Marren[33] Molinari and Stanek[34] Ong and Larke[32]
Demodex folliculorum	Czepita et al.[50] Kheirkhah et al.[51]
Eyelid tattooing	Kojima et al.[52]
Floppy eyelid syndrome	Gonnering and Sonneland[53]
Giant papillary conjunctivitis	Mathers and Billborough[54] Martin et al.[55] Molinari and Stanek[34]
Ichthyosis	Baden and Imber[56]
Salzmann's nodular corneal degeneration	Farjo et al.[57]
Trachoma	Bron and Tiffany[58]

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Factors Associated with MGD

Special Issue

The International Workshop on Meibomian Gland Dysfunction: Report of the Subcommittee on the Epidemiology of, and Associated Risk Factors for, MGD

Debra A. Schaumberg,[1] Jason J. Nichols,[2] Eric B. Papas,[3] Louis Tong,[4] Miki Uchino,[5] and Kelly K. Nichols[2]

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TABLE 5. Systemic Factors Hypothesized to Correlate with MGD

Factor	Reference
Aging	Den et al.[62]
	DEWS[46]
	Hykin and Bron[63]
	Schaumberg et al.[70]
	Schaumberg et al.[71]
	Sullivan et al.[64]
Androgen deficiency	Krenzer et al.[72]
	Sullivan et al.[73]
	Sullivan et al.[65]
Atopy	Bron et al.[15]
Benign Prostate Hyperplasia	Schaumberg et al.[70]
Cicatricial pemphigoid	Bron and Tiffany[58]
Complete androgen-insensitivity syndrome	Cermak et al.[74]
	Sullivan et al.[75]
Discoid lupus erythematosus	Ena et al.[76]
Ectodermal dysplasia syndrome	Kaercher[77]
Hematopoietic stem cell transplantation	Ogawa et al.[78]
Hypertension	Schaumberg et al.[70]
Menopause*	Mathers et al.[66]
	Sullivan et al.[65]
Parkinson's Disease	Tamer et al.[79]
Pemphigoid	Iovine et al.[80]
Polycystic ovary syndrome	Yavas et al.[81]
Psoriasis	Horwath-Winter et al.[82]
	Zengin et al.[83]
Rosacea	Akpek et al.[84]
	Alvarenga and Mannis[85]
	Zengin et al.[86]
	Zuber[87]
	Zuber[88]
Sjögren's syndrome	Goto et al.[68]
	Krenzer et al.†
	Pflugfelder et al.[69]
	Shimazaki et al.[43]
	Sullivan et al.[65]
	Sullivan et al.[89]
Stevens-Johnson syndrome	Sotozono et al.[90]
Toxic epidermal necrolysis	Di Pasquale et al.[91]
	Sotozono et al.[90]
Turner syndrome	Bron and Tiffany[58]

Factors Associated with MGD

Special Issue

The International Workshop on Meibomian Gland Dysfunction: Report of the Subcommittee on the Epidemiology of, and Associated Risk Factors for, MGD

TABLE 6. Medications Hypothesized to Correlate with MGD

Medication	Reference
Isotretinoin (13-*cis* retinoic acid) therapy*	Caffery and Josephson[94] Egger et al.[95] Mathers et al.[93]
Antiandrogens	Krenzer et al.[72] Sullivan et al.[73] Sullivan et al.[65]
Antidepressants	Chia et al.[96] Moss et al.[97] Schaumberg et al.[70]
Antihistamines	Moss et al.[97] Ousler et al.[98]
Medications used to treat benign prostate hyperplasia	Schaumberg et al.[70]
ω-3 Fatty acids (possibly protective)	Barabino et al.[99] Creuzot et al.[100] Kokke et al.[101] Macsai[102] Miljanović et al.[103] Pinna et al.[104] Rashid et al.[105] Viau et al.[106]
Postmenopausal hormone therapy	Chia et al.[96] Erdem et al.[107] Lin et al.[28] Schaumberg et al.[108]

* Accutane; Hoffman-LaRoche, Nutley, NJ; withdrawn from the market in 2009.

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Overlap of DED Symptoms and Clinical Signs of MGD

Study	Symptoms Assessed (all frequency)	Clinical Evaluations/ MGD Definition	% with Dry Eye Symptoms who also had MGD
Shihpai Eye Study (Lin, 2003)	Eye dryness Gritty/sandy Burning Sticky Watery/tearing Redness Lash crusting Eyes stuck shut (am)	Telangiectasis or gland plugging ≥ G1	61.7% (p = NR)
Bangkok Study (Lekhanont, 2006)*	Eye dryness Foreign body sensation Burning Discomfort Sticky Tearing	Telangiectasis, Collarettes, and Plugging	63.6% (p = 0.006)

Evaluation, Diagnosis and Grading of Severity of Meibomian Gland Dysfunction

Tear Film & Ocular Surface Society presents MGD Workshop 2010

A Report from the International Workshop on Meibomian Gland Dysfunction

Alan Tomlinson, MCOpt, Ph.D. (Chair)
Anthony J. Bron, F.R.C.S.
Donald R. Korb, O.D.
Shiro Amano, M.D., Ph.D.
Jerry R. Paugh, O.D.
E. Ian Pearce, Ph.D.
Richard Yee, M.D.
Norihiko Yokoi, M.D., Ph.D.
Reiko Arita, M.D., Ph.D.
Murat Dogru, M.D.

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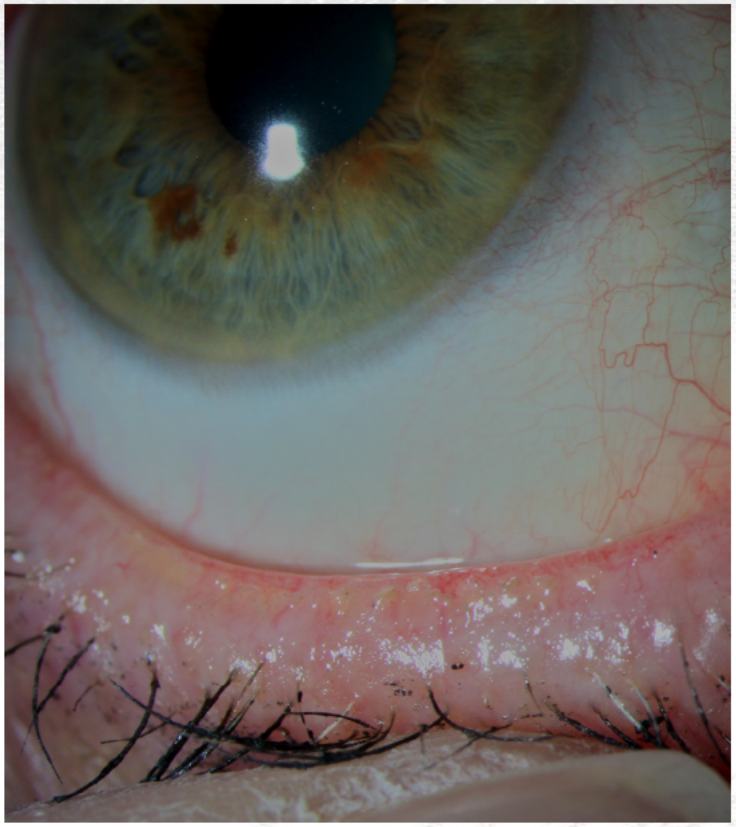
Testing Summary



- Symptoms (no validated survey)
- Expression (not widely accepted)
  - Quality/ Quantity
- Lid assessment
  - Redness (difficult to grade)
  - Irregularity
  - MG location
- Staining (fluorescein)
  - Photography
- Aq. Production (© 1903)

Stages of MGD

STAGE	CLINICAL DESCRIPTION	TREATMENT
STAGE 1	No *symptoms* of ocular discomfort, itching or photophobia *Clinical signs* of MGD based on gland expression Minimally altered secretions: Grade ≥2 - <4 Expressibility: 1 No ocular surface *staining*	*Inform* patient about MGD, the potential impact of diet and the effect of work/ home environments on tear evaporation, and the possible drying effect of certain systemic medications *Consider* eyelid hygiene including warming/ expression as described below (±)
STAGE 2	Minimal to mild *symptoms* of ocular discomfort, itching or photophobia Minimal to mild MGD *clinical signs* Scattered lid margin features Mildly altered secretions: Grade ≥4- <8 Expressibility: 1 None to limited ocular surface *staining* [DEWS grade 0-7; Oxford grade 0-3]	*Advise* patient on improving ambient humidity; optimizing workstations and increasing dietary omega-3 fatty acid intake (±) *Institute* eyelid hygiene with eyelid warming (a minimum of four minutes, once or twice daily) followed by moderate to firm massage and expression of MG secretions (+) *All the above, plus* (±) Artificial lubricants (for frequent use, non-preserved preferred) Topical emollient lubricant or liposomal spray Topical azithromycin Consider oral tetracycline derivatives
STAGE 3	Moderate *symptoms* of ocular discomfort, itching or photophobia with limitations of activities Moderate MGD *clinical signs* ↑ lid margin features: plugging, vascularity Moderately altered secretions: Grade ≥8- < 13 Expressibility: 2 Mild to moderate conjunctival and peripheral corneal *staining*, often inferior [DEWS grade 8-23; Oxford grade 4-10]	*All the above, plus* Oral tetracycline derivatives (+) Lubricant ointment at bedtime (±) Anti-inflammatory therapy for dry eye as indicated (±)
STAGE 4	Marked *symptoms* of ocular discomfort, itching or photophobia with definite limitations of activities Severe MGD *clinical signs* ↑ lid margin features: dropout, displacement Severely altered secretions: Grade ≥13 Expressibility: 3 Increased conjunctival and corneal *staining*, including central staining [DEWS grade 24-33; Oxford grade 11-15] ↑ Signs of inflammation: e.g. ≥ moderate conjunctival hyperemia, phlyctenules	*All the above, plus* Anti-inflammatory therapy for dry eye (+)

Key:

Meibum quality is assessed in each of 8 glands of the central third of the lower lid on a 0-3 scale for each gland: 0=clear meibum; 1=cloudy meibum; 2=cloudy with debris (granular); 3=thick, like toothpaste [range 0-24].

Expressibility of meibum is assessed from 5 glands: 0= all glands expressible; 1=3-4 glands expressible; 2= 1-2 glands expressible; 3=no glands expressible. This can be assessed in the lower or upper lid.

Numerical staining scores refer to a summed score of staining of the exposed cornea and conjunctiva. The Oxford scheme has a scale range of 0-15 and the DEWS scale has a scale range of 0-33.

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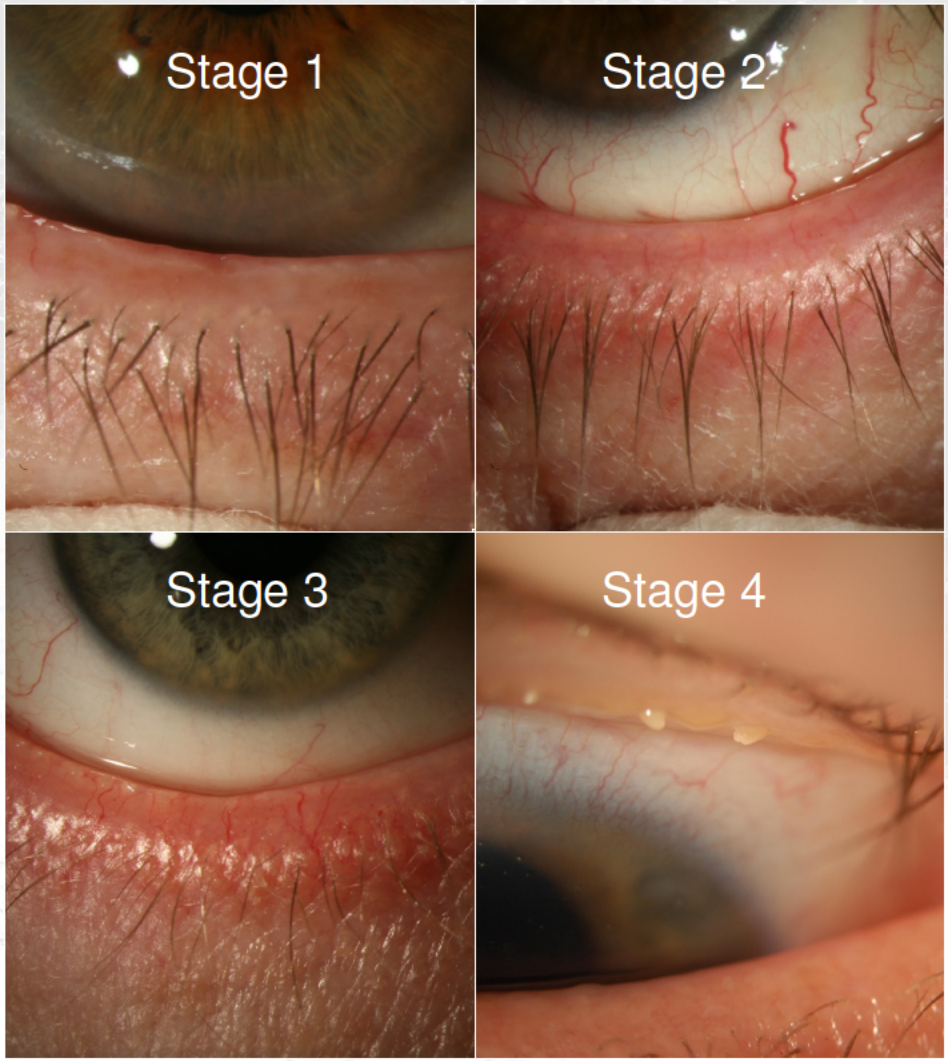
Stages of MGD



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Management and Therapy of Meibomian Gland Dysfunction

Tear Film & Ocular Surface Society presents MGD Workshop 2010

A Report from the International Workshop on Meibomian Gland Dysfunction

Gerd Geerling, M.D. (Chair)
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Christophe Baudouin, M.D., Ph.D.
Eiki Goto, M.D.
Yukihiro Matsumoto, M.D.
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Current Practice Patterns*

- Lid hygiene, warm compresses and lid massage
  - Cleaning of the lid margin with baby shampoo, cotton buds or wet towels, daily for 5-15 minutes
- Lubricants in cases with additional dry eye
- Topical antibiotic oint (moderate to severe)
- Systemic tetracyclines/ derivatives in recurrence
- Incision and curettage with optional steroid injection in chalazion

*Excerpted from Moorfields Manual, Wills Eye Manual (Guidelines for posterior blepharitis and meibomitis)

Current Practice Patterns

- World-wide variation
  - Underreporting → difficult to assess patterns
  - Underdiagnosis common, clinical follow-up irregular
- Lid warming and hygiene common
- Many use artificial lubricants
- Most Common Rx: Systemic tetracycline or derivatives (less frequent in EU/Japan)
  - 2nd most common Rx: topical antibiotic or antibiotic-steroid combination

Table 2. Clinical summary of MGD staging used to guide treatme

DISEASE STAGING			
Stage	**MGD grade**	**Symptoms**	**Corneal Staining**
1	+ (minimally altered expressibility and secretion quality)	Asymptomatic	None
2	++ (mildly altered expressibility and secretion quality)	Minimal to Mild	None to limited
3	+++ (moderately altered expressibility and secretion quality)	Moderate	Mild to moderate; mainly peripheral
4	++++ (severely altered expressibility and secretion quality)	Marked	Marked; central in addition
"PLUS DISEASE"	**Co-existing or accompanying disorders of the ocular surface and/ or eyelids**		

Recommended Staged Therapy

Stage =

1 **2** **3** **4** **Plus-**

+Disease **Inform** patient (about dietary / environmental / medication effects)
± Eyelid hygiene (warming / expression)

+Eyelid hygiene (warming / expression),
Advise re: potential benefits of ambient humidity / n-3 fatty acid,
± Lubricant/lipid, topical azithromycin, tetracycl. derivatives

+ Oral tetracyclines
± Ointment (pm), cyclosporine/steroid for DE

+ Anti-inflammatory therapy for DE

+ Steroids, CL, Surgery

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Design and Conduct of Clinical Trials

Tear Film & Ocular Surface Society presents MGD Workshop 2010

A Report from the International Workshop on Meibomian Gland Dysfunction

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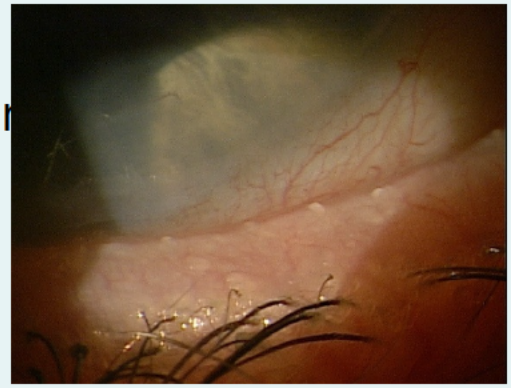
Existing Clinical Trials

Key Issues	Findings n = 26
Trial objective	Majority interventional treatment trials. 1/3 comparative (hot compresses or artificial tears).
Trial design /Methodology	Primarily small trials (<40 subjects) of short (<3 months) duration. Most prospective, 3 randomized controlled design, & 2 were double masked.
Study population	Chronic disease but selection criteria not uniformly defined; lid changes & symptoms most common clinical characteristics.
Inclusion criteria	No specific and consistent criteria; most common are lid margin signs (80%), dry eye findings (50%), symptoms of discomfort/foreign body sensation
Exclusion criteria	Classification of exclusion criteria in three different categories: 1) Ocular disease related/CL wear (most common); 2) Iatrogenic (e.g surgery, 1/3 studies); 3) Systemic disease related/pregnancy (15%).

Existing Clinical Trials

Issue	Findings n = 26
Outcome measures	1. Symptoms 2. TBUT 3. MG secretion/expressio 4. Schirmer 5. Corneal staining 6. MG obstruction 7. Eyelids 8. Lipid layer
Treatment	Most lacked washout period & did not check for relapse; 50% allowed concurrent use of other treatment & 30% treatment in the control group; large variability between Tx duration but pharmacological trials tended to be longer with follow up.
Statistics	Limited number of RCTs available; difficult to calculate effect size, power or required sample size. Limited information on how missing data e.g. loss to follow up, exclusion due to non-compliance, were handled.



Summary

Priorities for future clinical trials:

- Additional randomized, controlled, double-masked treatment trials with clearly defined objectives, relevant outcome measures based on pathophysiology, and refined inclusion & exclusion criteria
- Determination of the natural history of MGD
- Further understanding of the association with dry eye disease (and risk factors)
- Development and validation of a symptom questionnaire specific to MGD.

A Report from the TFOS International Workshop on Meibomian Gland Dysfunction

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Thank You!

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Research Areas

- Fire Fighting Technology
- Electronic Safety Equipment
- Fire Dynamics
- Firefighter Fatality & Injury Studies
- Fire Fighting Tactics
- Fire Forensics
- Fire Protection
- Personal Protective Equipment
- Staffing Studies
- Structural Collapse
- Wind Driven Fires

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Fire Dynamics

Fire Dynamics

Fire Dynamics is the study of how chemistry, fire science, material science and the mechanical engineering disciplines of fluid mechanics and heat transfer interact to influence fire behavior. In other words, Fire Dynamics is the study of how fires start, spread and develop. But what exactly is a fire?

Defining Fire

Fire can be described in many ways - here are a few:

- NFPA 921: *"A rapid oxidation process, which is a chemical reaction resulting in the evolution of light and heat in varying intensities."*
- Webster's Dictionary: *"A fire is an exothermic chemical reaction that emits heat and light"*

Fire can also be explained in terms of the Fire Tetrahedron - a geometric representation of what is required for fire to exist, namely, *fuel*, *an oxidizing agent*, *heat*, and *an uninhibited chemical reaction*.

Measuring Fire

Heat Energy is a form of energy characterized by vibration of molecules and capable of initiating and supporting chemical changes and changes of state (NFPA 921). In other words, it is the energy needed to change the temperature of an object - add heat, temperature increases; remove heat, temperature decreases. Heat energy is measured in units of Joules (J), however it can also be measured in Calories (1 Calorie = 4.184 J) and BTU's (1 BTU = 1055 J).

Temperature is a measure of the degree of molecular activity of a material compared to a reference point. Temperature is measured in degrees Farenheit (melting point of ice = 32 ° F, boiling point of water = 212 ° F) or degrees Celsius (melting point of ice = 0 ° C, boiling point of water = 100 ° C).

° C	° F	Response
37	98.6	Normal human oral/body temperature
44	111	Human skin begins to feel pain
48	118	Human skin receives a first degree burn injury
55	131	Human skin receives a second degree burn injury
62	140	A phase where burned human tissue becomes numb
72	162	Human skin is instantly destroyed
100	212	Water boils and produces steam
140	284	Glass transition temperature of polycarbonate
230	446	Melting temperature of polycarbonate
250	482	Charring of natural cotton begins
>300	>572	Charring of modern protective clothing fabrics begins
>600	>1112	Temperatures inside a post-flashover room fire

(b)(4) Reference

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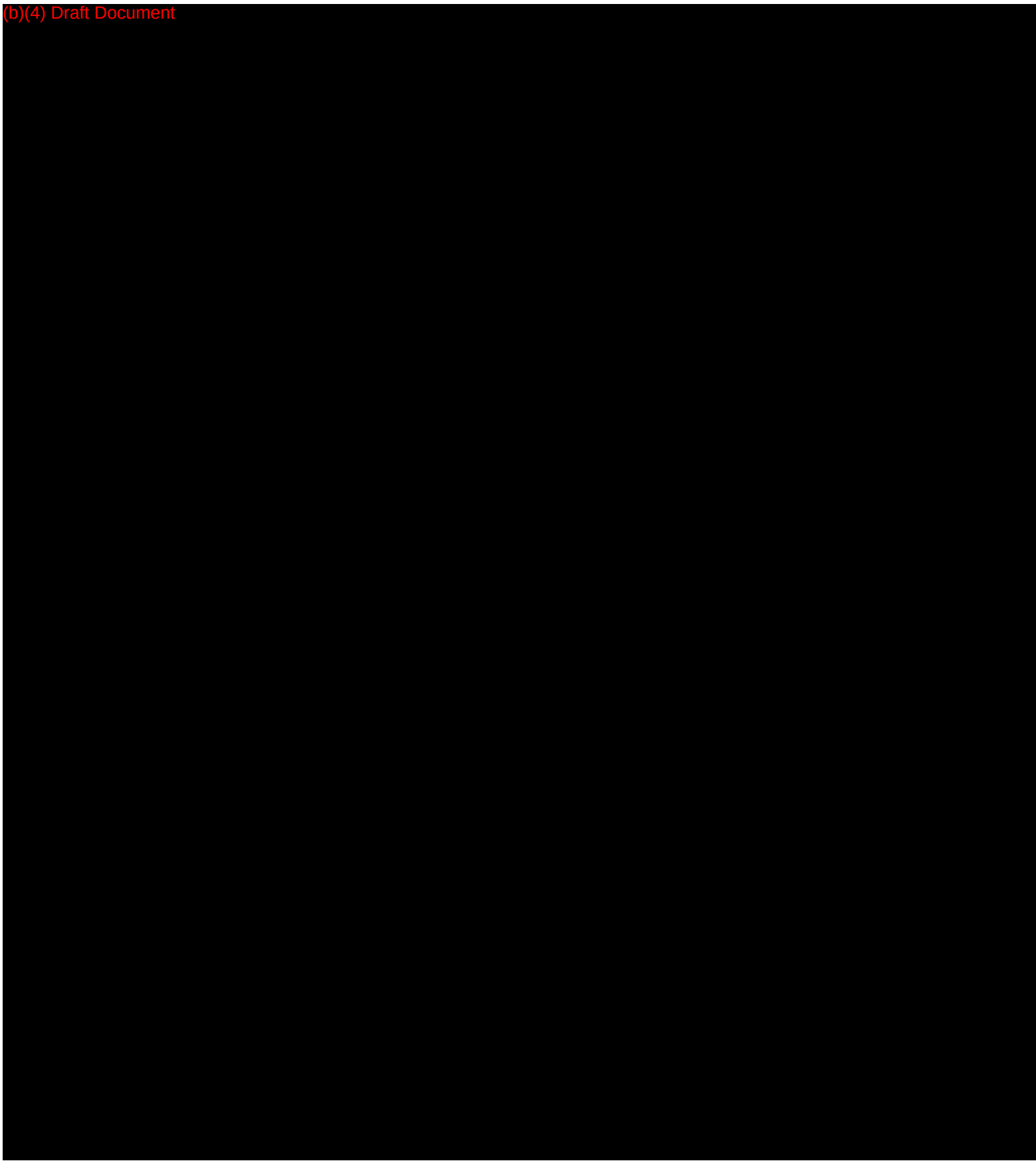
(b)(4) Draft Document



(b)(4) Draft Documents

(b)(4) Draft Documents

(b)(4) Draft Documents

0.0 GUIDANCE DOCUMENT USED FOR THIS 510(K) APPLICATION

Guidance Document for the Preparation of Premarket Notification [510(k)] Applications for Heating and Cooling Devices

This guidance was written prior to the February 27, 1997 implementation of FDA's Good Guidance Practices, GGP's. It does not create or confer rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both. This guidance will be updated in the next revision to include the standard elements of GGP's.

July 26, 1995
(reformatted 12/18/97)

This guidance document may contain references to addresses and telephone numbers that are now obsolete. The following contact information is to be used instead:

- **While this guidance document represents a final document, comments and suggestions may be submitted at any time for Agency consideration to the Restorative Devices Branch, 9200 Corporate Blvd., HFZ-410, Rockville, MD 20850.**
- **For questions regarding the use or interpretation of this guidance, contact the Restorative Devices Branch at 301-594-1296.**
- **To contact the Division of Small Manufacturers Assistance (DSMA), call 800-638-2041 or 301-443-6597; fax 301-443-8818; email dsmo@cdrh.fda.gov; or write to DSMA (HFZ-200), Food and Drug Administration, 1350 Piccard Drive, Rockville, Maryland 20850-4307. FACTS-ON-DEMAND (800-899-0381 or 301-827-0111) and the World Wide Web (CDRH home page: http://www.fda.gov/cdrh/index.html) also provide easy access to the latest information and operating policies and procedures.**

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
Center for Devices and Radiological Health
Rockville, MD 20850

PREFACE

The purpose of this document is to provide guidance to the sponsors of premarket notifications [510(k)'s] for restorative devices. This document is intended to assist the sponsors in organizing and providing the essential information that should be submitted to the Food and Drug Administration (FDA) for review.

This guidance is based on the Restorative Devices Branch's (REDB's) identification of specific criteria necessary to conduct an adequate evaluation of a 510(k) for the purpose of determining substantial equivalence for physical medicine/restorative devices. The objective of this document is to delineate to the device manufacturer important administrative, descriptive, and scientific information that should be included in a 510(k) for a restorative device. Individual 510(k) submissions may require additional information pertinent to each specific device. The suggestions and recommendations included in the guidance reflect the minimal requirements that would allow an evaluation of the device as determined by REDB. While the use of this document in the preparation of a 510(k) premarket notification will not ensure FDA clearance of a device, following the guidance will ensure that sufficient basic information is available to initiate a substantive review.

Note that the guidance document is a living document. It will be periodically revised as scientific knowledge and regulations change.

INTRODUCTION

Any 510(k) notification submitted under premarket notification procedures described in 21 Code of Federal Regulations (CFR) Part 807, Subpart E, for FDA's determination that a new device is substantially equivalent to a predicate (existing) device in 21 CFR 890.5950 (Powered Heating Unit), 21 CFR 890.5740 (Powered Heating Pad), 21 CFR 890.5500 (Infrared Lamp), 21 CFR 890.5720 (Water Circulating Hot or Cold Pack), or Class I by 21 CFR 890.5710 (Chemical Hot/Cold Pack) should follow the format below and must contain all specified information that is pertinent to the device.

ADMINISTRATIVE INFORMATION

1. Provide the name and address of the manufacturer and sponsor of the 510(k) submission.
2. Provide the FDA registration number (if available) of the manufacturer of the new device.
3. Identify the official contact person for all correspondence.

DEVICE IDENTIFICATION

1. As stated in 21 CFR 807.90(d), a 510(k) shall be submitted separately for each product the manufacturer intends to market. Therefore, a submission can describe no more than one new device.

   A submission can describe more than one component of, or attachment to, a single device. The submission must compare each such component or attachment with that of a predicate device, or must state that the predicate device lacks such a component or attachment.

2. The following information must be provided:

a. The proprietary name of the new device;
b. The generic name of the device;
c. The classification of the predicate device e.g., Class II. Refer to 21 CFR and section 513 of the Food, Drug, and Cosmetic Act;
d. The proposed regulatory class for the new device, e.g., Class II. (21 CFR 862-892 contains the regulatory classifications for medical devices); and
e. The panel code(s) for the device. [If the product is not classified under the physical medicine devices panel, identify the panel under which it is classified and provide the panel identification code (e.g., 89 is the code for the physical medicine devices panel)].

3. Specify whether this device:

a. Has been previously submitted to the FDA for identical or different indications;
b. Is currently being reviewed for different indications by the same or different branch within ODE; or
c. Has been previously cleared by the FDA for different indications.

DEVICE DESCRIPTIVE INFORMATION

Intended Use

Identify the specific intended use(s), including the specific therapeutic indications, for the subject device and the predicate device.

The new device must have the same intended medical uses as those specified for the predicate device, to the extent that the changes do not alter the therapeutic or diagnostic effect and do not affect the safety and effectiveness.

These intended uses must be consistent with the descriptions of intended medical uses contained within the CFR section that is applicable to the device and must identify the specific medical conditions for which the device is indicated.

If the indication differs, you must provide a justification as to how the change(s) do not affect safety and effectiveness. If special labeling claims are sought, information must be provided to support these claims.

It is not necessary to notify FDA of an intent to market a device if it will not be labeled or promoted for medical uses. However, FDA will regulate the equipment and may require premarket notification if any promotional material appears which makes medical claims after marketing begins.

Device Description

1. Provide a written description of the device, including all device components, instruments, and any new features of the device.
2. Identify all sizes, configurations, and functions of each device component.
3. Describe how the device works and interconnects with other components.
4. Engineering drawings and/or photographs and complete written descriptions of the new and predicate devices. The document must contain illustrations of all internal and external features of both devices. Engineering drawings must provide the lengths, widths, and heights of the devices and their major component parts.
5. Provide the temperature range of the device.

6. Provide the temperature range at the skin surface where device is applied.

Materials

Identify the specific materials for each component, any additional processing that may affect the material properties, and the voluntary standards with which the device materials will conform. In the case of powered heating pads, the material of the heating pad cover must be specified. Similarly, the chemicals and activator(s) used in hot/cold packs must be described.

Labeling

1. Provide draft or sample package labeling, package inserts, including complete operator's instructions for the new device.
2. Include copies of promotional materials for the new and predicate devices.
3. The following warning statement must be included in the labeling for all devices:

   "WARNING: Use carefully. May cause serious burns. Do not use over sensitive skin areas or in the presence of poor circulation. The unattended use of ..... by children or incapacitated persons may be dangerous."

Additional Information

1. The distance of the device from the area of application must be provided for infrared lamps.
2. The leakage current must be specified for powered heating pads, infrared lamps, and water circulating hot/cold packs.
3. The flow rate, pressure, and the liquid to be used must be specified for water circulating hot/cold packs.

SUBSTANTIAL EQUIVALENCE INFORMATION

1. The legally marketed predicate device with which the subject device is to be compared for the determination of substantial equivalence must be identified.
2. Evidence must be provided that the device was placed into interstate commerce for other than research uses or as part of a plant-to-plant transfer and was actually labeled and promoted for the intended use to which the submitter of the premarket notification is claiming substantial equivalence. This may be accomplished by providing copies of the firm's advertisements, catalog pages, or other promotional material dated prior to May 28, 1976 and shipping documents such as invoices, bills of lading, receipts showing the interstate transit of the device (for other information which can be used to prove Pre-Amendment status contact DSMA).

   Alternatively, the 510(k) number(s) of the predicate device(s) may be identified.

   The 510(k) number may be obtained from the Electronic Docket (ED), an automated retrieval system of the Division of Small Manufacturers Assistance (DSMA), which provides medical device regulations, FDA talk papers and press releases, device evaluation guidance, and the listing of all approved 510(k)s sorted by applicant name.

   This 510(k) information is located under the Product Clearance Main Menu Item # 12. Dial (301) 594-4802 or (800) 252-1366. For more guidance on how to assess this information, contact DSMA. Call toll free (800) 638-2041, (301) 443-6597, or fax (301) 443-8818.
3. The submission should include a description of all significant similarities and differences between the new and predicate device.
4. To facilitate the review, the submission should contain a table which compares the
   1. intended medical uses and
   2. the physical characteristics and
   3. functions of the two devices.

510(K) SUMMARY OR STATEMENT

1. Provide a 510(k) summary of safety and effectiveness information in the premarket notification submission upon which an equivalence determination could be based, written in accordance with the content and format requirements that are specified in 21 CFR 807.92 **or**
2. Provide a 510(k) statement that safety and effectiveness information will be made available to interested persons upon request. This statement must follow the format and contain the wording as specified in 21 CFR 807.93.

TRUTHFUL AND ACCURATE STATEMENT

Provide a statement that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted, as required by 21 CFR 807.87(j).

1.0 ADMINISTRATIVE INFORMATION

Applicant, Sponsor:	Digital Heat Corporation
Address:	5626 S. Captain Kidd Ct., Unit B Tempe, AZ 85283
FDA Registration Number:	
Contact Person:	John Devine (CEO)
Telephone Number:	(512) 560-7184

(b)(4) Draft Documents

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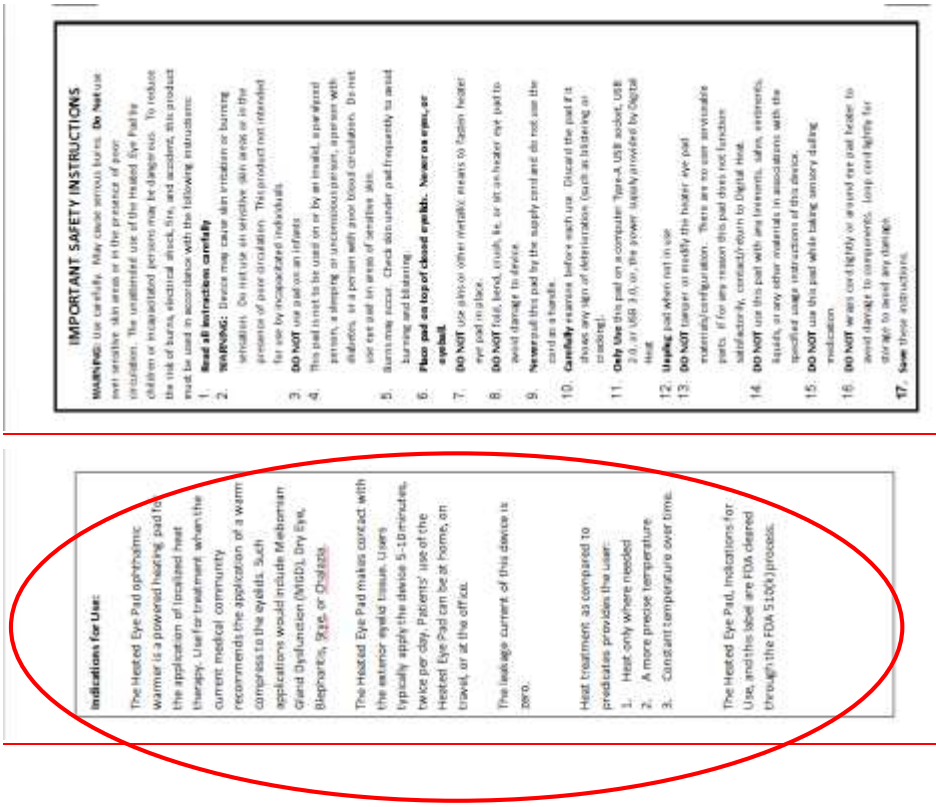


IMPORTANT SAFETY INSTRUCTIONS

WARNING: Use carefully. May cause serious burns. **Do Not** use over sensitive skin areas or in the presence of poor circulation. The unattended use of the Heated Eye Pad by children or incapacitated persons may be dangerous. To reduce the risk of burns, electrical shock, fire, and accident, this product must be used in accordance with the following instructions:

1. **Read all instructions carefully**
2. **WARNING:** Device may cause skin irritation or burning sensations. Do not use on sensitive skin areas or in the presence of poor circulation. This product not intended for use by incapacitated individuals.
3. **DO NOT** use pad on an infants
4. This pad is not to be used on or by an invalid, paralyzed person, a sleeping or unconscious person, a person with diabetes, or a person with poor blood circulation. Do not use eye pad on areas of sensitive skin.
5. Burns may occur. Check skin under pad frequently to avoid burning and blistering.
6. **Place pad on top of closed eyelids. Never on eyes, or eyeball.**
7. **DO NOT** use skin on other metallic means to fasten heater eye pad in place.
8. **DO NOT** fold, bend, crush, tie, or sit on heater eye pad to avoid damage to device.
9. **Never** pull this pad by the supply cord and do not use the cord as a handle.
10. **Carefully** examine before each use. Discard the pad if it shows any sign of deterioration (such as blistering or cracking).
11. **Only Use** this pad on a computer Type-A USB socket, USB 2.0, or USB 3.0, or, the power supply provided by Digital Heat
12. **Unplug** pad when not in use
13. **DO NOT** tamper or modify the heater eye pad materials/configuration. There are no user serviceable parts. If for any reason this pad does not function satisfactorily, contact/return to Digital Heat.
14. **DO NOT** use this pad with any liniments, salves, ointments, liquids, or any other materials in associations with the specified usage instructions of this device.
15. **DO NOT** use this pad while taking sensory dulling medication
16. **DO NOT** wrap cord tightly or around eye pad heater to avoid damage to components. Loop cord lightly for storage to avoid any damage.
17. **Save** these instructions.

Indications for Use:

The Heated Eye Pad ophthalmic warmer is a powered heating pad for the application of localized heat therapy. Use for treatment when the current medical community recommends the application of a warm compress to the eyelids. Such applications would include Meibomian Gland Dysfunction (MGD), Dry Eye, Blepharitis, Stye, or Chalazia.

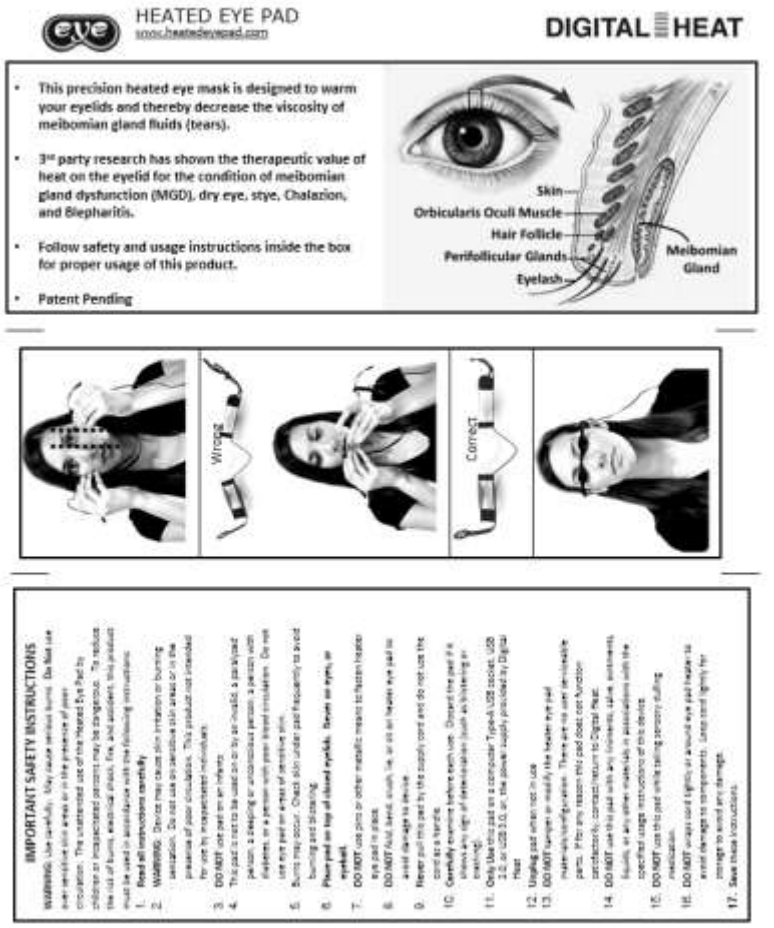
The Heated Eye Pad makes contact with the exterior eyelid tissue. Users typically apply the device 5-10 minutes, twice per day. Patients' use of the Heated Eye Pad can be at home, on travel, or at the office.

The leakage current of this device is zero.

Heat treatment as compared to predicates provides the user:

1. Heat only where needed
2. A more precise temperature
3. Constant temperature over time.

The Heated Eye Pad, Indications for Use, and the label are FDA cleared through the FDA 510(k) process.



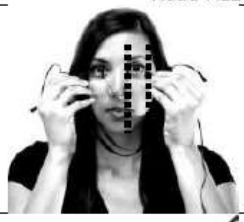
The Digital Heat, Heated Eye Pad package inserts will include user instructions font size 11, Calibri, and safety instructions at font size 12, Calibri (Figures 11, 12).

Figure 11: Package Insert User Instructions (not to scale)

HEATED EYE PAD eye
www.heatedeyepad.com

by DIGITAL HEAT
5626 S. Captain Kidd Ct., Unit B
Tempe, AZ 85283
(512) 517-6649

Instructions on how to use the Heated Eye Pad
Read ALL Safety Precautions before use.



Look in the mirror. Fold or expand the nose part of the Heated Eye Pad to fit your face and eyes.

The round section of the Heated Eye Pad should line up with your eyes, as shown in between the dashed lines.

As you fold the nose bridge, the Heated Eye Pad might go out of alignment. This is incorrect

Slightly bend the frame as needed to make it straight to your face.

This is correct. You are ready to wear.

1. Setup a timer (Watch, Clock, Phone, Etc.) if you wish to time your session.
2. Plug the heater into the power supply furnished by Digital Heat, or, a computer Type-A USB socket, USB 2.0, or USB 3.0. Do not use other power supplies.
3. Gently place the Heated Eye Pad on your CLOSED eyelids and position the elastic strap behind ears.
4. Adjust the tightness of the elastic strap for comfort, and place the electrical cord behind an ear.
5. DO NOT apply excessive pressure on your eyelids by over tightening the elastic strap.
6. Repeat steps 1 through 6 as needed for comfort.
7. If timed, after timer has expired remove the Heated Eye Pad from your eyelids and face.

Figure 12: Heated Eye Pad User Safety Instructions (not to scale)

HEATED EYE PAD eye
www.heatedeyepad.com

by DIGITAL HEAT
5626 S. Captain Kidd Ct., Unit B
Tempe, AZ 85283
(512) 517-6649

IMPORTANT SAFETY INSTRUCTIONS

WARNING: Use carefully. May cause serious burns. **Do Not** use over sensitive skin areas or in the presence of poor circulation. The unattended use of the Heated Eye Pad by children or incapacitated persons may be dangerous. To reduce the risk of burns, electrical shock, fire, and accident, this product must be used in accordance with the following instructions:

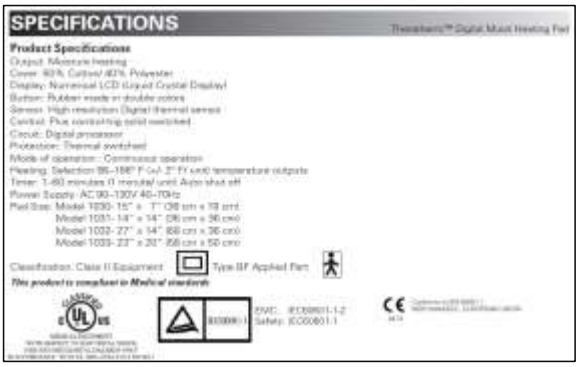
1. **Read all instructions carefully**
2. **WARNING:** Device may cause skin irritation or burning sensation. Do not use on sensitive skin areas or in the presence of poor circulation. This product not intended for use by incapacitated individuals.
3. **DO NOT** use pad on an infants
4. This pad is not to be used on or by an invalid, a paralyzed person, a sleeping or unconscious person, a person with diabetes, or a person with poor blood circulation. Do not use eye pad on areas of sensitive skin.
5. Burns may occur. Check skin under pad frequently to avoid burning and blistering.
6. **Place pad on top of closed eyelids. Never on eyes, or eyeball.**
7. **DO NOT** use pins or other metallic means to fasten heater eye pad in place.
8. **DO NOT** fold, bend, crush, lie, or sit on heater eye pad to avoid damage to device.
9. **Never** pull this pad by the supply cord and do not use the cord as a handle.
10. **Carefully** examine before each use. Discard the pad if it shows any sign of deterioration (such as blistering or cracking).
11. **Only Use** this pad on a computer Type-A USB socket, USB 2.0, or USB 3.0, or, the power supply provided by Digital Heat
12. **Unplug** pad when not in use
13. **DO NOT** tamper or modify the heater eye pad materials/configuration. There are no user serviceable parts. If for any reason this pad does not function satisfactorily, contact/return to Digital Heat.
14. **DO NOT** use this pad with any liniments, salve, ointments, liquids, or any other materials in associations with the specified usage instructions of this device.
15. **DO NOT** use this pad while taking sensory dulling medication.
16. **DO NOT** wraps cord tightly or around eye pad heater to avoid damage to components. Loop cord lightly for storage to avoid any damage.
17. **Save** these instructions.

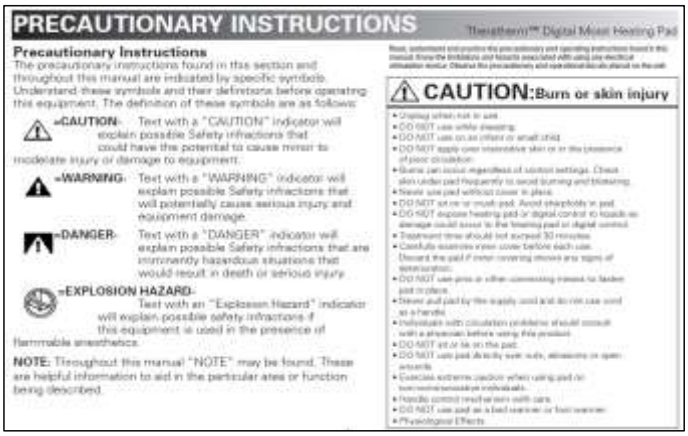
Contact Information:

Web:	www.heatedeyepad.com
Email:	Info@digitalheat911.com
Technical Support:	(512) 517-6649

3.4.2 Theratherm Labeling

Figure 13 Theratherm User Instructions and Safety Labeling





3.4.3 Kao Labeling

Figure 14 Kao Box, User Instructions and Safety Labeling

3.4.4 ThermalOn Labeling

Figure 15 ThermalOn User Instructions and Safety Labeling

(b)(4) Draft Documents

(b)(4) Draft Documents

(b)(4) Draft Documents

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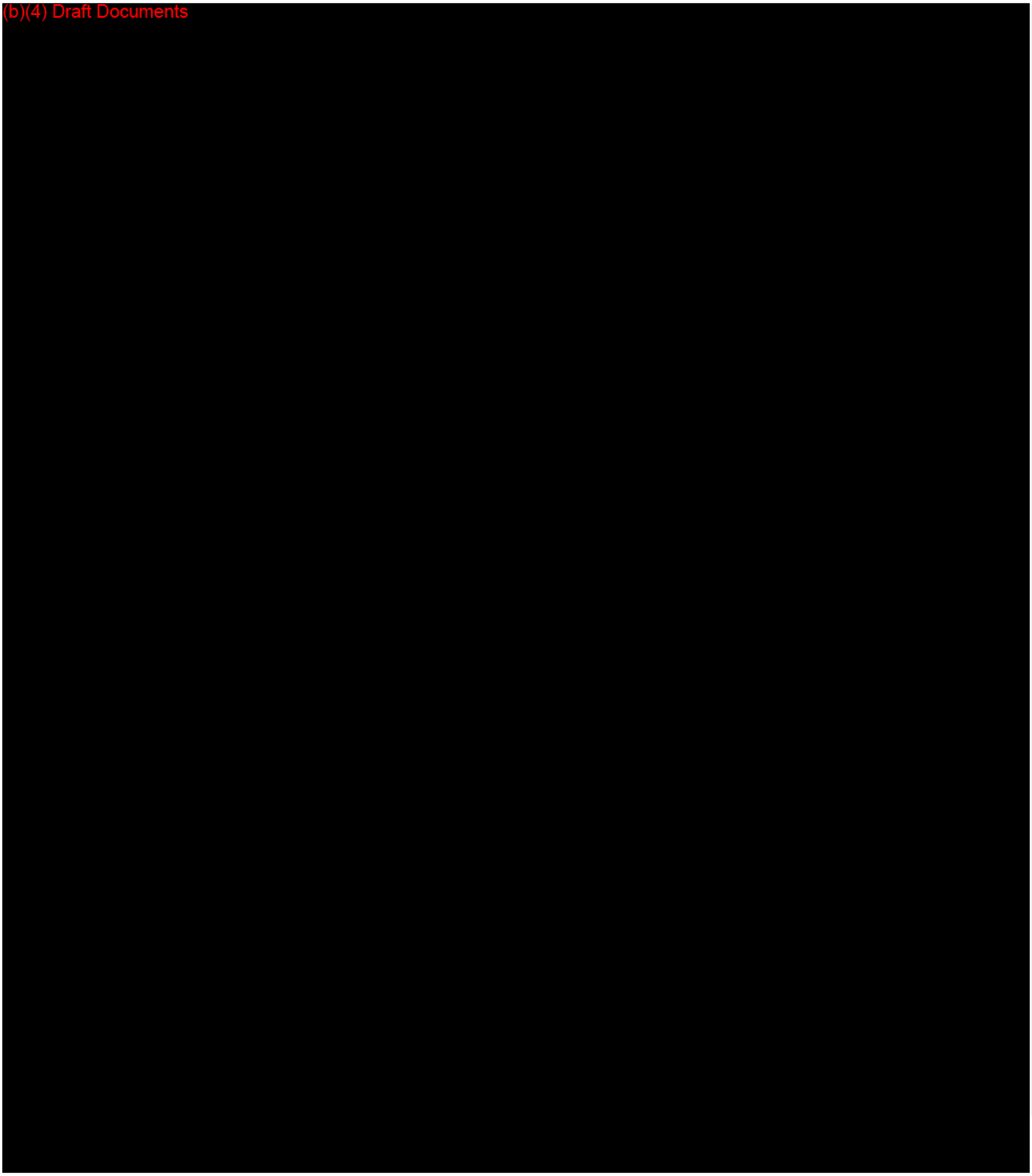


(b)(4) Draft Documents

(b)(4) Draft Documents

(b)(4) Draft Documents

(b)(4) Draft Documents

EU Regulatory Workshop: Meibomian Gland Dysfunction

Kelly K. Nichols, OD, MPH, PhD
FERV Professor
University of Houston College of Optometry
Chair, TFOS International Meibomian Gland Workshop

Disclosures

- K. Nichols
  - Paid consultant to:
    - Alcon
    - Allergan
    - Celtic/ Resolvyx
    - Eleven Biotherapeutics
    - InSite
    - Ista
    - SARcode
    - TearLab
- Research support
  - CL Tear Film Lab (OSU)
    - Alcon
    - CIBA
    - Inspire
    - TearLab
    - Pfizer
    - Vistakon
  - National Eye Institute
    - R01 EY015519 (PI)
    - R01 EY017951 (Co-I)
    - R34 EY017626 (Co-I)

MGD Contributes to Dry Eye

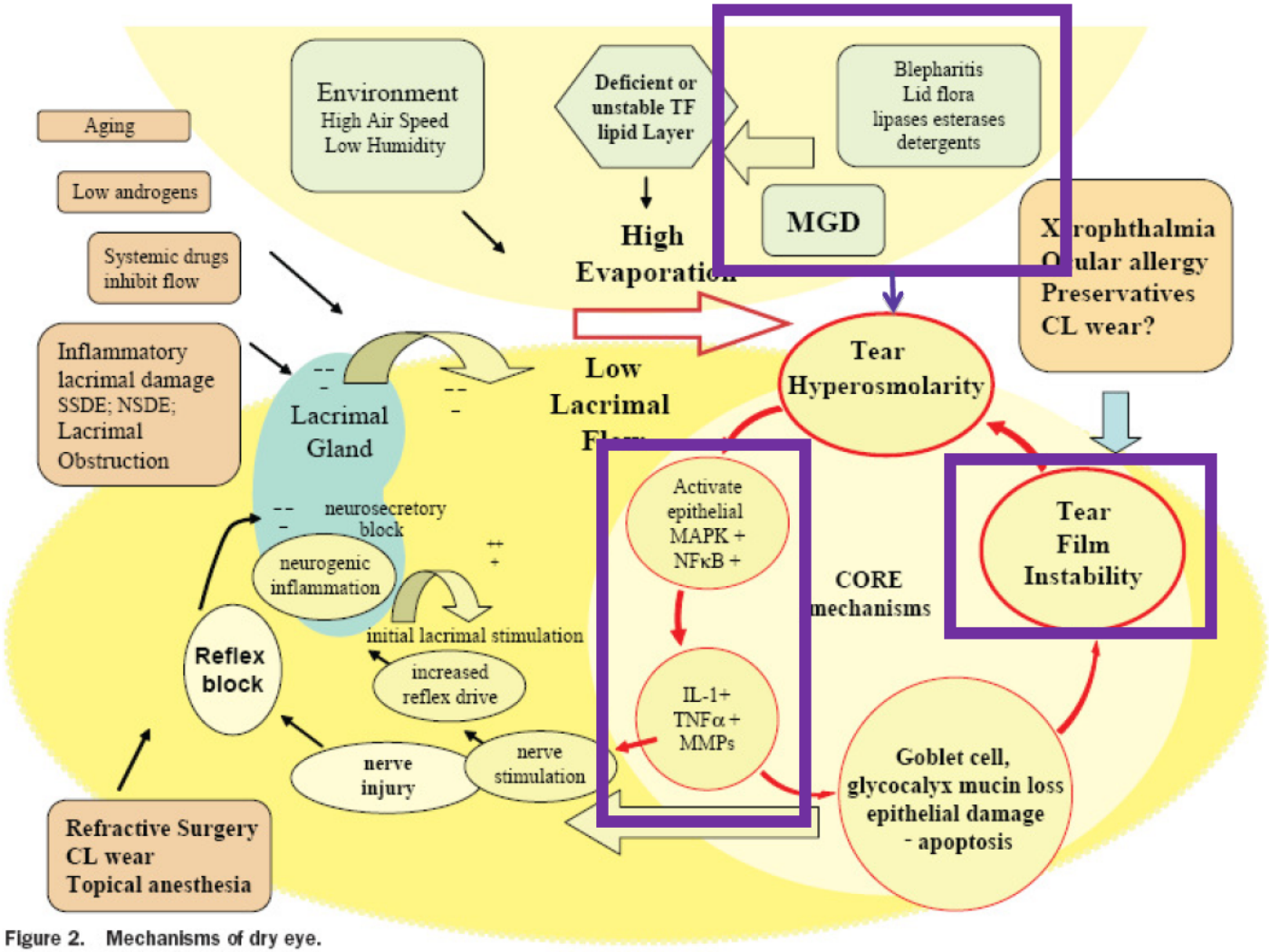


Figure 2. Mechanisms of dry eye.

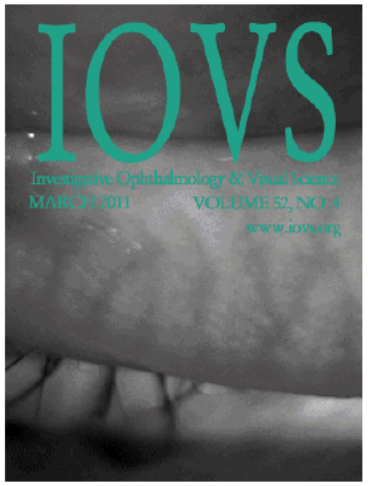
DEWS Definition and classification report. *Ocular Surface* 2007

Table 2. Dry eye severity grading scheme

Dry Eye Severity Level	1	2	3	4*
Discomfort, severity & frequency	Mild and/or episodic occurs under environ stress	Moderate episodic or chronic, stress or no stress	Severe frequent or constant without stress	Severe and/or disabling and constant
Visual symptoms	None or episodic mild fatigue	Annoying and/or activity limiting episodic	Annoying, chronic and/or constant limiting activity	Constant and/or possibly disabling
Conjunctival injection	None to mild	None to mild	+/–	+/++
Conjunctival staining	None to mild	Variable	Moderate to marked	Marked
Corneal staining (severity/location)	None to mild	Variable	Marked central	Severe punctate erosions
Corneal/tear signs	None to mild	Mild debris, ↓ meniscus	Filamentary keratitis, mucus clumping, ↑ tear debris	Filamentary keratitis, mucus clumping, ↑ tear debris, ulceration
Lid/meibomian glands	MGD variably present	MGD variably present	Frequent	Trichiasis, keratinization, symblepharon
TFBUT (sec)	Variable	≤ 10	≤ 5	Immediate
Schirmer score (mm/5 min)	Variable	≤ 10	≤ 5	≤ 2

*Must have signs AND symptoms. TBUT: fluorescein tear break-up time. MGD: meibomian gland disease

Reprinted with permission from Behrens A, Doyle JJ, Stern L, et al. Dysfunctional tear syndrome. A Delphi approach to treatment recommendations. *Cornea* 2006;25:90-7



TFOS International MGD Workshop

Special Issue

The International Workshop on Meibomian Gland Dysfunction: Executive Summary

Kelly K. Nichols,[1] Gary N. Foulks,[2] Anthony J. Bron,[3] Ben J. Glasgow,[4,5] Murat Dogru,[6] Kazuo Tsubota,[6] Michael A. Lemp,[7] and David A. Sullivan[8,9]

- Over 65 International clinicians, scientists, and industry participants
- 2+ year process
- Published in March 2011, *IOVS*
- #1 Most downloaded *IOVS* article for the last 12 months
- Downloaded over 5500 times
- All MGD workshop reports are in the "top 10"
- Translation into 12 languages
- www.tearfilm.org

The 65 Most-Frequently Read Articles
in Invest. Ophthalmol. Vis. Sci. during **October 2010 thru September 2011** -- updated monthly

Most-read rankings are recalculated at the beginning of the month and are based on full-text and pdf views.

1. Kelly K. Nichols, Gary N. Foulks, Anthony J. Bron, Ben J. Glasgow, Murat Dogru, Kazuo Tsubota, Michael A. Lemp, David A. Sullivan
The International Workshop on Meibomian Gland Dysfunction: Executive Summary
Invest Ophthalmol Vis Sci Mar 30, 2011; 52: 1922-1929.
(In "Special Issue") [Full Text] [PDF]
(Read 5554 times)

2. Kelly K. Nichols
The International Workshop on Meibomian Gland Dysfunction: Introduction
Invest Ophthalmol Vis Sci Mar 30, 2011; 52: 1917-1921.
(In "Special Issue") [Full Text] [PDF]
(Read 5318 times)

3. Erich Knop, Nadja Knop, Thomas Millar, Hiroto Obata, David A. Sullivan
The International Workshop on Meibomian Gland Dysfunction: Report of the Subcommittee on Anatomy, Physiology, and Pathophysiology of the Meibomian Gland
Invest Ophthalmol Vis Sci Mar 30, 2011; 52: 1938-1978.
(In "Special Issue") [Full Text] [PDF]
(Read 4663 times)

4. Alan Tomlinson, Anthony J. Bron, Donald R. Korb, Shiro Amano, Jerry R. Paugh, E. Ian Pearce, Richard Yee, Norihiko Yokoi, Reiko Arita, Murat Dogru
The International Workshop on Meibomian Gland Dysfunction: Report of the Diagnosis Subcommittee
Invest Ophthalmol Vis Sci Mar 30, 2011; 52: 2006-2049.
(In "Special Issue") [Full Text] [PDF]
(Read 4074 times)

5. Gerd Geerling, Joseph Tauber, Christophe Baudouin, Eiki Goto, Yukihiro Matsumoto, Terrence O'Brien, Maurizio Rolando, Kazuo Tsubota, Kelly K. Nichols
The International Workshop on Meibomian Gland Dysfunction: Report of the Subcommittee on Management and Treatment of Meibomian Gland Dysfunction
Invest Ophthalmol Vis Sci Mar 30, 2011; 52: 2050-2064.
(In "Special Issue") [Full Text] [PDF]
(Read 4027 times)

6. J. Daniel Nelson, Jun Shimazaki, Jose M. Benitez-del-Castillo, Jennifer P. Craig, James P. McCulley, Seika Den, Gary N. Foulks
The International Workshop on Meibomian Gland Dysfunction: Report of the Definition and Classification Subcommittee
Invest Ophthalmol Vis Sci Mar 30, 2011; 52: 1930-1937.
(In "Special Issue") [Full Text] [PDF]
(Read 3221 times)

7. Penny A. Asbell, Fiona J. Stapleton, Kerstin Wickström, Esen K. Akpek, Pasquale Aragona, Reza Dana, Michael A. Lemp, Kelly K. Nichols
The International Workshop on Meibomian Gland Dysfunction: Report of the Clinical Trials Subcommittee
Invest Ophthalmol Vis Sci Mar 30, 2011; 52: 2065-2085.
(In "Special Issue") [Full Text] [PDF]
(Read 2580 times)

8. Kari B. Green-Church, Igor Butovich, Mark Willcox, Douglas Borchman, Friedrich Paulsen, Stefano Barabino, Ben J. Glasgow
The International Workshop on Meibomian Gland Dysfunction: Report of the Subcommittee on Tear Film Lipids and Lipid–Protein Interactions in Health and Disease
Invest Ophthalmol Vis Sci Mar 30, 2011; 52: 1979-1993.
(In "Special Issue") [Full Text] [PDF]
(Read 2546 times)

9. Debra A. Schaumberg, Jason J. Nichols, Eric B. Papas, Louis Tong, Miki Uchino, Kelly K. Nichols
The International Workshop on Meibomian Gland Dysfunction: Report of the Subcommittee on the Epidemiology of, and Associated Risk Factors for, MGD
Invest Ophthalmol Vis Sci Mar 30, 2011; 52: 1994-2005.
(In "Special Issue") [Full Text] [PDF]
(Read 2437 times)

TFOS REPORTS

Tfos Scientific Reports

MGD REDEFINED: INTERNATIONAL WORKSHOP ON MEIBOMIAN GLAND DYSFUNCTION REPORT AVAILABLE

Report Overview, Link to Full Report & Press Release

BOSTON, MA, March 31, 2011-

The Tear Film & Ocular Surface Society (TFOS) reported the conclusions and recommendations of the International Workshop on Meibomian Gland Dysfunction (MGD).

The MGD Workshop, sponsored by TFOS, was conducted to provide an evidence-based evaluation of meibomian gland structure and function in health and disease. MGD is an extremely important condition, conceivably underestimated, and very likely the most frequent cause of dry eye disease.

The Report required over 2 years to complete and involved the efforts of more than 50 leading clinical and basic research experts from around the world.

- Report Overview
- Link to full Report (IOVS)

search TFOS

NEWS & EVENTS

- **Dry Eye Review Blog:. Industry Experts blogging about Dry Eye Disease**

subscribe now!or view entries!

- **TFOS Meibomian Gland Dysfunction Report online**

TFOS MGD Report available now

- **The 6th International Conference on the Tear Film & Ocular Surface**

Basic Science and Clinical Relevance
Abstract Book, Highlights & Historical Perspective

Anatomy, Physiology and Pathophysiology of the Meibomian Gland

Tear Film & Ocular Surface Society presents MGD Workshop 2010

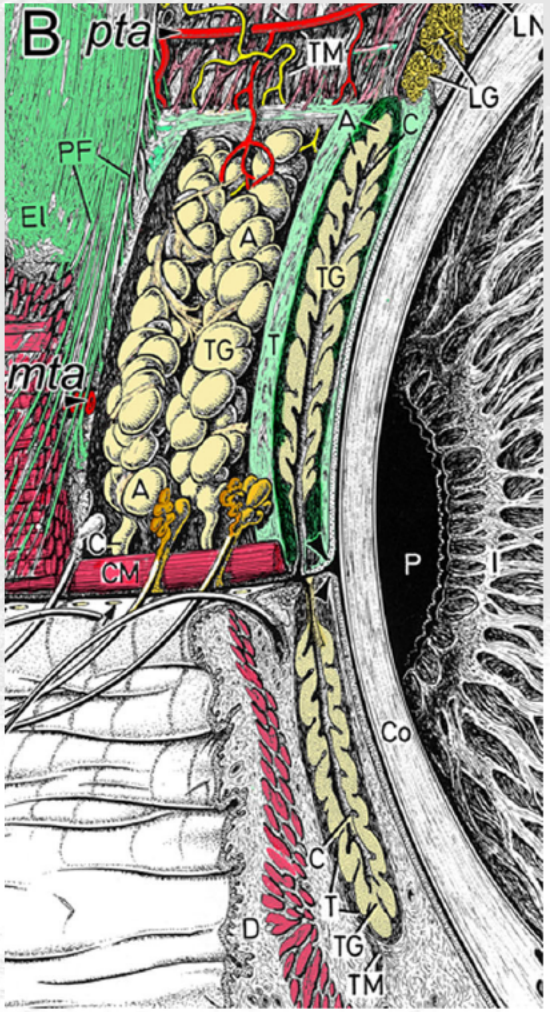
A Report from the International Workshop on Meibomian Gland Dysfunction

Erich Knop, M.D., Ph.D. (Chair)
Nadja Knop, M.D., Ph.D.
Thomas J. Millar, Ph.D.
Hiroto Obata, M.D.
David A. Sullivan, Ph.D.

tfos

Meibomian Gland - ANATOMY

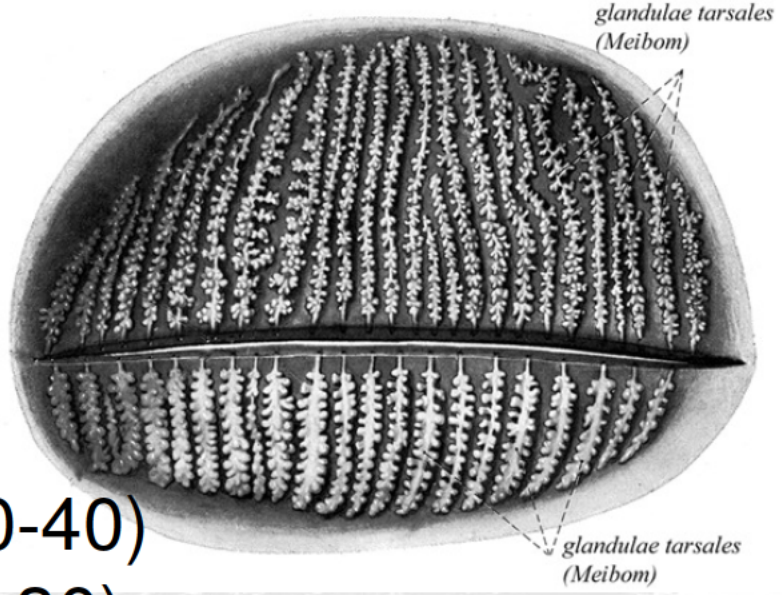
- Large sebaceous glands
- No direct contact to hair follicles
- Located in the tarsal plates
  - Upper and lower eye lids



Modified and colored from Krstic H. Human microscopic anatomy. Springer Medizin Verlag 1991, (reproduced from Knop N & Knop E Ophthalmologe 2009; 106:872–883)

Meibomian Gland - ANATOMY

- **Length**
  - Follows the tarsus
- **Number**
  - More in upper lid (30-40)
  - Less in lower lid (20-30)
- **Volume**
  - Higher in upper lid (26µl vs. 13µl)
- Relative functional contribution (upper vs. lower) to the tear film lipid layer is unknown



Modified from Sobotta Atlas der Anatomie des Menschen. Urban & Schwarzenberg Verlag 1982, (reproduced from Knop N & Knop E. Ophthalmologe 2009; 106:872–883)

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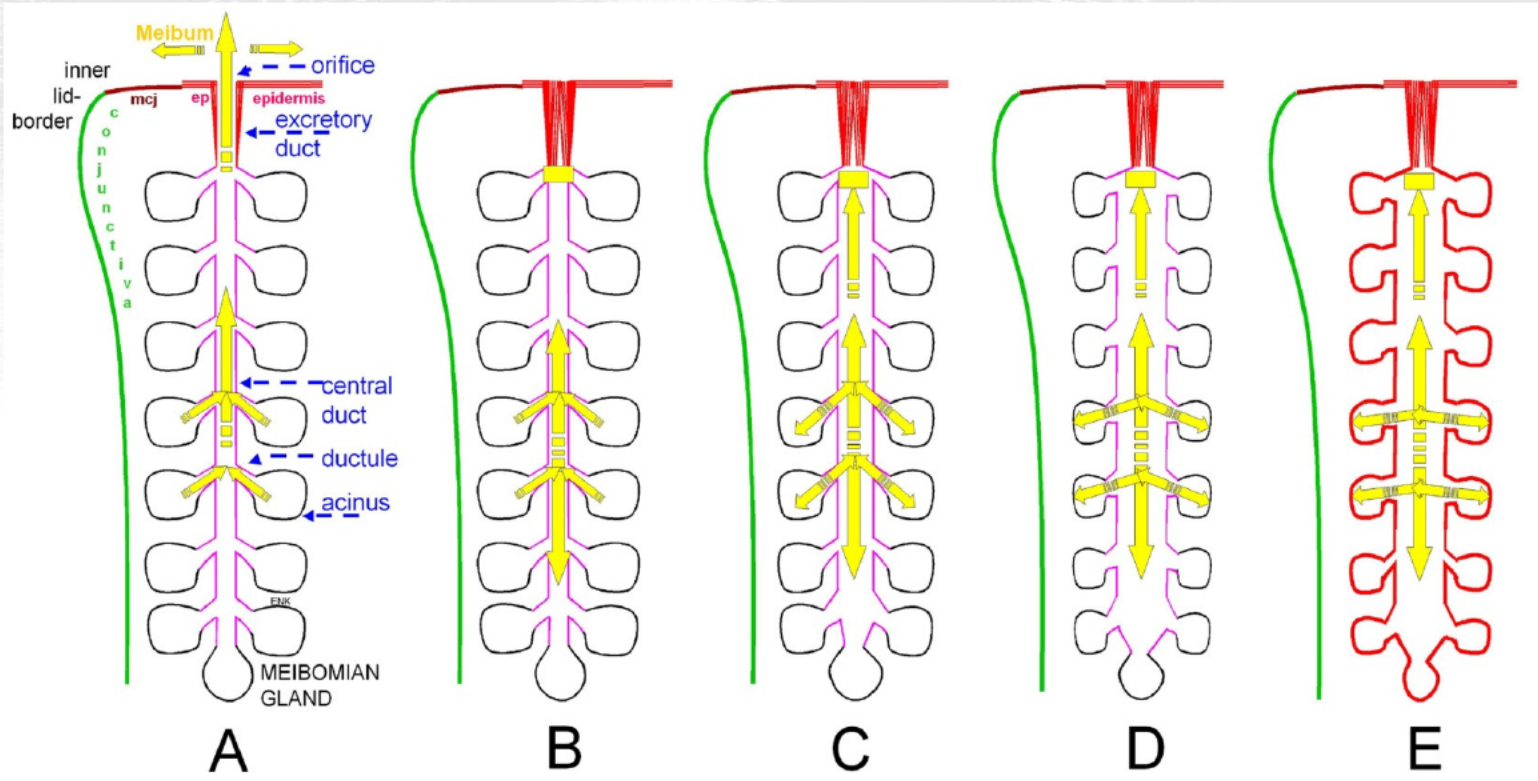
Meibomian Gland – PATHOLOGY

- Obstructive PATHOLOGY leads to a progressive ductal DILATATION and acinar ATROPHY



Fom Knop E & Knop N. Meibom-Drüsen Teil IV. Funktionelle Interaktionen in der Pathogenese der Dysfunktion (MGD). Ophthalmologe.2009;106:980–987

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Interacting Pathways in

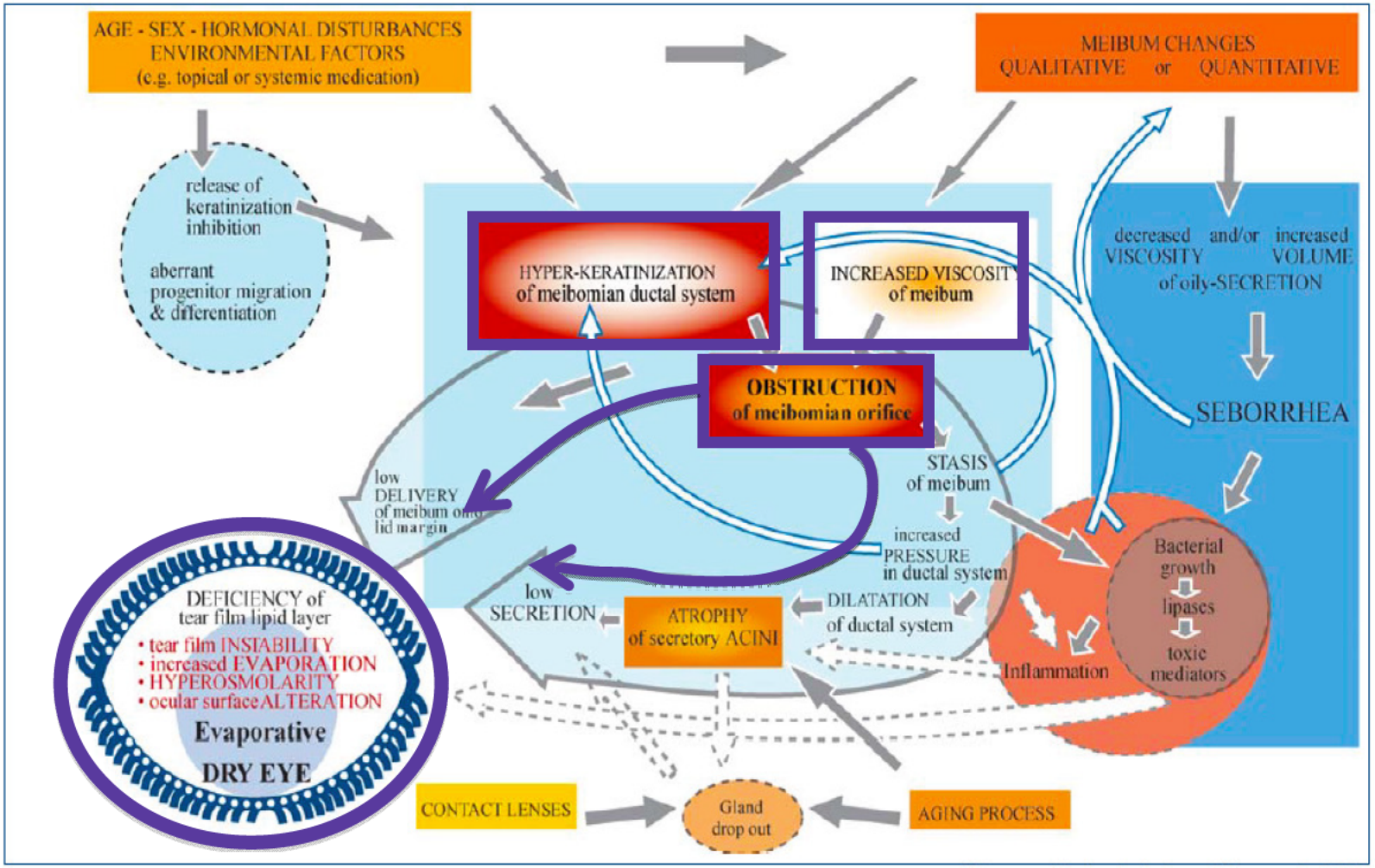

Figure 2. *Pathophysiology of obstructive MGD*

Modified from Knop E & Knop N. Meibom-Drüsen Teil IV. Funktionelle Interaktionen in der Pathogenese der Dysfunktion (MGD). Ophthalmologe.2009;106:980–987

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Meibomian Gland Dysfunction Definition & Classification

Tear Film & Ocular Surface Society presents MGD Workshop 2010

A Report from the International Workshop on Meibomian Gland Dysfunction

J. Daniel Nelson, M.D. (Co-Chair)
Jun Shimazaki, M.D., Ph.D. (Co-Chair)
Jose M. Benitez-del-Castillo, M.D., Ph.D.
Jennifer Craig, Ph.D., MCOptom
James P. McCulley, M.D.
Seika Den, M.D., Ph.D.
Gary N. Foulks, M.D.

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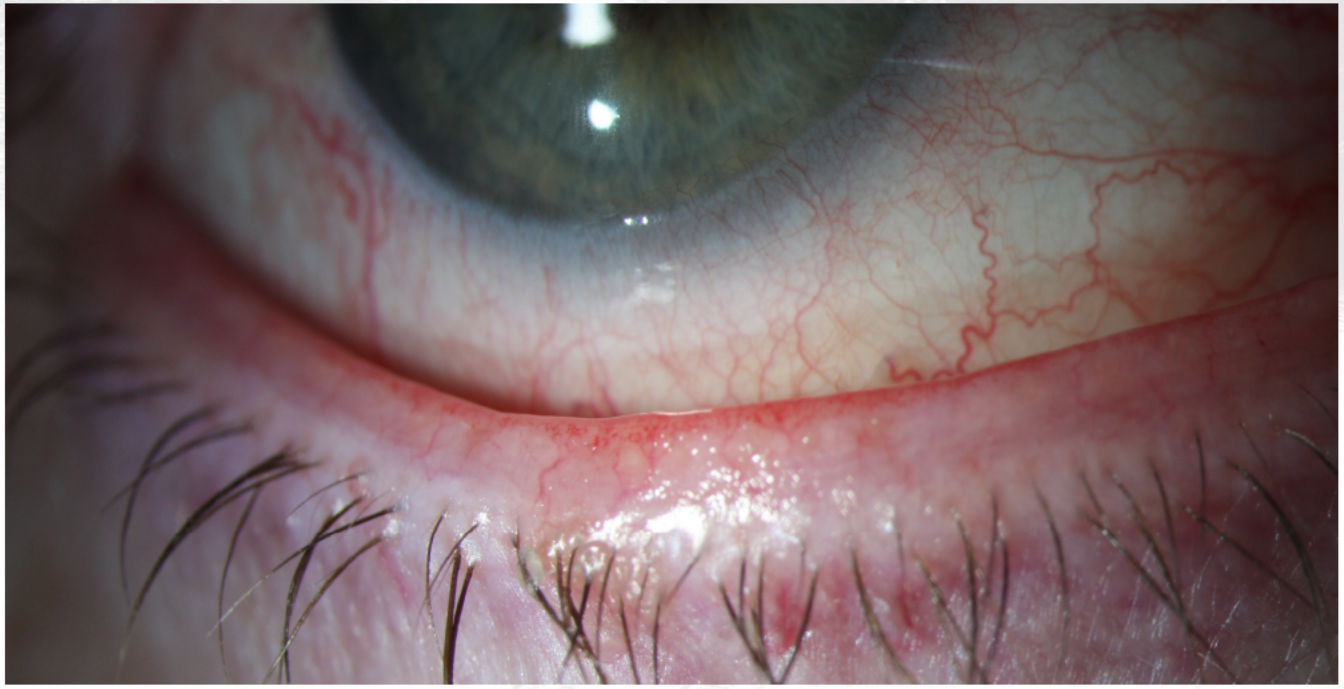
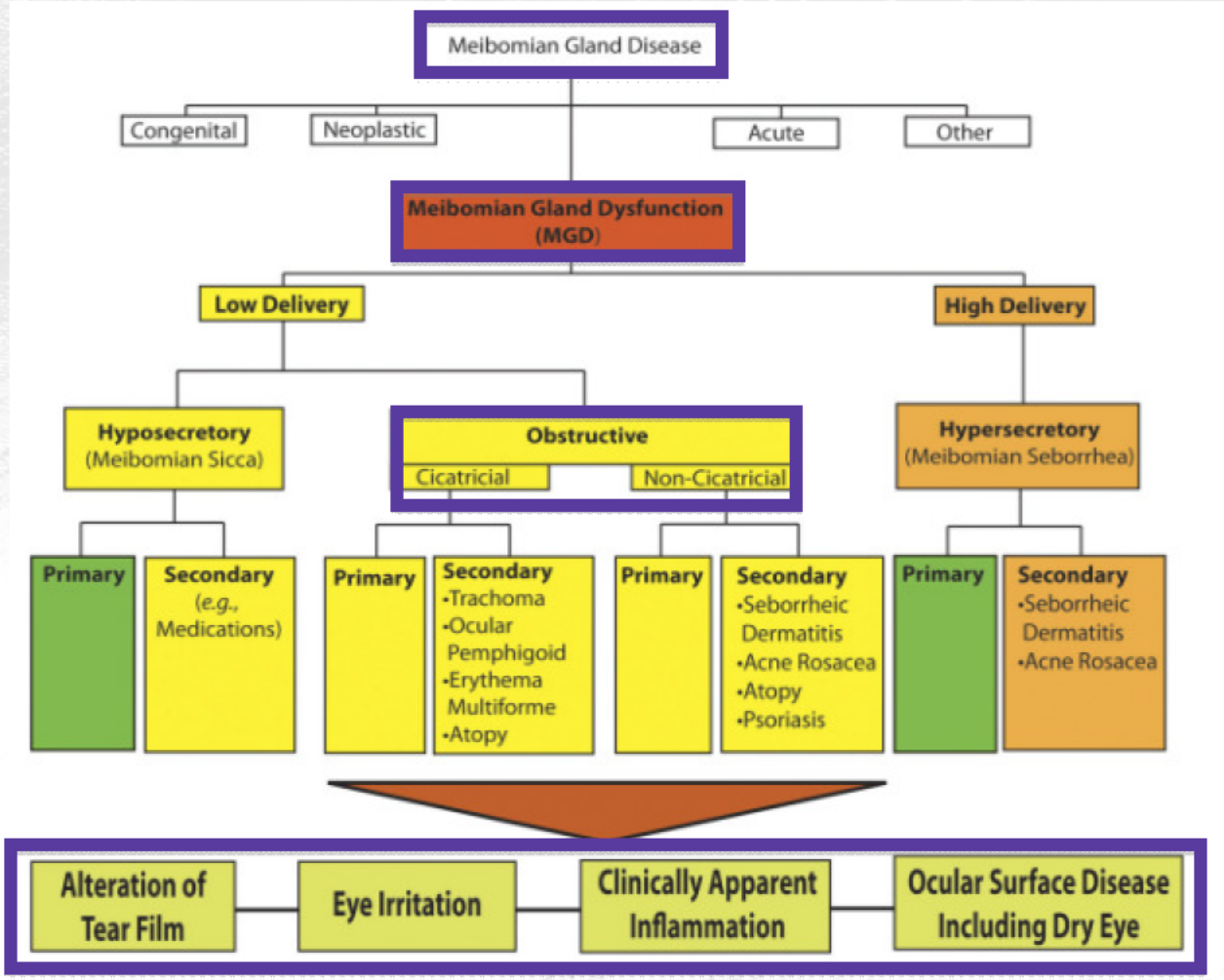
What is MGD?

The Workshop defined MGD as follows:

Meibomian gland dysfunction (MGD) is a chronic, diffuse abnormality of the meibomian glands, commonly characterized by terminal duct obstruction and/or qualitative/quantitative changes in the glandular secretion. This may result in alteration of the tear film, symptoms of eye irritation, clinically apparent inflammation, and ocular surface disease.



Classification of MGD



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Epidemiology and Associated Risk Factors of Meibomian Gland Dysfunction

Tear Film & Ocular Surface Society presents MGD Workshop 2010

A Report from the International Workshop on Meibomian Gland Dysfunction

Debra A. Schaumberg, Sc.D., O.D., M.P.H. (Chair)
Jason J. Nichols, O.D., M.P.H., Ph.D.
Eric B. Papas, M.Sc., O.D., Ph.D.
Louis Tong, F.R.C.S., M.B.B.S.
Miki Uchino, M.D.
Kelly K. Nichols, O.D., M.P.H., Ph.D.

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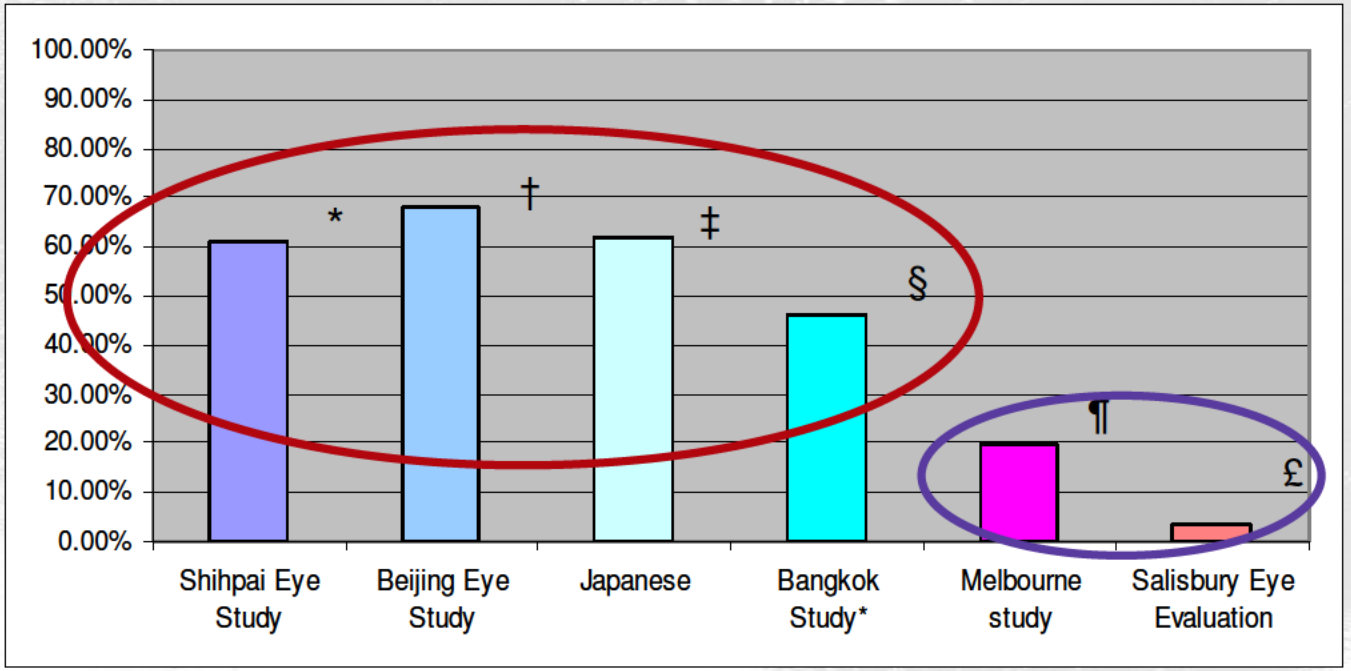
Prevalence of MGD



* Telangiectasia or Meibomian gland orifice plugging

† Telangiectasia

‡ Gland dropout, expressibility and nature of Meibum secretion

§ Telangiectasia or Meibomian gland orifice plugging OR collarettes

¶ Tear break up time < 1SD (10 sec)

£ Meibomian gland plugging OR collarettes (grade 2-3)

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Factors Associated with MGD

Special Issue

The International Workshop on Meibomian Gland Dysfunction: Report of the Subcommittee on the Epidemiology of, and Associated Risk Factors for, MGD

Debra A. Schaumberg,[1] Jason J. Nichols,[2] Eric B. Papas,[3] Louis Tong,[4] Miki Uchino,[5] and Kelly K. Nichols[2]

Factor	Reference
Aniridia	Jastaneiah and Al-Rajhi[48]
Chronic blepharitis (anterior or posterior)	Auw-Haedrich and Reinhard[40] Jackson[38] Mathers et al.[37] McCulley et al.[39] McCulley and Shine[49]
Contact lens wear	Arita et al.[36] Marren[33] Molinari and Stanek[34] Ong and Larke[32]
Demodex folliculorum	Czepita et al.[50] Kheirkhah et al.[51]
Eyelid tattooing	Kojima et al.[52]
Floppy eyelid syndrome	Gonnering and Sonneland[53]
Giant papillary conjunctivitis	Mathers and Billborough[54] Martin et al.[55] Molinari and Stanek[34]
Ichthyosis	Baden and Imber[56]
Salzmann's nodular corneal degeneration	Farjo et al.[57]
Trachoma	Bron and Tiffany[58]

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Factors Associated with MGD

Special Issue

The International Workshop on Meibomian Gland Dysfunction: Report of the Subcommittee on the Epidemiology of, and Associated Risk Factors for, MGD

Debra A. Schaumberg,[1] Jason J. Nichols,[2] Eric B. Papas,[3] Louis Tong,[4] Miki Uchino,[5] and Kelly K. Nichols[2]

www.tearfilm.org

TABLE 5. Systemic Factors Hypothesized to Correlate with MGD

Factor	Reference
Aging	Den et al.[62]
	DEWS[46]
	Hykin and Bron[63]
	Schaumberg et al.[70]
	Schaumberg et al.[71]
	Sullivan et al.[64]
Androgen deficiency	Krenzer et al.[72]
	Sullivan et al.[73]
	Sullivan et al.[65]
Atopy	Bron et al.[15]
Benign Prostate Hyperplasia	Schaumberg et al.[70]
Cicatricial pemphigoid	Bron and Tiffany[58]
Complete androgen-insensitivity syndrome	Cermak et al.[74]
	Sullivan et al.[75]
Discoid lupus erythematosus	Ena et al.[76]
Ectodermal dysplasia syndrome	Kaercher[77]
Hematopoietic stem cell transplantation	Ogawa et al.[78]
Hypertension	Schaumberg et al.[70]
Menopause*	Mathers et al.[66]
	Sullivan et al.[65]
Parkinson's Disease	Tamer et al.[79]
Pemphigoid	Iovine et al.[80]
Polycystic ovary syndrome	Yavas et al.[81]
Psoriasis	Horwath-Winter et al.[82]
	Zengin et al.[83]
Rosacea	Akpek et al.[84]
	Alvarenga and Mannis[85]
	Zengin et al.[86]
	Zuber[87]
	Zuber[88]
Sjögren's syndrome	Goto et al.[68]
	Krenzer et al.†
	Pflugfelder et al.[69]
	Shimazaki et al.[43]
	Sullivan et al.[65]
	Sullivan et al.[89]
Stevens-Johnson syndrome	Sotozono et al.[90]
Toxic epidermal necrolysis	Di Pasquale et al.[91]
	Sotozono et al.[90]
Turner syndrome	Bron and Tiffany[58]

Factors Associated with MGD

Special Issue

The International Workshop on Meibomian Gland Dysfunction: Report of the Subcommittee on the Epidemiology of, and Associated Risk Factors for, MGD

TABLE 6. Medications Hypothesized to Correlate with MGD

Medication	Reference
Isotretinoin (13-*cis* retinoic acid) therapy*	Caffery and Josephson[94] Egger et al.[95] Mathers et al.[93]
Antiandrogens	Krenzer et al.[72] Sullivan et al.[73] Sullivan et al.[65]
Antidepressants	Chia et al.[96] Moss et al.[97] Schaumberg et al.[70]
Antihistamines	Moss et al.[97] Ousler et al.[98]
Medications used to treat benign prostate hyperplasia	Schaumberg et al.[70]
ω-3 Fatty acids (possibly protective)	Barabino et al.[99] Creuzot et al.[100] Kokke et al.[101] Macsai[102] Miljanović et al.[103] Pinna et al.[104] Rashid et al.[105] Viau et al.[106]
Postmenopausal hormone therapy	Chia et al.[96] Erdem et al.[107] Lin et al.[28] Schaumberg et al.[108]

* Accutane; Hoffman-LaRoche, Nutley, NJ; withdrawn from the market in 2009.

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Overlap of DED Symptoms and Clinical Signs of MGD

Study	Symptoms Assessed (all frequency)	Clinical Evaluations/ MGD Definition	% with Dry Eye Symptoms who also had MGD
Shihpai Eye Study (Lin, 2003)	Eye dryness Gritty/sandy Burning Sticky Watery/tearing Redness Lash crusting Eyes stuck shut (am)	Telangiectasis or gland plugging ≥ G1	61.7% (p = NR)
Bangkok Study (Lekhanont, 2006)*	Eye dryness Foreign body sensation Burning Discomfort Sticky Tearing	Telangiectasis, Collarettes, and Plugging	63.6% (p = 0.006)

Evaluation, Diagnosis and Grading of Severity of Meibomian Gland Dysfunction

Tear Film & Ocular Surface Society presents MGD Workshop 2010

A Report from the International Workshop on Meibomian Gland Dysfunction

Alan Tomlinson, MCOpt, Ph.D. (Chair)
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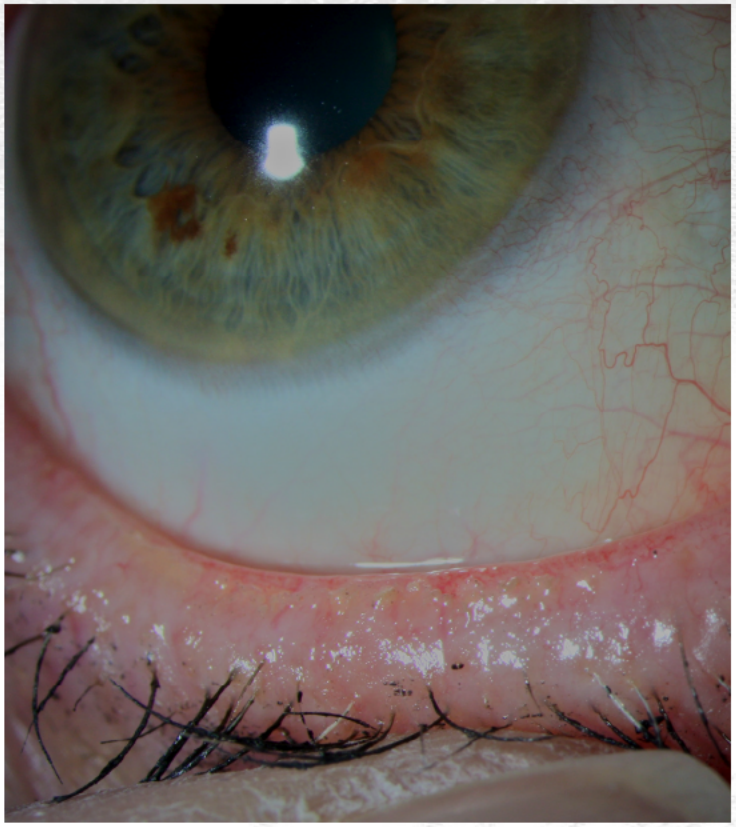
Testing Summary



- Symptoms (no validated survey)
- Expression (not widely accepted)
  - Quality/ Quantity
- Lid assessment
  - Redness (difficult to grade)
  - Irregularity
  - MG location
- Staining (fluorescein)
  - Photography
- Aq. Production (© 1903)

Stages of MGD

STAGE	CLINICAL DESCRIPTION	TREATMENT
STAGE 1	No *symptoms* of ocular discomfort, itching or photophobia *Clinical signs* of MGD based on gland expression Minimally altered secretions: Grade ≥2 - <4 Expressibility: 1 No ocular surface *staining*	*Inform* patient about MGD, the potential impact of diet and the effect of work/ home environments on tear evaporation, and the possible drying effect of certain systemic medications *Consider* eyelid hygiene including warming/ expression as described below (±)
STAGE 2	Minimal to mild *symptoms* of ocular discomfort, itching or photophobia Minimal to mild MGD *clinical signs* Scattered lid margin features Mildly altered secretions: Grade ≥4- <8 Expressibility: 1 None to limited ocular surface *staining* [DEWS grade 0-7; Oxford grade 0-3]	*Advise* patient on improving ambient humidity; optimizing workstations and increasing dietary omega-3 fatty acid intake (±) *Institute* eyelid hygiene with eyelid warming (a minimum of four minutes, once or twice daily) followed by moderate to firm massage and expression of MG secretions (+) *All the above, plus* (±) Artificial lubricants (for frequent use, non-preserved preferred) Topical emollient lubricant or liposomal spray Topical azithromycin Consider oral tetracycline derivatives
STAGE 3	Moderate *symptoms* of ocular discomfort, itching or photophobia with limitations of activities Moderate MGD *clinical signs* ↑ lid margin features: plugging, vascularity Moderately altered secretions: Grade ≥8- < 13 Expressibility: 2 Mild to moderate conjunctival and peripheral corneal *staining*, often inferior [DEWS grade 8-23; Oxford grade 4-10]	*All the above, plus* Oral tetracycline derivatives (+) Lubricant ointment at bedtime (±) Anti-inflammatory therapy for dry eye as indicated (±)
STAGE 4	Marked *symptoms* of ocular discomfort, itching or photophobia with definite limitations of activities Severe MGD *clinical signs* ↑ lid margin features: dropout, displacement Severely altered secretions: Grade ≥13 Expressibility: 3 Increased conjunctival and corneal *staining*, including central staining [DEWS grade 24-33; Oxford grade 11-15] ↑ Signs of inflammation: e.g. ≥ moderate conjunctival hyperemia, phlyctenules	*All the above, plus* Anti-inflammatory therapy for dry eye (+)

Key:

Meibum quality is assessed in each of 8 glands of the central third of the lower lid on a 0-3 scale for each gland: 0=clear meibum; 1=cloudy meibum; 2=cloudy with debris (granular); 3=thick, like toothpaste [range 0-24].

Expressibility of meibum is assessed from 5 glands: 0= all glands expressible; 1=3-4 glands expressible; 2= 1-2 glands expressible; 3=no glands expressible. This can be assessed in the lower or upper lid.

Numerical staining scores refer to a summed score of staining of the exposed cornea and conjunctiva. The Oxford scheme has a scale range of 0-15 and the DEWS scale has a scale range of 0-33.

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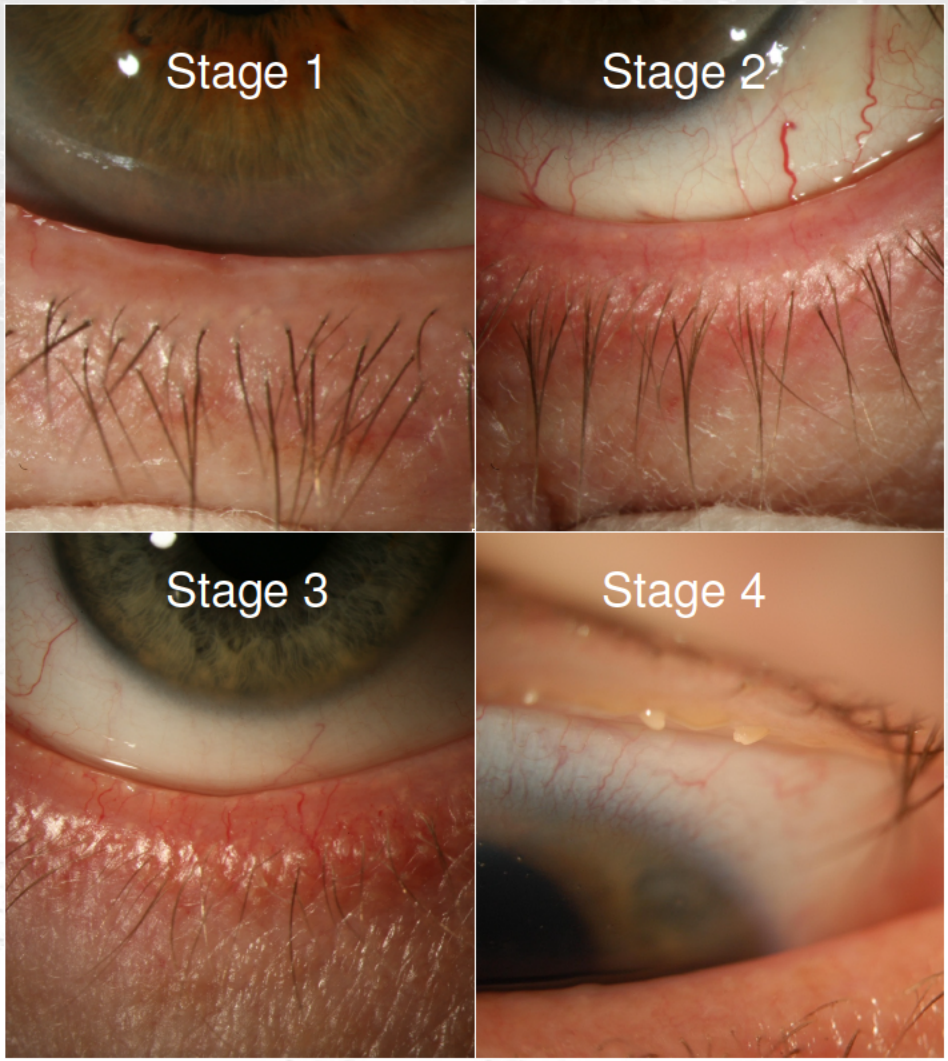
Stages of MGD



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Management and Therapy of Meibomian Gland Dysfunction

Tear Film & Ocular Surface Society presents MGD Workshop 2010

A Report from the International Workshop on Meibomian Gland Dysfunction

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Current Practice Patterns*

- Lid hygiene, warm compresses and lid massage
  - Cleaning of the lid margin with baby shampoo, cotton buds or wet towels, daily for 5-15 minutes
- Lubricants in cases with additional dry eye
- Topical antibiotic oint (moderate to severe)
- Systemic tetracyclines/ derivatives in recurrence
- Incision and curettage with optional steroid injection in chalazion

*Excerpted from Moorfields Manual, Wills Eye Manual (Guidelines for posterior blepharitis and meibomitis)

Current Practice Patterns

- World-wide variation
  - Underreporting → difficult to assess patterns
  - Underdiagnosis common, clinical follow-up irregular
- Lid warming and hygiene common
- Many use artificial lubricants
- Most Common Rx: Systemic tetracycline or derivatives (less frequent in EU/Japan)
  - 2nd most common Rx: topical antibiotic or antibiotic-steroid combination

Table 2. Clinical summary of MGD staging used to guide treatme

DISEASE STAGING			
Stage	**MGD grade**	**Symptoms**	**Corneal Staining**
1	+ (minimally altered expressibility and secretion quality)	Asymptomatic	None
2	++ (mildly altered expressibility and secretion quality)	Minimal to Mild	None to limited
3	+++ (moderately altered expressibility and secretion quality)	Moderate	Mild to moderate; mainly peripheral
4	++++ (severely altered expressibility and secretion quality)	Marked	Marked; central in addition
"PLUS DISEASE"	**Co-existing or accompanying disorders of the ocular surface and/ or eyelids**		

Recommended Staged Therapy

Stage =

1 2 3 4 Plus-Disease

+Inform patient (about dietary / environmental / medication effects)
± Eyelid hygiene (warming / expression)

+Eyelid hygiene (warming / expression),
Advise re: potential benefits of ambient humidity / n-3 fatty acid,
~~± Lubricant/lipid, topical azithromycin, tetracycl. derivatives~~

+ Oral tetracyclines
± Ointment (pm), cyclosporine/steroid for DE

+ Anti-inflammatory therapy for DE

+ Steroids, CL, Surgery

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Design and Conduct of Clinical Trials

Tear Film & Ocular Surface Society presents MGD Workshop 2010

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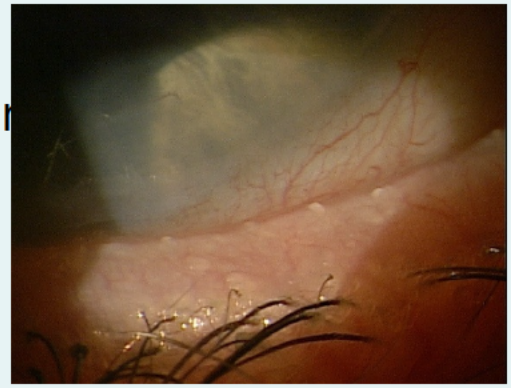
Existing Clinical Trials

Key Issues	Findings n = 26
Trial objective	Majority interventional treatment trials. 1/3 comparative (hot compresses or artificial tears).
Trial design /Methodology	Primarily small trials (<40 subjects) of short (<3 months) duration. Most prospective, 3 randomized controlled design, & 2 were double masked.
Study population	Chronic disease but selection criteria not uniformly defined; lid changes & symptoms most common clinical characteristics.
Inclusion criteria	No specific and consistent criteria; most common are lid margin signs (80%), dry eye findings (50%), symptoms of discomfort/foreign body sensation
Exclusion criteria	Classification of exclusion criteria in three different categories: 1) Ocular disease related/CL wear (most common); 2) Iatrogenic (e.g surgery, 1/3 studies); 3) Systemic disease related/pregnancy (15%).

Existing Clinical Trials

Issue	Findings n = 26
Outcome measures	1. Symptoms 2. TBUT 3. MG secretion/expressio 4. Schirmer 5. Corneal staining 6. MG obstruction 7. Eyelids 8. Lipid layer
Treatment	Most lacked washout period & did not check for relapse; 50% allowed concurrent use of other treatment & 30% treatment in the control group; large variability between Tx duration but pharmacological trials tended to be longer with follow up.
Statistics	Limited number of RCTs available; difficult to calculate effect size, power or required sample size. Limited information on how missing data e.g. loss to follow up, exclusion due to non-compliance, were handled.



Summary

Priorities for future clinical trials:

- Additional randomized, controlled, double-masked treatment trials with clearly defined objectives, relevant outcome measures based on pathophysiology, and refined inclusion & exclusion criteria
- Determination of the natural history of MGD
- Further understanding of the association with dry eye disease (and risk factors)
- Development and validation of a symptom questionnaire specific to MGD.

A Report from the TFOS International Workshop on Meibomian Gland Dysfunction

Definition
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Questions?
Thank You!

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Research Areas

- Fire Fighting Technology
- Electronic Safety Equipment
- Fire Dynamics
- Firefighter Fatality & Injury Studies
- Fire Fighting Tactics
- Fire Forensics
- Fire Protection
- Personal Protective Equipment
- Staffing Studies
- Structural Collapse
- Wind Driven Fires

Contact

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Fire Dynamics

Fire Dynamics

Fire Dynamics is the study of how chemistry, fire science, material science and the mechanical engineering disciplines of fluid mechanics and heat transfer interact to influence fire behavior. In other words, Fire Dynamics is the study of how fires start, spread and develop. But what exactly is a fire?

Defining Fire

Fire can be described in many ways - here are a few:

- NFPA 921: *"A rapid oxidation process, which is a chemical reaction resulting in the evolution of light and heat in varying intensities."*
- Webster's Dictionary: *"A fire is an exothermic chemical reaction that emits heat and light"*

Fire can also be explained in terms of the Fire Tetrahedron - a geometric representation of what is required for fire to exist, namely, *fuel*, *an oxidizing agent*, *heat*, and *an uninhibited chemical reaction*.

Measuring Fire

Heat Energy is a form of energy characterized by vibration of molecules and capable of initiating and supporting chemical changes and changes of state (NFPA 921). In other words, it is the energy needed to change the temperature of an object - add heat, temperature increases; remove heat, temperature decreases. Heat energy is measured in units of Joules (J), however it can also be measured in Calories (1 Calorie = 4.184 J) and BTU's (1 BTU = 1055 J).

Temperature is a measure of the degree of molecular activity of a material compared to a reference point. Temperature is measured in degrees Farenheit (melting point of ice = 32 ° F, boiling point of water = 212 ° F) or degrees Celsius (melting point of ice = 0 ° C, boiling point of water = 100 ° C).

° C	° F	Response
37	98.6	Normal human oral/body temperature
44	111	Human skin begins to feel pain
48	118	Human skin receives a first degree burn injury
55	131	Human skin receives a second degree burn injury
62	140	A phase where burned human tissue becomes numb
72	162	Human skin is instantly destroyed
100	212	Water boils and produces steam
140	284	Glass transition temperature of polycarbonate
230	446	Melting temperature of polycarbonate
250	482	Charring of natural cotton begins
>300	>572	Charring of modern protective clothing fabrics begins
>600	>1112	Temperatures inside a post-flashover room fire

(b)(4) References

(b)(4) References

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K142228/S002

January 5, 2014

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

RE: K142228/S001 is on Hold Pending Your Response

Dear Dr. Booker and Team:

Enclosed is the revised Digital Heat 510(k) material for the proposed product "Heated Eye Pad." The eCopy is an exact duplicate of the paper copy.

There were 8 deficiencies identified, and the subsequent files provide our responses and additional performance data for your consideration. We have labelled files with deficiency numbers for easier identification.

My contact information is provided below for any additional requirements or further correspondence on this 510(k) submission.

Sincerely,

John Devine

John Devine
President and CEO
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Email: john.devine@digitalheat911.com

1-CD

19

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January 5, 2014

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(b)(4) Deficiencies

[redacted]

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(b)(4) Deficiencies

[redacted]

(b)(4) Material Safety Data Sheet

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(b)(4) Deficiencies

[redacted]

Deficiency 3

(b)(4)

[redacted]

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(b)(4) Deficiencies

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(b)(4) Deficiencies

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(b)(4) Deficiencies

[redacted]

Form Approved: OMB No. 0910-0120; Expiration Date: 1/31/2017

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

Medical electrical equipment –Part 1:General requirements for basic safety and essential performance 60601-1 Edition 3:2005-12

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#19-4	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☒
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☒	☐
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☐
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

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Form Approved: OMB No. 0910-0120; Expiration Date: 1/31/2017

Department of Health and Human Services
Food and Drug Administration

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

Medical electrical equipment Part 1-2:General requirements for basic safety and essential performance Collateral standard: Electromagnetic compatibility Requirements and tests 60601-1-2 Edition 3:2007-3

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2] ?	☒	☐
FDA Recognition number [3]	#19-1	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☒
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Summary Report of Digital Heat Compliance to Medical electrical equipment –

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(b)(4) Summary Report of Digital Heat Compliance to Medical Electric Equipment

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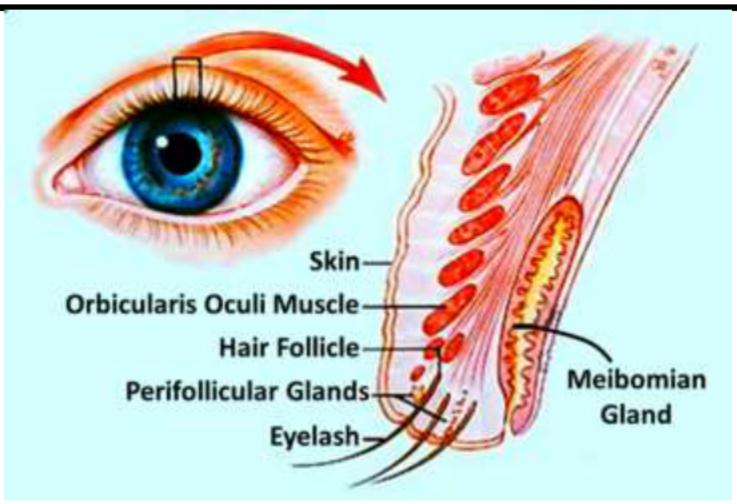
HEATED EYE PAD by DIGITAL HEAT
www.heatedeyepad.com
5626 S. Captain Kidd Ct., Unit B
Tempe, AZ 85283
(512) 517-6649

(b)(4) Deficiencies

[redacted]

- **This precision heated eye mask is designed to warm your eyelids and thereby decrease the viscosity of meibomian gland fluids (tears).**
- **The Heated Eye Pad ophthalmic warmer is a powered heating pad for the application of localized heat therapy in cases of chronic inflammatory and cystic conditions of the eyelids, including Meibomian Gland Dysfunction (MGD), Dry Eye, Blepharitis, Stye, or Chalazia.**
- **Follow safety and usage instructions inside the box for proper usage of this product.**
- **Patent Pending**



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IMPORTANT SAFETY INSTRUCTIONS

WARNING: Use carefully. May cause serious burns. **Do Not** use over sensitive skin areas or in the presence of poor circulation. The unattended use of the Heated Eye Pad by children or incapacitated persons may be dangerous. To reduce the risk of burns, electrical shock, fire, and accident, this product must be used in accordance with the following instructions:

1. **Read all instructions carefully**
2. **WARNING:** Device may cause skin irritation or burning sensation. Do not use on sensitive skin areas or in the presence of poor circulation. This product not intended for use by incapacitated individuals.
3. **DO NOT** use pad on an infants.
4. This pad is not to be used on or by an invalid, a paralyzed person, a sleeping or unconscious person, a person with diabetes, or a person with poor blood circulation. Do not use eye pad on areas of sensitive skin.
5. Burns may occur. Check skin under pad frequently to avoid burning and blistering.
6. **Place pad on top of closed eyelids. Never on eyes, or eyeball.**
7. **DO NOT** use pins or other metallic means to fasten heater eye pad in place.
8. **DO NOT** fold, bend, crush, lie, or sit on heater eye pad to avoid damage to device.
9. **Never** pull this pad by the supply cord and do not use the cord as a handle.
10. **Carefully** examine before each use. Discard the pad if it shows any sign of deterioration (such as blistering or cracking).
11. **Only** Use this pad on a computer Type-A USB socket, USB 2.0, or USB 3.0, or, the power supply provided by Digital Heat
12. **Unplug** pad when not in use
13. **DO NOT** tamper or modify the heater eye pad materials/configuration. There are no user serviceable parts. If for any reason this pad does not function satisfactorily, contact/return to Digital Heat.
14. **DO NOT** use this pad while wearing contact lenses or with other eye care products.
15. **DO NOT** use this pad with any liniments, salve, ointments, liquids, or any other materials in associations with the specified usage instructions of this device.
16. **DO NOT** use this pad while taking sensory dulling medication.
17. **DO NOT** wraps cord tightly or around eye pad heater to avoid damage to components. Loop cord lightly for storage to avoid any damage.

Save these instructions.

The Heated Eye Pad makes contact with the exterior eyelid tissue. Users typically apply the device 5-10 minutes, twice per day. Patients' use of the Heated Eye Pad can be at home, on travel, or at the office.

Clean the device before each use by wiping with a rinse free eyelid wipe.

The leakage current of this device is zero.

Heat treatment as compared to predicates provides the user:

1. Heat only where needed
2. A more precise temperature
3. Constant temperature over time.

Indications for Use:

The Heated Eye Pad ophthalmic warmer is a powered heating pad for the application of localized heat therapy. Use for treatment when the current medical community recommends the application of a warm compress to the eyelids. Such applications would include Meibomian Gland Dysfunction (MGD), Dry Eye, Blepharitis, Stye, or Chalazia.

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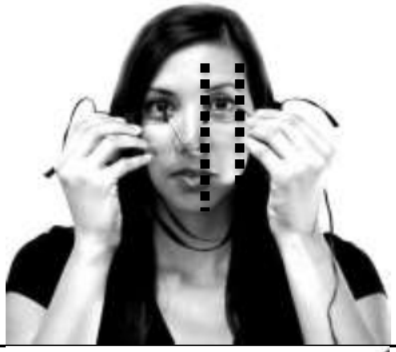
Instructions on how to use the Heated Eye Pad
Read ALL Safety Precautions before use.

	Clean the device before each use by wiping with a rinse free eyelid wipe. Look in the mirror. Fold or expand the nose part of the Heated Eye Pad to fit your face and eyes. The round section of the Heated Eye Pad should line up with your eyes, as shown in between the dashed lines.
	As you fold the nose bridge, the Heated Eye Pad might go out of alignment. This is incorrect
	Slightly bend the frame as needed to make it straight to your face.
	This is correct. You are ready to wear.
	1. Setup a timer (Watch, Clock, Phone, Etc.) if you wish to time your session. Users typically apply the device 5-10 minutes, twice per day. 2. Plug the heater into the power supply furnished by Digital Heat, or, a computer Type-A USB socket, USB 2.0, or USB 3.0. Do not use other power supplies. 3. Gently place the Heated Eye Pad on your CLOSED eyelids and position the elastic strap behind ears. 4. Adjust the tightness of the elastic strap for comfort, and place the electrical cord behind an ear. 5. DO NOT apply excessive pressure on your eyelids by over tightening the elastic strap. 6. Repeat steps 1 through 6 as needed for comfort. 7. If timed, after timer has expired remove the Heated Eye Pad from your eyelids and face.

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5.0 510(K) Statement:

I certify that, in my capacity as President and Chief Executive Officer, of Digital Heat Corporation, I will make available all information included in this premarket notification on safety and effectiveness within 30 days of request by any person if the device described in the premarket notification submission is determined to be substantially equivalent. The information I agree to make available will be a duplicate of the premarket notification submission, including any adverse safety and effectiveness information, but excluding all patient identifiers, and trade secret and confidential commercial information, as defined in 21 CFR 20.61.

John Devine

John Devine

December 1, 2014