



PMT Corp. • 1500 PARK ROAD • BOX 610 • CHANHASSEN, MINNESOTA 55317 USA • 1-800-MANKIND

SAFETY SUMMARY

PMT® METAL LOCATOR

510(k) ~~K~~911886

The PMT® Metal Locator poses no safety threat to the patient or the user. This device is non-invasive and not subject to sterilization. The power source is not capable of putting out harmful levels of electrical power. The circuit is double insulated so that the minute currents present cannot leak to the patient or physician. The relevant specifications of the PMT® Metal Locator are:

Power Source	9 Volt Household Battery
Maximum Circuit Voltage	9.45 VDC
Maximum Circuit Current	4.2 mA
Coil Material	Polycarbonate
Case Material	Aluminum
Weight	.5 lb.

1521
1521
1521



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
1390 Piccard Drive
Rockville MD 20850

AUG 12 1991

Mr. James Cox
Project Engineer
PMT Corporation
1500 Park Road
Box 610
Chanhassen, MN 55317

Re: K911886/A
PMT Model 3630-1 Metal Locator
Regulatory Class: II
Dated: July 26, 1991
Received: August 1, 1991

Dear Mr. Cox:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments. You may, therefore, market the device, subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act). The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under the Radiation Control for Health and Safety Act of 1968, or other Federal Laws or Regulations.

This letter immediately will allow you to begin marketing your device as described. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market, but it does not mean that FDA approves your device. Therefore, you may not promote or in anyway represent your device or its labeling as being approved by FDA. If you desire specific advice on the labeling for your device please contact the Division of Compliance Operations, Regulatory Guidance Branch (HFZ-323) at (301) 427-1116. Other general information on your responsibilities under the Act, may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,

Carl A. Larson, Ph.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Memorandum



ate 8-5-91

From REVIEWER(S) - NAME(S) Neil Ogden

Subject 510(k) NOTIFICATION K911886 / A

To THE RECORD

It is my recommendation that the subject 510(k) Notification:

- ☒ (A) Is substantially equivalent to marketed devices.
- ☐ (B) Requires premarket approval. NOT substantially equivalent to marketed devices.
- ☐ (C) Requires more data.
- ☐ (D) Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Additional Comments:

This 510(k) contains: (check appropriate box(es))

- ☒ A 510(k) summary of safety and effectiveness, or
- ☐ A 510(k) statement that safety and effectiveness information will be made available
- ☐ The required certification and summary for class III devices

The submitter requests under
21 CFR 807.95:*

- ☐ No Confidentiality
- ☐ Confidentiality for 90 days
- ☐ Continued Confidentiality
exceeding 90 days

Predicate Product Code w/panel
and class:

HPM-79 (Class II)

Additional Product Code(s)
w/Panel (optional):

REVIEW: [Signature]
act3 (BRANCH CHIEF)

GSDB 8/6/91
(BRANCH CODE) (DATE)

FINAL REVIEW: [Signature]
(DIVISION DIRECTOR)

8/9/91
(DATE)

OK
M. Shulman
2

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510(k) Submissions Compare New Devices to Marketed Devices. FDA Requests Additional Information if the Relationship Between Marketed and "Predicate" Devices is Unclear.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
1390 Piccard Drive
Rockville, Maryland 20850

AUGUST 2, 1991

PMT CORP.
ATTN: JAMES COX
1500 PARK ROAD
BOX 610
CHANHASSEN, MN 55317

510(k) Number: K911886
Received: 08-01-91
Product: PMT METAL LOCATOR,
MODEL 3630-1

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Because of equipment and personnel limitations we cannot accept telefaxed material as part of your official premarket notification submission, unless specifically requested of you by an FDA official.

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so within 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (301) 427-1190.

Sincerely yours,

Robert I. Chissler
Chief, Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health

K 96688L "SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

REVIEWER: Neil Ogden DIVISION/BRANCH: DGRD-650B

TRADE NAME: PMT Model 3630-1 COMMON NAME: retal locator

PRODUCT TO WHICH COMPARED: K781892

(510(k) NUMBER IF KNOWN)

- | | YES | NO | |
|--|-------------------------------------|-------------------------------------|---|
| 1. IS PRODUCT A DEVICE? | ☒ | ☐ | - IF NO STOP |
| 2. DEVICE SUBJECT TO 510(k)? | ☒ | ☐ | - IF NO STOP |
| 3. SAME INDICATION STATEMENT? | ☒ | ☐ | - IF YES GO TO 5 |
| 4. DO DIFFERENCES ALTER THE EFFECT OR RAISE NEW ISSUES OF SAFETY OR EFFECTIVENESS? | ☐ | ☐ | - IF YES STOP  |
| 5. SAME TECHNOLOGICAL CHARACTERISTICS? | ☐ | ☒ | - IF YES GO TO 7 |
| 6. COULD THE NEW CHARACTERISTICS AFFECT SAFETY OR EFFECTIVENESS? | ☐ | ☒ | - IF YES GO TO 8 |
| 7. DESCRIPTIVE CHARACTERISTICS PRECISE ENOUGH? | ☒ | ☐ | - IF NO GO TO 10
- IF YES STOP  |
| 8. NEW TYPES OF SAFETY OR EFFECTIVENESS QUESTIONS? | ☐ | ☐ | - IF YES STOP  |
| 9. ACCEPTED SCIENTIFIC METHODS EXIST? | ☐ | ☐ | - IF NO STOP  |
| 10. PERFORMANCE DATA AVAILABLE? | ☐ | ☐ | - IF NO REQUEST DAT |
| 11. DATA DEMONSTRATE EQUIVALENCE? | ☐ | ☐ |  |

 **NOTE:** IN ADDITION TO COMPLETING PAGE TWO, "YES" RESPONSES TO QUESTIONS 4, 6, 8, AND 11, AND EVERY "NO" RESPONSE REQUIRES AN EXPLANATION ON PAGE THREE AND/OR FOUR

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510K MEMO RECORD

DATE: August 5, 1991

TO: The record, K911886/A.MEM

FROM: Neil R. P. Ogden, Biomedical Engineer, (HFZ-410).

SUBJECT: PMT Corporation has submitted a 510(K) premarket notification for their PMT Metal Locator, Model 3630-1.

The sponsor wants to introduce this device into interstate commerce.

Summary:

The PMT Model 3630-1 is a battery powered aluminum and plastic hand-held electronic metal object locator. The device is indicated to locate invisible ferrous metals through nonmetallic barriers in a non-invasive and non-contact manner.

The device will be supplied non-sterile. Instructions for use are provided. The sponsor claims SE to the McGhan Magnafinder. No information is available on the McGhan device. I found another metal locator made by Keeler Optical Products (K781892). The Keeler device can locate ferrous and non-ferrous metals, and uses an audible signal when metal is detected. The PMT device has a LED that lights when the detector is near ferrous metal. The PMT device is moved over the area where a metal object has been implanted. As the device nears a metal object the LED is activated. The device is moved in a cross pattern to locate the object. The device contact with the patient is not necessary for the device to locate metal objects.

I spoke with the sponsor, James Cox, on 7-25-91 and asked for a summary of safety and effectiveness or certification, and more information about the predicate device to which they are claiming SE. He said it would be sent out today.

The requested information has been received and reviewed. A summary of safety and effectiveness was submitted, ~~and is adequate.~~ Promotional literature for the predicate device was submitted showing an SE device is on the market.

Recommendation:

I recommend that this application be found SE to the predicate and that this application be considered complete.

Neil R. P. Ogden

Neil R. P. Ogden

nrpo:K911886/A.mem

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*According to Neil,
he has shown
the summary to
Bob Chrysler. Bob
considers it acceptable.
9/6/91 to page 6*



PMT Corp. • 1500 PARK ROAD • BOX 610 • CHANHASSEN, MINNESOTA 55317 USA • 1-800-MANKIND

K911886 / A

July 26, 1991

FDA
Center for Devices and Radiological Health
Office of Device Evaluation
Attn: Mr. Neil Ogden
Document Mail Center HFZ-401
1390 Piccard Drive
Rockville, MD 20850

Dear Mr. Ogden:

Thank you for your call regarding the additional information required for PMT's 510(K) application (#K911886). Enclosed please find the two pieces of information requested for completion of your investigation.

1. Promotional literature from McMhan Medical Corporation marketing it's Magna-Site locating system.
2. A safety summary for PMT's Metal Locator as required by the Safe Medical Devices Act of 1990.

Thank you very much for your prompt attention in this matter.

Sincerely,

James Cox
Project Engineer

JC/rgb
cc: Al Iversen, President
Encl.

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SAFETY SUMMARY

PMT® METAL LOCATOR

510(k) #911886

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Power Source	9 Volt Household Battery
Maximum Circuit Voltage	9.45 VDC
Maximum Circuit Current	4.2 mA
Coil Material	Polycarbonate
Case Material	Aluminum
Weight	.5 lb.

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8

McGhan BIOSPAN™ Tissue Expanders

Unique BIOCELL® textured tissue expanders*
yield softer results and immobility!†



- BIOCELL® textured surface promotes mild tissue ingrowth for a more favorable implant/tissue interface.

• Inhibits migration of the implant during expansion.

- Oval shape designed to create a more natural breast shape.

• Yields greater tissue laxity during expansion.

• Patented** Magna-Site locating system allows easy location of injection site.

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*Patent Pending

**U. S. Patent No. 4,671,255 & 4,840,615

McGhan Medical Corporation



McGhan BIOSPAN Tissue Expanders

Style 131 Magna-Site / Oval Profile

We've taken our BIOCELL technology one step further to create BIOSPAN, a uniquely textured tissue expander. The all-silicone textured surface allows mild tissue ingrowth for a more favorable implant/tissue interface.

The BIOSPAN tissue expander promotes mild tissue ingrowth to inhibit migration of the implant and yield greater tissue laxity during expansion.



SEM of tissue/BIOSPAN interface
3 months postoperatively.

The oval shape for mammary expansion is designed for ptosis. The injection site is superior to the expansion envelope surface, so that injections avoid the hyperextended tissue or typical scar tissue.

Best results with the BIOSPAN tissue expander will be achieved by:

- Selecting expander according to desired base diameter. Appropriate expander size can be easily determined with the aid of McGhan's Tissue Expander Sizer/Templates, cat. #30-00005.

- Placing expander in exact desired location.
- Expanding as rapidly as tissue elasticity will allow without compromising viability.



SEM of tissue surrounding BIOSPAN
after removal of expander 3 months
postoperatively.

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References

1. Bobyn, J.D., Wilson, G.J., MacGregor, D.C., Pilliar, R.M., Weatherly, G.C.: Effect of Pore Size on the Peel Strength at Attachment of Fibrous Tissue to Porous-Surfaced Implants. *J. of Biomaterials Res.*, V16 (1982):571-584, V17 (1983):392.
2. Taylor, S.R., and Gibbons, D.F.: Effects of Surface Texture on the Soft Tissue Response to Polymer Implants. *J. of Biomaterials Res.*, V17 (1983): 205-227.
3. Salvatore, J.E., Gilmer, W.S., Kashgarian, M., and Barbee, W.R.: Experimental Study of the Influence of Pore Size of Implanted Polyurethane Sponges Upon Subsequent Tissue Formation, *Surg. Gyn. Obstet.*, 112, 463-470 (1961).
4. Maxwell, P. Panel discussion on breast reconstruction presented at Fourth Annual Breast Symposium, Santa Fe, NM, September 5-6, 1989.

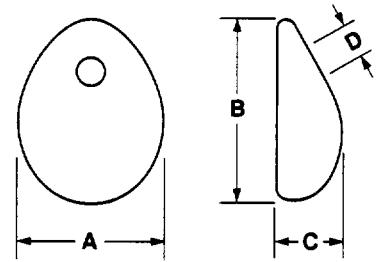
Limited Warranty, Limitation of Liability and Disclaimer of Other Warranties

McGhan Medical warrants that reasonable care was used in the manufacture and production of this product. Because McGhan Medical has no control over the conditions of use, patient selection, surgical procedure, post-surgical stresses, or handling of the device after it leaves our possession, McGhan Medical does not warrant either a good effect or against an ill effect following its use. McGhan Medical shall not be responsible for any incidental or consequential loss, damage or expenses directly or indirectly arising from use of this product. McGhan Medical's SOLE responsibility in the event McGhan Medical determines the product was defective when shipped by McGhan Medical, shall be replacement of the product. This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether express or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness for use.

Caution: United States Federal Law restricts this device to sale by or on the order of a licensed physician.

STYLE 131 MAGNA-SITE / OVAL PROFILE

Recommended saline fill	Catalog #	A Width	B Length	C Projection	D Injection Site Diameter
500-600cc	37-131600	11.5cm	14.0cm	5.0-7.5cm	2.8cm
600-800cc	37-131800	12.0cm	14.5cm	7.0-8.7cm	2.8cm
800-900cc	37-131900	13.0cm	15.5cm	6.5-8.5cm	2.8cm

**STYLE 131**

To order a Tissue Expansion System (Tissue Expander with a carton of 6 fill kits) simply add "S" to the end of the catalog number. For example: 37-131600S.

Note: *In vitro* tests show standard MAGNA-SITE is detectable through 60mm of phantom tissue.

WARNING: This device contains a strong rare earth/permanent magnet and is contraindicated where the magnetic field can affect other devices, e.g., pacemakers, drug infusion devices, artificial sensing devices and similar types of products.

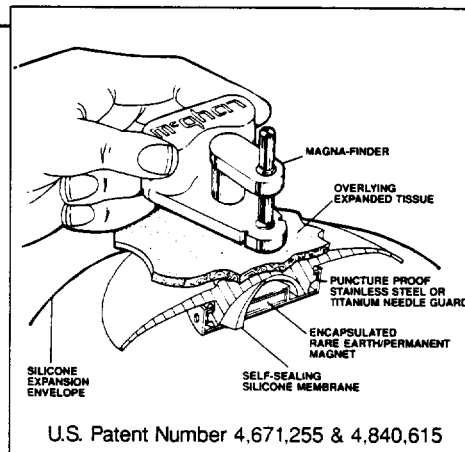
Nominal Dimensions

Implant dimensions are measured with the implant placed on a flat surface. The length is measured with a dial caliper placed across the centerline of the implant; the width is measured at the widest point. The projection is measured with a dial caliper from the flat surface to the bottom of a straight edge placed level across the top of the implant. Actual implant dimensions for the BIOSPAN tissue expanders are taken after the minimum and maximum recommended volume of saline fill is added.

Note: It should be understood that slight variations in size may occur in products of this type and that not every implant will conform exactly to the dimensions given.

Magnetic Location System

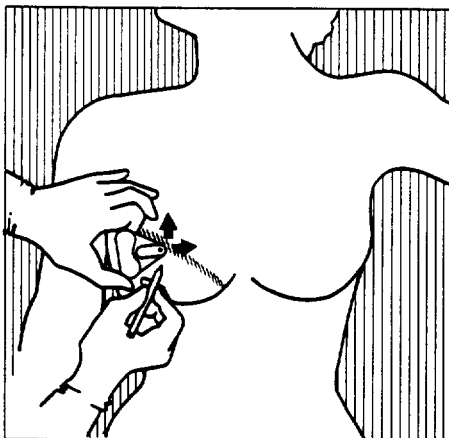
- Injection site easily identified by a rare earth/permanent magnet and MAGNA-FINDER locating device.
- Magnetic system solves location problems when excess muscle tissue or fluids make palpation difficult.



- Rare earth/permanent magnet assures long term efficacy of the location system.

**MAGNA-FINDER
Locating Device**

The MAGNA-FINDER locating device is supplied sterile with each expander. The locating device has a magnetic locating rod which centers directly over the magnet embedded in the MAGNA-SITE Tissue Expander. Two right angle passes locate the injection site center, which can be marked with a marking pen for ease in repeated injections.



- Magnetic system eliminates the need for hard, protruding palpation surfaces which might lead to tissue erosion.
- Magnetic system provides *precise* location and allows use of the integral injection site minimizing the potential for puncturing the expansion envelope. Eliminates the need for remote injection sites and tunneling of tissue. Provides ease of implantation and removal.

BIOCELL is a registered trademark of McGhan Medical Corporation.
BIOSPAN & MAGNA-SITE are trademarks of McGhan Medical Corporation.

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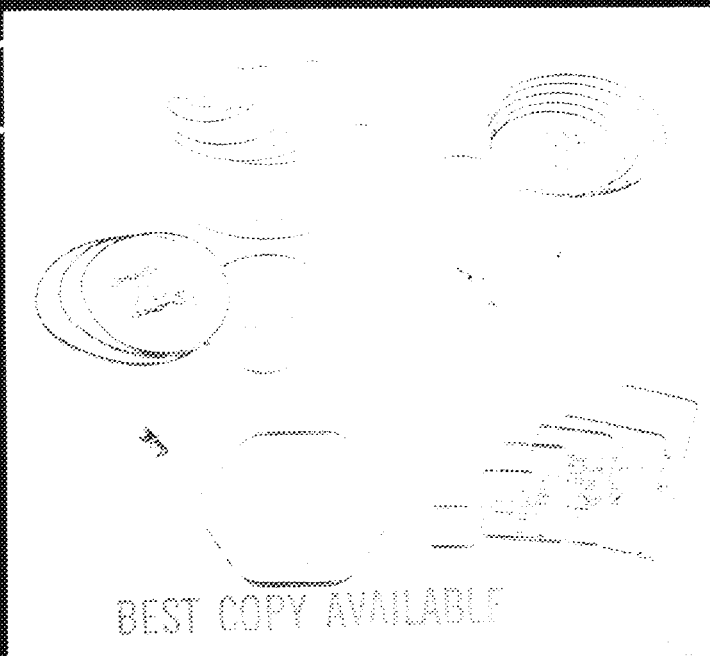
McGhan Fill Kit

Single use accessory system designed for delivery of sterile saline into tissue expanders.

Design Features

- Closed, sterile, single-puncture filling system provides easy delivery of sterile saline to tissue expanders.
- Refill of syringe occurs automatically after each infusion.
- No need to disconnect syringe or break sterility.
- Patient discomfort is minimized by single puncture and gentle filling procedure.
- Usable with vented or non-vented IV systems or sterile basin.*
- Six sterile kits per carton.

*Note: Universal spike does not fit McGaw Kendall bottle.



Accessories

Catalog #	Units	Description
30-00003 (Sterile)	6/cn	McGHAN FILL KIT , includes: 10cc syringe pump, 2-way check valve, 21g butterfly needle, 106cm tubing
To order a Tissue Expansion System (Tissue Expander with a carton of 6 fill kits) simply add "S" to the end of the catalog number. For example: 37-131600S.		
30-00004 (Sterile)	1/ea	MAGNA-FINDER , Magnetic Locating Device
30-00005 (Non-Sterile)	1 set	Sizer/Templates , Clear Plastic Measuring Templates, a variety of sizes and shapes.
00-VD002	1/ea	<i>The Use of Textured Silicone Tissue Expansion in Immediate Breast Reconstruction</i> . Video tape by G. Patrick Maxwell, M.D.
00-VD005	1/ea	<i>Laboratory and Clinical Evaluation of Textured Mammary Tissue Expanders</i> . Video tape by G. Patrick Maxwell, M.D.

Tissue Expander Sizer/Templates

Tissue Expander Sizer/Templates are available in various sizes and shapes to aid in tissue expander selection. These templates correspond to the base size of every tissue expander. Each template is printed with the necessary information for making the right choice of size and shape: base dimensions, projection, volume and style.

Product Information or to order:

(800) MCGHAN 1 (624-4261)
(800) 228-8967 Inside California
(805) 683-6761

M206 8/90

Telex 853269 MCGHAN MED SB
Fax 805-967-5839



McGhan Medical Corporation
700 Ward Drive
Santa Barbara, CA 93111 USA

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Printed in U.S.A.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
1390 Piccard Drive
Rockville, Maryland 20850

JULY 22, 1991

PMT CORP.
ATTN: JAMES COX
1500 PARK ROAD
BOX 610
CHANHASSEN, MN 55317

510(k) Number: K911886
Product: PMT METAL LOCATOR,
MODEL 3630-1

We are holding your above-referenced Premarket Notification (510(k)) for 30 days pending receipt of the additional information that was requested by the Office of Device Evaluation. Please remember that all correspondence concerning your submission MUST be sent in duplicate to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Because of equipment and personnel limitations, we cannot accept telefax material as part of your official premarket notification submission unless specifically requested of you by an FDA official.

If after 30 days the requested information is not received, we will discontinue review of your submission and proceed to delete your file from our review system. Pursuant to 21 CFR 20.29, a copy of your 510(k) submission will remain in the Office of Device Evaluation. If you then wish to resubmit this 510(k) notification, a new number will be assigned and your submission will be considered a new premarket notification submission.

Please remember that the Safe Medical Devices Act of 1990 states that you may not place this device into commercial distribution until you receive a decision letter from FDA allowing you to do so.

If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (301) 427-1190.

Sincerely yours,

Robert I. Chissler
Chief, Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health

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DO NOT REMOVE THIS ROUTE SLIP!!!!

K-91-1886

7/22/91

FROM: PMT CORP. ATTN: JAMES COX 1500 PARK ROAD BOX 610 CHANHASSEN, MN 55317		LETTER DATE 04/19/91	LOGIN DATE 04/29/91	DUE DATE 07/28/91
SHORT NAME: PMT		TYPE OF DOCUMENT: 510 (k)		CONTROL # K911886
		PHONE NO: 800-MAN-KIND		
		ESTABLISHMENT NO:		
TO: ODE/DMC		CONT. CONF.: ? STATUS : H REV PANEL : SU PAN/PROD CODE(S): SU/ / /		
SUBJECT: PMT METAL LOCATOR, MODEL 3630-1				
DECISION: DECISION DATE: / /		RQST INFO DATE: 07/22/91		INFO DUE DATE: 08/21/91
		DATE: / /		DATE: / /
		DATE: / /		DATE: / /
		DATE: / /		DATE: / /
		DATE: / /		DATE: / /
		DATE: / /		DATE: / /

DO NOT REMOVE THIS ROUTE SLIP!!!!



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Memorandum

Date 7-18-91

From REVIEWER(S) - NAME(S)

Neil Ogden

Subject 510(k) NOTIFICATION

K911886

To THE RECORD

It is my recommendation that the subject 510(k) Notification:

- _____ (A) Is substantially equivalent to marketed devices.
- _____ (B) Requires premarket approval. NOT substantially equivalent to marketed devices.
- ☒ (C) Requires more data.
- _____ (D) Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Additional Comments:

Provide predicate device information and summary statement.

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The submitter requests under 21 CFR §807.95:

- _____ No Confidentiality
- ☒ Confidentiality for 90 days
- _____ Continued Confidentiality exceeding 90 days

Predicate Product Code w/Panel and class:

HPM-79-(II)

Additional Product Code(s) w/Panel (optional):

REVIEW:

(BRANCH CHIEF)

GSOB

(BRANCH CODE)

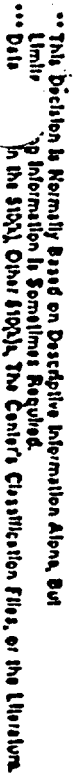
(DATE)

FINAL REVIEW:

(DIVISION DIRECTOR)

(DATE)

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFE-401)
1390 Piccard Drive
Rockville, Maryland 20850

MAY 1, 1991

PMT CORP.
ATTN: JAMES COX
1500 PARK ROAD
BOX 610
CHANHASSEN, MN 55317

510(k) Number: K911886
Received: 04-29-91
Product: PMT METAL LOCATOR,
MODEL 3630-1

We have received the Premarket Notification you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (Act) for the above referenced product. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in any future correspondence that relates to this submission. We will notify you when the processing of your premarket notification has been completed or if any additional information is required.

The Safe Medical Devices Act of 1990 (SMDA), signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so within 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

In addition, the SMDA requires all persons submitting a premarket notification submission to include either (1) a summary of the safety and effectiveness information in the premarket notification submission upon which an equivalence determination is based, or (2) state that such information will be made available to interested persons upon request. Safety and effectiveness information refers to information in the premarket notification submission, including adverse safety and effectiveness information that supports a finding of substantial equivalence. The information could be descriptive information about the new and predicate device, or performance or clinical testing information. We cannot issue a final decision on your 510(k) unless you comply with this requirement.

FDA acknowledges that the law provides the 510(k) submitter a choice of providing the agency either a summary of safety and effectiveness information or stating that the information will be made available to the public. FDA encourages manufacturers to make their safety and effectiveness information available to the public, excluding confidential manufacturing process information, in lieu of submitting summaries of the information to the agency, until FDA promulgates a regulation on the

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content and format of summaries. Since the law requires that FDA must make the summary (referred to in (1), above) publicly available within 30 days of making an equivalence determination, we advise you that we must disregard any request for extended confidentiality for those 510(k)s containing this summary. Requests for extended confidentiality will be adhered to, per 21CFR 807.95, if you include the statement in (2) above.

Additionally, this legislation also requires any person who asserts that a device is substantially equivalent to a class III device to: (1) certify that they have conducted a reasonable search of all information known, or otherwise available, about the generic type of device; and (2) provide a summary description of the types of safety and effectiveness problems associated with the type of device and a citation to the literature, or other sources of information, upon which they have based the description. The description should be sufficiently comprehensive to demonstrate that an applicant is fully aware of the types of problems to which the device is susceptible. If you have not provided this certification and description (with citations) in your premarket notification, please provide it as soon as possible. We cannot complete the review of your submission until you do so.

Please note that the SMDA may have additional requirements affecting your device. You will be informed of these requirements as they become effective.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the Document Mail Center will not be considered as part of your official premarket notification submission. Because of equipment and personnel limitations we cannot accept telefaxed material as part of your official premarket notification submission, unless specifically requested of you by an FDA official.

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Sincerely yours,

Robert I. Chissler
Chief, Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health

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K 911886



PMT Corp. • 1500 PARK ROAD • BOX 610 • CHANHASSEN, MINNESOTA 55317 USA • 1-800-MANKIND

April 19, 1991

Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
1390 Piccard Dr.
Rockville, MD. 20850

Re: 510 (K) Notification

Dears Sirs:

This letter is to inform you of our intent to market the PMT Metal Locator, Model 3630-1. Please be advised these units are noninvasive and nonsterile and will be used for general examination and surgical procedures. Equivalent products are used in various medical fields and FDA classification is unknown to PMT® Corporation.

The Model 3630-1 Metal Locator is described in the information enclosed with this notification. Information about presently marketed equivalent products is also enclosed. Samples of proposed labels and manuals are also enclosed.

We look forward to hearing from you at your earliest convenience. Please feel free to contact me direct at 612/470-0866. PMT Corporation's FDA Registration # is 2182979.

I thank you for your attention to this matter in advance.

Sincerely yours,

James Cox
Project Engineer
PMT® Corporation

Enclosures

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APR 21 1991

PMT METAL LOCATOR

MODEL 3630-1

510(K) NOTIFICATION

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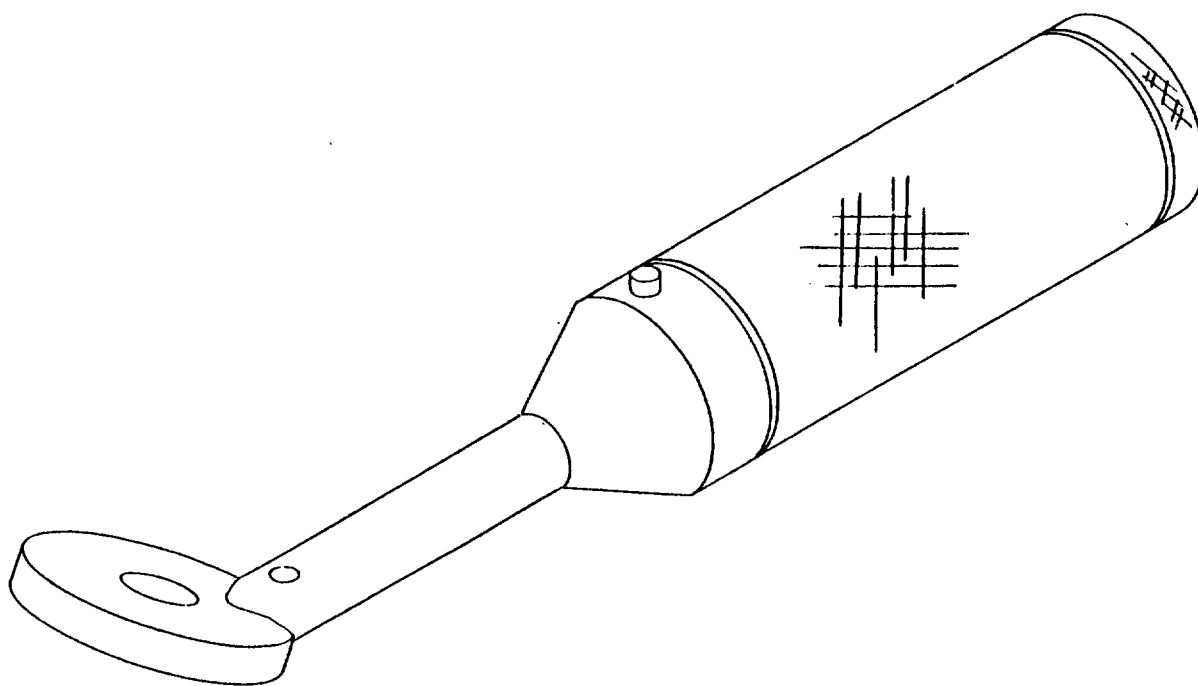
PRODUCT DESCRIPTION

The PMT® Model 3630-1 is a hand-held electronic metal object locator. The instrument is lightweight and battery powered with an aluminum and plastic housing.

The PMT® Model 3630-1 is designed to locate invisible ferrous metals through nonmetallic barriers in a noninvasive and noncontact manner.

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II. PRODUCT DRAWING:



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III. PROPOSED LABELING:

PMT
Model 3630-1

Description: METAL LOCATOR
Surgical/Medical Instrument

PMT
CPMT Corp., 1990

Mfg'd in U.S.A.
"Manufacturers of Quality Instruments and Medical Disposables"

CAUTION: Federal law
(USA) restricts this device to
the sale by or on the order of
a physician.
PMT Corp.
Box 610
Chaska, MN 55317
TOLL FREE 1-800-MANKIND

Non Sterile

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DEVICE MANUAL

PMT®

MODEL 3630-1

METAL LOCATOR

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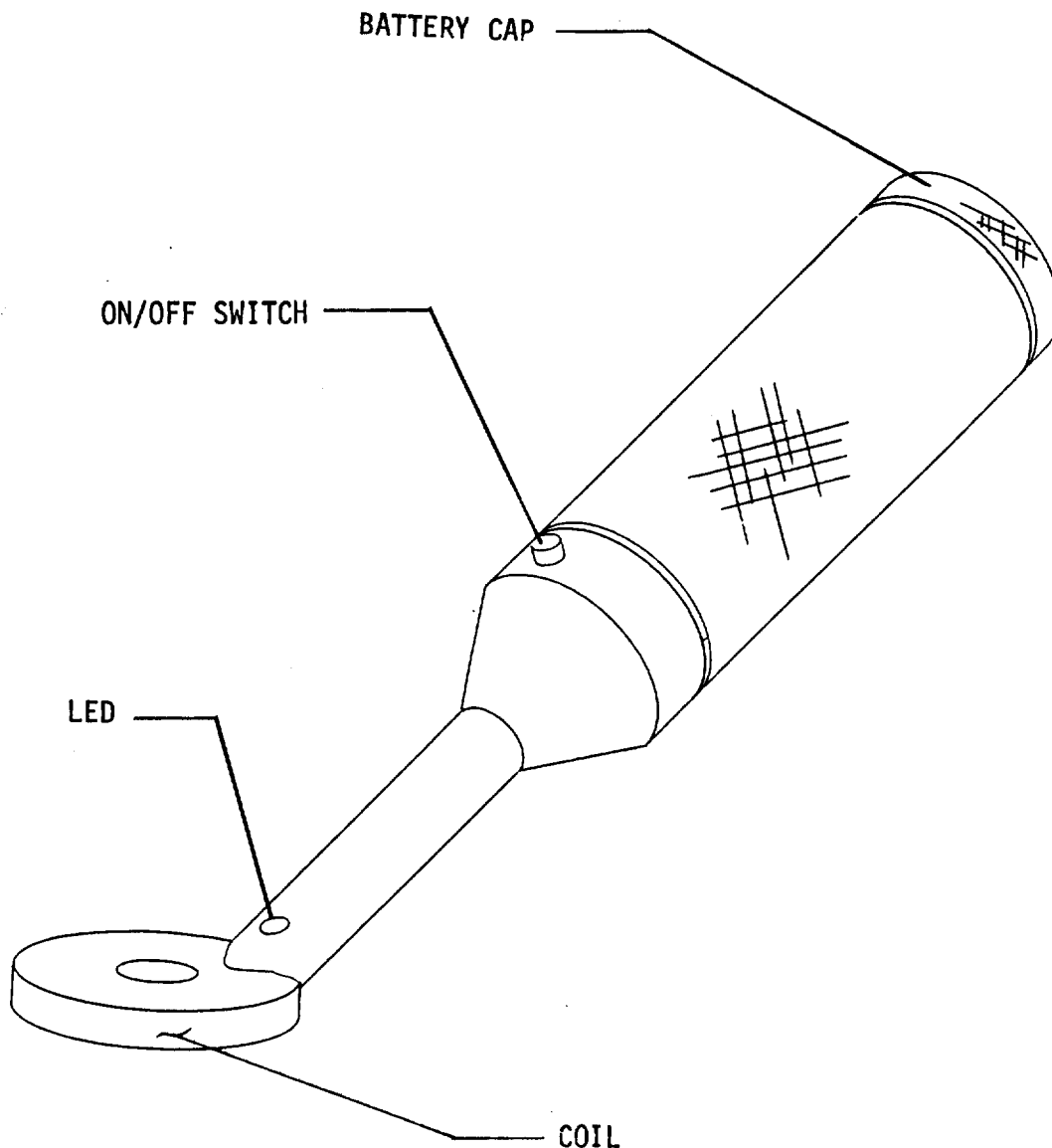
PMT® Corporation
PO Box 610
1500 Park Road
Chanhassen, MN 55317 USA
Toll Free: 1-800-MANKIND
Minnesota: 612-470-0866
Fax: 612-470-0865

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1. Description

The PMT Model 3630-1 is a compact hand held metal locator. The model 3630-1 features replaceable battery and LED to indicate metal object.



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2. Indications for Use

The PMT[®] Metal Locator should be used whenever invisible metals at shallow depths need to be located.

3 Contraindications

The PMT[®] Model 3630-1 Metal Locator is tuned to operate at depths of 0mm-25mm and is not recommended for applications outside these parameters.

3. How Supplied

The 3630-1 is provided non-sterile. Included is a 9v battery and a test device (Model 3631-1).

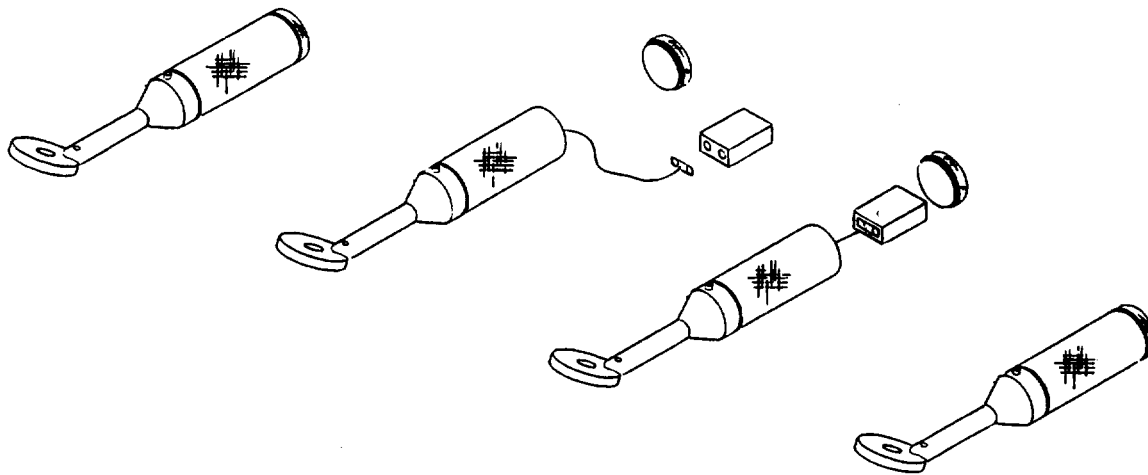
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4. Instructions for Use

I. LOADING BATTERY

Unscrew the Battery Cap by turning the Battery Cap counter-clockwise. Connect the Battery to the Battery Clip. Push the connected battery gently back into the Locator and replace the Battery Cap by threading clockwise.



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CAUTION: There is no need to over-tighten the cap. Doing so may make the cap difficult to remove in the future.

II. OPERATION

Testing of Metal Locator Prior To Use

WARNING: It is extremely important to test the Metal Locator before each use to verify Battery condition and Metal Locator function.

BATTERY CONDITION:

Now check that the locator is functioning properly by using the Test Device. Slowly move the Locator close to the flat surface of the Test Device. The Indicator LED should light as you pass the Coil against the surface of the Test Device. If the Metal Locator is not functioning in a predictable fashion, see the Trouble Shooting Section of the Manual.

WARNING: If the Metal Locator does not perform satisfactorily with the test device, do not use it. Contact PMT at 1-800-MAN-KIND (1-800-626-5463) with any questions.

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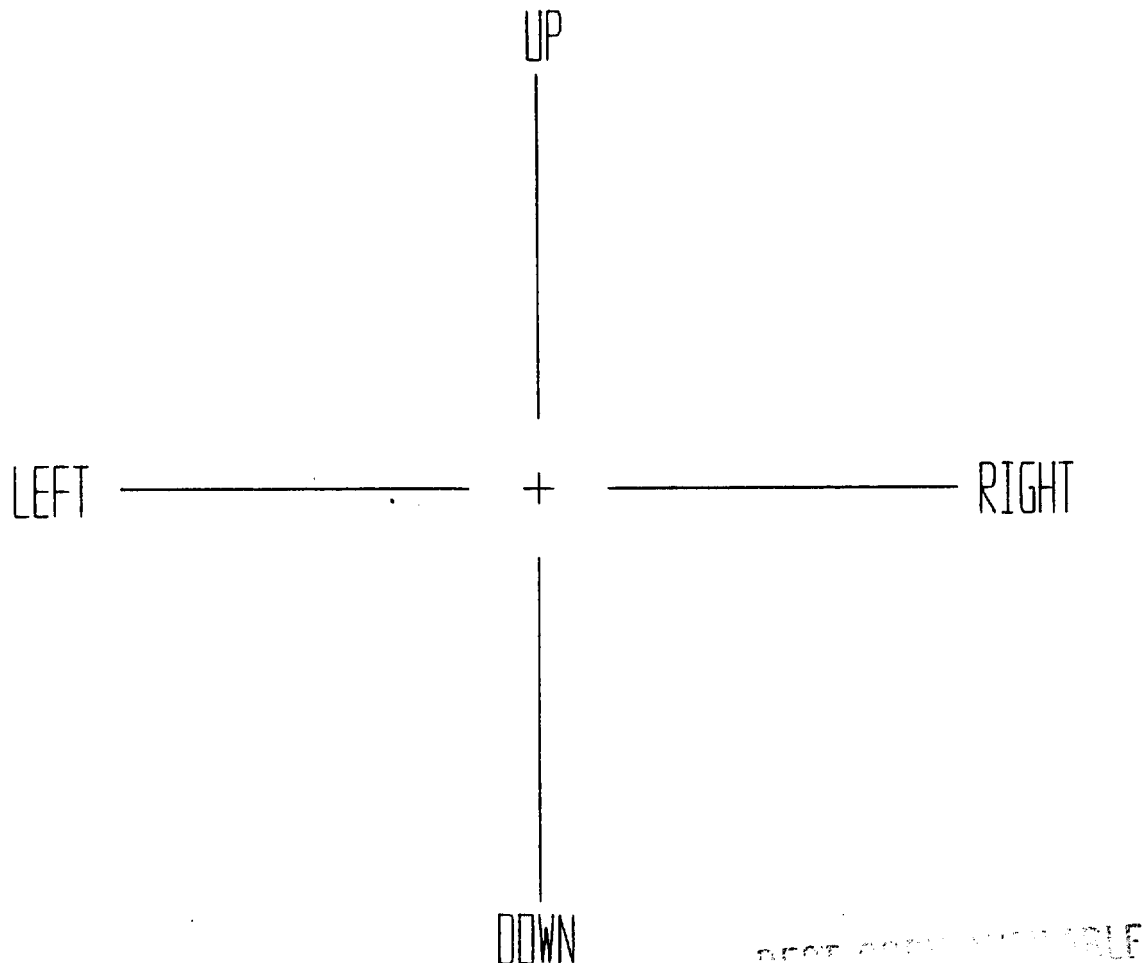
Using The 3601-1 Metal Locator

Now that you have verified the function of your Metal Locator you are ready to use it. As with the Test Device, you must hold the On/Off Switch down. Slowly move (about 5mm/second) the Metal Locator over the surface of the object in question.

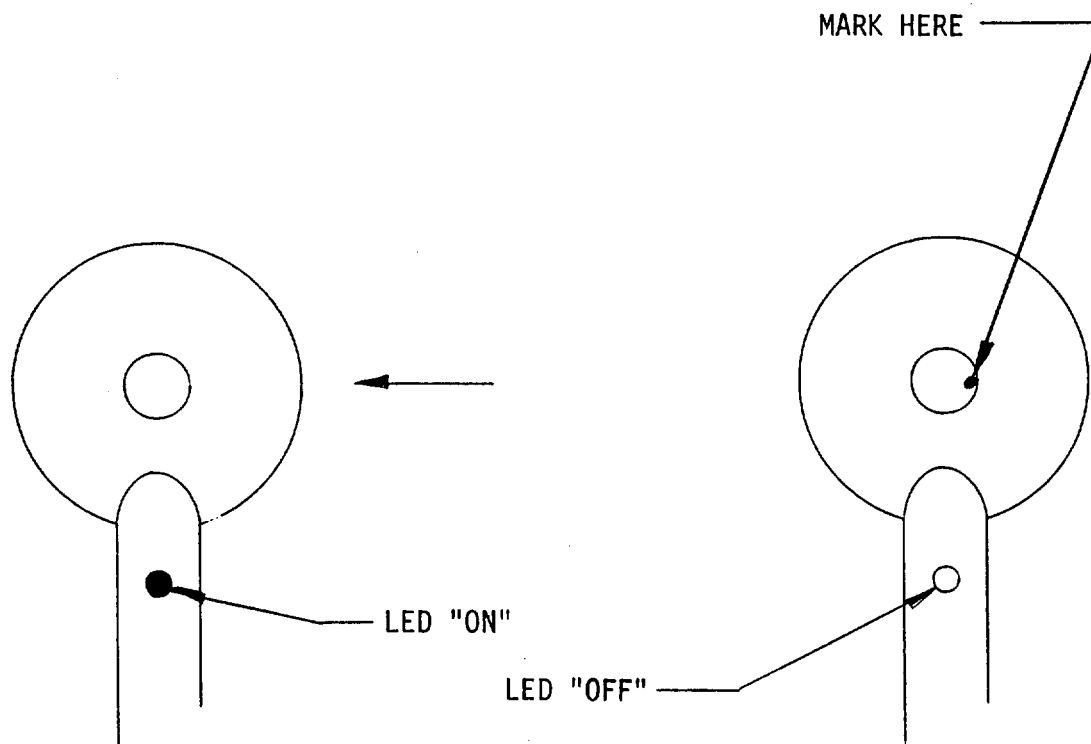
CAUTION: The locator will only register objects directly below the Coil, so be sure to cover the area in question with a systematic scanning movement.

When the LED lights or flickers you are near a metal object. To accurately locate the object, you must place four reference marks as follows:

- 1) Establish a four-direction coordinate system such as the one shown:



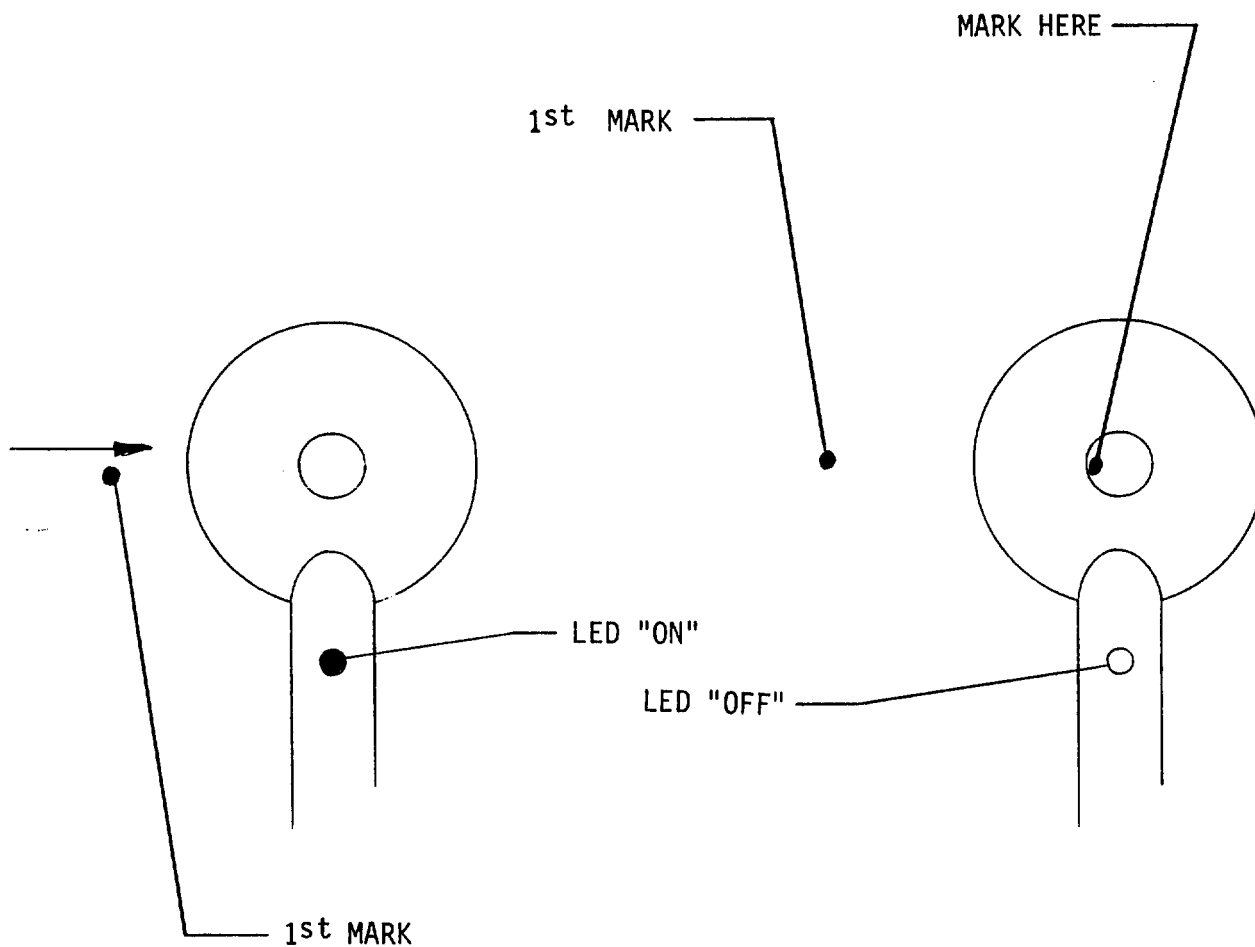
2) Move the Metal Locator left until the LED flickers and goes off. Now place a mark inside the coil on the right edge as below:



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Now repeat to ensure precision.

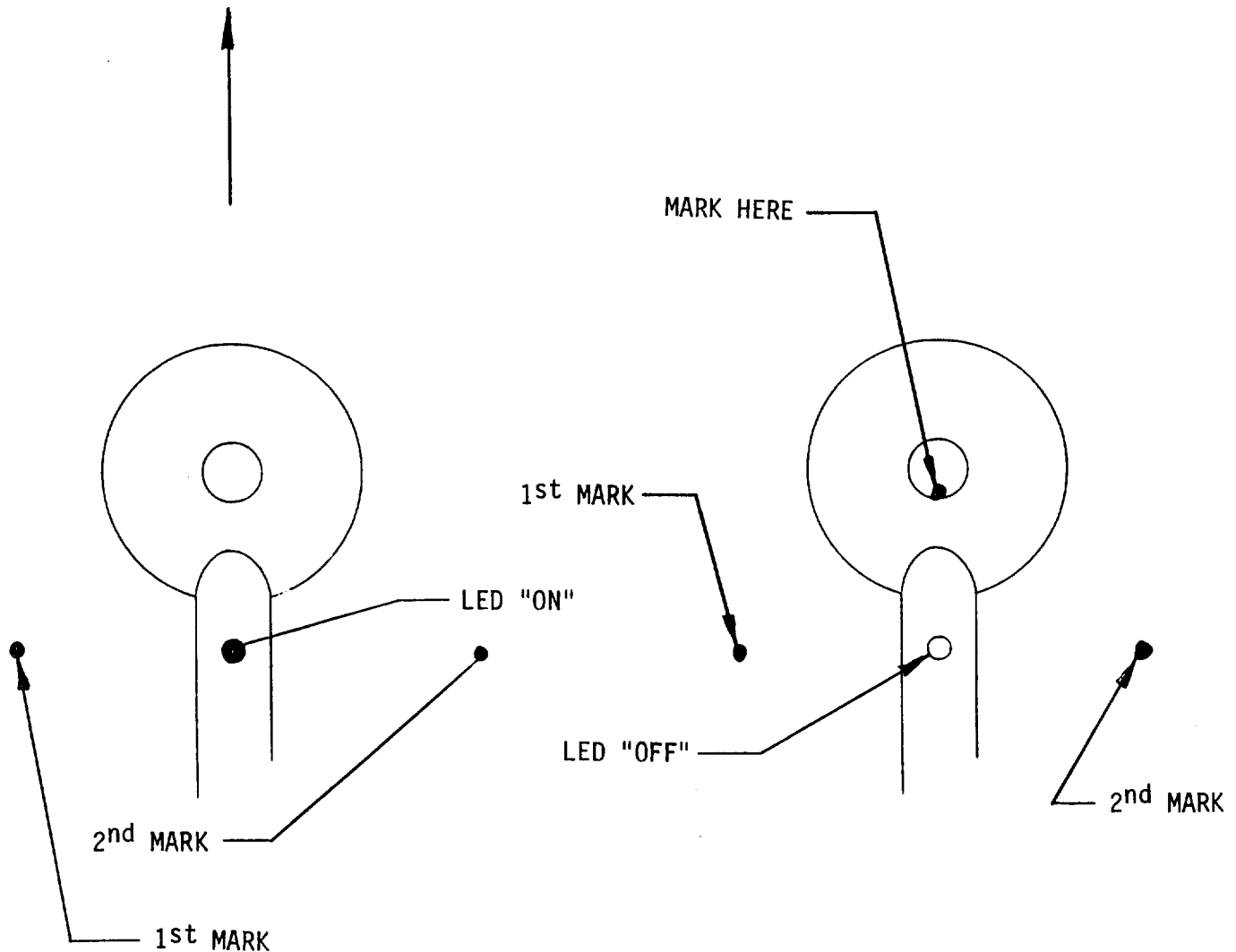
3) Next, move the Metal Locator right until the LED flickers and goes off. Now place a mark inside the coil on the left edge as below:



Now repeat to ensure precision.

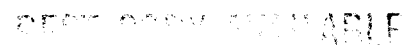
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4) Next, move the Metal Locator up until the LED goes off. Now place a mark inside the coil on the Down edge as below.



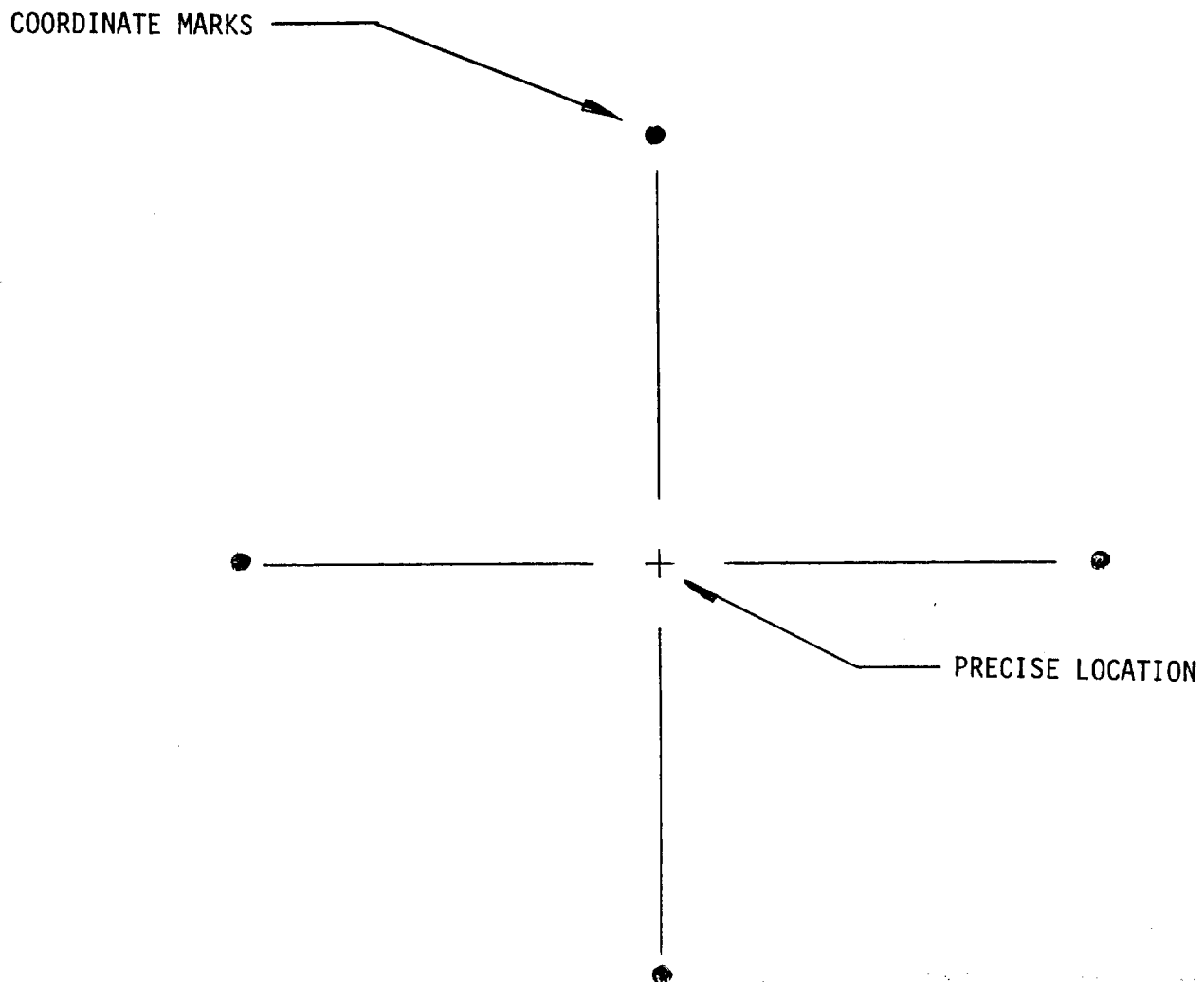
2025 0000 0000 0000

Repeat to ensure precision.



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6) Now mark the location as the center of the square created by the eight marks previously placed.



TROUBLE SHOOTING

IF THE LED DOES NOT LIGHT:

- Replace the Battery with a new one.
- If the Locator does not function properly, call 1-800-MANKIND for service.

IF THE LED LIGHTS WHEN NO METAL IS PRESENT:

-Double check that no metal is within 12 inches of the locator. Keep in mind that many desks and pieces of furniture have metal in them.

-Try a new battery

-If the Locator does not function properly, call 1-800-MANKIND for service.

IF THE LED REMAINS ON LONGER THAN TEN SECONDS WHILE TESTING:

-Check that the Locator is no closer than 12 inches to any metal object. If you are sure no metal is near that could be setting off the Locator, replace the battery.

-If the Locator does not function properly, call 1-800-MANKIND for service.

IF ANY PROBLEMS OR UNUSUAL PERFORMANCE NOT MENTIONED ABOVE ARE ENCOUNTERED:

-Call 1-800-MANKIND

5. Service

PMT® recommends that the BATTERY be replaced when:

- the LED stays on for 10 seconds or more at start-up
 - when no LED light is obtained over the Test Device
 - three months has passed since the battery was last changed
- which ever comes first.

WARNING: PMT® recommends that the Metal Locator be returned to PMT for recalibration every six months to ensure proper operation.

6. Specifications

OPERATING VOLTAGE.....9V DC

POWER SOURCE.....9v BATTERY

WARRANTY AND DISCLAIMER

All parts and labor of the PMT® Model 3630-1 Metal Locator are guaranteed for six months from the date of purchase. PMT® Corporation warrants that reasonable care was used in the choice of materials and manufacture of this product. PMT® Corporation shall not be liable for any incidental or consequential loss, damage, expense or injury directly or indirectly arising from the use of this product, other than the replacement of it should PMT® Corporation's investigation show the product was defective at the time of shipment by PMT® Corporation. The foregoing warranties, as conditioned and limited are in lieu of and exclude all other warranties not expressly set forth herein, whether expressed or implied by operation of law or otherwise, including, but not limited to, any implied warranties of MERCHANTABILITY OR FITNESS-FOR-USE. PMT® Corporation neither assumes nor authorizes any other person to assume for it, any other or ADDITIONAL LIABILITY OR RESPONSIBILITY IN connection with this product.

CAUTION: Federal Law (USA) restricts this device to sale by or on the order of a physician.

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SUBSTANTIAL EQUIVALENCE

The PMT Model 3630-1 Metal Locator is substantially equivalent to the McGhan Magnafinder.

Both units are handheld devices

Both units are sold and used nonsterile.

Both units use magnetism to locate the object.

The key differences are:

the PMT Model 3630-1 uses an electromagnetic field and electronic means of target indication for the following benefits:

PMT features

- more accuracy

- more precision

- locates more types of metal (for example, Stainless Steel)

- no body contact required

- more appealing marketable package

the McGhan device uses a permanent magnet and physical means of indicating a metal object.

The PMT Model 3630-1 may be equivalent to other marketed devices that PMT is not aware of.

COMPETITIVE LITERATURE

Competitive literature on the McGhan product, or other products, is not available to PMT at this time.