

User Manual

Cold Compression Wrap Pro
Version: A/2

Distributed By: ManaMed, LLC 2612 Sirius Dr., Denton, TX 76208
Ph: 888-508-0712 www.ManaMed.com

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/ Intended Use

The Cold Compression Wrap Pro is indicated for the temporary relief of minor muscle aches and pains.

The device is indicated for temporary increase in circulation of the treated areas in people who are in good health, and simulates kneading and stroking of tissues using an inflatable wrap.

The cold wrap is indicated for localized therapy in situations where cold temperature therapy is necessary or desirable.

/ Contraindications

Do NOT use the device if any of the below condition applies:

*Suspected, active or untreated:

- Deep vein thrombosis (blood clots in a deep vein of the leg or arm);
- Ischemic vascular disease (buildup of plaque in blood vessels and blood supply is restricted);
- Severe arteriosclerosis (hardening and thickening of blood vessel walls causing loss of blood flow);
- Pulmonary edema (abnormal buildup of fluid in the lungs making it hard to breathe);
- Heart failure (heart can't pump enough blood to meet the body's needs);
- Thrombophlebitis (inflammation of a vein related to blood clots);
- An active infection;

*On a limb where wraps would interfere with the following conditions:

- Vein ligation (procedure to tie off varicose veins);
- Gangrene (death tissue due to a lack of blood flow or a serious bacterial infection);
- Dermatitis (skin inflammation such as itchiness, redness or rash);
- Open wounds, a recent skin graft, massive edema or extreme deformity of the affected area;

* Neuropathy (peripheral nerve damage);

* Extremely insensitive to pain;

* Where increased blood circulation is undesirable;

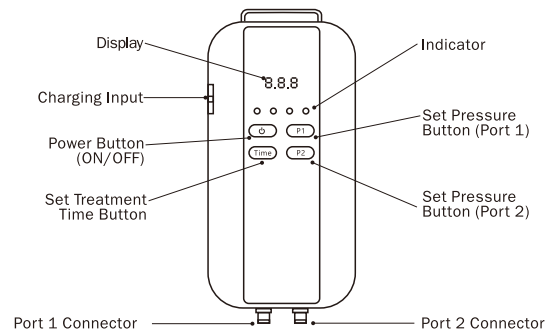
* Those with significant vascular impairment in the affected area such as prior frostbite, diabetes and ischemia (deficient supply of blood to a body part);

* Those with blood related disease condition which affect thrombosis: such as paroxysmal cold hemoglobinuria (blood disorder after cold exposure), cryoglobulinemia (abnormal blood proteins in cold temperature), sickle-cell disease (a group of inherited health conditions that affect the red blood cells) and serum cold agglutinins (red blood cells to clump together at low temperatures).

Product Introduction

The Cold Compression Wrap Pro consists of a main unit and cold wraps. Main unit inflates the wrap to a specified pressure of 20 mmHg, 40 mmHg, 60 mmHg, 80 mmHg or 100 mmHg (set by the user), and once the pressure reached the targeted level, it will hold for 5 seconds before releasing, then decompresses and the air pressure drops. The cycle begins again. Default working time is 30 minutes;

The cold wrap is expected for 30 minutes' cold therapy per use, the gel cold pack should be removed from the wrap after 30 minutes if continued use of the pressure function of the wraps is desired.



Performance Characteristics

Model	A02-C-006
Adaptor Input	100-240V~50/60Hz
Adaptor Output	12V 2A
Compression Range	20 mmHg, 40 mmHg, 60 mmHg, 80 mmHg, 100 mmHg(±15mmHg)
Treatment Time	10 min, 20 min, 30 min, 40 min, 50 min, 60 min, 70 min, 80 min, 90 min, 100 min, 110 min, 120 min
Dimension	190*90*33 mm
Net Weight	300 g
Noise Level	≤ 55 dB

NOTE:

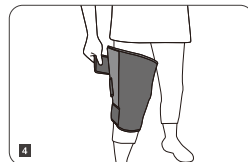
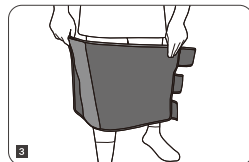
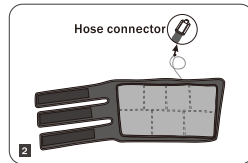
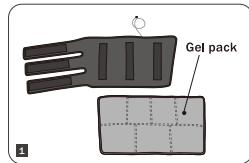
- Default time setting is 30 minutes.
- Anti kink Luer connector is used for quick connection/disconnection and avoid kinked tube.

How To Use

If you want compression treatment with cold therapy, follow steps 1.1 and 1.2 to prepare the gel pack; For compression therapy alone, start from step 1.3.

1. Prepare Wrap (Low limbs (Calf and upper leg) as example)

- 1.1 Freeze the gel pack for around 6 hours in a freezer or a refrigerator (temperature: $-18^{\circ}\text{C} \pm 2^{\circ}\text{C}$).
- 1.2 Place the external wrap flat with Velcro facing up, attach gel pack to wrap, see Pic 1 & 2 below.
- 1.3 Secure wrap on the low limbs (Calf and upper leg), adjust to snug fit through Velcro and straps, Pic 3 & 4.



Note:

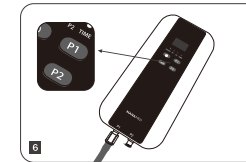
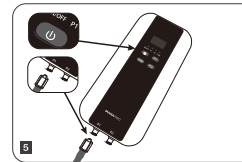
Do not use the cold wrap on exposed skin, a cloth barrier/ clothing should be used under the wraps (regardless of whether the gel pack is used) to prevent skin contact with all components of the device.

The gel cold pack should never be used beyond 30 minutes and that gel cold pack should always be worn with 1-2 layers of clothing to provide a protective barrier between the gel cold pack and the skin.

For replacement gel pack, please contact the after-sale service.

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- 1.4 Connect the air hose of wrap to main unit, Pic 5.



2. Operate the device

- 2.1 Connect adaptor to main unit and plug into an outlet, long press the Power Button to turn the device on.
- 2.2 Press the P1/P2 button (according to P1/P2 port where wrap is connecting with) to set the pressure.

Three seconds afterwards without further action, it starts working, pressure can be adjusted during operation.

3. Press the TIME button to switch the interface to set working time, it starts working after 3 seconds.

The default time is 30 minutes, if you do not set the time, it will automatically shut down after 30 minutes working.

4. After using, long press the Power button to turn it off.

Notice:

1. When main unit is working, the pressure displayed is a real-time value.
2. When using, ensure the wrap is properly connected to main unit port P1/P2; If targeted pressure level is not reached in several minutes, the main unit prompts and corresponding port indicator flashes. Main unit will stop working and please check if wrap is properly connected or if the wrap is leaking.

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Battery Instructions

The main unit can be battery powered with two pieces of flat top 18650 lithium batteries.

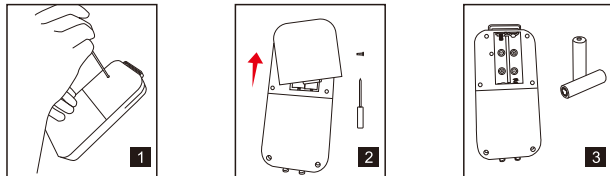
Battery capacity: 1800 mAh ~ 2600 mAh;

Battery size: length 65~69.5 mm * diameter 18~18.6 mm

How to install and replace battery:

1. Use the screwdriver provided to loosen the screw holding the upper battery cover of main unit, pic 1.

2. Remove the screw and push the battery cover upwards to open, pic 2 & 3.

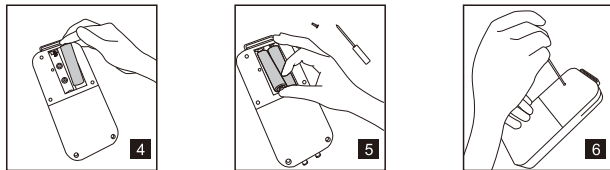


3. Place batteries in, connect battery terminals correctly according to the symbol “+” and “-” marked inside the slot, pic 4 & 5.

Note: Use protected 18650 battery only.

4. Install battery cover and the screw back, use screwdriver to tighten it, pic 6.

Note: Main unit can be used while the battery is charging.



WARNING & CAUTION

1. Do not open or remove main unit covers personally.
2. If pulsations, numbness or throbbing occur, the wrap may be wrapped too tightly. Loosen immediately.
3. Stop using device if swelling occurs and consult your doctor.
4. Ensure the main unit is turned off and unplugged from the wall outlet prior to and while cleaning.
5. Device should not be used in the presence of any flammable, anesthetic mixture with oxygen or nitrous oxide.
6. Stay away from water, do not immerse the product in any liquid for any reason.
7. Do not operate device in a wet environment.
8. Avoid the main unit from extreme shocks, such as dropping.
9. Contains no user serviceable parts.
10. The product is used with the AC adaptor plugged into an outlet; For use with battery power, please refer to section Battery Instructions to install batteries.
11. Product is shipped out without battery, please choose protected 18650 batteries (with protection circuit) for installation.
12. Do not use the wrap on exposed skin, a layer of clothing is required.
13. The device is intended for use by adults (age \geq 22 years).

/ Main Materials

Main Unit: Acrylonitrile Butadiene Styrene

Wrap: Polyvinyl chloride and nylon composite

Gel pack: Polyvinyl chloride and nylon composite, the gel is made from Glycerin, resin and water.

Connecting tube: Polyvinyl chloride

/ Environment Requirements

Operating:

Temperature: 5 °C ~ 40 °C (41 °F ~ 104 °F)

Relative humidity: 10% ~ 90%

Atmospheric pressure: 700 ~ 1060hpa

Transport & Storage:

Temperature: -25 °C ~ 55 °C (-13 °F ~ 131 °F)

Relative humidity: 10% ~ 90%

Atmospheric pressure: 700 ~ 1060hpa

/ Expected Service Life (Shelf-life + Use life)

Shelf-life

The shelf-life is not applicable to the main unit because of the low likelihood of time-dependent product degradation.

Shelf life of Wrap is defined as one year.

Use life

Main unit 1000 hours, Wrap 250 hours

Software Version

KRP_A02-C-006-A-V2

/ Cleaning

Caution: Main unit must be turned off and disconnected from power mains (wall outlet) prior to cleaning.

Caution: No modification of this equipment is allowed.

* Use soft cloth or towel to wipe to clean.

Troubleshooting

Problem	Description	Solutions
Missing Accessory	When receiving the device, certain accessory such as adaptor or cold wrap is found missing.	Contact dealer (or manufacturer) to ship the missing item.
Damage to main unit shell	Collision, falling or rough handling beyond fatigue limit may cause damage to main unit.	Return it for repairer exchange.
Can not turn it on	Battery has installed, but no response to button pressing.	Check if the battery positive and negative is correctly installed.
	Adaptor has plugged in, but no response to button pressing.	Check if the connection to power outlet is firm. Check if the DC plug is properly connected to main unit.
No pressure when working	Can not feel wrap pressure.	Check if the hose is folded. Check if the joint part between wrap and hose is kinked.
Button not responding	No response to button pressing or button stocks.	Check if there is any obstacle at button area, clear it.
Buzzer beeping, "OP1" or "OP2" on display	P1 port is not connected to wrap or wrap air pressure is abnormal.	Check if wrap, hose or connector is loose or damaged; replace the abnormal wrap and continue using.
	"OP2" means P2 port is not connected to wrap or wrap air pressure is abnormal.	Check if wrap, hose or connector is loose or damaged; replace the abnormal wrap and continue using.
Short battery hours	Battery capacity is small. Voltage of 2 batteries differs.	Replace it with battery bigger than 2000 mAh capacity. Replace it with a new battery.

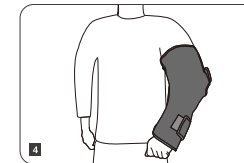
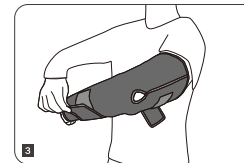
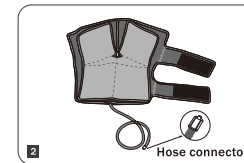
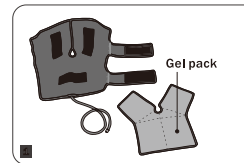
Standards Compliance

This device adheres to the following standards: IEC 60601-1 ANSI AAMI ES60601-1; IEC 60601-1-2; AAMI/IEC 60601-1-2;

Wear Instructions for Available Wraps

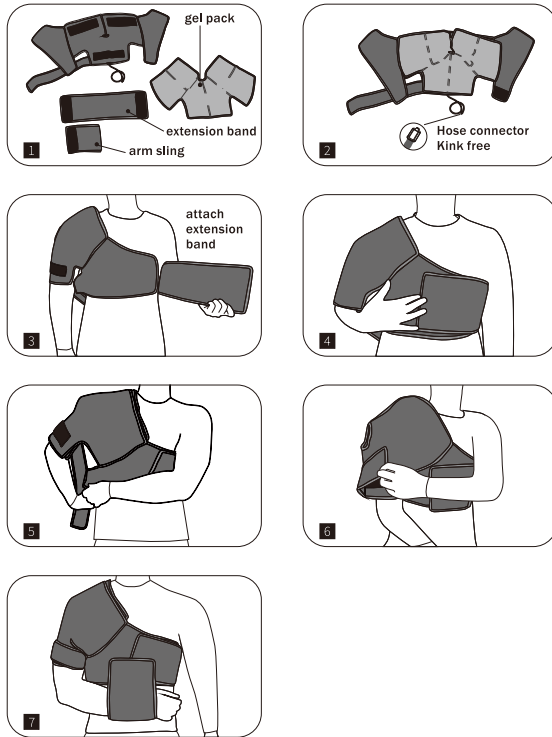
Note: Do not use the cold wrap on exposed skin, a cloth barrier/ clothing should be used under the wraps (regardless of whether the gel pack is used) to prevent skin contact with all components of the device.

Elbow/arm Wrap:



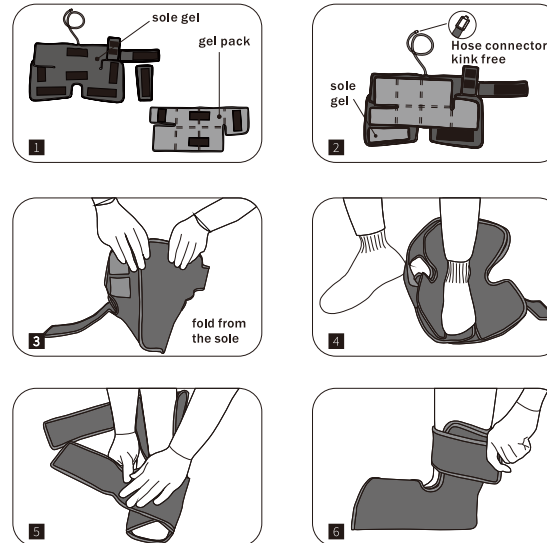
Shoulder Wrap:

Extension band: attach it to the back, go through the armpit to the chest and stick (P3-P4).
Arm sling: hang the forearm to avoid unnecessary movement (P7).



Ankle/foot Wrap:

Sole gel: an independent piece of gel pack for sole cold therapy. Attach it to the external wrap (P2).



Electromagnetic Compatibility Information

The device satisfies the EMC requirements of the international standard IEC 60601-1-2. The requirements are satisfied under the conditions described in the table below. The device is an electrical medical product and is subject to special

Precautionary measures with regard to EMC which must be published in the instructions for use.

Table1 for Emissions

GUIDANCE AND MANUFACTURER'S DECLARATION ELECTROMAGNETIC EMISSIONS		
The product is intended for use in the electromagnetic environment specified below, the customer or the user of the product should assure that it is used in such an environment.		
EMISSIONS TEST	COMPLIANCE	ELECTROMAGNETIC ENVIRONMENT - GUIDANCE
Terminal disturbance voltage RF emissions CISPR11	Group 1	The product is only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
Radiation disturbance RF emissions CISPR11	Class B	The product is suitable for use in all establishments including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purpose.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

Table2 for RF Immunity


RECOMMENDED SEPARATION DISTANCES BETWEEN PORTABLE AND MOBILE RF COMMUNICATIONS EQUIPMENT AND THE PRODUCT			
The product is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the product can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the product as recommended below, according to the maximum output power of the communications equipment.			
RATED MAXIMUM OUTPUT POWER OF TRANSMITTER W	SEPARATION DISTANCE ACCORDING TO FREQUENCY OF TRANSMITTER		
	150 kHz to 80 MHz $d = 1.2 \sqrt{P}$	80 MHz to 800 MHz $d = 1.2 \sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

Table3 for Electromagnetic Immunity


GUIDANCE AND MANUFACTURER'S DECLARATION ELECTROMAGNETIC IMMUNITY			
The product is intended for use in the electromagnetic environment specified below. The customer or the user of the product should assure that it is used in such an environment.			
IMMUNITY TEST	IEC 60601 TEST LEVEL	COMPLIANCE LEVEL	ELECTROMAGNETIC ENVIRONMENT - GUIDANCE
Electrostatic discharge(ESD) IEC 61000-4-2	± 8kV contact ±2, 4, 8, 15 kV air	± 8kV contact ± 2, 4, 8, 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative Humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2kV for Power supply lines	± 2kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 0.5, 1kV line(s) to line(s)	± 0.5, 1kV line(s) to line(s)	Mains power quality should be that of a typical commercial or hospital environment.

Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 300 cycles	<5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the product requires continued operation during power mains interruptions, it is commended that the product be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Proximity fields from RF wireless communications equipment IEC 61000-4-3	Complies	Complies	/
NOTE: UT is the AC mains voltage prior to application of the test level.			

Table4 for RF Electromagnetic Immunity

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY			
The product is intended for use in the electromagnetic environment specified below. The customer or the user of the product should assure that it is used in such an environment.			
IMMUNITY TEST	IEC 60601 TEST LEVEL	COMPLIANCE LEVEL	ELECTROMAGNETIC ENVIRONMENT- GUIDANCE
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the product, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2 \sqrt{P}$ $d = 1.2 \sqrt{P}$ $d = 2.3 \sqrt{P}$ 800 MHz to 2.7 GHz where P is the maximum output Power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 
	6Vrms 150 kHz to 80 MHz ISM frequency band	6Vrms	
Radiated RF IEC 61000-4-3	80 MHz to 2.7GHz	10 V/m	
NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2: These guide lines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

Symbol Index


 **Caution**
Indicates that important cautionary information, such as warnings and precautions, cannot be presented on the medical device itself and are Presented in the instructions for use.

 Refer to instruction manual  Type BF applied part


 Unique Device Identifier, Indicates a carrier that contains Unique Device Identifier information


 Manufacturer  Date of manufacturer



 Batch code  Serial number

 For indoor use only  Direct current


IP21 Ingress Protection Marking of IP21: Protected from touch by hands greater than 12 millimeters, Protected from condensation.

 Unique Device Identifier. Indicates a carrier that contains Unique Device Identifier information.

 MR Unsafe; The item should not enter the MR scanner room, patients with MR unsafe devices should not be scanned.

 Disposal of product according to local regulations.  This side up

 Keep Dry  Fragile

 Maximum number of packages that may be stacked

/ Disposal

Do not discard the product in regular waste; The device and packaging must be disposed of in accordance with respective local or national environmental regulations.

/ Warranty Information

We warrant that the product, if properly used, will be free from defects in materials or workmanship for a limited period, main unit is warranted for one (1) year and wrap 6 months after the date of original purchase.

If the product, which is the subject of this Limited Warranty, malfunctions during the warranty period for reasons covered by this Limited Warranty, we, at our options, may elect to replace or repair the returned product with either a new or reconditioned product. This limited warranty exists only to the original purchaser of the product and are non-transferable.

The limited warranty does not cover damages due to external causes, including, without limitation, accident, usage not in accordance with product instructions, misuse, neglect, alteration, normal wear and tear or unauthorized repairs.

/ Warranty Registration Card

Please fill out and return upon purchase of the product.

Your Name: _____

Phone No.: _____

Email Address: _____

Company or Organization: _____

Purchase From: _____

Purchase date: _____

Model No.: _____

Series No.: _____

MedWatch is the Food and Drug Administration's (FDA) program for reporting serious reactions, product quality problems, therapeutic inequivalence/failure, and product use errors with human medical products, including drugs, biologic products, medical devices, dietary supplements, infant formula, and cosmetics.

If you think you or someone in your family has experienced a serious reaction to a medical product, you are encouraged to take the reporting form to your doctor. Your health care provider can provide clinical information based on your medical record that can help FDA evaluate your report.

However, we understand that for a variety of reasons, you may not wish to have the form filled out by your health care provider, or your health care provider may choose not to complete the form. Your health care provider is not required to report to the FDA. In these situations, you may complete the Online Reporting Form yourself.

You will receive an acknowledgement from FDA when your report is received. Reports are reviewed by FDA staff. You will be personally contacted only if we need additional information.

Submitting Adverse Event Reports to FDA

Use one of the methods below to submit voluntary adverse event reports to the FDA:

Report Online at

www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home

Consumer Reporting Form FDA 3500B. Follow the instructions on the form to either fax or mail it in for submission. For help filling out the form, see MedWatchLearn. The form is available at

www.fda.gov/downloads/aboutFDA/reportsmanualsforms/forms/ucm349464.pdf

Call FDA at 1-800-FDA-1088 to report by telephone.

Reporting Form FDA 3500 commonly used by health professionals.

The form is available at

www.fda.gov/downloads/aboutFDA/reportmanualsforms/forms/ucm163919.pdf