



GentleSharp™ Operator's Manual

Pre-Clinical Blood Sampling Tool

- + Read the entire Operator's Manual before using GentleSharp Model 101. Disregarding the cautions and instructions presented in this manual constitutes abnormal use and can result in injury.
- + For use with the GentleSharp Model 101 Control Box.

EC REP

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GentleSharp.com

Pat. actuatedmedical.com/ip



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Keep this Manual in a safe location for future reference.



Operator Assistance Information

If you have questions regarding the use of GentleSharp, please contact:

Customer Service Department at Actuated Medical, Inc.

310 Rolling Ridge Drive, Bellefonte, PA 16823

Phone +1 (814) 355-0003 ext. 117 / Fax +1 (814) 355-1532

Monday through Friday

8:00 am - 5:00 pm U.S.A. Eastern Standard Time

Training Materials

Training materials are accessible on our website at GentleSharp.com.

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1.0 Intended Use

GentleSharp should only be used by individuals qualified per their facility's policies and protocols to perform blood sampling in Rodents (i.e., Qualified Personnel).

GentleSharp is a device for assisting Qualified Personnel in performing vascular puncture for the purpose of obtaining blood samples in Rodents.

GentleSharp consists of a Handpiece connected to a Control Box. GentleSharp is compatible with standard Luer Lock or Luer Slip Sharps (i.e., needles or lancets) sold separately.



1.1) Indications for Use

GentleSharp Model 101 is intended for use only and solely in the process of assisting Qualified Personnel in performing vascular puncture for the purpose of obtaining blood samples in Rodents.

1.2) Contraindications


Do NOT use GentleSharp Model 101 if:

- + You are accessing or collecting blood from a human.
- + You are not qualified to perform blood sampling in Rodents.
- + The Rodent is showing signs of illness or injury.
- + The site you desire to sample blood contains abnormalities.
- + You are collecting blood via retro-orbital bleed.

	Attention, read instructions before use.
	Do NOT operate in the presence of flammable anesthetics. (<i>Flammable anesthetics are gases or vapors, including, but not limited to, fluroxene, ethyl chloride, ethyl ether and ethylene, which may form flammable or explosive mixtures with air, oxygen or reducing gases such as nitrous oxide.</i>)

2.0 Cautions

Read the entire Operator's Manual before using GentleSharp. Disregarding the cautions and instructions presented in this manual constitutes ABNORMAL USE and can result in injury.

 Handpiece temperature increases during activation. Continuous use longer than 20 minutes may cause discomfort.

Sharps are sold separately. **Make certain that the correct size Sharp is selected for the Rodent and sampling site according to your facility's policies and protocols.**

- + Use a new Sharp for each Rodent or when Sharp sterility is uncertain.



Ensure that the GentleSharp Control Box is securely placed on a level surface to reduce the risk of the Control Box falling.



Ensure that the Handpiece is placed on a level surface and the Connection Cable is not twisted before and after use to reduce the risk of the Handpiece falling.



Ensure that the Handpiece is stopped before and after use to reduce the risk of the Handpiece falling off the surface (such as a table) due to vibration.



Do NOT re-cap the Sharp. Remove and dispose of the Sharp according to your facility's policies and protocols.



No modification of this equipment is allowed.



Rodents may show signs of discomfort during any blood sampling procedure.



GentleSharp contains magnets inside the Handpiece. **Do NOT** place the Handpiece within 15 cm (6 in) of pacemakers, defibrillator, and other electronic devices (*including, but not limited to, credit cards, video tapes, televisions, computer monitors, and other CRT displays*) because the magnets may interfere with the operation of those devices.

3.0 Operator Profile

GentleSharp is intended for use by Qualified Personnel trained by their facility's policies and protocols to perform blood sampling in Rodents. Read the Operator's Manual completely for training on GentleSharp.

For more information, contact Actuated Medical's Customer Service Department at **+1 (814) 355-0003 ext. 117** or visit the website **GentleSharp.com**.

4.0 Device Description

GentleSharp is a device for assisting Qualified Personnel in performing vascular puncture for the purpose of obtaining blood samples in Rodents.

GentleSharp consists of a reusable Handpiece connected to a reusable Control Box.

GentleSharp is designed to connect to a disposable Sharp prior to accessing the Rodent's vascular system and to disconnect from a Sharp after completing the blood sampling procedure.

GentleSharp is designed only to be used in the act of puncturing the vessel; a container, such as a capillary tube, should be used in conjunction with GentleSharp to collect the blood from the puncture site (see Fig. 1).

FIGURE 1: Illustration of Rodent Tail Blood Collection Procedure with GentleSharp.



FIGURE 2: Illustration of GentleSharp with Labeled Components.

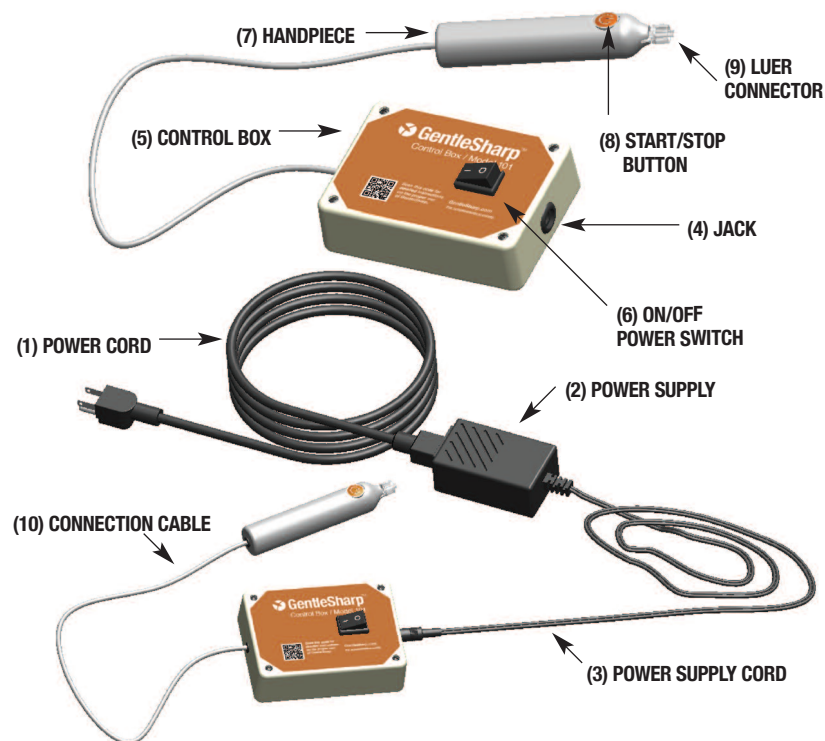


TABLE 1: GentleSharp Component List.

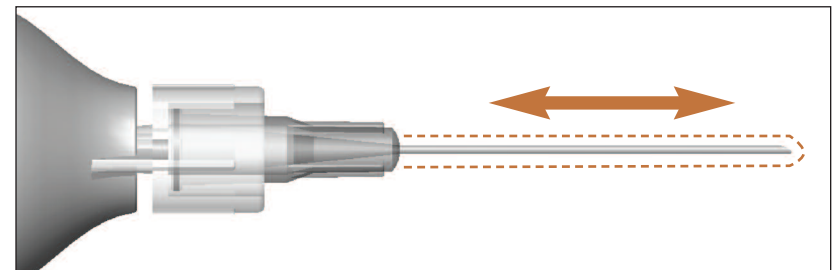
Item No.	Name	Description
1	Power Cord	Plugs into a standard outlet and into the Power Supply (2).
2	Power Supply	Reduces Voltage to the Control Box (5).
3	Power Supply Cord	Attached to the Power Supply (2) and plugs into the Jack (4) on the Control Box (5).
4	Jack	Connector for Power Supply Cord (3).
5	Control Box	Contains the Drive Electronics.
6	On/Off Power Switch	Allows power to the Control Box (5).
7	Handpiece	Contains the Motor.
8	Start/Stop Button	Initiates/terminates power to the Handpiece (7).
9	Luer Connector	Allows standard Luer Lock or Luer Slip Sharp to connect to GentleSharp.
10	Connection Cable	Connects the Handpiece (7) and the Control Box (5).

GentleSharp consists of a Handpiece and a Control Box and is powered by an external Power Supply (see Fig. 2).

The Control Box (5) includes a Jack (4) to plug the Power Supply (2) into, and an On/Off Power Switch (6). The Control Box (5) contains the Drive Electronics which power the Handpiece (7) when it is triggered by the Start/Stop Button (8) on the Handpiece (7).

The Handpiece (7) includes a male Luer Connector (9) which accepts a standard Luer Lock or Luer Slip Sharp. The Sharp attached to the Handpiece (7) moves quickly backward and forward when triggered by pressing the Start/Stop Button (8). The Luer Connector (9) moves the Sharp approximately 0.05 cm (0.02 in) (see Fig. 3).











FIGURE 3: Illustration of Sharp Movement.



This backward and forward movement of the Sharp allows the Sharp tip to penetrate through the skin and into the vessel with less force and trauma to the puncture site.

GentleSharp is externally powered. A Power Cord (1) and a Power Supply (2) are included with GentleSharp. The Power Cord (1) plugs into a standard wall outlet.

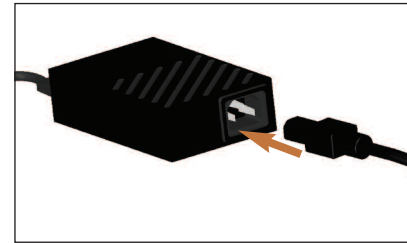
TABLE 2: Symbols on Device and/or Packaging.

Symbol	Meaning	Symbol	Meaning
	Product conforms with the essential requirements of the applicable EC directives.		Read the documentation
	Not made with natural rubber latex.	IPX4	Ingress Protection Rating. Solid particle protection not tested. Liquid ingress protection against splashing water.
	Temperature Limitations		Type BF Applied Part
NON-STERILE	Non-sterile		Direct Current
	Batch		Manufactured date
	Caution		Manufacturer

5.0 Set-up Instructions

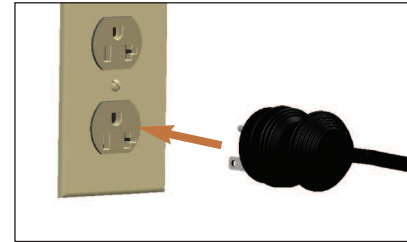
- 5.1) When using GentleSharp, it is recommended that the Operator wears protective gown, gloves, eye protection, and any other personal protective equipment required by your facility's policies.
- 5.2) Place the Control Box on a level surface (such as a table) to reduce the risk of the Control Box falling.
- 5.3) While Setting up, place Handpiece on a level surface to reduce the risk of the Handpiece falling off of the surface.

5.4)



Verify that the Power Cord is securely plugged into the Power Supply.

5.5)



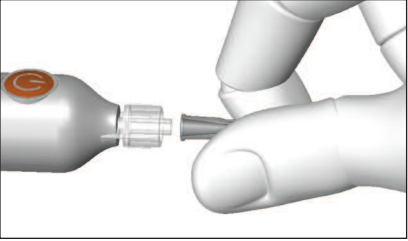
Plug the Power Cord into a standard 100 - 240 V @ 50/60 Hz outlet.

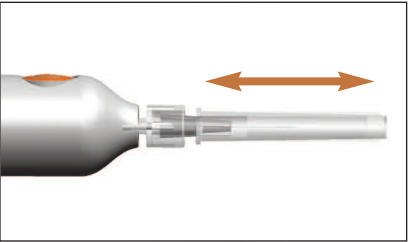
5.6)



Plug the Power Supply into the Jack on the Control Box.

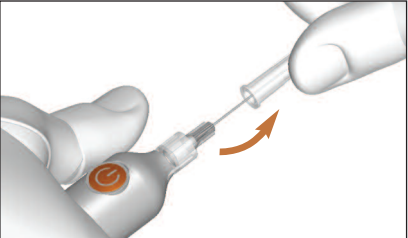
- 5.7) Verify the Control Box is operational by pushing the On/Off Power Switch to the 'ON' position. The Control Box will produce an audible tone when powered 'ON'. **NOTE: GentleSharp will not start at this time. The Start/Stop Button on Handpiece must be pressed down before GentleSharp will operate.**

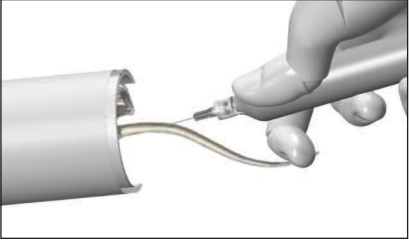
5.8)  Attach a standard Luer Lock or Luer Slip Sharp to the Luer Connector on the Handpiece. **NOTE: It is recommended that the Sharp stays capped until it is connected to the Luer Connector and ready to use.**

5.9)  Before use, verify Handpiece vibration by firmly pressing the Start/Stop Button on the Handpiece. The Handpiece will produce an audible tone when the Handpiece is started and a *slight vibration will be felt in your hand*. Once vibration of Handpiece is verified, Stop the vibration until you are ready to begin blood sampling. **NOTE: Follow your facility's policies and protocols for Sharp handling and recapping.**

6.0 Operating Instructions

- 6.1) Read the Operator's Manual before operating GentleSharp.
- 6.2) Set-up GentleSharp and attach a Sharp as directed in Step 5.8.
- 6.3) Loosen, but do **NOT** completely remove the cap on the Sharp. Do **NOT** press the Start/Stop Button on the Handpiece until Step 6.6.
- 6.4) Secure the Rodent according to your facility's policies and protocols for anatomical site blood sampling.

6.5)  Remove cap from Sharp.

6.6)  Turn the Handpiece until the Bevel is in the desired orientation. Start GentleSharp vibration by pressing the Start/Stop Button, see Step 5.9, and insert the Sharp into the puncture site. **NOTE: Firmly press the Start/Stop Button on the Handpiece to Start GentleSharp. The Handpiece will produce an audible tone when the Handpiece is started and a slight vibration will be felt in your hand.**

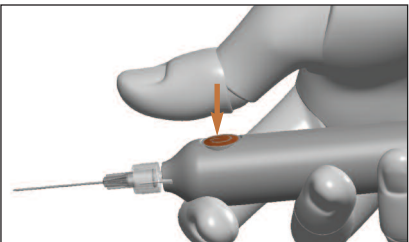
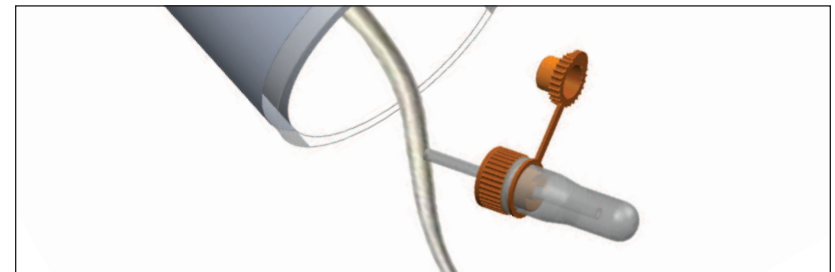

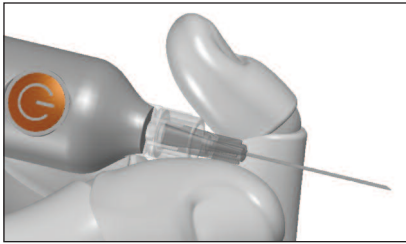
6.7)  After puncturing the vessel, press the Start/Stop Button on Handpiece again to Stop GentleSharp. Set Handpiece on a level surface. Collect your blood sample (see Fig. 4).

FIGURE 4: Blood Collection with a Capillary Tube (sold separately).



6.8)  If your blood sample volume is not sufficient repeat Steps 6.6 - 6.8. **NOTE: Follow your facility's policies and procedures for Sharp handling and recapping.**

6.9)



After sufficient blood collection, remove the Sharp from the Handpiece.

NOTE: It is recommended that you remove the Sharp from the Luer Connector, keeping your hand away from the tip of the Sharp.

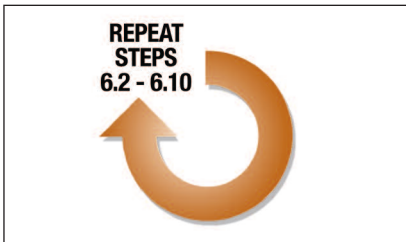
It is also recommended that you never recap the Sharp.

6.10)



Dispose of used Sharps according to your facility's policies and protocols and applicable government regulations.

6.11)



Repeat Steps 6.2 - 6.10 as needed to continue blood sampling from Rodents.

7.0 GentleSharp Cleaning Instructions

- 7.1) Turn 'OFF' and unplug GentleSharp prior to cleaning.
- 7.2) With no Sharp attached, thoroughly clean GentleSharp after each use. Do **NOT** submerge GentleSharp in liquid.
- 7.3) Clean GentleSharp by wiping all exterior surfaces with (a) a cloth dampened with isopropyl alcohol or with (b) disinfectant wipes.

8.0 Maintenance

Other than careful cleaning of GentleSharp after each use, GentleSharp does not require maintenance.

9.0 Storage

Store GentleSharp in a clean, dry area. It is recommended that GentleSharp be stored at temperatures between -20°C (-4°F) and 60°C (140°F) and relative humidity between 25% and 80%. Do **NOT** exceed temperatures below -20°C (-4°F) or above 60°C (140°F) or relative humidity of 25% and 80%.

10.0 Return Policy

Actuated Medical takes pride in the quality of our product. If the device is found to be defective, contact our Customer Service Department at **+1 (814) 355-0003 ext. 117** for prompt replacement. You will be provided with a Return Authorization (RA) number and return shipping information. All returns must be accompanied by an RA number and reason(s) for return.

11.0 Disposal

Follow local governing ordinances and recycling plans regarding disposal or recycling of medical device components. Prior to the disposal of your device, any possible risk of infection from blood borne pathogens must also be eliminated by appropriate disinfection.

12.0 Troubleshooting Guide

Issue	Solution Options
If the Sharp is not moving after Start/Stop Button is pressed.	<p>The Sharp may not be attached correctly to the Luer Connector.</p> <p>The Power Cord may not be securely plugged in to the Control Box. Turn the On/Off Power Switch 'ON' then 'OFF' (i.e., cycle the power). If GentleSharp still does not turn 'ON', then contact Actuated Medical's Customer Service Department for instructions.</p> <p>The Start/Stop Button may not have been pressed firmly. Press the Start/Stop Button firmly, listen for an audible tone and slight vibration felt in your hand. If GentleSharp does not start then contact Actuated Medical's Customer Service Department for instructions.</p>

13.0 Technical Data

13.1) Environmental Conditions that Affect Use

Operating conditions: From 0°C (32°F) to 35°C (95°F).

Relative humidity from 25% to 80%. Altitude range \leq 2,000 m.



Transport and storage conditions: From -20°C (-4°F) to 60°C (140°F). Relative humidity from 25% to 80%.

13.2) Classification - GentleSharp is:

WARNING: To avoid risk of electric shock, this equipment must only be connected to a supply mains with protective earth.

- + Isolated through means of double insulation.
- + An externally-powered device.
- + Non-sterile.
- + **NOT** suitable for use in the presence of flammable anesthetics.
- + **NOT** suitable for continuous operation.

13.3) Thermal

The maximum steady state surface temperature of the GentleSharp Handpiece is approximately 43°C (109.4°F). This temperature will only be reached if the Handpiece is left continuously activated for longer than 50 minutes. A temperature of 41°C (105.8°F) is reached after 20 minutes of continuous activation. See 2.0 Cautions.

13.4) Accessories

- + Power Cord – Hospital Grade (US), Shielded, IEC 320 Connector, RoHS Compliant.
- + Power Supply (Transformer) – Input: 100 - 240 V, 50/60 Hz, Output: 9 VDC, up to 2.2 A, 3-pin IEC 320 Inlet, RoHS Compliant.



Use of Power Supplies and Power Cords other than those specified in **Section 13.4** may result in improper functioning of GentleSharp.

13.5) Electromagnetic Emissions / Immunity

Guidance regarding electromagnetic emissions and electromagnetic immunity is presented in **Table 3**, **Table 4**, **Table 5** and **Table 6**.

TABLE 3: Guidance & Manufacturer's Declaration – Electromagnetic Emissions.

Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF emissions CISPR 11 EN55011	Group 1	GentleSharp Model 101 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11 EN55011	Class B	GentleSharp Model 101 is suitable for use in all establishments, including domestic, and those directly connected to the public low-voltage power supply network that supplies buildings for domestic purposes.
Harmonic emissions IEC/EN 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Compliant	

The GentleSharp Model 101 is intended for use in the electromagnetic environment specified above. The customer or user of the GentleSharp Model 101 should ensure that it is used in such an environment.

TABLE 4: Guidance & Manufacturer's Declaration – Electromagnetic Immunity.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic Environment - Guidance
Electrostatic discharge (ESD) EN/IEC 61000-4-2	± 6kV contact +6kV/-4kV VCP contact +6kV/-1.5kV HCP contact ± 8kV air	± 6kV contact +6kV/-4kV VCP contact +6kV/-1.5kV HCP contact ± 8kV 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 EN/IEC 61000-4-4	± 2kV Mains ± 1kV I/Os	± 2kV Mains ± 1kV I/Os	Mains power quality should be that of a typical commercial or hospital environment.
Surge EN/IEC 61000-4-5	± 1kV differential ± 2kV common	± 1kV differential ± 2kV common	Mains power quality should be that of a typical commercial or hospital environment.
Voltage Dips/Dropout EN/IEC 61000-4-11	>95% dip for 0.5 cycle 60% dip for 5 cycles 30% dip for 25 cycles >95% dip for 5 Seconds	100% dip for 0.5 cycle 60% dip for 5 cycles 30% dip for 25 cycles 100% dip for 5 Seconds	Mains power quality should be that of a typical commercial or hospital environment. If the Operator of GentleSharp Model 101 requires continued operation during power mains interruptions, it is recommended that GentleSharp Model 101 be powered from an uninterruptible power supply or battery.
Power frequency (50/60 Hz) Magnetic Field EN/IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

The GentleSharp Model 101 is intended for use in the electromagnetic environment specified above. The customer or user of the GentleSharp Model 101 should ensure that it is used in such an environment.

TABLE 5: Guidance & Manufacturer's Declaration – Immunity Equipment and Systems that are NOT Life-Supporting.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic Environment - Guidance
Conducted RF EN/IEC 61000-4-6	3 Vms 150 kHz - 80 MHz	(V1) = 3 Vms	Portable and mobile communications equipment should be separated from GentleSharp Model 101 by no less than the distances calculated / listed below: $D = (3.5/V1)(\text{Sqrt } P)$ 150 kHz - 80 MHz
Radiated RF EN/IEC 61000-4-3	3 V/m 80 MHz - 2.5 GHz	(E1) = 3 V/m	$D = (3.5/E1)(\text{Sqrt } P)$ 80 - 800 MHz $D = (7/E1)(\text{Sqrt } P)$ 800 MHz - 2.5 GHz Where P is the max power in watts and D is the recommended separation distance in meters. Field strengths from fixed transmitters, as determined by an electromagnetic site survey, should be less than the compliance levels (V1 and E1). Interference may occur in the vicinity of equipment containing a transmitter.

The GentleSharp Model 101 is intended for use in the electromagnetic environment specified above. The customer or user of the GentleSharp Model 101 should ensure that it is used in such an environment.

TABLE 6: Recommended Separation Distances for GentleSharp Model 101.

Max Output Power (Watts)	Separation (m) 150 kHz - 80 MHz $D=(3.5/\sqrt{P})(\sqrt{P})$	Separation (m) 80 MHz - 800 MHz $D=(3.5/\sqrt{P})(\sqrt{P})$	Separation (m) 800 MHz - 2.5 GHz $D=(7/\sqrt{P})(\sqrt{P})$
0.01	0.11667	0.11667	0.23333
0.1	0.36894	0.36894	0.73785
1	1.1667	1.1667	2.3333
10	3.6894	3.6894	7.3785
100	11.667	11.667	23.333

The GentleSharp Model 101 is intended for use in the electromagnetic environment in which radiated disturbances are controlled. The customer or user of the GentleSharp Model 101 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF Communications Equipment and the GentleSharp Model 101 as recommended above, according to the maximum output power of the communications equipment.

14.0 Limited Warranty

Actuated Medical, Inc. (“Manufacturer”) makes certain limited warranties set forth in this Limited Warranty regarding the following products (the “Products” and each a “Product”): **GentleSharp Model 101**

Manufacturer warrants to the purchaser of the Products (“Customer”) that the Products will be free from defects in material and workmanship per AMI Product specifications for a period of 13 months from the date of purchase (the “Warranty Period”). The foregoing limited warranties are solely to and for the Customer’s benefit.

Limited Warranties do not apply where any Product (a) has been subjected to abuse, misuse, neglect, negligence, accident, improper testing, improper installation, improper storage, improper handling, abnormal physical stress, abnormal environmental conditions or use contrary to any instructions issued by Manufacturer; or (b) has been reconstructed, repaired or altered by persons other than Manufacturer or its authorized representative.

During the Warranty Period, regarding any defective Product deemed defective by the Manufacturer, Manufacturer’s liability under any Limited Warranty is discharged, in Manufacturer’s sole discretion and at its expense, by (i) repairing or replacing the defective Product; or (ii) crediting or refunding the price of the defective Product, less any applicable discounts, rebates or credits.

All claims for breach of a Limited Warranty must be received by Manufacturer no later than fifteen (15) calendar days after the expiration of the Warranty Period.

THIS LIMITED WARRANTY SETS FORTH CUSTOMER’S SOLE REMEDY AND MANUFACTURER’S ENTIRE LIABILITY FOR ANY BREACH OF ANY WARRANTY RELATING TO THE PRODUCTS. EXCEPT FOR THE EXPRESS LIMITED WARRANTIES DESCRIBED IN THIS LIMITED WARRANTY, NEITHER MANUFACTURER NOR ANY PERSON ON MANUFACTURER’S BEHALF HAS MADE OR MAKES ANY EXPRESS OR IMPLIED REPRESENTATION OR WARRANTY WHATSOEVER, INCLUDING ANY WARRANTIES OF: (i) MERCHANTABILITY; (ii) FITNESS FOR A PARTICULAR PURPOSE; (iii) TITLE; (iv) NON-INFRINGEMENT; OR (v) PERFORMANCE OF PRODUCTS TO STANDARDS SPECIFIC TO THE COUNTRY OF IMPORT, WHETHER ARISING BY LAW, COURSE OF DEALING, COURSE OF PERFORMANCE, USAGE OF TRADE OR OTHERWISE, ALL OF WHICH ARE EXPRESSLY DISCLAIMED.