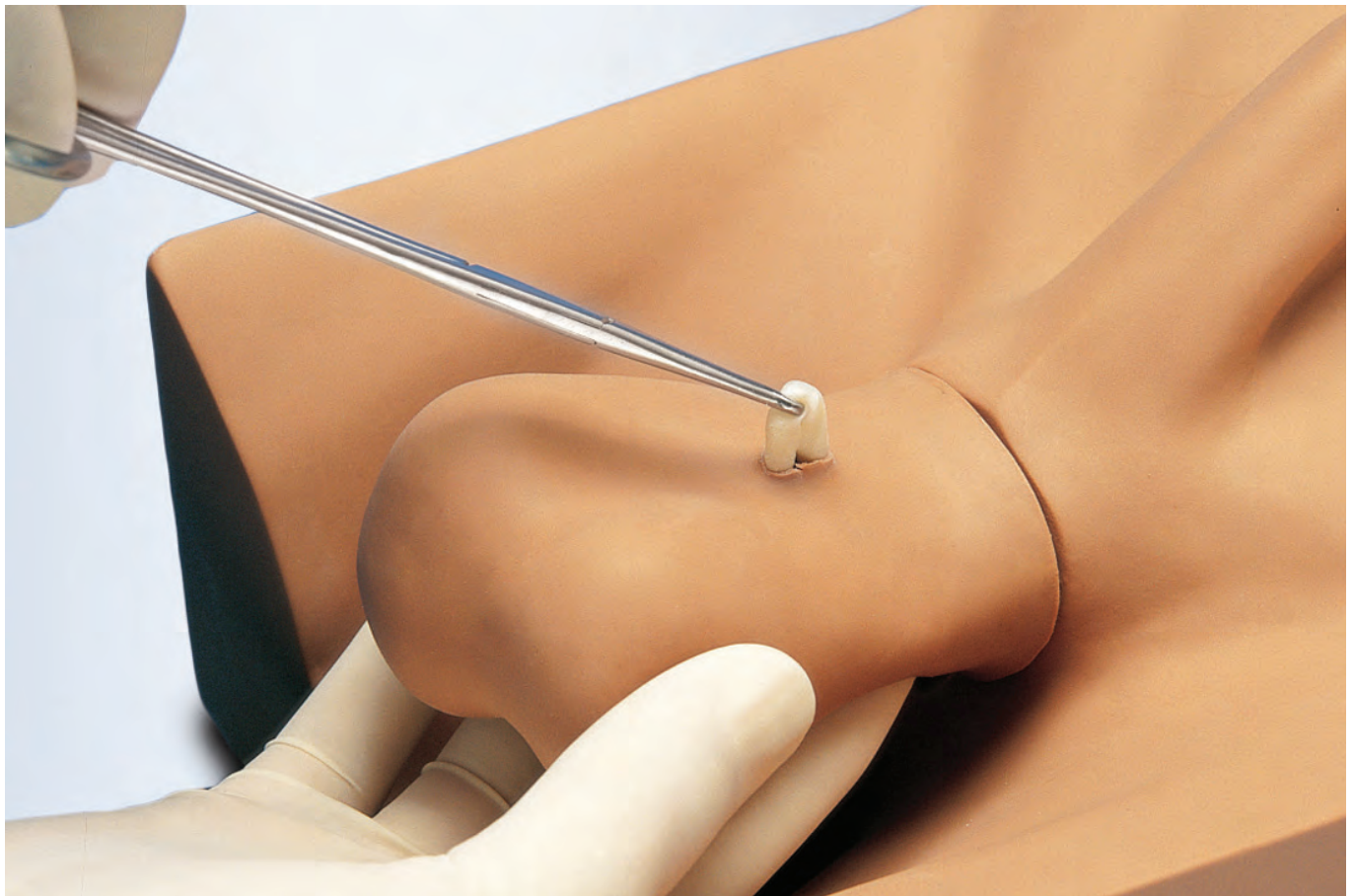




# S518

## NO SCALPEL VASECTOMY

### USER GUIDE



The S518 No Scalpel Vasectomy Simulator is an interactive educational system developed to assist a certified instructor. It is not a substitute for a comprehensive understanding of the subject matter and not intended for clinical decision making.



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## 1. INTRODUCTION

### 1.1 SPECIFICATIONS

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Length: 10 inches

Width: 6  $\frac{7}{8}$  inches

Height: 4  $\frac{1}{2}$  inches

Weight: 2.6 Lbs. (1.2 Kg)

### 1.2 CARE AND MAINTENANCE

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**Damage caused by misuse is not covered by your warranty. It is critical to understand and comply with the following guidelines.**

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#### General

- Ball point pens, ink, and markers permanently stain the skin.
- Do not wrap this or any other Gaumard product in newsprint.
- Marks made with ballpoint pens, ink or marker cannot be removed.
- Replacement parts are available from Gaumard Scientific or from your Distributor.

#### Operating Conditions

- The simulator will only power on when connected to the AC power supply.
- Operating temperature: 50°-95° F (10°-35° C)
- Humidity: 5%-95% (non-condensing)

#### Storage Conditions

- Store the simulator in a cool, dry place. Extended storage above 85 degrees Fahrenheit (29 Celsius) will cause the simulator to soften and slowly warp.
- Humidity: 40%-60% (non-condensing)
- Do not stack or store heavy materials on top of the case the simulator is stored in.

**WARNING: To avoid damage to the simulator, please store and ship it in the clear poly bag provided.**

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## Procedures

- The Gaumard S518 No-Scalpel Vasectomy (NSV) Simulator was developed to assist in learning a method of vas occlusion. It should be used only as part of an approved instructional program conducted by a certified professional.
- The NSV simulator is ideal for demonstrating and practicing No-Scalpel Vasectomy techniques.

## General Cleaning

- The simulator is "splash-proof" but not water-proof. Do not submerge or allow water or other liquids to enter the interior of the simulator.
- The simulator should be cleaned with a cloth dampened with diluted liquid dishwashing soap.
- Dry thoroughly after every cleaning.
- A secondary cleaning with a cloth dampened with 70% isopropyl alcohol can be performed if required.
- Do not clean with harsh abrasives.
- Do NOT use povidone-iodine or any similar solution on the simulator.
- Dry thoroughly after every cleaning.
- After drying, application of talcum powder can return the simulator to its lifelike feel.

## 2. OVERVIEW

The S518 No-Scalpel Vasectomy (NSV) Simulator was developed to assist in learning a new method of vas occlusion.

This compact simulator consists of the following:

- A section of the Male lower abdomen
- Two removable scrotal skins
- Two testicle assemblies (pre-assembled Long Vas tubing attached to a pair of testicles)

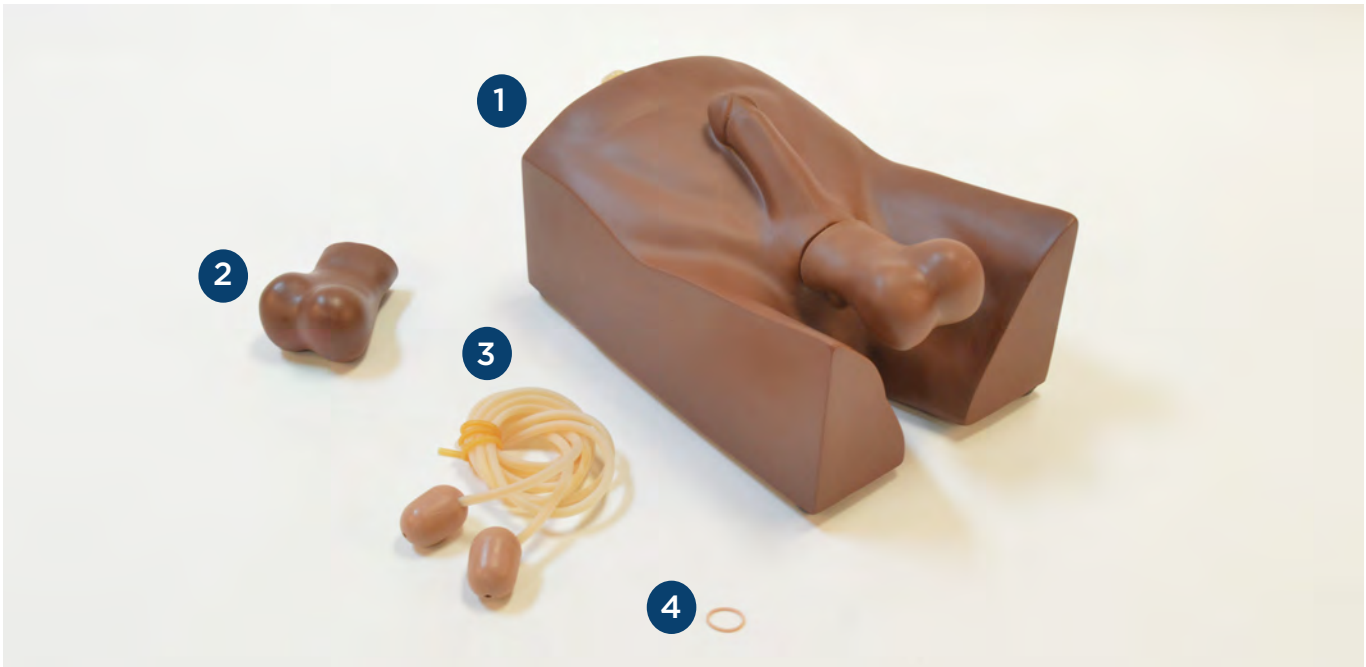
The leg stumps of the simulator are designed to "get in the way" of the student as the procedure is mastered.

## 3. INITIAL SETUP

### 3.1 UNBOXING

- The S518 NSV Simulator is pre-assembled.
- Rest the simulator on a patient bed or table capable of supporting the weight.

### 3.2 PACKAGE CONTENTS



1. S518 NSV Simulator (pre-assembled)

2. Scrotal skin (1 installed, 1 spare)

3. Testicle Assembly (1 installed, 1 spare)

4. Rubber bands (1 installed, 1 spare)

## 4. WORKING WITH S518 NSV

### 4.1 ADJUSTING THE VAS DEFERENS

If necessary, the Vas Deferens tubing that is attached to the testicle assembly can be adjusted to prepare for a simulation exercise.

To do this:

1. Remove the scrotal skin from the pre-assembled simulator.
2. Remove the rubber band from the elliptical ridge beneath the penis that keeps the Vas Deferens tubing in place.
3. Pull on the Vas Deferens tubing from the top of the simulator to adjust the length and tension of the tubing.



4. Once satisfied with the adjustment, place the rubber band on the elliptical ridge beneath the penis to secure the tubing.



5. Insert the testicles back into the opening of the scrotal skin.



6. Fit the scrotal skin back onto the elliptical ridge that is beneath the penis.



The simulator is now ready for use.

## **4.2 SUGGESTED PROCEDURES**

The S518 NSV is ideal for demonstrating and practicing No-Scalpel Vasectomy techniques.

It is possible to pierce the scrotal skin with dissecting forceps to access the Vas Deferens tubing.

After any simulation the used Vas Deferens segments can be discarded and the testicles used again to repeat the procedures.



## 5. ROUTINE MAINTENANCE

### 5.1 REATTACHING VAS DEFERENS TUBING TO TESTICLES

After performing a procedure any cut Vas Deferens may need to be reattached to the testicle.

To do this:

1. Remove the scrotal skin from the simulator.
2. Discard any used segments of the Vas Deferens tubing.



3. Remove the cut tubing from the testicle by pulling on it.



4. Pull on the remaining length of the Vas Deferens tubing from the simulator and tie a small knot at the end.



5. Push the knot into the large hole on the testicle.

**NOTE:** You may need to use a tool to push the knot completely into the testicle.



6. Reassemble the testicles, Vas Deferens, and scrotal skin like in section "4.1 Adjusting the Vas Deferens" on page 7.

## 5.2 INSTALLING NEW TESTICLE ASSEMBLY

Once the Vas Deferens tubing that is attached to the testicle assembly is used up there are two ways to replenish the tubing. One way is to save the testicles and order a Long Vas Assembly (item# 30081272B), which is just the tubing alone, then reattach the tubing to the testicles as shown in section "5.1 Reattaching Vas Deferens Tubing to Testicles" on page 9. The second way is to order the entire Testicle Assembly (item# 30030333B), which has the Long Vas tubing pre-assembled to the testicles.

Either way, to replace and install the new testicle assembly:

1. Remove the scrotal skin, rubber band, and pull out any remaining Vas Deferens tubing with the testicles attached.



2. Obtain the new Vas Deferens tubing with the testicles attached and insert the first tube through one of the holes on the elliptical ridge beneath the penis.



3. Insert the second tube through the remaining hole on the elliptical ridge beneath the penis.



4. Stand the simulator up right to access and pull the tubing through the large opening in the back.



5. One at a time, feed the ends of the Vas Deferens tubing through the two holes at the top of the simulator.



6. Pull the Vas Deferens tubing through the holes at the top of the simulator and make any adjustments to the length of the Vas Deferens in the pelvic area.



7. Secure the Vas Deferens tubing in the pelvic area by placing the rubber band around the elliptical edge beneath the penis.



8. Reassemble the scrotal skin onto the simulator.



## 6. APPENDIX

### 6.1 REPLACEMENT PARTS

Item #	Name	Description
S518.736	Rubber Band	Rubber band (set of 2) used to secure the vas deferens tubing
S518.822.L	Removable Scrotal Skin (light)	Replacement scrotal skin in light skin tone
S518.822.M	Removable Scrotal Skin (medium)	Replacement scrotal skin in medium skin tone
S518.822.D	Removable Scrotal Skin (dark)	Replacement scrotal skin in dark skin tone
S518.964.L	Testicles (light)	Replacement testicles in light skin tone
S518.964.M	Testicles (medium)	Replacement testicles in medium skin tone
S518.964.D	Testicles (dark)	Replacement testicles in dark skin tone
30081272B	Long Vas Assembly	Replacement Vas tubing to connect to the testicles
30030333B	Testicle Assembly	Set of 2 testicles attached to Long Vas tubing
30081269B	Vasectomy Kit (light)	Set of 2 scrotal skins and 2 testicle assemblies in light skin tone
30081270B	Vasectomy Kit (medium)	Set of 2 scrotal skins and 2 testicle assemblies in medium skin tone
30081271B	Vasectomy Kit (dark)	Set of 2 scrotal skins and 2 testicle assemblies in dark skin tone

## 6.2 GAUMARD SALES TERMS AND CONDITIONS

These Gaumard Scientific Company, Inc. (“Gaumard”) Sales Terms and Conditions (“Terms”) apply to the sale or use of Gaumard equipment (“Equipment”), Software (“Software” as defined in paragraph 13), and supplies (“Supplies”), collectively referred to as “Product” or “Products” between Gaumard and the entity named on the applicable Gaumard Purchase Order (“Customer”) (collectively, “Party” or “Parties”). The Parties, intending to be legally bound, agree as follows.

1. Agreement. Customer agrees to purchase from Gaumard the Products set forth in quotes and purchase orders accepted by both Customer and Gaumard. These Terms, along with any Exhibits, any applicable Gaumard Purchase Order documents, Gaumard Warranty documents, Gaumard Cares Service Plan documents, and any other purchasing or service documents executed by the Parties constitute the complete and entire agreement between Gaumard and Customer (collectively referred to herein as the “Agreement”). This Agreement will supersede all other quotations, agreements, understandings, warranties, and representations (whether written or oral) between the Parties with respect to the subject matter set forth in the Agreement. Any Customer documentation (including Customer’s purchase order terms and conditions) that conflicts with or attempts to modify the Agreement in any way is hereby rejected and of no effect unless specifically agreed to in writing and signed by the Parties. No provision of this Agreement shall be waived, amended, modified, superseded, canceled, terminated, renewed, or extended except in a written document signed by both Parties or signed by the Party against whom the modification is sought to be enforced. This agreement can be terminated by Gaumard without cause by giving thirty (30) days prior written notice to Customer.

2. Prices. Prices, fees, and charges for Products and services (including maintenance, installation, and training as described in the applicable Gaumard Purchase Order documents, Gaumard Warranty documents, Gaumard Cares Service Plan documents) (“Service” or “Services”) are payable in United States (U.S.) Dollars only, and do not include any applicable taxes or shipping charges. If Customer claims any tax exemption, it must furnish a valid tax exemption certificate before shipment of Products. Unless such certificate is furnished, Customer agrees to pay at its sole expense all applicable taxes, assessments, fees, penalties, import duties, and merchandise processing fees that may be levied or assessed upon Customer or Gaumard with respect to this Agreement, the Products, or any interest thereon. Gaumard reserves the right to increase prices on thirty (30) days written notice to Customer.

3. Payment. Customer shall pay all invoiced amounts within twenty (20) days from the invoice date, unless otherwise agreed upon by Gaumard in writing. Gaumard may require some or all of the purchase price to be paid in advance by Customer, unless Gaumard grants credit approval as determined in Gaumard’s sole discretion on a case by case basis (taking into account factors such as credit rating, payment history, and size of order). A late charge will be due on any unpaid balance at a rate of 1.0% per month or the maximum rate otherwise permitted by law, whichever is lower. Gaumard may charge interest at the maximum rate permitted by law on all amounts not paid by the invoice due date. Gaumard retains a purchase money security interest in all Products sold to Customer to secure payment of the total purchase price thereof. Customer hereby grants Gaumard the right to file a copy of this Agreement with any appropriate authorities to evidence this security interest. Customer agrees to execute and deliver such other documents as Gaumard may request in connection therewith. Gaumard shall not be obligated to deliver any Product or perform any Service during any period when Customer payment is past due. Customer will be responsible for all costs (including reasonable attorneys’ fees) incurred by Gaumard to collect overdue payments and/or to take possession or otherwise dispose of Products for which payment is overdue.

4. Product Shipment and Risk of Loss. Unless otherwise agreed to in writing by Gaumard All Products will be shipped

F.O.B. Origin, regardless of any provisions for payments of freight, insurance, the form of shipping documents, or selection of carrier by Gaumard. F.O.B. Origin means title to the Products passes to the Customer at the shipping dock of Gaumard or Gaumard's supplier or authorized agent. Customer is responsible for shipping charges and for the cost of insurance paid to cover any losses from Gaumard's shipment point to Customer's receipt. Gaumard will assist Customer in processing any loss claims. Gaumard shall use reasonable efforts to meet the specified delivery dates. If Gaumard fails to make delivery within a reasonable time for reasons other than Customer's fault or circumstances beyond Gaumard's reasonable control, then Customer's only remedy is the right to terminate the applicable Purchase Order, whereupon Gaumard will refund any prepayments received from Customer relating to such Purchase Order.

5. Installation and Acceptance. Product orders are subject to 1) written acceptance by Gaumard, 2) receipt of specified deposits, as applicable and 3) continuing credit approval. If applicable, Gaumard will install Equipment at an agreed upon location ("Installation"). Installation shall be complete upon Gaumard's demonstration that the Equipment meets Gaumard's then-current operating specifications ("Installation"). Installation is subject to Customer cooperating in preparing and maintaining the site in compliance with Gaumard specifications, including but not limited to, applicable electrical and other connection regulations and all environmental conditions. If Customer fails to accept shipment of

Products other than for breach of warranty, Customer shall immediately pay the full purchase price as if shipment and Installation had occurred. If Customer fails to accept Products and if Gaumard decides to store ordered Products, Customer shall be responsible for Gaumard's reasonable insurance, handling, and storage charges. If Gaumard elects not to store ordered Products, Gaumard may arrange shipment and storage in a bonded warehouse at Customer's sole risk and expense.

6. Delay of Performance. The Parties' obligations under this Agreement are subject to force majeure, including but not limited to, civil insurrection, terrorism, fire, flood, labor disputes, shortages, delays of suppliers or contractors, or government priority systems, actions taken or threatened by any governmental agencies, acts of God or other contingencies or acts not within the sole control of the Parties. Gaumard reserves the right during any shortage period to (a) make Supplies available to Customer (as it sees fit) without any liability to Customer, and (b) to make substitutions and modifications in the specification of any Products, provided such substitutions or modifications do not materially affect the performance of Products.

7. WARRANTIES. Gaumard warrants that if a Product proves to be defective in material or workmanship within one year from the date on which title to the Product passes to the Customer ("Warranty Period"), Gaumard will, at Gaumard's option, repair or replace the Gaumard product. This limited warranty covers all defects in material and workmanship in the Gaumard product, except: (a) Damage resulting from accident, misuse, abuse, neglect, or unintended use of the Gaumard product; (b) Damage resulting from failure to properly maintain the Gaumard product in accordance with Gaumard product instructions, including failure to properly clean the Gaumard product; and (c) Damage resulting from a repair or attempted repair of the Gaumard product by anyone other than Gaumard or a Gaumard representative. Replacement parts are warranted for the remainder of the Warranty Period or ninety (90) days from shipment, whichever is longer. Services are warranted to be supplied in a workman-like manner. Gaumard does not warrant that use of the Products will be uninterrupted or error-free, or that the Products will operate with non-Gaumard authorized third-party products. THE FOREGOING WARRANTIES ARE IN LIEU OF AND EXCLUDE ALL OTHER WARRANTIES, WHETHER EXPRESS OR IMPLIED BY OPERATION OF LAW OR OTHERWISE, INCLUDING BUT NOT LIMITED TO ANY IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, OR NON-INFRINGEMENT. SUCH LIMITED WARRANTY IS GIVEN SOLELY TO THE ORIGINAL CUSTOMER AND IS NOT GIVEN TO ANY THIRD PARTY INCLUDING, WITHOUT LIMITATION, SUBSEQUENT PURCHASERS OR USERS OF THE PRODUCTS OR CUSTOMERS OF THE CUSTOMER. THIS WARRANTY IS VOID UPON TRANSFER OF



PRODUCT BY CUSTOMER TO ANY OTHER ENTITY. SOME STATES DO NOT ALLOW THE EXCLUSION OF IMPLIED WARRANTIES SO THE ABOVE EXCLUSIONS MAY NOT APPLY TO CUSTOMER. These warranties do not apply to any Products that are supplied on a pre-release or “as-is” basis.

8. Warranty Claims and Remedies. In the event of any warranty claim, Gaumard will replace with new or repaired items any Product part or component that is in breach of the above limited warranties. Alternatively, Gaumard may elect to repay or credit to Customer an amount equal to the purchase price of the defective Product. Items replaced shall become Gaumard property. All claims shall be initiated by contacting Gaumard within the applicable Warranty Period and within thirty (30) days after discovery of the non-conformity. If Customer has failed to notify Gaumard within the Warranty Period, then Customer shall be barred from instituting any action thereafter. Customer shall not return the Product to Gaumard without prior authorization from Gaumard. If the necessary repairs to the Product are covered by this limited warranty, then Customer will pay only the incidental expenses associated with the repair, including any shipping, handling, and related costs for sending the product to Gaumard and for sending the product back to the first purchaser. However, if the repairs are not covered by this limited warranty, then Customer will be liable for all repair costs in addition to costs of shipping and handling. Upon request, Gaumard must be given access to and an opportunity to inspect the Product and any working areas and storage areas. These remedies shall comprise Gaumard’s entire liability and Customer’s exclusive remedy for breach of warranty and are in lieu of any other remedies at law or equity.

9. LIMIT OF LIABILITY. GAUMARD SHALL NOT BE LIABLE FOR ANY SPECIAL, INCIDENTAL, PUNITIVE, EXEMPLARY, OR CONSEQUENTIAL LOSSES, DAMAGES, OR EXPENSES (INCLUDING BUT NOT LIMITED TO LOSS OF PROFITS, DATA, OR USE), DIRECTLY OR INDIRECTLY ARISING FROM THE SALE, HANDLING, SERVICE, OR USE OF PRODUCT OR SERVICES ORDERED OR FURNISHED, OR FROM ANY CAUSE RELATING THERETO. EXCEPT FOR PERSONAL INJURY OR DEATH TO THE EXTENT RESULTING FROM GAUMARD’S NEGLIGENT OR INTENTIONALLY WRONGFUL ACTS OR OMISSIONS, IN NO EVENT SHALL GAUMARD BE LIABLE UNDER ANY LEGAL THEORY OR FOR ANY CAUSE RELATED TO A PRODUCT OR SERVICE, WHETHER BASED UPON WARRANTY, CONTRACT, TORT, NEGLIGENCE, OR OTHER THEORY, EVEN IF ADVISED OF THE POSSIBILITY THEREOF, FOR ANY AMOUNT IN EXCESS OF THE PRICE, FEE, OR CHARGE RECEIVED BY GAUMARD FOR SUCH PRODUCT OR SERVICE.

10. Governmental Authorizations. Customer is responsible for compliance and costs associated with all required licenses, permits, or other governmental authorizations, including but not limited to, any license or certification needed for Customer to use the Product, and any export or import license, exchange permit, or the like (“Licenses”), even if applied for by Gaumard on Customer’s behalf. If any authorization is delayed, denied, revoked, restricted, or not renewed, Gaumard shall not be liable, and Customer is not relieved of its obligations. Customer represents and agrees that it will handle all Product and technical data related to the Licenses so that it conforms to all applicable U.S. laws and regulations, including U.S. export licensing laws and the U.S. Foreign Corrupt Practices Act. Customer shall not trans-ship, divert, re-export or otherwise dispose of any U.S. origin goods or technology obtained from Gaumard except as U.S. laws and regulations expressly permit.

11. Indemnity.

Gaumard agrees to indemnify, defend and hold Customer, its officers, directors, employees, agents and contractors harmless from and against all loss, damage, liability, cost and expense (including reasonable attorneys’ fees and expenses) by reason of any claims or actions by third parties against Customer for (1) bodily injury or death, and damage, loss or destruction of any real or tangible personal property, which third party claims arise out of or relate to Gaumard’s gross negligence or willful misconduct or (2) infringement or misappropriation by Gaumard of any intellectual property rights under this Agreement.

a. Customer agrees to indemnify, defend and hold Gaumard, its officers, directors, employees, agents and contractors harmless from and against all loss, damage, liability, cost and expense (including reasonable attorneys’



fees and expenses) by reason of any claims or actions by third parties against Gaumard for (1) bodily injury or death or damage, loss or destruction of any real or tangible personal property, which third party claims arise out of or relate to Customer's gross negligence or willful misconduct; (2) infringement or misappropriation by Customer of any intellectual property rights; or (3) Customer's or its customer's use of the Products or Services, including without limitation, defamation, libel, slander, obscenity, pornography, or violation of the rights of privacy or publicity, or spamming or any other tortious or illegal conduct.

12. **Software License.** For purposes of these Terms, the term "Software" includes all Gaumard computer software, firmware, and associated documentation, whether in printed or machine-readable form, supplied by reason of this Agreement or for use in connection with Equipment or Services. To the extent the Product includes Software, Customer's use of the Software is governed by the Gaumard End User License Agreement attached as Exhibit A to these Terms.

13. **Confidential Information.** Customer shall maintain the confidentiality of any information provided or disclosed by Gaumard relating to the Software (as defined above), business or customers of Gaumard, as well as this Agreement and its terms (including the pricing and other financial terms under which the Customer will be obtaining the Services hereunder). Customer shall use reasonable care to protect the confidentiality of Gaumard's information disclosed, but no less than the degree of care it would use to protect its own confidential information, and shall only disclose Gaumard's confidential information to its employees and agents having a need to know this information and who are subject to confidentiality agreements having terms at least as restrictive as those contained herein. The obligations of confidentiality set forth herein shall not apply to any information in the public domain at the time of disclosure.

14. **Intended Uses.** Products are only intended for the uses described in the applicable user's manual or instructions for use. Customer assumes all risks associated with non-listed uses of Products and hereby indemnifies and holds Gaumard harmless from any claim associated with such non-listed uses.

15. **Compliance with Laws.** Gaumard and Customer agree to comply with all federal and state laws that govern the enforceability and performance of this Agreement.

16. **HIPAA Compliance.** As of the Effective date, the Parties are not planning to transfer any personal patient information between them. However, the Parties understand and agree that this Agreement may become subject to the Health Insurance Portability and Accountability Act of 1996 as amended ("HIPAA"), the privacy and security regulations promulgated thereunder, including 45 C.F.R. 160, 162 and 164, as amended (the "HIPAA Regulations"), and Title XIII of Division A and Title IV of Division B (the "Health Information Technology for Economic and Clinical Health Act" ("HITECH")), part of the American Recovery and Reinvestment Act of 2009 (Pub. L. 111-5) ("ARRA"). The Parties agree to strictly comply with HIPAA and to execute any documents that may be required by HIPAA, HITECH, and any other applicable federal or state privacy laws and regulations. The Parties agree that if they directly or indirectly gain access to Protected Health Information ("PHI") held by the other Party during any interaction, the receiving Party will keep the PHI confidential under the terms of this Agreement.

17. **State Reporting and Disclosure Laws.** Unless otherwise noted in this Agreement, the cost of any Product training provided by Gaumard shall be included in the purchase price of the Product where applicable. Customer acknowledges and agrees that state reporting laws may require Gaumard to disclose certain aspects of this arrangement.

18. **Fraud and Abuse.** Gaumard hereby certifies that it is not currently a listed vendor in the: (a) Federal General Services Administration's "List of Parties Excluded from Federal Procurement or Nonprocurement Programs" in accordance with

Presidential Executive Orders 12549 and 12689 “Debarment and Suspension;” and (b) in the Office of the Inspector General of the Department of Health and Human Services’ “List of Excluded Individuals/Entities.” Any discounted pricing terms offered under this Agreement may be a “discount or other reduction in price” under the Federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b). Customer shall take all actions necessary to comply with the Anti-Kickback Statute discount safe harbor regulations, 42 C.F.R. § 1001.952(h), including but not limited to, (1) maintaining accurate records reflecting the pricing terms of items and Services purchased under this Agreement, (2) fully and accurately report any discount received under this Agreement if applicable, and (3) make available information provided to Customer by Gaumard concerning cost reports and other filings with the government, including but not limited to, the Secretary of the U.S. Department of Health and Human Services or other state agencies.

19. **Bankruptcy.** Except as may be prohibited by applicable bankruptcy laws, a Party to this Agreement may elect to terminate this Agreement (including any Purchase Orders) if any of the following situations arise: (1) the other Party becomes insolvent or is unable to pay debts as they become due; (2) a voluntary or involuntary bankruptcy proceeding is instituted by or against a Party hereto; or (3) an appointment of a receiver or assignee for the benefit of creditors occurs on behalf of a Party hereto.

20. **Waiver and Severability.** If either Party fails to perform obligations under this Agreement, such nonperformance shall not affect the other Party’s right to enforce performance at any time. Waiver of any remedy or material breach of any subject matter contained in this Agreement shall not be viewed as a waiver unless agreed to by the Parties in writing. Each provision of this Agreement is separate and independent of one another, and the unenforceability of any provision will not affect the enforceability of any other provision. If any provision is held to be excessively broad or unenforceable, such provision shall be modified so that it is enforceable to the fullest extent possible by law.

21. **Assignment.** Customer shall not assign this Agreement without the prior written consent of Gaumard, which consent shall not be unreasonably withheld or delayed. Subject to the foregoing, the rights and obligations herein will be binding upon the successors and assigns of Customer.

22. **Notices.** Any required notices will be given in writing to Gaumard as set forth in the applicable Gaumard Purchase Order or other purchasing document.

23. **Governing Law.** Upon execution, this Agreement shall be governed and viewed under the laws of the State of Florida without reference to its conflict of laws provisions. Customer and Gaumard specifically agree that any action relating to the relationship between the Parties, the Agreement, or Products provided, purchased or licensed hereunder, shall be brought and tried in the Courts of Dade County, Florida. Customer waives all objections to, and consents to the jurisdiction of such Courts.

24. **Miscellaneous.** See applicable Gaumard Purchase Order documents, Gaumard Warranty documents, and Gaumard Cares Service Plan documents for other terms and conditions, which may include, but are not limited to: Term, Termination, Customer Training and Support, and Product Repairs and Tune Ups.

## 6.3 END USER LICENSE AGREEMENT

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### GAUMARD END USER LICENSE AGREEMENT

This End User License Agreement (“EULA”) sets forth the respective rights and responsibilities between the entity named in the Purchase Order associated with this EULA (“End User”) and Gaumard Scientific Company, Inc., a Florida corporation (“Gaumard”), relative to the Gaumard Software (as defined below). This EULA is effective as of the date Gaumard accepts and confirms the Purchase Order (the “Effective Date”). BY USING THE GAUMARD SOFTWARE, END USER IS AGREEING TO BE BOUND BY THE TERMS OF THIS EULA. IF END USER DOES NOT AGREE, END USER MAY NOT USE THE GAUMARD SOFTWARE.

#### 1. Definitions.

1.1 “Gaumard Documentation” means the Gaumard user and operations manuals, guides, and related materials provided by Gaumard to End User to facilitate use of the Gaumard Products.

1.2“Gaumard Equipment” means Gaumard hardware components for medical simulation and training, including manikins and associated instrumentation, and other hardware and tangible products sold by Gaumard to End User.

1.3“Gaumard Products” means Gaumard Software licensed and Gaumard Equipment sold or otherwise made available by Gaumard to End User currently or in the future.

1.4 “Gaumard Software” means the object code form of computer programs and Gaumard Documentation owned by Gaumard or its licensors and licensed to End User in accordance with this EULA. Gaumard Software includes (a) computer programs embedded in firmware in the Gaumard Equipment; (b) computer programs embedded in a separate medium (such as CD or flash drive) for use in conjunction with the Gaumard Equipment; (c) computer programs downloaded or received via mail from Gaumard; (d) computer programs used on servers storing or processing data related to the Gaumard Products; and (e) computer programs used to create and manage a network for the Gaumard Equipment, interface with the components of the Gaumard Equipment, manage and compute location information related to the Gaumard Equipment, and monitor health of the Gaumard Equipment.

## 2. Software License and Restrictions.

2.1License. Subject to End User’s compliance with the terms and conditions of this EULA, the Gaumard Sales Terms and Conditions, the Purchase Order, and the Gaumard Cares Service Plan Agreement, Gaumard grants End User a non-exclusive, non-transferable (except as otherwise set forth herein), personal license to execute and use the Gaumard Software for End User’s internal purposes, but only so long as the Gaumard Software is installed on the Gaumard Product on which it was originally installed. End User may not, directly or indirectly, sell, sublicense, display, timeshare, loan, lease, distribute, or create derivative works of the Gaumard Software.

2.2Ownership. All rights, title, and interest in and to the Gaumard Software, and any derivative works thereof, whether created by Gaumard, End User, or a third party, will remain at all times solely and exclusively owned by Gaumard. Nothing in this EULA or the Purchase Order will be construed to grant End User any rights of any kind with respect to the Gaumard Software, except as expressly set forth in this EULA.

2.3Reverse Engineering and Other Restrictions. End User will not, and will not allow any third party to, tamper with, modify, decompile, disassemble, derive the source code of, reverse engineer, or attempt to obtain the internal design of the Gaumard Software or Gaumard Products for any purpose whatsoever (collectively, “Restricted Acts”). If applicable law permits End User to take any of the Restricted Acts notwithstanding the previous prohibition, and End User wishes to take any Restricted Act notwithstanding the previous prohibition, End User will first provide Gaumard with thirty (30) days prior written notice. Gaumard may terminate this EULA at any time during such notice period without liability arising from such termination. The parties agree that all information needed for interoperability is available from Gaumard in accordance with applicable government directives.

2.4Updates. From time to time Gaumard may develop new versions or updates for the Gaumard Software that may be made available to the End User as agreed under the terms of the Gaumard Sales Terms and Conditions, Gaumard Purchase Order documents, Gaumard Warranty documents, or Gaumard Cares Service Plan documents. Unless otherwise agreed to by Gaumard, End User sHAL®I be responsible for installing the provided new versions or updates for the Gaumard Software.

2.5Proprietary Notices. End User agrees to maintain and reproduce on all copies of the Gaumard Software, any names, logos, copyright notices, trademarks, other proprietary markings, and legends that appear on the Gaumard Software.

2.6Control of Duplication. End User will not, nor will it allow any third party to, circumvent the protection controlling the duplication or use of the Gaumard Software, for example and without limitation, any software lock controlling the number of copies End User may make of the Gaumard Software.

2.7No Source Code. End User acknowledges and agrees that its rights under this EULA do not include rights to source code. In its exercise of the rights granted under this EULA, End User agrees not to take any action that would result in any requirement to disclose or make available to other parties the Gaumard Software in source code format.

2.8Certification. Upon thirty (30) days written notice to End User from Gaumard, End User sHAL®I certify End User’s compliance with the restrictions and obligations in this EULA. Such requests will not occur more frequently than once per calendar year. If End User has used the Gaumard Software in violation of this EULA, End User sHAL®I, in addition to any other remedies Gaumard may have, pay Gaumard additional fees for the excess use according to Gaumard’s then-current price list and policies, plus a late payment charge of one percent (1.0%) per month (or the highest amount allowed by applicable law, if lower) for each month of excess use from the date of initial excess use.

2.9Privacy and Recordings. End User will comply with all applicable laws, rules and regulations related to privacy, publicity and data protection related to use of the Gaumard Products. End User sHAL®I not use the Gaumard Software to record or collect personal data from any person in violation of End User’s policies or privacy statements. End User sHAL®I receive express consent from all persons recorded by the Gaumard Software sufficient for End User’s use, storage, and distribution of such recordings.

## 3. Term and Termination

3.1Term. This EULA commences on the Effective Date and continues perpetually, unless terminated earlier in accordance with the terms hereof.

3.2Termination for Cause. This EULA is automatically terminated by Gaumard if the other party materially breaches this EULA, the Gaumard Sales Terms and Conditions, the Purchase Order, or the Gaumard Cares Service Plan Agreement. In addition, Gaumard may terminate this EULA if (a) End User becomes insolvent or makes an assignment for the benefit of End User’s creditors; or (b) a receiver is appointed or a petition in bankruptcy is filed with respect to End User and such petition is not dismissed within thirty (30) days.

3.3Effect of Termination. Upon the termination of this EULA for any reason, all licenses granted in Section 2 above will immediately cease and terminate. Upon termination, End User will immediately cease using the Gaumard Software.

3.4 Survival. Sections 3 through 6 will survive the termination of this EULA.

## 4. Confidential Information; Trademarks.

4.1Confidential Information. End User acknowledges and agrees that the Gaumard Software is confidential information and contains trade secrets of Gaumard. End User agrees to (i) hold the Gaumard Software in the strictest confidence, (ii) not disclose the Gaumard Software to any third party for any purpose, and (iii) use at least the same security measures as End User to protect its own confidential and trade secret information but no less than reasonable measures to protect the confidentiality of the Gaumard Software. End User agrees and acknowledges that any breach of the provisions regarding ownership or confidentiality contained in this Agreement sHAL®I cause Gaumard irreparable harm and Gaumard may obtain injunctive relief without the requirement to post a bond as well as seek all other remedies available to Gaumard in law and in equity in the event of breach or threatened breach of such provisions.

4.2Trademarks. End User may not use Gaumard’s trademarks, logos, service marks, or names in press releases, web sites, marketing, or other forms of public materials without the prior written consent of Gaumard. All use of the Gaumard trademarks and all goodwill associated with them will inure solely to the benefit of Gaumard.

## 5. Disclaimer; Limitation of Liability; Infringement Indemnification

5.1 Warranty and Disclaimer. For a period of twelve (12) months from the Effective Date, Gaumard will (a) provide all updates to the Software that are made available generally, and (2) use reasonable efforts to fix or provide a workaround for any Gaumard Software defect or bug which prevents operation in substantial conformity with the Gaumard Documentation. Other than the above, the Gaumard Software is provided "as-is," with no express or implied warranties of any kind, including the warranties of merchantability, fitness for a particular purpose, or non-infringement.

5.2 Limitation of Liability. THE TOTAL LIABILITY, IF ANY, OF GAUMARD TO END USER OR ANY THIRD PARTY FOR ALL DAMAGES BASED ON ALL CLAIMS, WHETHER ARISING FROM BREACH OF CONTRACT, BREACH OF WARRANTY, NEGLIGENCE, INDEMNITY, STRICT LIABILITY, TORT, OR OTHERWISE, ARISING FROM THE GAUMARD PRODUCTS IS LIMITED TO ONE HUNDRED DOLLARS. IN NO EVENT WILL GAUMARD BE LIABLE TO END USER OR ANY THIRD PARTY FOR ANY SPECIAL, INDIRECT, CONSEQUENTIAL, OR PUNITIVE DAMAGES, INCLUDING BUT NOT LIMITED TO, LOSS OF REVENUES, LOSS OF PROFITS, OR LOSS OF DATA, EVEN IF SUCH PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES.

5.3 Infringement Indemnification. Gaumard will, as further described below, indemnify, defend, and hold End User harmless, at its expense, against any claim or suit brought by a third party against End User alleging that any Gaumard Software furnished under this EULA infringes the United States patent, trademark, copyright or other intellectual property right of a third party. Gaumard will pay all settlements entered into or damages finally awarded, including attorneys' fees and costs, based on any such claim or suit; provided that End User gives Gaumard prompt written notice of such claim and gives Gaumard information, reasonable assistance, and sole authority to defend or settle the claim. In defense or settlement of the claim, Gaumard may obtain for End User the right to continue using the Gaumard Software, replace or modify the Gaumard Software so that it becomes non-infringing, or, if such remedies are not reasonably available, grant End User a refund for the associated Gaumard Products (depreciated over three years) and accept their return. Gaumard will not have any liability if the alleged infringement is based upon (a) the use or sale of the Gaumard Software in combination with other products or devices not furnished by or approved by Gaumard; (b) the use of the Gaumard Software in a manner for which they were not designed as described by the Gaumard Documentation; (c) any modification of the Gaumard Software not performed by or authorized by Gaumard;

(d) any use of Gaumard Software by End User after End User learns of such allegation of infringement; or (e) any failure by End User to utilize a non-infringing version of the Gaumard Software made available by Gaumard along with notice that such update is non-infringing. The obligations set forth in this Section 5.3 are Gaumard's sole obligations, and End User's sole and exclusive remedy, for the Gaumard Software infringing third party intellectual property rights.

## 6. Miscellaneous.

6.1 Binding Effect; Assignment. This EULA will be binding upon, and inure to the benefit of, End User's and Gaumard's respective permitted successors and permitted assigns. Neither party may assign or transfer this EULA or any of the rights, privileges, duties or obligations under this EULA without the prior written consent of the other party, except that either party may assign this Agreement to any entity controlled by, controlling, or under common control with such party at such time, as well as in connection with the sale, transfer, merger, or acquisition, whether by operation of law or otherwise, of substantially all of the assets of such party. In addition, if End User transfers the Gaumard Product on which the Gaumard Software is installed to a third party, End User may assign this EULA to such third party, provided that the third party agrees in writing with Gaumard to be bound by this EULA.

6.2 Notices. Any written notice required by this EULA will be deemed made (a) when delivered by personal service, (b) one (1) business day after being sent by recognized international overnight courier service (such as FedEx), or (c) when received, if sent by certified or registered mail, postage prepaid, return receipt requested. Any such notice given to a party shall be sent to the addresses on the attached Purchase Order. By giving to the other party written notice thereof, the parties hereto and their respective permitted successors and assigns will have the right from time to time to change by written notice their respective addressee or address for notices.

6.3 Applicable Law. The validity of this EULA and the rights, obligations and relations of the parties hereunder shall be construed and determined under and in accordance with the substantive laws of the State of Florida. All disputes arising under or related to this EULA shall be resolved exclusively in the State or Federal Courts located in Dade County, Florida. The parties consent to the jurisdiction and venue of such courts and waive any claims as to inconvenient forum. The judgments of such courts may be enforced in any court of competent jurisdiction.

6.4 Export Control. End User will not export or re-export the Gaumard Software, including any technical data, except as authorized and permitted by, and in compliance with, the laws and regulations, including but not limited to all export and re-export laws and regulations, of the United States.

6.5 Severability. If any provision of this EULA is invalid or unenforceable in any circumstances, it will be interpreted as much as possible to reflect the intent of the parties, and its application in any other circumstances and the remaining provisions of this EULA will not be affected thereby.

6.6 Entire Agreement. This EULA constitutes the entire agreement and understanding of the parties relating to the subject matter thereof. This EULA supersedes all prior written and oral agreements and all other communications between End User and Gaumard (or a Gaumard distributor) regarding the subject matter hereof. No contradictory terms and conditions of any purchase order, invoice, or other document issued by End User relating to the subject matter of this EULA shall be binding, unless agreed by the parties.

6.7 Waiver of Breach. No waiver by a party of any breach of this EULA will constitute a waiver of any other breach of the same or other provisions of this EULA. No waiver by a party will be effective unless made in a record signed or otherwise authenticated by an authorized representative of such party.

6.8 Relationship of the Parties. The parties are independent contractors. Nothing in this EULA or in the activities contemplated by the parties will be deemed to create an agency, partnership, employment or joint venture relationship between the parties. Neither party will have any responsibility nor liability for the actions of the other party except as expressly provided in this EULA. Neither party will have any right or authority to bind or obligate the other party in any manner or make any representation or warranty on behalf of the other party. This EULA is made and entered into for the sole protection and benefit of Gaumard, its licensors and suppliers, and End User, and no other person or entity shall be a direct or indirect beneficiary of or shall have any direct or indirect cause of action or claim arising from this EULA.

All rights not expressly granted in this license agreement are reserved by Gaumard.

## ACKNOWLEDGMENT

**By installation of this software, you acknowledge that you have read and understand the foregoing and that you agree to be bound by its terms and conditions. You also agree that this agreement is the complete and exclusive statement of agreement between the parties and supersedes all proposed or prior agreements, oral or written, and any other communications between the parties relating to the license described herein.**

## 6.4 EXCLUSIVE ONE-YEAR LIMITED WARRANTY

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Gaumard warrants that if the accompanying Gaumard product proves to be defective in material or workmanship within one year from the date on which the product is shipped from Gaumard to the customer, Gaumard will, at Gaumard's option, repair or replace the Gaumard product.

This limited warranty covers all defects in material and workmanship in the Gaumard product, except:

- » Damage resulting from accident, misuse, abuse, neglect, or unintended use of the Gaumard product;
- » Damage resulting from failure to properly maintain the Gaumard product in accordance with Gaumard product instructions, including failure to properly clean the Gaumard product;
- » Damage resulting from a repair or attempted repair of the Gaumard product by anyone other than Gaumard or a Gaumard representative.

**This one-year limited warranty is the sole and exclusive warranty provided by Gaumard for the accompanying Gaumard product, and Gaumard hereby explicitly disclaims the implied warranties of merchantability, satisfactory quality, and fitness for a particular purpose.** Except for the limited obligations specifically set forth in this one-year limited warranty, Gaumard will not be liable for any direct, indirect, special, incidental, or consequential damages, whether based on contract, tort, or any other legal theory regardless of whether Gaumard has been advised of the possibilities of such damages. Some jurisdictions do not allow disclaimers of implied warranties or the exclusion or limitation of consequential damages, so the above disclaimers and exclusions may not apply and the first purchaser may have other legal rights.

**This limited warranty applies only to the first purchaser of the product and is not transferable.** Any subsequent purchasers or users of the product acquire the product "as is" and this limited warranty does not apply.

**This limited warranty applies only to the products manufactured and produced by Gaumard.** This limited warranty does not apply to any products provided along with the Gaumard product that are manufactured by third parties. For example, third-party products such as computers (desktop, laptop, tablet, or handheld) and monitors (standard or touch-screen) are not covered by this limited warranty. However, third-party products are covered by the warranties provided by the respective third-party manufacturers and such warranties are transferred from Gaumard to purchaser upon purchase of the Gaumard product. Defects in third-party products are covered exclusively by the warranties provided by the third-parties. Gaumard does not provide any warranty, express or implied, with respect to any third-party products. Please contact the third-party manufacturer for information regarding the availability of extended warranties for third-party products.

Any waiver or amendment of this warranty must be in writing and signed by an officer of Gaumard.

- » In the event of a perceived defect in material or workmanship of the Gaumard product, the first purchaser must:
  - » Contact Gaumard and request authorization to return the Gaumard product. Do NOT return the Gaumard product to Gaumard without prior authorization.
  - » Upon receiving authorization from Gaumard, send the Gaumard product along with copies of (1) the original bill of sale or receipt and (2) this limited warranty document to Gaumard at 14700 SW 136 Street, Miami, FL, 33196-5691 USA.

If the necessary repairs to the Gaumard product are covered by this limited warranty, then the first purchaser will pay only the incidental expenses associated with the repair, including any shipping, handling, and related costs for sending the product to Gaumard and for sending the product back to the first purchaser. However, if the repairs are not covered by this limited warranty, then the first purchaser will be liable for all repair costs in addition to costs of shipping and handling.

### Extended Warranty

In addition to the standard one year of coverage we offer a range of service plans through our Gaumard Cares program. For more information about Gaumard Cares service planes please contact customer service.

## 6.5 CONTACT TECHNICAL SUPPORT

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Before contacting Technical Support, please make sure to have the following:

1. Your simulator's serial number
2. Access to the simulator for possible troubleshooting as needed

### Technical Support

Email: [support@gaumard.com](mailto:support@gaumard.com)

USA: 800-882-6655

INT: 01-305-971-3790

## 6.6 GENERAL INFORMATION

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### Sales and Customer Service

E-mail: [sales@gaumard.com](mailto:sales@gaumard.com)

USA: 800-882-6655

INT: 01-305-971-3790

Fax: 305-252-0755

### Post

Gaumard Scientific

14700 SW 136 Street

Miami, FL 33196-5691

USA

### Office Hours

Monday-Friday, 8:30am - 7:30pm EST (GMT-5)

