North Carolina Department of Health and Human Services
Division of Health Service Regulation

Pat McCrory
Governor

Aldona Z. Wos, M.D.
Ambassador (Ret.)
Secretary DHHS

Drexdal Pratt
Division Director

October 7, 2013

Alan Terry
Carolina Lithotripsy, LTD
2014 Litho Place
Fayetteville, NC 28304

Exempt from Review - Replacement Equipment

Facility:	Mobile: Carolina Lithotripsy, LTD
Project Description:	Replace two (2) lithotripsy systems not including the mobile coaches
County:	Eastern North Carolina

Dear Mr. Terry:

In response to your letter of September 27, 2013, the above referenced proposal is exempt from certificate of need review in accordance with N.C.G.S 131E-184(a)(7). Therefore, you may proceed to acquire, without a certificate of need, the two Edap Technomed lithotripter's, model number Sonolith i-move serial numbers SIMT 091 and SIMT 101 to replace the two existing Siemens Medical lithotripter's model number B132G serial numbers 01137 and 01139. This determination is based on your representations that the existing unit will be removed from North Carolina and will not be used again in the State without first obtaining a certificate of need. Further please be advised that as soon as the replacement equipment is acquired, you must provide the CON Section and the Medical Facilities Planning Section with the serial number of the new equipment to update the inventory, if not already provided.

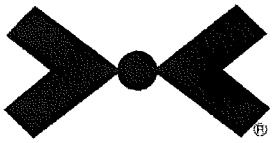
It should be noted that this Agency's position is based solely on the facts represented by you and that any change in facts as represented would require further consideration by this Agency and a separate determination. If you have any questions concerning this matter, please feel free to contact this office.

Sincerely,

Gregory F. Yakaboski
Project Analyst

Craig R. Smith, Chief
Certificate of Need Section

Carolina Lithotripsy, LTD.



24 September 2013

Craig Smith, Chief
Certificate of Need Section
Department of Health and Human Services
State of North Carolina
2704 Mail Service Center
Raleigh, NC 27699-2704

RE: Carolina Lithotripsy, Ltd. Replacement Equipment Request and Information

Dear Mr. Smith:

Carolina Lithotripsy has provided extracorporeal shock wave lithotripsy for the treatment of urinary stones since October of 1985. The service is presently provided at 22 acute care hospitals and/or surgery centers in eastern North Carolina by two (2) mobile lithotripters. These present lithotripsy systems were last updated and replaced in November of 2000 (unit #1) and December of 2001 (unit #2).

In late 2011, the equipment manufacturer (Siemens Medical Systems) notified our maintenance service provider that as of December 31, 2013, the present lithotripters would be obsolete and that Siemens would no longer provide support or replacement parts. As a result, Carolina Lithotripsy, Ltd. was left no choice but to prepare for the purchase of replacement lithotripsy equipment. The present mobile coaches will not need to be replaced at this time and the two (2) new lithotripsy systems will be installed in the two (2) present mobile transportation units.

We have taken a critical look at all the new lithotripsy systems which would meet the treatment needs of Carolina Lithotripsy, Ltd. including equipment manufactured by Dornier MedTech, Siemens Medical Systems, Nuesys, and Edap Technomed. After evaluation, it has been determined that our physician providers' and service sites' needs will best be met by purchasing two (2) new Edap Technomed lithotripsy systems which are described below and on the attached forms.

We are in receipt of the information you have provided which specifies the replacement equipment requirements. Carolina Lithotripsy, Ltd. is pleased to provide all requested information, in the format specified, and specifically warrants that our replacement equipment request regarding the equipment to be acquired is consistent with the definition of replacement equipment in G.S. 131E-176(22a) and 10A NCAC 14C .0303.

2014 Litho Place, Fayetteville, NC 28304 (877) 906-0826 ext. 1 (910) 223-0600 fax

As requested, we are providing the following information to the Certificate of Need Section for review and approval. All supporting documents are attached and referenced.

1. Evidence to demonstrate conformance with each criterion in G.S.131E-176 (22a).
G.S. 131E-176(22a)
The total cost for the purchase of two (2) lithotripsy systems, including trade in and discounts, is $767,000.00. The cost per lithotripsy system is $383,500.00 with the purchase of all upgrades. This is well below the $2,000,000 limit for replacing comparable equipment. The present obsolete lithotripsy systems will be disposed of when replaced.

   The above costs includes the costs of all equipment, studies, surveys, designs, plans, working drawings, specifications, construction, installation, and other activities essential to acquiring and making operational the replacement equipment. The executed Edap Technomed purchase contracts are attached as required.

2. A comparison of the existing and replacement equipment, using the specified format, is attached. The manufacturer's model and serial numbers are specifically provided as requested.

3. Extracorporeal shockwave lithotripsy systems consist of a sophisticated device for the generation of high energy acoustic shock waves. These waves are focused with integrated x-ray, fluoroscopy, and ultrasound imaging devices on urinary stones (kidney, ureter, or bladder) so that they are fragmented and passed spontaneously out of the urinary tract. The treatment requires a specialized motorized table to move the patient. Patients require conscious sedation, monitored anesthesia care, or general anesthesia. The treatment is performed by a urologist and the procedure requires the assistance of a specially trained radiological lithotripsy technician and nurse. The newly acquired litho technology will allow for better urinary stone imaging with digital imaging and upgraded ultrasound equipment and a deeper depth of shock wave penetration and a larger table weight capacity for obese patients.

4. The replacement equipment will ***not*** be leased. Carolina Lithotripsy, Ltd. has always purchased all lithotripsy equipment. No lease purchases have been utilized in the past.

5. The replacement equipment will be **purchased** by Carolina Lithotripsy, Ltd..

6. A letter from the company taking possession of the existing equipment that acknowledges the existing equipment will be permanently removed from North Carolina, will no longer be exempt from requirements of the North Carolina Certificate of Need law, and will not be used in North Carolina is attached. Since the present systems are deemed by Siemens to be obsolete, it is not expected that either of these older systems will be in further service at any location.

7. As reported to the CON section on an annual basis, and as published in each year's NC SMFP, the existing lithotripsy systems were purchased in 11/2000 and 12/2001 and have been in continuous service since that time.

Evidence to demonstrate conformance with each criterion in10A NCAC 14C .0303

10A NCAC 14C .0303

(a) The purpose of this Rule is to define the terms used in the definition of "replacement equipment" set forth in G.S. 131E-176(22a). Carolina Lithotripsy, Ltd. has addressed each of the requirements affirmatively as noted below.

(b) "Activities essential to acquiring and making operational the replacement equipment" means those activities which are indispensable and requisite, absent which the replacement equipment could not be acquired or made operational. Without the replacement equipment, Carolina Lithotripsy, Ltd. could not continue to offer mobile lithotripsy services. All activities taken with regard to obtaining and making any replacement equipment operational are indispensible and requisite to continuation of this mobile lithotripsy service.

(c) "Comparable medical equipment" means equipment which is functionally similar and which is used for the same diagnostic or treatment purposes. Carolina Lithotripsy affirms and warrants that the replacement lithotripsy equipment is a newly upgraded model of the existing lithotripsy equipment and that the replacement equipment performs exactly the same diagnostic and therapeutic services as the equipment being replaced.

(d) Replacement equipment is comparable to the equipment being replaced if:

(1) The new lithotripsy equipment has the same basic technology as the equipment currently in use, although it possesses expanded capabilities due to technological improvements in diagnostic and therapeutic digital imaging, shock wave depth of penetration, and a patient table with greater weight capacity. Carolina Lithotripsy, Ltd. certifies that the replacement equipment meets this requirement and the accompanying litho system descriptions confirm the functional capabilities of the replacement lithotripsy systems.

(2) The new lithotripsy equipment is functionally similar and is used for the same diagnostic or treatment purposes as the equipment currently in use and is not used to provide a new health service; and

(3) the acquisition of the new lithotripsy equipment will not result in more than a 10% increase in patient charges or per procedure operating expenses within the first twelve months after the replacement equipment is acquired. Carolina Lithotripsy, Ltd. warrants that these requirements (2 & 3) are met with the replacement equipment specified.

(e) Replacement equipment is not comparable to the equipment being replaced if:

(1) the replacement equipment is new or reconditioned, the existing equipment was purchased second-hand, and the replacement equipment is purchased less than three years after the acquisition of the existing equipment; or

(2) the replacement equipment is new, the existing equipment was reconditioned when purchased, and the replacement equipment is purchased less than three years after the acquisition of the existing equipment; or

(3) the replacement equipment is capable of performing procedures that could result in the provision of a new health service or type of procedure that has not been provided with the existing equipment; or

(4) the replacement equipment is purchased and the existing equipment is leased, unless the lease is a capital lease; or

(5) the replacement equipment is a dedicated PET scanner and the existing equipment is:

(A) a gamma camera with coincidence capability; or

(B) nuclear medicine equipment that was designed, built, or modified to detect only the single photon emitted from nuclear events other than positron annihilation

Carolina Lithotripsy, Ltd. warrants and affirms that it does not meet any of the requirements, definitions, or specifications in item (e) above which would disqualify the replacement lithotripsy equipment as equipment comparable to the existing equipment. The company specifically affirms that it meets all necessary requirements of 10A NCAC 14C .0303 are met and has provided responses which specifically demonstrate compliance will all applicable requirements.

As requested, we have attached a completed Equipment Comparison Form, the Capital Cost Form, and the completed quote and purchase order for the new replacement equipment.

If you need further information, certification or specific, please contact us at our corporate office at (877) 906-0826. We will be pleased to provide any further information and look forward to your approval.

Regards,

Dan A. Myers

By: Dan A. Myers, M.D.
ESL, Inc.
Corporate General Partner

Alan Terry

By: Alan Terry
ESL, Inc.
Corporate General Partner

EQUIPMENT COMPARISON

	EXISTING EQUIPMENT	REPLACEMENT EQUIPMENT
Type of Equipment (List Each Component)	Lithotripter	Lithotripter
Manufacturer of Equipment	Siemens Medical	Edap Technomed
Tesla Rating for MRIs	N/A	N/A
Model Number	B132G	Sonolith i-move
Serial Number	01137 and 01139	SIMT 091 and SIMT 101
Provider's Method of Identifying Equipment	Site visits	Site visits
Specify if Mobile or Fixed	Mobile	Mobile
Mobile Trailer Serial Number/VIN # (Self contained mobile units)	* See below	* See below
Mobile Tractor Serial Number/VIN #	N/A	N/A
Date of Acquisition of Each Component	11/15/2000 & 12/15/2001	12/1/2013
Does Provider Hold Title to Equipment or Have a Capital Lease?	Title	Title
Specify if Equipment Was/Is New or Used When Acquired	New	New
Total Capital Cost of Project (Including Construction, etc.) <Use Attached Form>	NA	$767,000
Total Cost of Equipment	$846,000	$767,000
Fair Market Value of Equipment	NA	$767,000
Net Purchase Price of Equipment	NA	$767,000
Locations Where Operated	22 hospitals	22 hospitals
Number Days In Use/To be Used in N.C. Per Year	260	260
Percent of Change in Patient Charges (by Procedure)	NA	0
Percent of Change in Per Procedure Operating Expenses (by Procedure)	NA	0
Type of Procedures Currently Performed on Existing Equipment	Lithotripsy	NA
Type of Procedures New Equipment is Capable of Performing	NA	Lithotripsy

*** Trailer #1 – Vin # 1FVHCYBS6BDAW8121, Trailer #2 – Vin #1FVHCYBS8BDAW8122 (*Trailers not being replaced*)**

PROPOSED TOTAL CAPITAL COST OF PROJECT

Project Name: _____ **Replacement Lithotripters** _____
Provider/Company:_____ **Carolina Lithotripsy, Ltd.** _____

A. **Site Costs**			
(1) Full purchase price of land		$_____	
Acres _____ Price per Acre $_____			
(2) Closing costs	$_____		
(3) Site Inspection and Survey		$_____	
(4) Legal fees and subsoil investigation		$_____	
(5) Site Preparation Costs			
Soil Borings.....	$_____		
Clearing-Earthwork...	$_____		
Fine Grade For Slab...	$_____		
Roads-Paving.....	$_____		
Concrete Sidewalks....	$_____		
Water and Sewer.....	$_____		
Footing Excavation....	$_____		
Footing Backfill.....	$_____		
Termite Treatment....	$_____		
Other (Specify).....	$_____		
Sub-Total Site Preparation Costs		$_____	
(6) Other (Specify)		$_____	
(7) **Sub-Total Site Costs**			$_____
B. **Construction Contract**			
(8) Cost of Materials			
General Requirements	$_____		
Concrete/Masonry	$_____		
Woods/Doors & Windows/Finishes	$_____		
Thermal & Moisture Protection	$_____		
Equipment/Specialty Items	$_____		
Mechanical/Electrical	$_____		
Other (Specify)	$_____		
Sub-Total Cost of Materials.....		$_____	
(9) Cost of Labor.....		$_____	
(10) Other (Specify).....		$_____	
(11) **Sub-Total Construction Contract**			$_____
C. **Miscellaneous Project Costs**			
(12) Building Purchase.....		$_____	
(13) Fixed Equipment Purchase/Lease		$_____	
(14) Movable Equipment Purchase/Lease		$**767,000.00**	
(15) Furniture		$_____	
(16) Landscaping		$_____	
(17) Consultant Fees			
Architect and Engineering Fees	$_____		
Legal Fees.....	$_____		
Market Analysis.....	$_____		
Other (Specify).....	$_____		
Other (Specify).....	$_____		
Sub-Total Consultant Fees.....		$_____	
(18) Financing Costs (e.g. Bond, Loan, etc.).		$_____	
(19) Interest During Construction.		$_____	
(20) Other (Specify)		$_____	
(21) **Sub-Total Miscellaneous..**			$_____
(22) **Total Capital Cost of Project** (Sum A-C above)			$**767,000.00**

I certify that, to the best of my knowledge, the costs of the proposed project named above are complete and correct.

_____ Date Certified: _____
(Signature of Licensed Architect or Engineer)

I assure that, to the best of my knowledge, the above costs for the proposed project are complete and correct and that it is my intent to carry out the proposed project as described.

Alan Terry _____Date Signed: _____09/23/2013_____
(Signature and Title of Officer Authorized to Represent Provider/Company)

edap tms

Bringing New Horizons to Therapy

September 23, 2013

CON Board of North Carolina

RE: Edap Sonolith I-Move Lithotripters

To Whom It May Concern: Edap Technomed will be removing and replacing two lithotripsy systems with Carolina Litho. Edap will be de-installing the current equipment at Carolina Litho and will replace it with two Sonolith I-move systems. Edap plans to remove the de-installed equipment from the state of North Carolina for disposal.

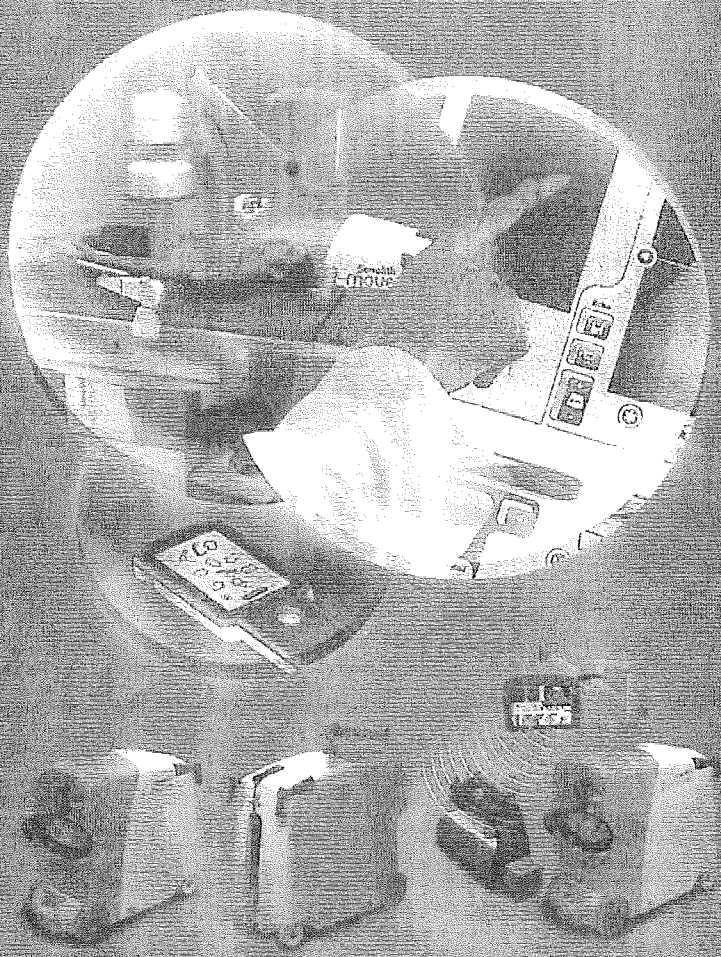
Please do not hesitate to contact me if you have any questions or concerns.

Best regards,

Jeff Howell
Vice President
Edap Technomed, Inc.
jhowell@edap-usa.com
678-772-8974

Sonolith

i-move



Sales Offer

edap tms

Bringing New Horizons to Therapy

Sonolith i-move

September 19, 2013 Ref: JHO/AAS/IMOVE/190913-1

SALES OFFER

To:
Carolina Litho
Dan Myers, MD
2014 Litho Place
Fayetteville NC 28304

Validity: 3 months from dates of issue

I - INTRODUCTION

EDAP TMS has designed, developed and manufactured in France a device called **Sonolith® i-move** (hereinafter **"the Equipment"**), that it markets throughout the world. The characteristics of this Equipment are more fully described in Appendix I. EDAP TMS France (the **"Seller"**) and the Buyer agreed upon certain terms on the sale of Equipment as defined below (the **"Sales Offer"**).

Equipped with the Electro-Conductive Generator (DIATRON V), the Sonolith i-move enables fast, easy and safe stone disintegration.

The Sonolith i-move is a compact, mobile and independent module composed of :

- an electro-conductive shock wave pressure generator
- an easy-to-use and functional interface, in the form of a simplified remote control keyboard

II – SPECIFIC SALE TERMS

ARTICLE 1: SUBJECT OF THE SALE

The Seller agrees to sell to Carolina Litho ("the Buyer"), and Buyer accepts to purchase the Equipment, such as it exists, without exception or reservation, and for which a list and description, acknowledged by the Parties, are annexed to the present contract (the "Contract") (Appendix I).

Depending on the terms specified in the General Sale Terms, delivery of the Equipment shall entail furnishing the following services: Sonolith i-move equipment, parts and warranty.

ARTICLE 2: PRICE

Net DDP Price: US$383,500.00 corresponding to the price for a two system purchase ($383,500 for each system), its accessories and services provided, as specified in Appendix I, and summarized hereunder:

- Sonolith i-move ESWL module **(Touch Configuration)**
- Karbon W2E Table
- X-Ray C-arm : OEC 9900 Super C
- Amatech Arm Support
- Philips ECG Monitor
- Supply of Electrodes during the warranty period (*); also to include other consumables such as membrane covers for the generator
  (*): Electrodes will be delivered on a regular basis and in consistency with effective utilization of the device. During the warranty or service agreement period only.
- 1 year warranty (parts and service)
- Installation and training onsite

Incoterms: DDP Fayetteville, NC

Terms for Payment of Price:

- 25% Down Payment at the order
- 50% Payment at delivery
- 25% Payment after first treatment performed.

This agreement will become binding upon confirmation of financing for Carolina Litho.

Upon receipt of the invoice, the Buyer will have to settle this price by Bank transfer to the Seller's bank account, for which the details are.

NATIXIS BANQUE
30, Avenue Pierre Mendès France - 75 013 Paris - FRANCE
Account n° FR76 3000 7530 2904 0076 2700 062
BIC : NATXFRPPXXX

Beneficiary : EDAP TMS France

ARTICLE 4 – TRANSPORT, DELIVERY, INSTALLATION, INSURANCE, WARRANTY

Transport will be carried out according to the Incoterm DDP Fayetteville, NC.

Delivery of Equipment shall be carried out within a maximum of 3 months from receipt of the firm and final order, execution of the present Contract and receipt of the up-front downpayment.

Installation: The Seller shall take responsibility to install the Equipment at the premises designated by the Buyer

Warranty: 12 months from the date of installation.

ARTICLE 5 : TRAINING

The Training conditions are indicated in Appendix II as well as in the General Sale Terms.

Marc OCZACHOWSKI
President
EDAP Technomed, Inc.
EDAP TMS France

Alan Terry
General Partner
Carolina Litho, Inc.
Fayetteville, NC

Jeff Howell
Vice President
EDAP Technomed, Inc.

III - GENERAL SALE TERMS

ARTICLE 1 – PRIMACY OF THE CONTRACT

The Sale, for which the terms are given in the Specific Sale Terms, involves acceptance without reservation by the Buyer of this Contract, which prevails over any other document of the Buyer, and in particular, over any general purchase terms of the Buyer, without express and preliminary agreement to the contrary from the Seller. Any document other than this Contract, and particularly catalogues, prospectuses, advertisements or notices, have only an informative and indicative, rather than contractual value.

ARTICLE 2 – TRANSPORT, DELIVERY AND INSTALLATION OF THE EQUIPMENT

2.1 - The delivery time frame is given only for information. In particular, it depends on the availability of transport companies. Consequently, delays in delivery may not give way to any penalty or compensation or reason for cancelling the Sale. The Equipment shall be put at the disposal of the Buyer in good functioning condition and with all accessories and any technical documentation needed. It shall be delivered free of any pledge, claim or rights of third parties.

2.2 - The transfer of risks of the Equipment sold will be implemented FCA (Free Carrier At), unless specifically mentioned otherwise in the Specific Sale Terms. The liability of the Seller may in no case be brought into question due to occurrences during transport, destruction, damages, loss or theft, even because of the Seller's choice of Transport Company. The Buyer shall indicate receipt of the Equipment by signing a receipt. In the event of damage to the Equipment delivered, it is up to the Buyer to furnish all necessary reservations to the transport company. Any Equipment, in all or in part, which has not been the subject of reservations by registered letter with return receipt sent to the transport company within 3 days of its receipt, with a copy sent simultaneously to the Seller, shall be considered accepted by the Seller. No return of the Equipment may validly be made by the Buyer without the express and written advance agreement of the Seller. Only the transport company selected by the Seller is authorized to return the Equipment. Receipt of the Equipment without reservation covers any apparent flaw and/or missing part. Any possible claim made by the Buyer shall not be cause for suspending payment for the Equipment.

2.3 - The Buyer shall ensure, before Delivery, that the premises in which the Equipment is installed, are compatible with the use to be made of the Equipment. The Buyer alone shall assume the expenses and costs which must be undertaken to conform to this provision.

ARTICLE 3 – TRAINING OF PERSONNEL WHO WILL BE USERS

The Seller shall undertake to train under the specific terms given in dedicated APPENDIX the number of doctors and technicians agreed upon. It shall bring all necessary care to the adequate training of said persons, with the goal of proper use of the Equipment.

ARTICLE 4 – LATE INTEREST

Any amount not paid by the due date will give way to payment by the Buyer of penalties set at one and one half times the legal rate of interest. Said penalties shall be due and payable automatically, without advance warning, in conformity with article L.441-6 of the Commercial Code under French law.

ARTICLE 5 – TRANSFER OF OWNERSHIP

5.1 – Transfer of ownership of the Equipment and risks attached to the Equipment sold, shall be made in accordance with the Incoterm used in the Specific Sale Terms or upon signing the Delivery Form (for a delivery in France). However, in the event of Buyer's default on full payment of Equipment, can recover the ownership of the Equipment.

5.2 – In the event of Buyer's default on full payment of Equipment, the Seller will be in its right to apply current Article 5.1. and to recover ownership of Equipment by implementing any appropriate action.

5.3 – Despite above reservation of ownership clause, liability for economic risks associated with the Equipment are fully transferred to the Buyer upon delivery. As from delivery of Equipment, the Buyer is the responsible for the Equipment. Consequently, the Buyer will be directly and personally responsible for any deterioration, loss or theft of Equipment and its accessories, upon delivery.

ARTICLE 6 – USE OF THE EQUIPMENT BY THE BUYER

6.1 - The Buyer is responsible for obtaining all authorizations, discharges and licenses necessary to use the Equipment.

6.2 - The Buyer shall undertake to make certain that only a qualified person who is informed of the conditions for using the Equipment has access to it. It shall also make sure that the users of the Equipment respect the instructions given by the Seller as to its functioning, in conformity with the User Manual. Under penalty of losing the benefit of the Warranty, the Buyer shall undertake to make no modification of the Equipment, to affix no additional part to the Equipment and to use no hardware or equipment in relation to the Equipment without having obtained advance written agreement from the Seller. All consequences of any kind, resulting from improper use of the Equipment shall remain the full and complete responsibility of the Buyer.

ARTICLE 7 – INTELLECTUAL PROPERTY

7.1 - The Buyer expressly acknowledges that the Seller is the sole holder of all the intellectual and industrial property rights attached to the Equipment, and in particular of all the patents, software and hardware, drawings and models for manufacture, marketing and use of the Equipment, as well as registered trademarks. Any invention, improvement, or modification of the Equipment suggested by the Buyer or generated by the use of the Equipment by the Buyer, shall be the exclusive property of the Seller. It shall have the sole right to take any steps for purposes of translating such inventions, improvements or modifications into patents or other protections of intellectual and industrial property rights.

7.2 - The Buyer shall undertake to alert The Seller immediately and by every means, of any request, demand or claim of any third parties concerning intellectual and industrial property rights attached to the Equipment. The Buyer shall also alert the Seller immediately if he knows of any hardware, consumable item or equipment put into circulation violating the intellectual and industrial property rights of the Seller. The Seller is alone responsible for the decision for prosecution, complaint, proof, defense, backup, all formalities modifying the registration or any other steps with the appropriate authorities and courts. The Buyer shall undertake to collaborate with the Seller upon its request.

7.3 - All technical documents given to the Buyer shall remain the exclusive property of the Seller, the sole holder of the intellectual and industrial property rights for the documents. The Buyer shall undertake to make no use of these documents under conditions which are likely to damage the intellectual or industrial property rights of the Seller. It shall undertake in particular not to divulge them to any third party.

ARTICLE 8 - THE SELLER 'S WARRANTY

8.1 - The Equipment must be checked by the Buyer upon its Delivery, and all claims, reservations or disputes related to missing parts and apparent defects must be made under the conditions set in article 2. When an apparent flaw is observed by the Seller or its representative after the inspection, the Buyer may only request the replacement of the elements not conforming and/or the additional part to be brought to complete what is missing, without being able to claim any compensation or termination of the sale. The Buyer will have to furnish any proof as to the reality of the observed defects. The Seller reserves the right to proceed directly or indirectly with any observation or verification at the site.

8.2 - The accusation of defects existing at the time of the Delivery and revealed upon receipt of the products will have to be made by the Buyer in writing within a time limit of 3 days following the date on which he discovered the lack of conformity. No accusation shall be considered if it comes more than 3 clear days after delivery of the Equipment.

8.3 - Defects and deteriorations of the Equipment following abnormal conditions of storage and/or upkeep at the Buyer's place, particularly in case of an accident of any kind may not give any right to the warranty due by the Seller.

The Warranty is excluded in the event of:

- lack of respect of the instructions specified in the technical documentation and the User Manual by the users of the Equipment;
- use of the equipment for purposes others than for those for which it was designed or under abnormal conditions;
- poor maintenance of the Equipment;
- Use, addition or modification of elements or parts not authorized by the Seller;
- Partial or total destruction resulting from a case of force majeure;
- a fault in the fitting out of the premises housing the Equipment;
- refusal of the Buyer to cooperate with the Seller to make it possible for it to make repairs of the Equipment;

8.4 - The Seller warranties the Equipment against all hidden defects under the conditions below:

- Hidden defects are understood to be flaws in the realization of the Equipment making it unsuitable for its use and unlikely to be uncovered by the Buyer before its use. A flaw in the design is not a hidden defect, and the Buyer is considered to have received all technical information concerning the Equipment.
- The Warranty is limited to replacing or repairing the defective parts.
- The length of the Warranty is 12 months following Delivery, unless there is a contrary agreement in the specific terms. It shall cease automatically at the end of this period or if the Buyer has not given notice of the alleged defect within the time limit of twenty days following its discovery.
- Under this Warranty against hidden defects, the Seller shall be obligated only to replace without cost, the defective products, without the Buyer being able to claim damages and interest, for any reason.
- During the duration of the warranty period, the Seller warrants that the Equipment put at the disposal of the Buyer shall be in a good functional state. In the event of breakdown or poor functioning of all or part of the Equipment, the liability of the Seller, however, may not be sought and required beyond providing the following services, which it shall undertake to furnish: any operation to repair the Equipment; any replacement of the defective part, or, if needed, of all or part of the Equipment. Subject to the provisions specified in 8.5 hereinafter, the costs necessary to respect this provision shall be the responsibility of the Seller.

8.5 - Throughout the duration of the warranty period, the cost of any possible repair, return to a functioning state or replacement related to the Equipment, shall be the responsibility of the Buyer in the following cases:

- All or part of the Equipment is subject to poor function or breakdown due to damage, fault or negligence of the Buyer or any other person not authorized by the Seller, who had access to the Equipment.
- All or part of the Equipment has been used by the Buyer in a way that is inappropriate and contrary to the recommendations given in the User Manual and specified to that effect.
- All or part of the Equipment has been the subject of a incorrect repair or manipulation by any person not authorized by the Seller, and/or has been repaired using spare parts not furnished by the Seller;
- All or part of the Equipment is moved from its original site without the move having been authorized in advance by the Seller;
- All or part of the Equipment does not function or does not function correctly due to a case of force majeure, in particular any events or circumstances that are abnormal or independent of the will and control of the Seller, such as, for example, any climatic disturbances, strikes and/or political conflicts;

8.6 – The Equipment is CE mark, conforming European 93/42 Recommendation on Medical Devices. The Seller has established a dedicated Quality Assurance system conforming European ISO 9001 (2008) and ISO 13485 (2003) standards. In line with European 2002/95/CE and 2002/96/CE recommendations, the Seller can provide the data necessary to identify components. The Seller considers it is the Buyer's responsibility to take care of the collection and recycling of the Equipment and its accessories; if parties agree differently, it should be specified in the Specific Sale Terms.

8.7 - If the Buyer decides to assign or rent the Equipment to a third party, in any manner, the Seller shall not have any obligation to this third party and shall be discharged from any responsibility toward this third party and the Buyer.

8.8 - Maintenance - Upkeep: Throughout the warranty period specified in 8.4 above, the Seller shall ensure the maintenance and upkeep of the Equipment, which it may subcontract under its own responsibility. Maintenance shall include the possibility that the Seller may regularly inspect the Equipment or have it inspected by qualified technicians. The Seller shall select the time period for this inspection. It will agree with the Buyer on the dates for its appearance. To that effect, the Seller shall alert the Buyer at least 15 days in advance of its intention of conducting such a review. Any maintenance shall be carried out by the Seller at the Buyer's premises at times that the Parties have determined in advance. The Buyer shall undertake to alert the Seller immediately by every means in the event of improper function or breakdown of the Equipment, or of any other event or circumstance involving a technical problem of the Equipment.

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For performance of the Contract, the Parties elect domicile at their respective registered offices as indicated at the head of this document. The Parties shall undertake to notify each other mutually of any changes in possible addresses. In this event, the new address will be equivalent to a new election of domicile as of the date the abovementioned notification is received.

ARTICLE 11 – WAIVERS - RIDERS

No delay whatever made by a Party in the exercise of any of its rights or claims will be considered as a waiver on its part of the right or claim in question, and the fact that whichever Party has exercised such a right or claim on a single occasion or in a partial manner in no way prevents the Party in question from exercising said right or claim again or in full. This Contract may be modified only by a written rider, signed by the two Parties.

ARTICLE 12 – AUTONOMY

If any one of the stipulations of this Contract or its application under certain circumstances is considered impossible, null and void or illicit by a competent court or administration, this stipulation shall be considered as unwritten or inapplicable under said circumstance, and the other Contract stipulations shall not be affected. The Parties will then have to begin negotiations in good faith to replace the stipulation concerned by a valid, licit, or applicable stipulation which will have a financial effect as close as possible to that of the stipulation concerned.

ARTICLE 13 – APPLICABLE LAW - ARBITRATION

13.1 - This Contract shall be governed by French Law.

13.2 - ARBITRATION: The Parties agree that all differences or disputes which may occur on the occasion of interpretation or performance of the Contract shall be settled by means of arbitration introduced according the procedure hereinafter.

- Each Party, if it desire recourse to arbitration, shall alert the other by registered letter with return receipt requested, notifying it on the one hand, of the name and address of the arbitrator that it has designated to represent it, and on the other hand, by presenting succinctly the subject of the dispute or matter contested that it wishes to see settled by arbitration.
- The other Party shall have a time limit of thirty clear days to designate its own arbitrator and give notice to the complainant. Lacking such, the party which has not designated its arbitrator within the time limit granted shall be considered as having yielded in the dispute or contest raised.
- The two arbitrators so designated by the Parties shall consult each other to designate by mutual agreement a third arbitrator within 15 days from the naming of the second arbitrator.
- The court of arbitration which has its seat in Lyon shall be validly appointed as soon as the three arbitrators accept their mission. In the event that the parties have not designated their arbitrator within the time limit above or the arbitrators have not named the third arbitrator, the missing arbitrator or arbitrators shall be designated by the chief judge of the Commercial Court of Lyon, ruling in a summary manner, upon the request of the most diligent Party or arbitrator. In case of hindrance, abstention, departure or death of one of the arbitrators, he will be replaced under the conditions described above.
- The procedure will be that stipulated by French law, and more particularly by Book IV of the New Code of Civil Procedure. The court of arbitration shall not have the power of amicable settlement.
- The decision will have to be handed down as soon as possible, and at the latest within a time limit of three (3) months after bringing the matter before the arbitration court. In its decision, the court of arbitration shall set the costs of arbitration which will have to be borne in equal parts by each Party, with the exception, however, of the expenses and fees of attorneys, counsels and experts coming upon the exclusive request of one of the Parties, which shall then be borne by the Party which has asked for the appearance of said attorney, counsel and experts. The arbitration court may ask the Parties for any advances which they consider necessary during the procedure. These advances will be settled in an equal manner between the Parties.
- The decision of the arbitration court may not be appealed.

ARTICLE 14 – COSTS AND SURCHARGES

All fines, amounts for infractions, taxes and surcharges, revenue tax stamps or registrations, publicity costs at the office of the clerk of the court, which are due and payable by reason of use of the Equipment or more generally by performance of the Contract, are the responsibility of the Buyer. In the event of variation in the tax and surcharge system related to use of the Equipment, the Seller may apply any variations in surcharges to the amounts of invoices. In particular, the Buyer will have to settle all amounts that the Seller may be called upon to pay to the tax authorities.

APPENDIX I - DESCRIPTION OF THE EQUIPMENT

The Sonolith® i-move is an extra-corporal lithotripsy module used for the non-invasive disintegration of urinary tract stones. The Equipment offered is CE marked in conformity with the requirement of directive DM 93/42 CEE. EDAP TMS France has established a system of quality assurance and control which conforms the requirements of ISO 9001 (2008) and ISO 13485 (2003) standards.

ELECTROCONDUCTIVE ENERGY PRINCIPLES

The electroconductivity is based upon the principle of the F1 focus control and of the perfect control of the shock wave emitted by an encapsulated electrode containing a supraconductive solution which is located in the Diatron V generator.

With this technology, shock waves generated in a highly conductive electrolytic solution are precise, delivering a reproducible energy at a stable shot-to-shot intensity.
The electro-acoustic efficiency is greatly improved by the new shallow ellipsoidal reflector specially designed for ECL with high-energy concentration maximized on the stone. Disintegration efficacy is therefore highly optimised.

By increasing the diameter of the ellipse, we have enlarged the entry area of the shock wave at the skin level for a painless treatment. Therefore, the Sonolith® i-move can be used without anesthesia.

The electroconductive generator of the Sonolith® i-move uses an electrode to generate the pressure waves. The electrode's life span is limited by the number of shock waves produced as well as by the preservation limit after the first date of use.

A storage bench for the electrodes is delivered with the Sonolith® i-move and enables the use of an electrode 15 days after opening of the packaging (within the limits of the number of shock waves produced).

1. SONOLITH I-MOVE EXTRACORPOREAL SHOCKWAVE LITHOTRIPOR MODULE

a) Isocentric Electroconductive® shock wave generator model Diatron V.

- Dry patient coupling system with silicone membrane
- Internal water tank
- Automatic draining and filling-up
- Adjustable shock wave pressure level (100 levels from 1% to 100%)
- Real time pressure control: PVDF hydrophone built-in with indication of the delivered "lithotripsy dose"
- Opening angle of the shockwaves: 80°
- Treatment depth: 160mm
- Aperture : 250 mm
- 2 treatment positions (0° / 50° relative to the vertical axis). The rotation from one position to the other is achieved manually

b) Hand Control Touch-screen remote control

- Treatment parameters (power, frequency, ...)
- Firing button

2. I-MOVE TOUCH CONFIGURATION

a) Integrated computer

- Patient and treatment database
- R/X and U/S image acquisition (depending on C-arm and U/S system used)
- Treatment and analysis software included

b) 20" LCD color monitor (1600 X 1200 px) attached to the module, touch screen user's interface

- Full control of the Sonolith® i-move and table motorized movements and parameters
- Patient and treatment database
- Dual X-Ray and U/S live imaging (depending on C-arm and U/S system used)

3. KARBON-W2E TABLE

a) Table Description

The full-carbon dual cut-out 4-axis motorized table enables ESWL and Cystoscopy procedures. A remote control operates the movements of the table. Designed for use in an ambulatory clinical environment, this table is also available for operation if the anaesthetizing gases used are not explosive. The patient support is the complement of the electroconductive® generator and has been developed in order to correspond to the needs of mobile lithotripsy and cystoscopy for urologists, ideal for all interventions in the lower urinary tract.

- Endo-urological applications
- Retrograde uretroscopies
- Intracorporal lithotripsy
- Urethral catheterization
- Cystoscopies
- TURP
- PCN

Combined applications with radiology C-arm:

- KUB (with or without preparation)
- Pelvography
- Ureterocystography
- Ureterography
- Vasovesiculography

Combined applications with Ultrasound:

- Diagnosis of the entire urinary tract
- Diagnosis of the entire urogenital area
- Imaging of the blood vessels of the urinary tract
- Brachytherapy

This motorised table is composed of:

- A patient support unit comprising a 4 axis motion radiolucent table-top with two apertures for lithotripsy (one on each side for the treatment head) and custom shutters,
- A head extension unit
- A foot extension unit and stirrup couplings
- Standard side-rails for accessories
- A remote control

b) Table Sepcifications

Total length with extension: .....2615 mm
Total length without extension: ..1265 mm
Width (without extensions): .....730 mm
Maximum patient weight: .....200 kg
Total table weight: .....350 kg

Range of displacement in Litho mode:

- Longitudinal: 60mm (+/- 30mm)
- Transversal: 110mm (-30 / +80 mm)
- Vertical: 170mm (-60 / +110 mm)

Range of displacement in Endo-Uro mode:

- Longitudinal: 345mm (-245 / +100mm)
- Transversal: 147mm (-145 / +2 mm)
- Vertical: 180mm (0 / +180 mm)
- Trendelenburg: +/- 15°

Manual controls via:

- The specific table remote control placed on the side of patient loading
- The remote control attached on the Sonolith® i-move module
- The User's Interface on the LCD touch screen

c) Table Accessories (Option)

List accessories offered:

- Amatech Lift Assist Boot Stirrups (one pair)
- Amatech Arm rest

Sonolith

4. X-ray SYSTEM: OEC 9900 Super C mobile C-arm

1. 9900 Super C Portable C-arm System.
2. 15 KW Generator
3. 9" Image Intensifier
4. Digital Image Rotation
5. Preview Collimator
6. Fluoro & Pursed Fluoro Mode
7. Digital Spot Mod3
8. ABS (Automatic Brightness Stabilization

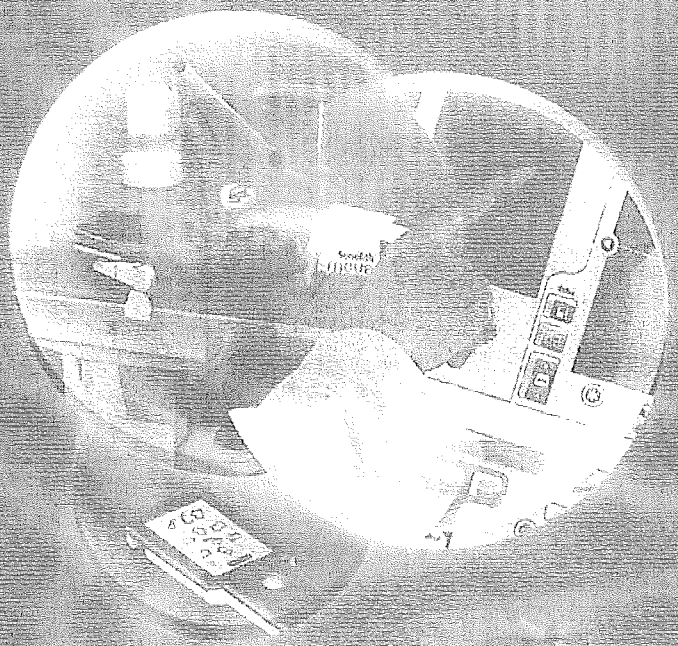
APPENDIX II - TRAINING

The Seller reminds the Buyer that only operators trained on the Sonolith® i-move shall have access to operate the Equipment.

One physician designated by the Buyer will undergo a two-day training course on site by an EDAP-TMS France Applications Specialist, to achieve proficiency in the use of the equipment.

Sonolith

i-move



Sales Offer

edap tms

Bringing New Horizons to Therapy

September 19, 2013 Ref: JHO/AAS/IMOVE/190913-2

SALES OFFER

To:
Carolina Litho
Dan Myers, MD
2014 Litho Place
Fayetteville NC 28304

Validity: 3 months from dates of issue

I - INTRODUCTION

EDAP TMS has designed, developed and manufactured in France a device called **Sonolith® i-move** (hereinafter "**the Equipment**"), that it markets throughout the world. The characteristics of this Equipment are more fully described in Appendix I. EDAP TMS France (the "**Seller**") and the Buyer agreed upon certain terms on the sale of Equipment as defined below (the "**Sales Offer**").

Equipped with the Electro-Conductive Generator (DIATRON V), the Sonolith i-move enables fast, easy and safe stone disintegration.

The Sonolith i-move is a compact, mobile and independent module composed of :

- an electro-conductive shock wave pressure generator
- an easy-to-use and functional interface, in the form of a simplified remote control keyboard

II – SPECIFIC SALE TERMS

ARTICLE 1: SUBJECT OF THE SALE

The Seller agrees to sell to Carolina Litho ("the Buyer"), and Buyer accepts to purchase the Equipment, such as it exists, without exception or reservation, and for which a list and description, acknowledged by the Parties, are annexed to the present contract (the "Contract") (Appendix I).

Depending on the terms specified in the General Sale Terms, delivery of the Equipment shall entail furnishing the following services: Sonolith i-move equipment, parts and warranty.

ARTICLE 2: PRICE

Net DDP Price: US$383,500.00 corresponding to the price for a two system purchase ($383,500 for each system), its accessories and services provided, as specified in Appendix I, and summarized hereunder:

- Sonolith i-move ESWL module **(Touch Configuration)**
- Karbon W2E Table
- X-Ray C-arm : OEC 9900 Super C
- Amatech Arm Support
- Philips ECG Monitor
- Supply of Electrodes during the warranty period (*); also to include other consumables such as membrane covers for the generator
  (*): Electrodes will be delivered on a regular basis and in consistency with effective utilization of the device. During the warranty or service agreement period only.
- 1 year warranty (parts and service)
- Installation and training onsite

Incoterms: DDP Fayetteville, NC

Terms for Payment of Price:

- 25% Down Payment at the order
- 50% Payment at delivery
- 25% Payment after first treatment performed.

This agreement will become binding upon confirmation of financing for Carolina Litho.

Upon receipt of the invoice, the Buyer will have to settle this price by Bank transfer to the Seller's bank account, for which the details are:

NATIXIS BANQUE
30, Avenue Pierre Mendès France - 75 013 Paris - FRANCE
Account n° FR76 3000 7530 2904 0076 2700 062
BIC : NATXFRPPXXX

Beneficiary : EDAP TMS France

ARTICLE 4 – TRANSPORT, DELIVERY, INSTALLATION, INSURANCE, WARRANTY

Transport will be carried out according to the Incoterm DDP Fayetteville, NC

Delivery of Equipment shall be carried out within a maximum of 3 months from receipt of the firm and final order, execution of the present Contract and receipt of the up-front downpayment.

Installation: The Seller shall take responsibility to install the Equipment at the premises designated by the Buyer.

Warranty: 12 months from the date of installation.

ARTICLE 5 : TRAINING

The Training conditions are indicated in Appendix II as well as in the General Sale Terms.

Marc OCZACHOWSKI
President
EDAP Technomed, Inc.
EDAP TMS France

Alan Terry
General Partner
Carolina Litho, Inc.
Fayetteville, NC

Jeff Howell
Vice President
EDAP Technomed, Inc.

III - GENERAL SALE TERMS

ARTICLE 1 – PRIMACY OF THE CONTRACT

The Sale, for which the terms are given in the **Specific Sale Terms**, involves acceptance without reservation by the Buyer of this Contract, which prevails over any other document of the Buyer, and in particular, over any general purchase terms of the Buyer, without express and preliminary agreement to the contrary from the Seller. Any document other than this Contract, and particularly catalogues, prospectuses, advertisements or notices, have only an informative and indicative, rather than contractual value.

ARTICLE 2 – TRANSPORT, DELIVERY AND INSTALLATION OF THE EQUIPMENT

2.1 - The delivery time frame is given only for information. In particular, it depends on the availability of transport companies. Consequently, delays in delivery may not give way to any penalty or compensation or reason for cancelling the Sale. The Equipment shall be put at the disposal of the Buyer in good functioning condition and with all accessories and any technical documentation needed. It shall be delivered free of any pledge, claim or rights of third parties.

2.2 - The **transfer of risks** of the Equipment sold will be implemented FCA (Free Carrier At), unless specifically mentioned otherwise in the Specific Sale Terms. The liability of the Seller may in no case be brought into question due to occurrences during transport, destruction, damages, loss or theft, even because of the Seller's choice of Transport Company. The Buyer shall indicate receipt of the Equipment by signing a receipt. In the event of damage to the Equipment delivered, it is up to the Buyer to furnish all necessary reservations to the transport company. Any Equipment, in all or in part, which has not been the subject of reservations by registered letter with return receipt sent to the transport company within 3 days of its receipt, with a copy sent simultaneously to the Seller, shall be considered accepted by the Seller. No return of the Equipment may validly be made by the Buyer without the express and written advance agreement of the Seller. Only the transport company selected by the Seller is authorized to return the Equipment. Receipt of the Equipment without reservation covers any apparent flaw and/or missing part. Any possible claim made by the Buyer shall not be cause for suspending payment for the Equipment.

2.3 - The Buyer shall ensure, before Delivery, that the premises in which the Equipment is installed, are compatible with the use to be made of the Equipment. The Buyer alone shall assume the expenses and costs which must be undertaken to conform to this provision.

ARTICLE 3 – TRAINING OF PERSONNEL WHO WILL BE USERS

The Seller shall undertake to train under the specific terms given in dedicated APPENDIX the number of doctors and technicians agreed upon. It shall bring all necessary care to the adequate training of said persons, with the goal of proper use of the Equipment.

ARTICLE 4 – LATE INTEREST

Any amount not paid by the due date will give way to payment by the Buyer of penalties set at one and one half times the legal rate of interest. Said penalties shall be due and payable automatically, without advance warning, in conformity with article L.441-6 of the Commercial Code under French law.

ARTICLE 5 – TRANSFER OF OWNERSHIP

5.1 – Transfer of ownership of the Equipment and risks attached to the Equipment sold, shall be made in accordance with the Incoterm used in the Specific Sale Terms or upon signing the Delivery Form (for a delivery in France). However, in the event of Buyer's default on full payment of Equipment, can recover the ownership of the Equipment.

5.2 – In the event of Buyer's default on full payment of Equipment, the Seller will be in its right to apply current Article 5.1. and to recover ownership of Equipment by implementing any appropriate action.

5.3 – Despite above reservation of ownership clause, liability for economic risks associated with the Equipment are fully transferred to the Buyer upon delivery. As from delivery of Equipment, the Buyer is the responsible for the Equipment. Consequently, the Buyer will be directly and personally responsible for any deterioration, loss or theft of Equipment and its accessories, upon delivery.

ARTICLE 6 – USE OF THE EQUIPMENT BY THE BUYER

6.1 - The Buyer is responsible for obtaining all authorizations, discharges and licenses necessary to use the Equipment.

6.2 - The Buyer shall undertake to make certain that only a qualified person who is informed of the conditions for using the Equipment has access to it. It shall also make sure that the users of the Equipment respect the instructions given by the Seller as to its functioning, in conformity with the User Manual. Under penalty of losing the benefit of the Warranty, the Buyer shall undertake to make no modification of the Equipment, to affix no additional part to the Equipment and to use no hardware or equipment in relation to the Equipment without having obtained advance written agreement from the Seller. All consequences of any kind, resulting from improper use of the Equipment shall remain the full and complete responsibility of the Buyer.

ARTICLE 7 – INTELLECTUAL PROPERTY

7.1 - The Buyer expressly acknowledges that the Seller is the sole holder of all the intellectual and industrial property rights attached to the Equipment, and in particular of all the patents, software and hardware, drawings and models for manufacture, marketing and use of the Equipment, as well as registered trademarks. Any invention, improvement, or modification of the Equipment suggested by the Buyer or generated by the use of the Equipment by the Buyer, shall be the exclusive property of the Seller. It shall have the sole right to take any steps for purposes of translating such inventions, improvements or modifications into patents or other protections of intellectual and industrial property rights.

7.2 - The Buyer shall undertake to alert The Seller immediately and by every means, of any request, demand or claim of any third parties concerning intellectual and industrial property rights attached to the Equipment. The Buyer shall also alert the Seller immediately if he knows of any hardware, consumable item or equipment put into circulation violating the intellectual and industrial property rights of the Seller. The Seller is alone responsible for the decision for prosecution, complaint, proof, defense, backup, all formalities modifying the registration or any other steps with the appropriate authorities and courts. The Buyer shall undertake to collaborate with the Seller upon its request.

7.3 - All technical documents given to the Buyer shall remain the exclusive property of the Seller, the sole holder of the intellectual and industrial property rights for the documents. The Buyer shall undertake to make no use of these documents under conditions which are likely to damage the intellectual or industrial property rights of the Seller. It shall undertake in particular not to divulge them to any third party.

ARTICLE 8 - THE SELLER'S WARRANTY

8.1 - The Equipment must be checked by the Buyer upon its Delivery, and all claims, reservations or disputes related to missing parts and apparent defects must be made under the conditions set in article 2. When an apparent flaw is observed by the Seller or its representative after the inspection, the Buyer may only request the replacement of the elements not conforming and/or the additional part to be brought to complete what is missing, without being able to claim any compensation or termination of the sale. The Buyer will have to furnish any proof as to the reality of the observed defects. The Seller reserves the right to proceed directly or indirectly with any observation or verification at the site.

8.2 - The accusation of defects existing at the time of the Delivery and revealed upon receipt of the products will have to be made by the Buyer in writing within a time limit of 3 days following the date on which he discovered the lack of conformity. No accusation shall be considered if it comes more than 3 clear days after delivery of the Equipment.

8.3 - Defects and deteriorations of the Equipment following abnormal conditions of storage and/or upkeep at the Buyer's place, particularly in case of an accident of any kind may not give any right to the warranty due by the Seller.

The Warranty is excluded in the event of:

- lack of respect of the instructions specified in the technical documentation and the User Manual by the users of the Equipment;
- use of the equipment for purposes others than for those for which it was designed or under abnormal conditions;
- poor maintenance of the Equipment,
- Use, addition or modification of elements or parts not authorized by the Seller;
- Partial or total destruction resulting from a case of force majeure;
- a fault in the fitting out of the premises housing the Equipment;
- refusal of the Buyer to cooperate with the Seller to make it possible for it to make repairs of the Equipment;

8.4 - The Seller warranties the Equipment against all hidden defects under the conditions below:

- Hidden defects are understood to be flaws in the realization of the Equipment making it unsuitable for its use and unlikely to be uncovered by the Buyer before its use. A flaw in the design is not a hidden defect, and the Buyer is considered to have received all technical information concerning the Equipment.
- The Warranty is limited to replacing or repairing the defective parts.
- The length of the Warranty is 12 months following Delivery, unless there is a contrary agreement in the specific terms. It shall cease automatically at the end of this period or if the Buyer has not given notice of the alleged defect within the time limit of twenty days following its discovery.
- Under this Warranty against hidden defects, the Seller shall be obligated only to replace without cost, the defective products, without the Buyer being able to claim damages and interest, for any reason.
- During the duration of the warranty period, the Seller warrants that the Equipment put at the disposal of the Buyer shall be in a good functional state. In the event of breakdown or poor functioning of all or part of the Equipment, the liability of the Seller, however, may not be sought and required beyond providing the following services, which it shall undertake to furnish: any operation to repair the Equipment; any replacement of the defective part, or, if needed, of all or part of the Equipment. Subject to the provisions specified in 8.5 hereinafter, the costs necessary to respect this provision shall be the responsibility of the Seller.

8.5 - Throughout the duration of the warranty period, the cost of any possible repair, return to a functioning state or replacement related to the Equipment, shall be the responsibility of the Buyer in the following cases:

- All or part of the Equipment is subject to poor function or breakdown due to damage, fault or negligence of the Buyer or any other person not authorized by the Seller, who had access to the Equipment.
- All or part of the Equipment has been used by the Buyer in a way that is inappropriate and contrary to the recommendations given in the User Manual and specified to that effect.
- All or part of the Equipment has been the subject of a incorrect repair or manipulation by any person not authorized by the Seller, and/or has been repaired using spare parts not furnished by the Seller;
- All or part of the Equipment is moved from its original site without the move having been authorized in advance by the Seller;
- All or part of the Equipment does not function or does not function correctly due to a case of force majeure, in particular any events or circumstances that are abnormal or independent of the will and control of the Seller, such as, for example, any climatic disturbances, strikes and/or political conflicts;

8.6 – The Equipment is CE mark, conforming European 93/42 Recommendation on Medical Devices. The Seller has established a dedicated Quality Assurance system conforming European ISO 9001 (2008) and ISO 13485 (2003) standards. In line with European 2002/95/CE and 2002/96/CE recommendations, the Seller can provide the data necessary to identify components. The Seller considers it is the Buyer's responsibility to take care of the collection and recycling of the Equipment and its accessories; if parties agree differently, it should be specified in the Specific Sale Terms.

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- The other Party shall have a time limit of thirty clear days to designate its own arbitrator and give notice to the complainant. Lacking such, the party which has not designated its arbitrator within the time limit granted shall be considered as having yielded in the dispute or contest raised.
- The two arbitrators so designated by the Parties shall consult each other to designate by mutual agreement a third arbitrator within 15 days from the naming of the second arbitrator.
- The court of arbitration which has its seat in Lyon shall be validly appointed as soon as the three arbitrators accept their mission. In the event that the parties have not designated their arbitrator within the time limit above or the arbitrators have not named the third arbitrator, the missing arbitrator or arbitrators shall be designated by the chief judge of the Commercial Court of Lyon, ruling in a summary manner, upon the request of the most diligent Party or arbitrator. In case of hindrance, abstention, departure or death of one of the arbitrators, he will be replaced under the conditions described above.
- The procedure will be that stipulated by French law, and more particularly by Book IV of the New Code of Civil Procedure. The court of arbitration shall not have the power of amicable settlement.
- The decision will have to be handed down as soon as possible, and at the latest within a time limit of three (3) months after bringing the matter before the arbitration court. In its decision, the court of arbitration shall set the costs of arbitration which will have to be borne in equal parts by each Party, with the exception, however, of the expenses and fees of attorneys, counsels and experts coming upon the exclusive request of one of the Parties, which shall then be borne by the Party which has asked for the appearance of said attorney, counsel and experts. The arbitration court may ask the Parties for any advances which they consider necessary during the procedure. These advances will be settled in an equal manner between the Parties.
- The decision of the arbitration court may not be appealed.

ARTICLE 14 - COSTS AND SURCHARGES

All fines, amounts for infractions, taxes and surcharges, revenue tax stamps or registrations, publicity costs at the office of the clerk of the court, which are due and payable by reason of use of the Equipment or more generally by performance of the Contract, are the responsibility of the Buyer. In the event of variation in the tax and surcharge system related to use of the Equipment, the Seller may apply any variations in surcharges to the amounts of invoices. In particular, the Buyer will have to settle all amounts that the Seller may be called upon to pay to the tax authorities.

APPENDIX I - DESCRIPTION OF THE EQUIPMENT

The Sonolith® i-move is an extra-corporal lithotripsy module used for the non-invasive disintegration of urinary tract stones. The Equipment offered is CE marked in conformity with the requirement of directive DM 93/42 CEE. EDAP TMS France has established a system of quality assurance and control which conforms the requirements of ISO 9001 (2008) and ISO 13485 (2003) standards.

ELECTROCONDUCTIVE ENERGY PRINCIPLES

The electroconductivity is based upon the principle of the F1 focus control and of the perfect control of the shock wave emitted by an encapsulated electrode containing a supraconductive solution which is located in the Diatron V generator.

With this technology, shock waves generated in a highly conductive electrolytic solution are precise, delivering a reproducible energy at a stable shot-to-shot intensity.
The electro-acoustic efficiency is greatly improved by the new shallow ellipsoidal reflector specially designed for ECL with high-energy concentration maximized on the stone. Disintegration efficacy is therefore highly optimised.

By increasing the diameter of the ellipse, we have enlarged the entry area of the shock wave at the skin level for a painless treatment. Therefore, the Sonolith® i-move can be used without anesthesia.

The electroconductive generator of the Sonolith® i-move uses an electrode to generate the pressure waves. The electrode's life span is limited by the number of shock waves produced as well as by the preservation limit after the first date of use.

A storage bench for the electrodes is delivered with the Sonolith® i-move and enables the use of an electrode 15 days after opening of the packaging (within the limits of the number of shock waves produced).

1. SONOLITH I-MOVE EXTRACORPOREAL SHOCKWAVE LITHOTRIPOR MODULE

a) Isocentric Electroconductive® shock wave generator model Diatron V.

- Dry patient coupling system with silicone membrane
- Internal water tank
- Automatic draining and filling-up
- Adjustable shock wave pressure level (100 levels from 1% to 100%)
- Real time pressure control: PVDF hydrophone built-in with indication of the delivered "lithotripsy dose"
- Opening angle of the shockwaves: 80°
- Treatment depth: 160mm
- Aperture : 250 mm
- 2 treatment positions (0° / 50° relative to the vertical axis). The rotation from one position to the other is achieved manually

b) Hand Control Touch-screen remote control

- Treatment parameters (power, frequency, ...)
- Firing button

2. I-MOVE TOUCH CONFIGURATION

a) Integrated computer

- Patient and treatment database
- R/X and U/S image acquisition (depending on C-arm and U/S system used)
- Treatment and analysis software included

b) 20" LCD color monitor (1600 X 1200 px) attached to the module, touch screen user's interface

- Full control of the Sonolith® i-move and table motorized movements and parameters
- Patient and treatment database
- Dual X-Ray and U/S live imaging (depending on C-arm and U/S system used)

3. KARBON-W2E TABLE

a) Table Description

The full-carbon dual cut-out 4-axis motorized table enables ESWL and Cystoscopy procedures. A remote control operates the movements of the table. Designed for use in an ambulatory clinical environment, this table is also available for operation if the anaesthetizing gases used are not explosive. The patient support is the complement of the electroconductive® generator and has been developed in order to correspond to the needs of mobile lithotripsy and cystoscopy for urologists, ideal for all interventions in the lower urinary tract.

- Endo-urological applications
- Retrograde uretroscopies
- Intracorporal lithotripsy
- Urethral catheterization
- Cystoscopies
- TURP
- PCN

Combined applications with radiology C-arm:

- KUB (with or without preparation)
- Pelvography
- Ureterocystography
- Ureterography
- Vasovesiculography

Combined applications with Ultrasound:

- Diagnosis of the entire urinary tract
- Diagnosis of the entire urogenital area
- Imaging of the blood vessels of the urinary tract
- Brachytherapy

This motorised table is composed of:

- A patient support unit comprising a 4 axis motion radiolucent table-top with two apertures for lithotripsy (one on each side for the treatment head) and custom shutters.
- A head extension unit
- A foot extension unit and stirrup couplings
- Standard side-rails for accessories
- A remote control

b) Table Sepcifications

Total length with extension: ..... 2615 mm
Total length without extension: .. 1265 mm
Width (without extensions): ..... 730 mm
Maximum patient weight: ..... 200 kg
Total table weight: ..... 350 kg

Range of displacement in Litho mode:

- Longitudinal: 60mm (+/- 30mm)
- Transversal: 110mm (-30 / +80 mm)
- Vertical: 170mm (-60 / +110 mm)

Range of displacement in Endo-Uro mode:

- Longitudinal: 345mm (-245 / +100mm)
- Transversal: 147mm (-145 / +2 mm)
- Vertical: 180mm (0 / +180 mm)
- Trendelenburg: +/- 15°

Manual controls via:

- The specific table remote control placed on the side of patient loading
- The remote control attached on the Sonolith® i-move module
- The User's Interface on the LCD touch screen

c) Table Accessories (Option)

List accessories offered:

- Amatech Lift Assist Boot Stirrups (one pair)
- Amatech Arm rest

4. X-ray SYSTEM: OEC 9900 Super C mobile C-arm

1. 9900 Super C Portable C-arm System.
2. 15 KW Generator
3. 9" Image Intensifier
4. Digital Image Rotation
5. Preview Collimator
6. Fluoro & Pursed Fluoro Mode
7. Digital Spot Mod3
8. ABS (Automatic Brightness Stabilization

APPENDIX II - TRAINING

The Seller reminds the Buyer that only operators trained on the Sonolith® i-move shall have access to operate the Equipment.

One physician designated by the Buyer will undergo a two-day training course on site by an EDAP-TMS France Applications Specialist, to achieve proficiency in the use of the equipment.