

STONELITH[®] SMART

EXTRACORPOREAL SHOCK WAVE LITHOTRIPTER



The **SMART** Solution to Your
Lithotripsy Requirements

■ The Stonelith *SMART* is the fourth version of PCK's new generation extracorporeal shock wave lithotripter that was developed to disintegrate kidney and urinary tract stones safely and effectively. More than one hundred of PCK's Version 3 ESWL models are successfully operating in Europe, Latin America, the Middle East, Asia and the Far East. The Stonelith series has become increasingly popular in the global ESWL market due in large part to its exceptional quality-to-price ratio. The Stonelith *SMART* is certain to carry on this impressive heritage by adding advancements and improvements onto the solid foundation of this popular and proven lithotripsy system.

■ The Stonelith *SMART*'s PC computer-based control system employs electro-hydraulic shock wave generation through the underwater discharge of an electric spark. This charge produces a spherical shock wave in the form of pressure pulses. The ellipsoid focuses shock waves on calculi to be pulverized. The *SMART* has a dry patient coupling with a closed-loop water controller. A soft, elastic membrane in contact with the patient's skin couples shock waves and transmits them efficiently. Stones under transmitted pulse pressures are broken into particles and completely eliminated through the urinary system. The treatment time is shortened via high frequency shock wave triggering.

■ Over the past two years, PCK Co., Ltd. has had the distinction of being the world's fastest growing lithotripsy manufacturer, maintaining a growing reputation for quality and leadership in the medical equipment manufacturing industry. PCK backs up their Stonelith *SMART* with comprehensive support covering all phases of its installation, warranty and maintenance periods. The company also provides training for medical personnel and the area technicians who will provide local service for this and other PCK products.



The Stonelith *SMART* has many special features:

- 1. Space Friendly :** The Stonelith *SMART* is amazingly small in size and especially light in weight. It does not require a special room, treated water, drain connectors, or air/gas networks. It is completely mobile, being able to be easily moved by one person through standard doors and elevators. It also does not take a lot of time to set up since, unlike full systems, there is no equipment that needs to be fastened to ceilings or walls. Another advantage of this ultra-compact lithotripter is its exceptional suitability as the featured equipment in a mobile lithotripsy clinic (i.e., Mobilith).
- 2. Patient Friendly :** Like PCK's Version 3 ESWL, a special electrohydraulic electrode system and superior ellipsoidal design have been incorporated into the Stonelith *SMART*. This unique combination increases the preciseness of the reflection while helping to eliminate unwanted pain-producing scattered shock waves. In addition to decreasing patient discomfort, the traditional damage to surrounding tissue is also limited. Based on experiences of tens of thousands of successfully treated patients, not only is anesthesia not needed but an analgesia is not necessarily required.
- 3. User Friendly :** The incorporation of a PC computer-based control system makes for simple and accurate, not to mention pleasant, operation of the Stonelith *SMART*. The *SMART*'s treatment table is X-ray transparent so it can be adapted for this purpose. It can also be used as an urological table if the leg supports (stirrups) and other optional accessories are ordered. The motorized table can be used for examinations and even operations. The revolutionary PCK Calculith intracorporeal pneumatic lithotripter can additionally be provided.
- 4. Imaging Friendly :** The Stonelith *SMART* + Lithovision U-arm or Polaris C/U-arm X-ray combination together with the Ultralith ultrasound computer-controlled stone localization system means that both a motorized mobile X-ray unit and an ultrasound scanner can be incorporated. This allows the operator to easily locate and treat all types of stones in the entire urinary tract, in addition to the biliary tract.
- 5. Service Friendly :** The Stonelith *SMART*'s dependence on software over extra electronic boards greatly increases the reliability of this lithotripter. The *SMART*'s streamlined mechanical and electronic design minimizes down-time while reducing the frequency and duration of service calls.
- 6. Budget Friendly :** The Stonelith *SMART*'s non-invasive stone treatment system is economically superior to other lithotripters, being affordable and highly cost effective after the sale. This is true in spite of the fact that some of its standard features cannot even be found on much more expensive units. In terms of operation, PCK's long-life electrodes makes the *SMART*'s treatments virtually cost-free. Surprising our customers, while disappointing our competitors, the Stonelith *SMART* remains the most affordable high-quality ESWL available in the market today.

■ Like earlier Stonelith versions, the *SMART* is able to increase effectiveness while decreasing discomfort due in part to its unique long-life electrode system. In comparable machines, the traditional spark gap electrode is designed so two thick pieces of metal, that become thin towards the ends, face each other. After about 1,000 shocks the distance between the two metal ends gets wider, resulting in thicker parts of the metal pieces being used to translate the spark. The spark eventually loses its focus as a result of having to use the wider pieces of metal while traveling a greater spark distance between the two parts of the electrode. This degeneration continually increases the pain the patient feels while decreasing the treatment's effectiveness.

■ In short, the traditional spark gap electrode degenerates at a fast rate due to its improper design (thick-to-thin) and non-adjustable nature. This limits the life span of an electrode to approximately one treatment, or 3,000 shocks. However, of this amount it can be said that the first third (1-1,000) works better than the next third (1,001-2,000), while the final third (2,001-3,000) of the shocks are given with comparatively less effectiveness and greater pain to the patient.

■ PCK's electrode system avoids the problems of the traditional spark gap electrodes. The long-life electrodes have been designed so that they begin thin and stay thin throughout their lifetime. There is no thick part to disrupt the focusing efficiency of the spark to the second focal point. Even when the distance is greater, after approximately 1,000 shocks, the spark maintains its focusing strength much better than the traditional electrodes.

■ The other major advantage of the *SMART*'s electrodes is that they are adjustable. There is no need for the patient to have to suffer through the last third of the session. Without disrupting the treatment, the doctor can simply adjust the distance between the electrodes with an equally slight turn of both electrode handles. This makes the electrodes "as good as new" even after thousands of shocks have been administered. Each long-life electrode pair can last approximately 150,000 shocks, or 50 sessions of 3,000 shocks each.

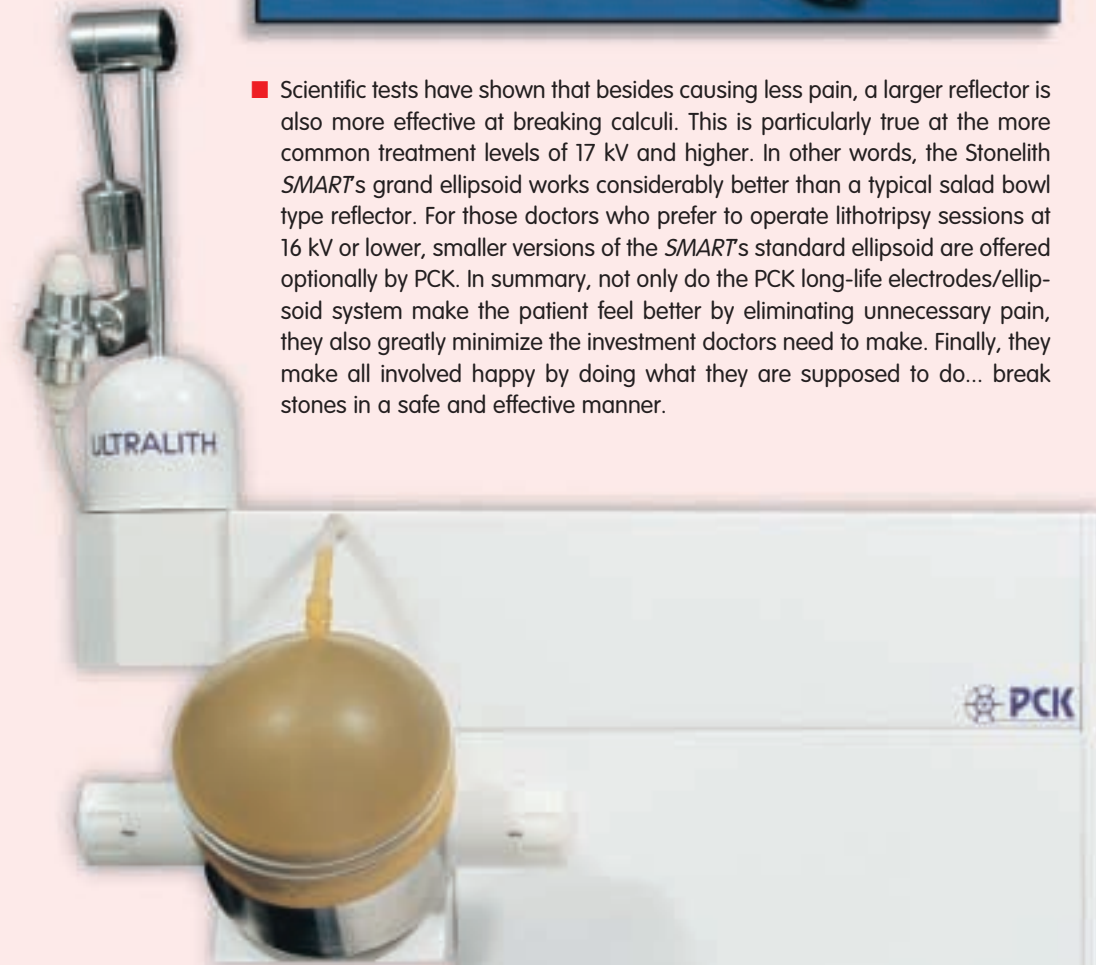
■ In today's budget-conscious medical establishments, it is also important to consider the important factor of price. Depending on the company and country, the price per disposable electrode, which can be translated as price per session, can range from approximately \$ 5.00 to \$ 100.00. Taking the 50 treatments per electrode pair as a standard, by the time the Stonelith *SMART* operator is ready to change a pair of electrodes, the traditional electrode user will have changed 50 electrodes and paid anywhere from \$ 250.00 to \$ 5,000.00 for these consumables. In short, the PCK long-life electrode system is the best way to ensure a more effective treatment without the pain and high costs associated with the out-dated method.



■ Besides long-life electrodes, another factor that increases effectiveness while decreasing discomfort is PCK's computer-designed ellipsoids. The size and shape of these reflectors, made from an especially strong alloy, have been chosen to maximize the amount of shock waves that reflect off the deep ellipsoid. This helps minimize the percentage of shock waves that are "lost" and not reflected towards the second focal point. Since "lost" waves contribute to the pain that patients feel during treatments, the *SMART*'s exceptionally large standard ellipsoid reduces unnecessary discomfort caused by improper mechanical design and use of inferior metal.



The chalk is being pulverized in the test pool by the Stonelith's shock waves



■ Scientific tests have shown that besides causing less pain, a larger reflector is also more effective at breaking calculi. This is particularly true at the more common treatment levels of 17 kV and higher. In other words, the Stonelith *SMART*'s grand ellipsoid works considerably better than a typical salad bowl type reflector. For those doctors who prefer to operate lithotripsy sessions at 16 kV or lower, smaller versions of the *SMART*'s standard ellipsoid are offered optionally by PCK. In summary, not only do the PCK long-life electrodes/ellipsoid system make the patient feel better by eliminating unnecessary pain, they also greatly minimize the investment doctors need to make. Finally, they make all involved happy by doing what they are supposed to do... break stones in a safe and effective manner.



OLD SYSTEM



PCK SYSTEM

PCK's Long-Life Electrodes:

- Less pain in patients
- Are easy to adjust and replace
- Last approximately 50 sessions
- Increase the effectiveness of the shock waves
- Have a very low cost





smART Program

The Stonelith SMART's smART software is a PCK-developed control program for the ESWL that works on a Pentium PC under Windows 95 and higher versions. With smART, all of the functions necessary for advanced stone treatment are conveniently at the command of the operator, including: ESWL controls, table movements, and X-ray and/or ultrasound operations. The real time fluoroscopy on the Stonelith SMART's PC integrated control environment (ICE) monitor allows for easy viewing and manipulation of the image. Besides image manipulation and processing, smART also includes other special utilities, such as: patient database with statistical information and graphics, remote diagnostics through a modem, and ESWL shock counters for the treatments and generator. The program also permits control of more than one function simultaneously. The software allows for easy installation of the system while minimizing downtime and service calls.

Patient Database

The smART's database stores patient information for statistical use and later recollection. Biographical, operator, diagnostic, stone and treatment information are recorded along with miscellaneous notes and comments. All of the data can be easily stored, searched, recalled, printed and deleted. With a click of the mouse, treatment information including: date, biographical details of patient, operating mode, average kV applied, average frequency, number of shocks sent, and duration of treatment can be instantly stored for future reference. Graphics and real time snap-shot images from the treatment can also be attached to this database for later use. With the smART's remote diagnostics capabilities, a third party- whether at a nearby hospital or perhaps somewhere on the other side of the world- can be sent details from the patient database and information on the ESWL itself via modem.

Seven Different Operating Modes

The Stonelith SMART's versatility is confirmed by being the only ESWL machine that can operate seven different ways: automatic, remote, respiratory, ECG, respiratory/ECG, remote respiratory/ECG, and saO₂. This wide diversity allows for the proper operating mode to be chosen according to the special needs of the patient and the characteristics of the stone.

Adjustable Frequency, kV and Water Control

Another unique advantage of the Stonelith SMART is its ability to provide for the fast, accurate selection of the frequency of the shock wave pulses. The number of shocks per minute ranges from 30 to 160, with 80 the default. For moving stones, doubling or tripling pulses up to 60 shocks per minute is also possible. For example, a double pulse of 50 equals 100 s.p.m., while a triple pulse at 60 totals 180 s.p.m.. Frequency control works under automatic mode and can be adjusted before or during the treatment. The Stonelith SMART also has adjustable kV control (up to 24+) in addition to automatic quick filling and draining of the ellipsoid with water.

Convenient Remote Controller

The Stonelith SMART comes with a remote controller that is able to command the functions of the ESWL and treatment table remotely. It can also control the movements of a PCK mobile X-ray unit. A total of 17 different functions can be commanded.

Adjustable Treatment Table

The X-ray transparent motorized table is engineered to provide easy patient positioning; having three-dimensional, Trendelenburg and lateral tilting movements. It can also be used alone as an urological table.



Lithovision Polaris

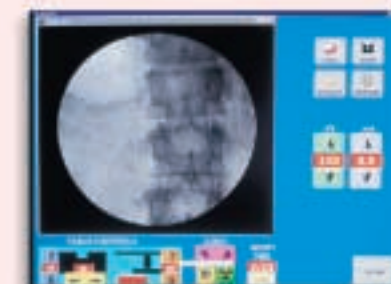
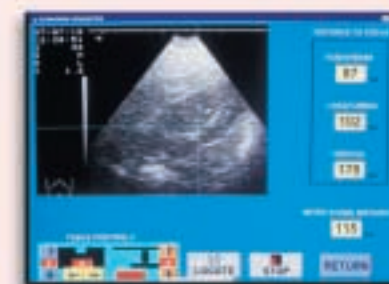
U-arm Motorized Mobile X-ray C-arm (U-arm) Motorized Mobile X-ray

- The Lithovision U-arm is a high-tech, high-quality mobile X-ray unit with motorized oblique movements. Its compact size makes it especially suitable to meet the fluoroscopy needs of the PCK ESWL. The Polaris C-arm is a fuller mobile X-ray system with oblique and vertical movements motorized. It also has manual horizontal and swiveling movements as well as arc rotation. The Polaris U-arm has all the features of the C-arm except for the orbiting action. Both the Lithovision and Polaris X-rays are microcontroller-based and incorporate a user friendly soft-touch operating panel and many other special features.

X-lith Ultralith Autolith

X-ray computer-controlled stone localization system Ultrasound computer-controlled stone localization system X-ray & ultrasound computer-controlled stone localization system

- The Stonelith SMART can be upgraded to include the primary feature of what may be referred to as high-end lithotripsy systems: automatic stone localization. This includes locating the stone by use of fluoroscopy (X-lith), ultrasonography (Ultralith) or both types of imaging (Autolith). The X-lith (and half of the Autolith) C²SLS (Computer Controlled Stone Localization System) upgrades work in coordination with either a Lithovision or Polaris X-ray unit. The X-lith allows the operator to locate the targeted stones in patients accurately and automatically. The Ultralith (and the other half of the Autolith) C²SLS options incorporate the PCK-developed robotic arm, which holds the convex or sector probe in place. The Ultralith's robotic arm can work in conjunction with a variety of different ultrasound scanners.



- To open the Ultralith screen, the ultrasound button under localization is chosen. With the ultrasonography option, the targeted calculus is found on the monitor's real-time ultrasound imaging by manipulating the robotic arm. The distance of the stone is then entered into the computer. After initiating the stone localization, the table then moves the patient to the proper focusing position in order for the treatment to begin.
- The Autolith user is able to operate both X-ray and ultrasound applications. This ultimate upgrade combines both the X-lith and Ultralith C²SLS for maximum localizing flexibility and effectiveness. All of PCK's computer-controlled stone localization systems allow for adjustments to occur simultaneously during the treatment.

- Like all of PCK's products, a major advantage of these upgrade options is their user friendly nature. On the Stonelith SMART's PC integrated control environment, a section has been devoted for automatic stone localization. Clicking the X-ray button will give the operator the proper X-lith screen, complete with real-time fluoroscopy imaging. The operator simply finds the targeted stone on the monitor, clicks it, then presses the locate button. The treatment table then automatically moves to the proper location. A manual override is also possible by adjusting the visualized treatment table's position on the X-lith's screen. The status of the PCK X-ray can also be seen and controlled from this window.



**The PCK Stonelith Version 4:
The SMART System.
The SMART Choice.**

STONELITH SMART SPECIFICATIONS

Energy source	Electrohydraulic spark gap system	
Focusing	Ellipsoidal	
Patient coupling	Dry patient coupling, water cushion with automatic pressure stabilization, elastic and soft hypoallergenic membrane	
Localization	X-ray fluoroscopy and/or ultrasound system	
Operating voltage	7.5 kV to 24 kV, adjustable	
Ellipsoid aperture	Ø 219.5	<i>(standard ellipsoid)</i>
Focal distance	130 mm	<i>(standard ellipsoid)</i>
Focal pressure	0 to 1200 bar	<i>(standard ellipsoid)</i>
Water cushion capacity	9 lt	<i>(standard ellipsoid)</i>
Water tank capacity	13 lt	
Height	124 cm	(49")
Length	81 cm	(32")
Width (wheel base)	66 cm	(26")
Weight	54 kg	(119 lbs)

Urological Treatment Table

Patient surface	220 cm x 64 cm	(87" x 25")
Height adjustment	30 cm	(12")
Longitudinal adjustment	15 cm	(6") ; 20 cm (8"), optional
Transverse adjustment	15 cm	(6") ; 20 cm (8"), optional
Patient size (max)	160 kg	(353 lbs)
Weight	150 kg	(331 lbs)

Power Requirements

Power voltage	220V AC/50 Hz or 110 AC/60 Hz, 1kVA, single phase	
Power voltage fluctuation	± 10%	
Grounding	100 Ω or less in grounding resistance	
Electrical isolation	Transformer protection, current leakage interrupter	
Safety standard	IEC 601.1 class 1, type B	

Environmental Conditions

Operating temperature	10°C to 30°C
Humidity	35% to 85%
Non-operating temperature	-15°C to +40°C
Space requirement	3 m x 3 m

Composition

- Main ESWL unit
- Shock wave generator
- Focusing attachment
- Pentium PC
- Treatment table

Options

- U-arm/C-arm X-ray systems for ESWL, urological and general applications
- X-ray and/or ultrasound computer-controlled stone localization systems
- Ultrasound scanner
- Medium and small ellipsoids
- Remote controller
- Respiratory device, ECG monitor
- Leg supports, lateral supports and infusion rods for treatment table

Due to continued product innovation, specifications may change without notice.



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