



PiezoLith3000_{plus}

ESWL Based on Experience and Innovation

Double-layer Piezo Technology
Automatic Patient Positioning
DSR Localization · Triple Focus





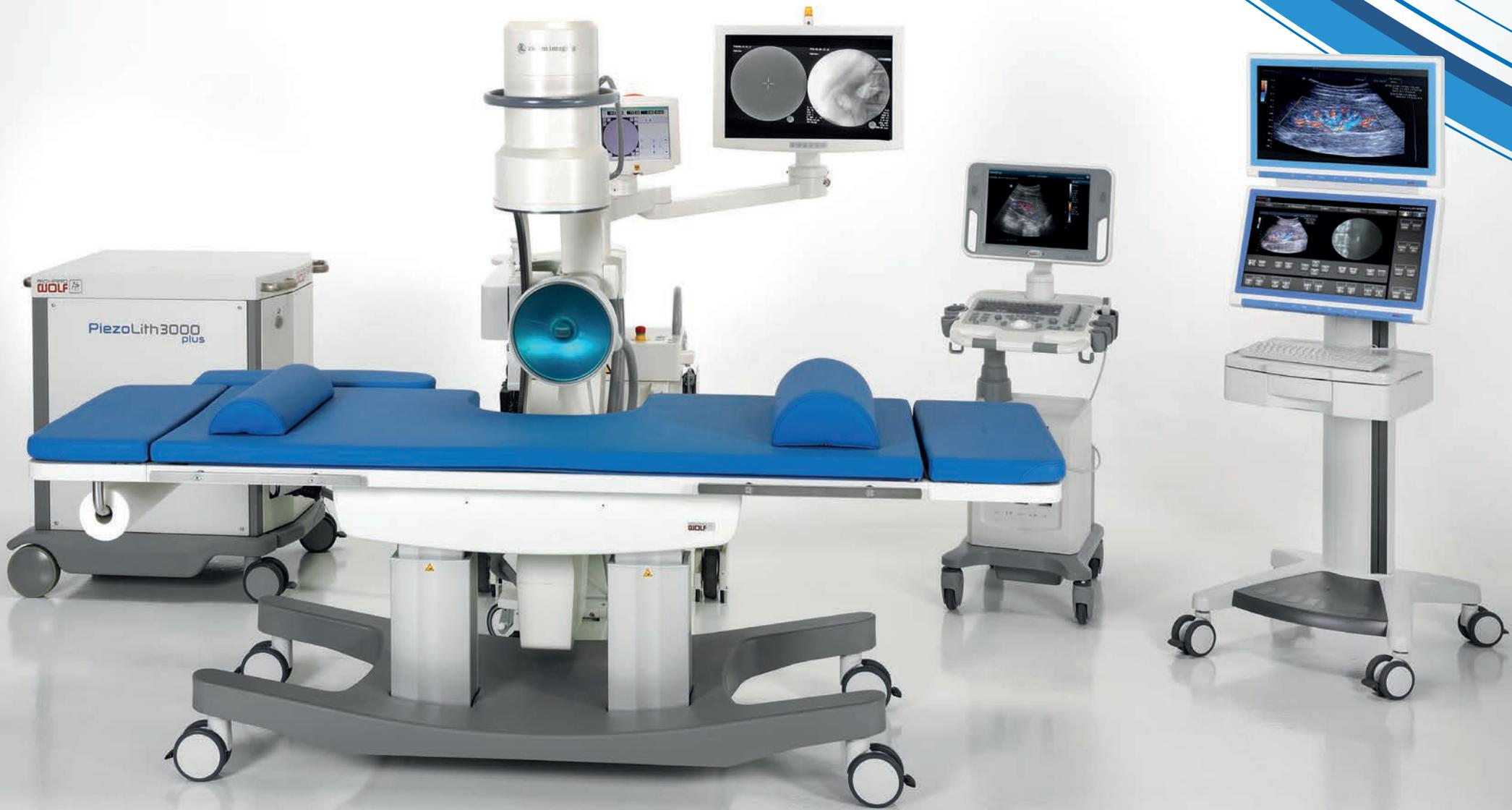
Richard Wolf GmbH and ELvation Medical GmbH - Using Innovation and Experience to Treat Stone Disease

The medical products of Richard Wolf are a byword for innovative technology. The medical devices meet the highest requirements of surgical teams all over the world and set new benchmarks.

A specialist for urological stone treatment, Richard Wolf has been researching and developing pioneering and complementary solutions in extracorporeal shockwave lithotripsy and the endo-urological treatment of stones for decades. Together with

ELvation Medical, we have been looking into new avenues which will also allow us to offer professional specialist support.

With more than 35 years' experience in the field of piezoelectric lithotripter technology and more than 900 systems installed worldwide, we are proud to present the next generation of shockwave units: the PiezoLith 3000Plus. We have combined all our expertise to set new standards in precision, efficacy and user-friendliness for ESWL.



WOLF
PiezoLith3000
plus

WOLF

Medical workstation with two monitors displaying scan images.

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PiezoLith 3000Plus - The Focus is on Multimodal Stone Management

A number of different procedures are currently used to manage urological stones; however, extracorporeal shockwave lithotripsy has already established itself as the most important approach.

Combining this approach with endourological procedures requires a special multimodal ESWL workstation for the management of stone disease. The innovative modular

and mobile PiezoLith 3000Plus concept with its pioneering user philosophy more than meets these stringent requirements. With the PiezoLith 3000Plus, the new generation of ESWL units offers automatic patient positioning together with unique features such as piezoelectric double-layer technology, triple focus, and dual simultaneous real-time localization.



Accessories optional





The PiezoLith 3000Plus Operating Concept

Computer and software-assisted automatic patient positioning with in-picture navigation

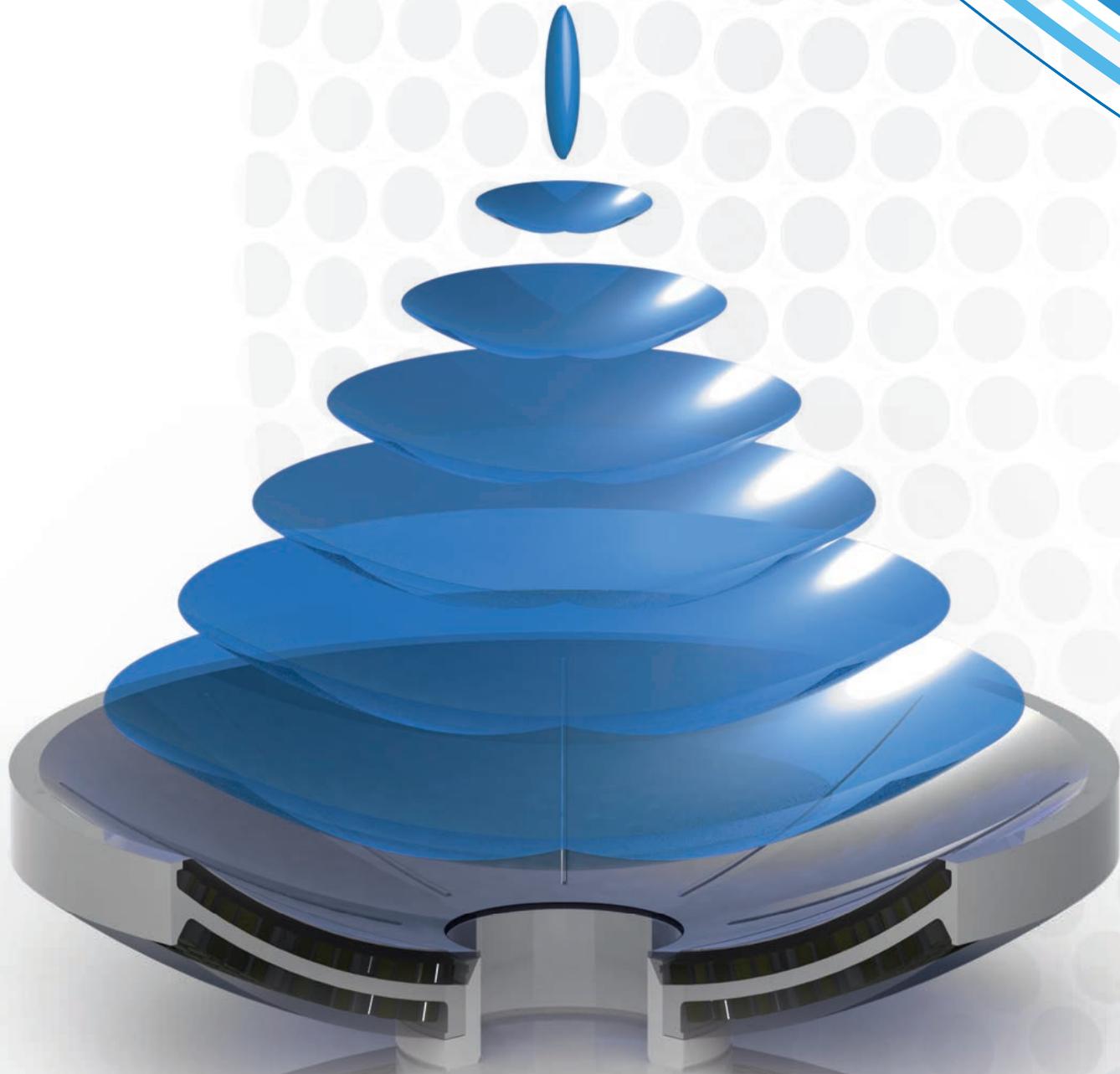
The PiezoLith 3000Plus provides an innovative control system for computer and software-assisted automatic positioning using newly developed in-picture navigation. The menu-guided touch screen for all central ESWL operations and display functions

has been combined with live ultrasound and X-ray imaging to set a new standard in ESWL.

The unit features new control technology with a choice of five options for simple, quick and comfortable patient positioning:

1. Manual positioning of the table either at the table itself or using a touch panel on the monitor cart or in a separate control room
2. Software and computer-assisted automatic positioning with ultrasound localization
3. Software and computer-assisted automatic positioning with X-ray localization
4. Software and computer-assisted in-picture navigation with ultrasound localization
5. Software and computer-assisted in-picture navigation with X-ray localization

With the PiezoLith 3000Plus, patient data and treatment information can be recorded and the data can be made network compatible (optional, DICOM).



The Piezo Shockwave - Unique Precision with Outstanding Rates of Stone Elimination

The piezo elements are arrayed on a spherical dome and precisely aligned with the therapy focus. A high-voltage pulse is used to briefly and simultaneously expand the piezo elements by a few micrometers and create a pressure pulse. The precise focusing of the pulse creates a shockwave at the focus of treatment.

The piezo shockwave technology of Richard Wolf is currently the only shockwave system to use "direct focusing", which means that it does not require additional reflectors. This has made it possible to design a compact and ergonomic therapy source and ensures that the focal zone is precise and well defined. Treatment is quiet and almost painless, with a strong pressure pulse generated at the point of focus.

Energy coupling is spread over a large area, which reduces the energy density at the skin surface and significantly decreases the pain response. The precise focal zone means that treatment is highly targeted and offers optimal protection to surrounding tissue areas.

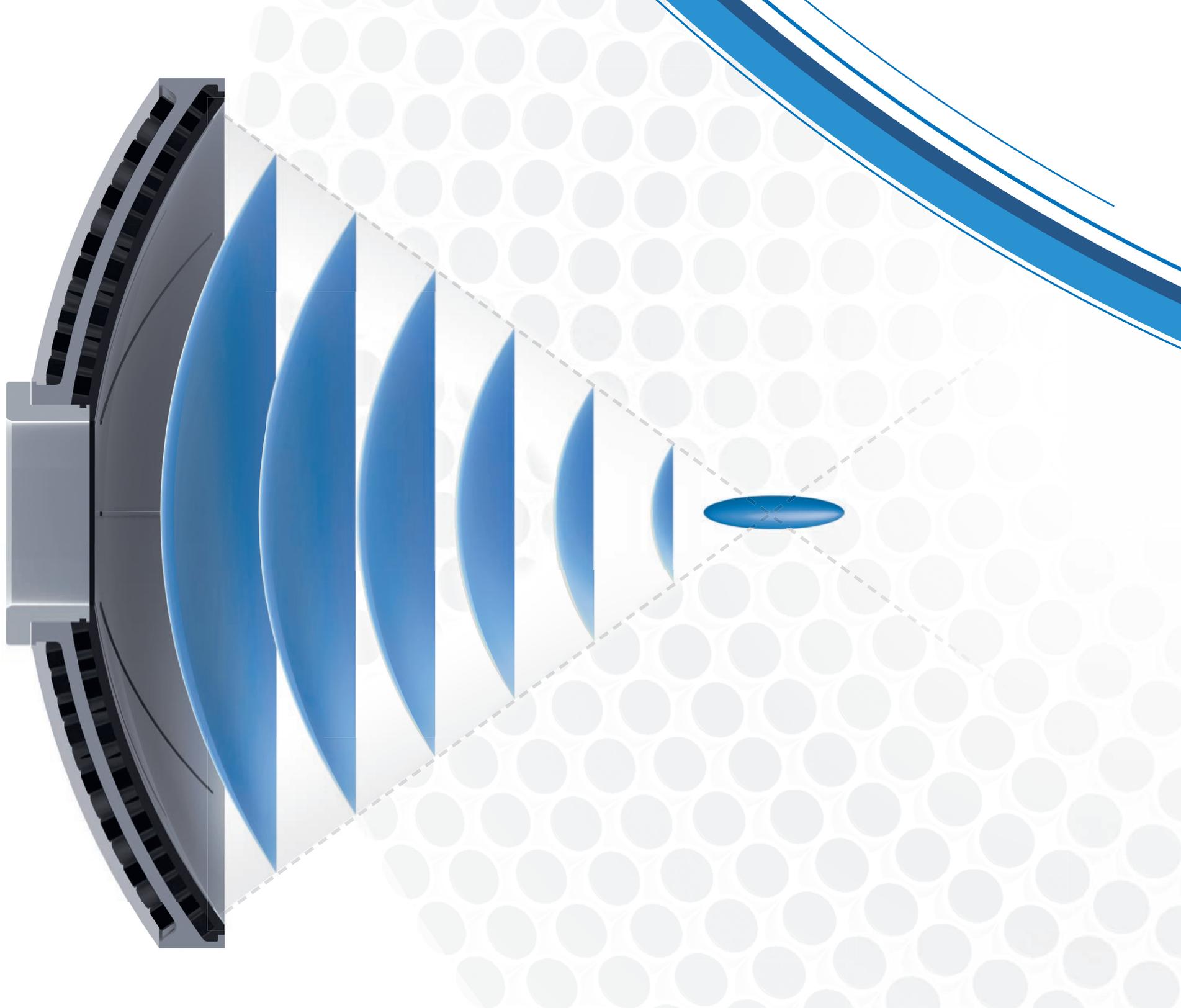
The patented double-layer technology (DLT) of the therapy source of the PiezoLith 3000Plus almost doubles the energy output, resulting in excellent stone disintegration rates. Medical staff can choose between applying single pulses or continuous pulses of 30-360 shockwaves per minute with ECG synchronization..

The PiezoLith 3000Plus has an unusually broad dynamic range and excellent performance data:

Max. peak pressure: 126 MPa

Max. pulse energy: 140 mJ

Penetration depth: 165 mm centrally / 200 mm distally (-6dB)



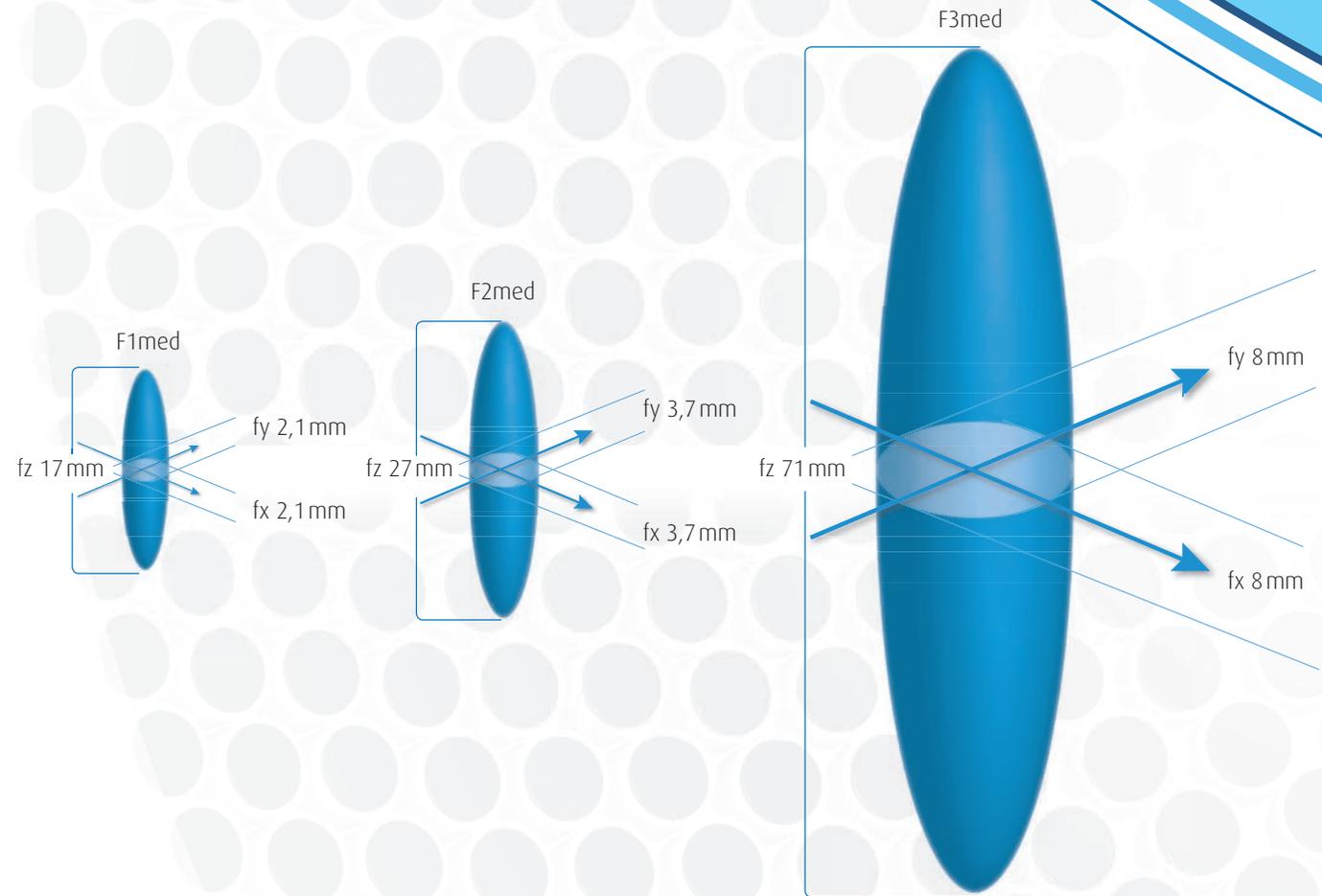


Direct Focusing (DFL) - Three Effective Ways of Eliminating Treatment Pain

The Richard Wolf piezoelectric shockwave is the only shockwave technology to use “direct focusing”. With this technology, the pressure pulse created by the piezo elements is focused directly on the focal zone with no additional reflector or acoustic lens. The extremely precise focusing means that steepening, which creates the shockwave, only occurs at the focal point of treatment. This technology also allows for a compact design with a wide angle aperture. “Direct focusing” has three features which help minimize pain:

1. No additional pain from uncontrolled reflection waves
2. Wide angle aperture means no pain at the coupling interface
3. The impact on tissue at the point of shockwave entry is reduced, as steepening only occurs at the focal point

Experience has shown that extracorporeal lithotripsy carried out using piezoelectric shockwaves can usually be administered without anesthesia or sedation.





Triple Focus – Variable Focus Adapted to the Size of the Stone

The size of the focal area required to disintegrate a stone must fulfil a number of requirements. On the one hand, the area must be small and compact in order to protect the surrounding tissue – however the pulse must still be strong enough to effectively break up even hard stones. On the other hand, the focal area has to be large enough that even large stones or stone fragments will disintegrate. It is not uncommon that the cyclical changes in the stone's position due to respiration require

a larger focal area.

To perform such individual adjustments, the PiezoLith 3000Plus uniquely offers a choice of three different focal zone sizes. The size of the focal zone can be adjusted even during treatment. This unique variability owes much to the way in which piezo-electric shockwaves are generated. The electronic activation of the double piezo layer makes it possible to create different, extremely precisely defined focal areas.





Dual Simultaneous Real-time (DSR) Localization - The Most Precise Continuous Form of Localization

DSR localization means that medical staff can carry out ultrasound and X-ray localization simultaneously, alternately, or separately. All localization systems are motor-controlled and driven. The design of the therapy source and the Richard Wolf piezoelectric shockwave concept allow the ultrasound probe to be placed "inline" for continuous monitoring of shockwave lithotripsy procedures.

The "outline" concept used for X-ray localization results in optimal quality images while limiting patients' exposure to radiation. Both X-ray localization and ultrasound localization can be carried out without interrupting the shockwave lithotripsy procedure and without mechanical modifications.



PiezoLith3000
plus



X-ray Localization Using the Patented Wolf Lithoarm

The development of the Wolf Lithoarm has made it possible to adapt the therapy source of the PiezoLith 3000Plus to fit the requirements of different X-ray units while retaining the mobility of the X-ray C-arm and the modularity of the individual components of the lithotripsy system. Outline localization means that no airbags are required.

The visibility of the X-ray image is not restricted. Scattered radiation is reduced to a minimum. The exposure of physicians and patients to radiation is kept as low as possible while providing high-quality images. The X-ray system is motor-driven and controlled, with a smooth lateral rotation between 0° and $\pm 30^\circ$.

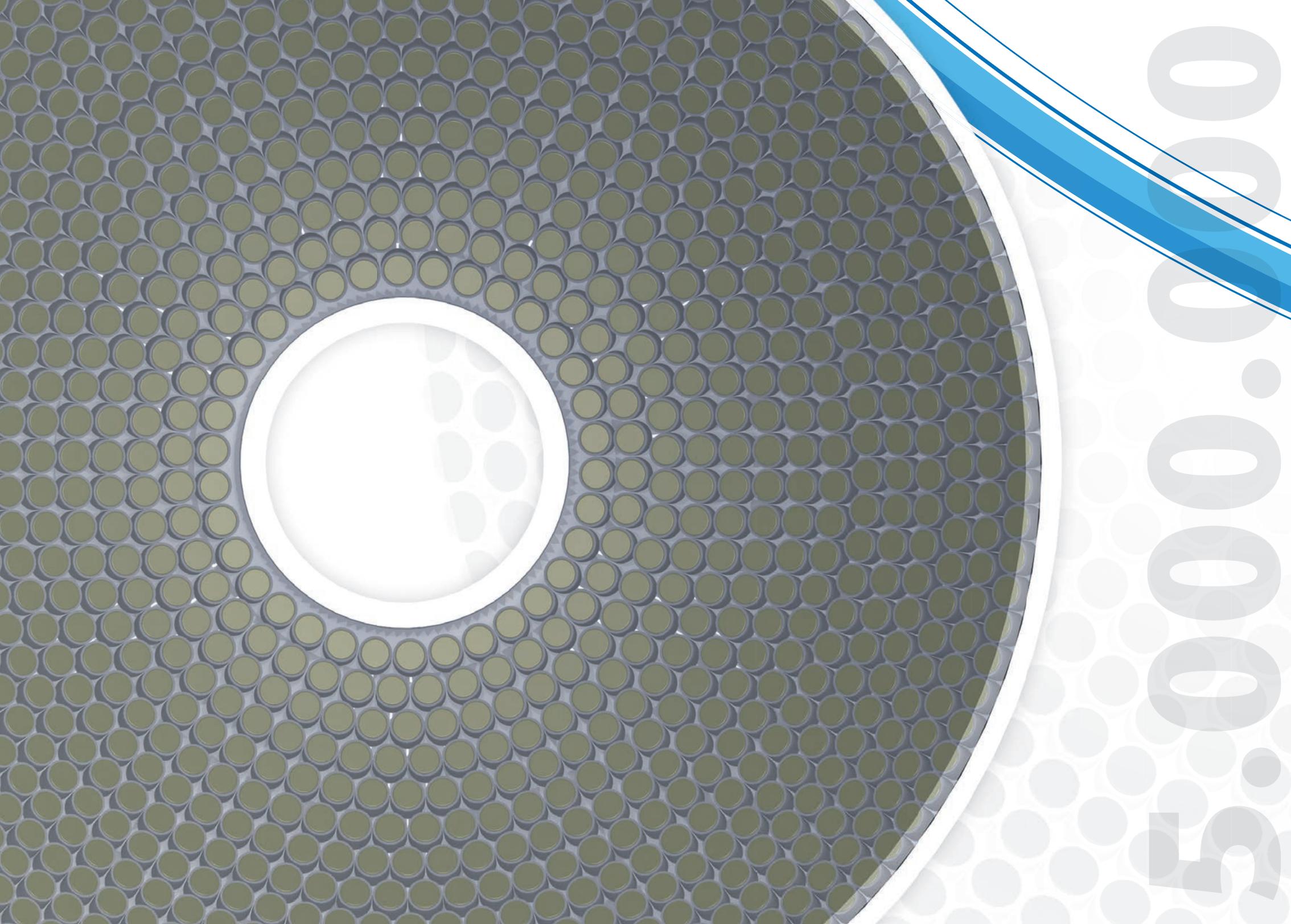


Inline Ultrasound Localization - Continuous Monitoring

The ultrasound probe fitted in the shockwave source enables a simple and precise localisation of the treatment area. The rotatable and axially adjustable inline probe is motor-operated and controlled and is aligned coaxially and isocentrically to the focus of treatment.

Direct contact combined with the axial adjustment of the ultrasound probe helps avoid multiple reflections while ensuring high-quality high-resolution images. The localization concept makes it possible to carry out continuous ultrasound localization, which has the additional benefit of being able to immediately detect obstacles lying in the path of the shockwaves.







Durable and Quiet - Other people just talk about it. We guarantee it.

The piezoelectric shockwave technology of Richard Wolf is extremely durable. We guarantee it. When the therapy source of the PiezoLith 3000Plus is delivered, it comes with a unique guarantee of 5 million pulses or a working life of 2 years. The long lifespan is due to the extraordinary durability of the piezo elements, which only expand by a few micrometers.

This is an advantage which is also reflected by the unit's acoustic impact. With a maximum sound level of 82 dB(A), the Richard Wolf piezoelectric shockwave technology of the PiezoLith 3000Plus is very quiet.



Ultrasound-assisted ESWL with the P3000Plus Articulated Bracket. Good value, flexible and effective.

The unique inline ultrasound localization system can be mounted on an articulated bracket to provide almost complete patient coverage, allowing medical staff to locate treatment stones in patients for whom standard ESWL is indicated. Exposure of patients and medical staff to radiation can be avoided by dispensing with X-ray localization. The articulated bracket allows the therapy source to be easily adjusted to the different positions of individual patients during treatment.

Because of the flexibility of the therapy source, locating the target area requiring treatment is both easy and quick. The PiezoLith 3000Plus and the articulated bracket do not need much room, making them suitable for use even in the smallest treatment rooms. It is a reasonably priced, space-saving and effective solution for simple, standard, ultrasound-assisted ESWL procedures carried out by experienced medical staff well trained in the use of ultrasound.

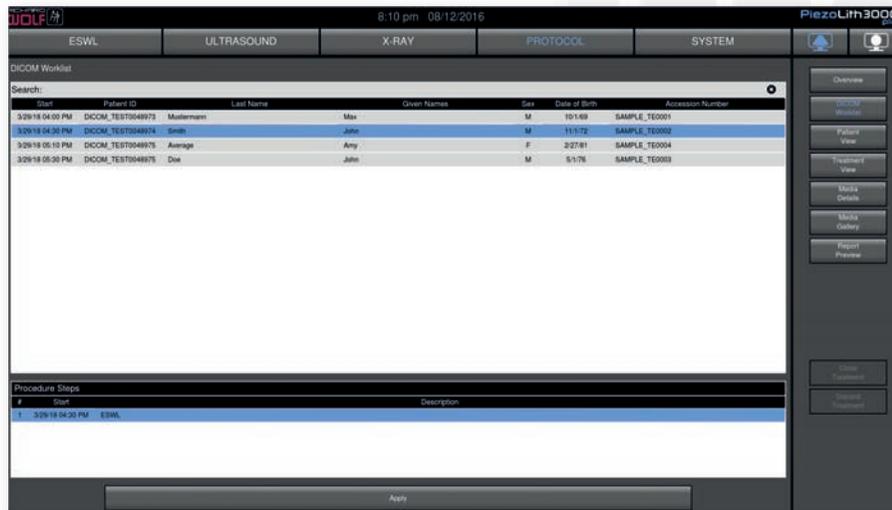


DICOM 3.0 Documentation System

DICOM (Digital Imaging and Communications in Medicine) is a standard format used to store and exchange medical images and image-related information and improve connectivity between medical devices and systems.

The unique patient and treatment documentation of the PiezoLith 3000Plus allows patient data to be recorded faster and accelerates workflows.

The user-friendly graphic interface can be used to record all data obtained from ESWL treatments and store the data on different media.



Remote Service

Remote service allows our specialists to detect errors quickly and increase system availability.

The benefit for you:

Efficient on-site visits – due to remote diagnosis of defects and the proactive supply of spare parts

Shorter down times – with diagnosis, maintenance and repairs carried out by remote access





The PiezoLith 3000Plus

- Unique piezoelectric shockwave technology
 - Mobile modular ESWL system
 - Innovative, unique, computer & software-assisted in-picture navigation with ultrasound and X-ray localization
 - Software-assisted automatic patient positioning
 - Live ultrasound and X-ray imaging
 - Multipanel operation and remote control possible
 - Motor-operated isocentric system drives
 - Outpatient treatment without anesthesia or sedation possible
- New multifunctional patient table:
- Easily adaptable to the new PiezoLith with plug & play
 - Can be converted for use in lithotripsy and urology procedures
 - 3 radiolucent CFRP areas for ESWL and endo-urological applications
 - Isocentric tilting for ESWL
 - Bilateral isoclinic tilting for endo-urological procedures
 - Multi-control operation using manual switches or touch panels

Dual Simultaneous Real-time (DSR) Localization

Inline ultrasound localization

- Continuous inline ultrasound monitoring without radiation exposure and without interrupting the shockwave treatment possible
- The inline probe is motor operated and aligned coaxially and isocentrically to the focus of treatment
- Continuous motor-operated adjustment of settings between 0 and 120 mm (short, medium and long-range) for individual patient monitoring with motor-driven coaxial vertical adjustment
- Coaxial isocentric inline ultrasound localization with motor-driven rotation from 0° to $\pm 90^\circ$

Outline X-ray localization

- All X-ray systems are motor-driven and controlled
- Confocal isocentric alignment to the focus of treatment
- Continuous, motor-driven lateral rotation from 0° to $\pm 30^\circ$
- Top-quality images and low exposure to radiation due to outline localization concept
- X-ray imaging possible at any time without interrupting the shockwave treatment





Control unit

- Touch panel with wide screen format
- Menu-guided user-friendly touch screen for clear, quick, intuitive and comfortable operation
- Live ultrasound and X-ray imaging for dual simultaneous real-time video imaging
- Optional wide screen monitor to additionally display ultrasound and X-ray images and switch between them as required
- Mobile monitor cart with accessories
- Multipanel operation: multiple controls and remote control operation if required
- Can be configured and expanded according to individual users' specific requirements
- Can be mounted on a base on the control unit, the mobile monitor cart or in a separate control room with a radiation protection wall
- Optional documentation of patient and treatment data

Therapy source

- Directly focused piezoelectric shockwave technology
- Extremely long product lifespan and very low maintenance
- No reflection waves and much lower pain response
- Unique guaranteed lifespan of 5 million shockwaves (or 2 working years)
- Very compact design due to patented piezo double-layer technology
- Excellent performance data for highly effective treatment
- Peak pressure: 125 MPa
- Pulse energy: 140 mJ
- Penetration depth: max. 165 mm centrally/ 200 mm distally (-6dB)
- Unique triple focus for stone fragmentation according to the individual indication
- Broad dynamic range for low, medium and high energy procedures
- Single pulses or continuous pulse of 30-360 shockwaves per minute with ECG synchronization possible
- Lower shockwave noise level of max. 82dB(A)
- Precise focusing protects surrounding tissue; this results in low complication rates and fewer side effects
- Individual motor-driven adjustment of confocal therapy source from 0° to ±50°; therapy source can be adapted for use in under-table and over-table applications





Sales and Service
Partner Piezo Systems



spirit of excellence

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