



PiezoLith3000 plus

DSR Localization · Triple-focus

Double-layer Piezo Technology · Automatic Patient Positioning

ESWL Based on Experience + Innovation



Richard Wolf GmbH and ELvation Medical GmbH **Therapy for Stones Based on Innovation and Experience**

Medical products by Richard Wolf are a byword for innovative technologies – technologies which fulfill the highest requirements of surgical teams all over the world and set new standards.

Working for decades in the field of urological stone therapy, the Richard Wolf company has researched and developed pioneering, complementary solutions, including extracorporeal shockwave lithotripsy, for the endo-urological treatment of stones. Together with ELvation Medical we are exploring new avenues which allow us to offer professional, specialist support.

Backed by more than 30 years' experience with piezoelectric lithotripsy technology and with more than 800 systems installed worldwide, we are proud to present the next shockwave generation: the PiezoLith 3000Plus. We have combined all our expertise to set new standards in precision, efficacy and user-friendliness for ESWL.



PiezoLith 3000Plus - Focusing on Multimodal Stone Management

Numerous procedures are currently being used to manage urological stones; among these procedures extracorporeal shockwave lithotripsy has established itself as a key treatment option. Combining this procedure with endo-urological interventions requires a special type of multimodal ESWL workstation for stone management. The innovative, modular and mobile PiezoLith 3000Plus concept with its pioneering user philosophy more than fulfills these requirements.

With the PiezoLith 3000Plus, the new ESWL generation offers automatic patient positioning combined with unique selling points such as piezoelectric double-layer technology, triple focus, and dual simultaneous real-time localization.





PiezoLith 3000Plus Operating Concept

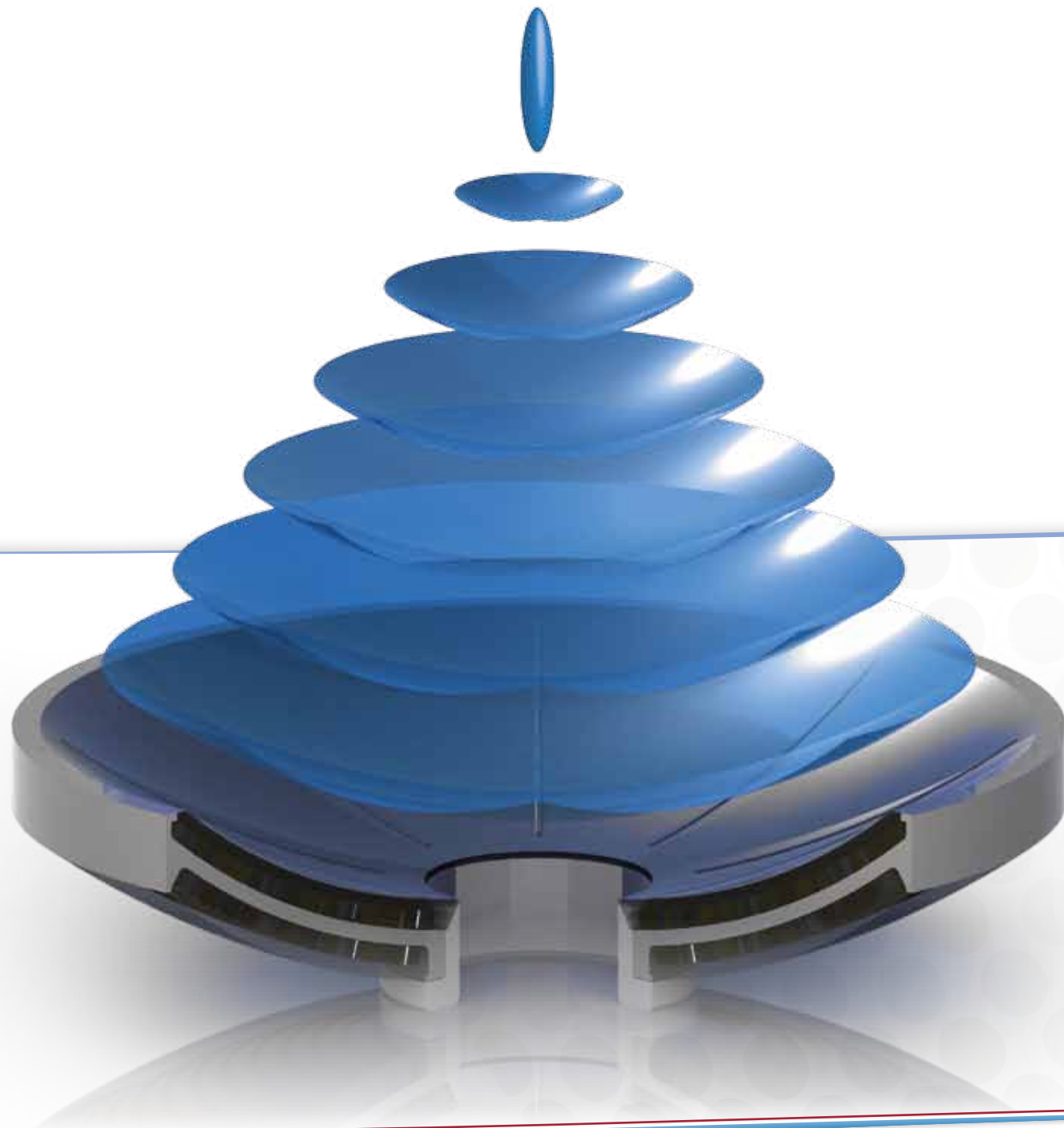
Computer and software-assisted automatic patient positioning with in-picture navigation

The PiezoLith 3000Plus offers an innovative control system for computer and software-assisted automatic positioning using newly developed in-picture navigation. The unit's menu-guided touch-screen operation for all central ESWL operations and display functions, and its live ultrasound and X-ray imaging set new standards in ESWL.

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

1. Manual table positioning, either directly at the table 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

The PiezoLith 3000Plus allows patient and treatment data to be recorded and is network compatible (optional/DICOM).



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

The piezo elements are arranged on a concave surface; a high-voltage pulse is used to briefly and simultaneously expand the piezo elements by a few micrometers, creating a pressure pulse. The piezo elements are aligned precisely to the therapy focus. The precise focusing of the pulse results in steepening of the shockwaves at the therapy focus.

The piezo shockwave technology of Richard Wolf is currently the only shockwave system to use "direct focusing" and does not require additional reflectors. This makes the therapy source compact and ergonomic and ensures that the focal zone is precise and well defined. The technology is quiet, almost painless, and generates a strong pressure wave at the point of focus.

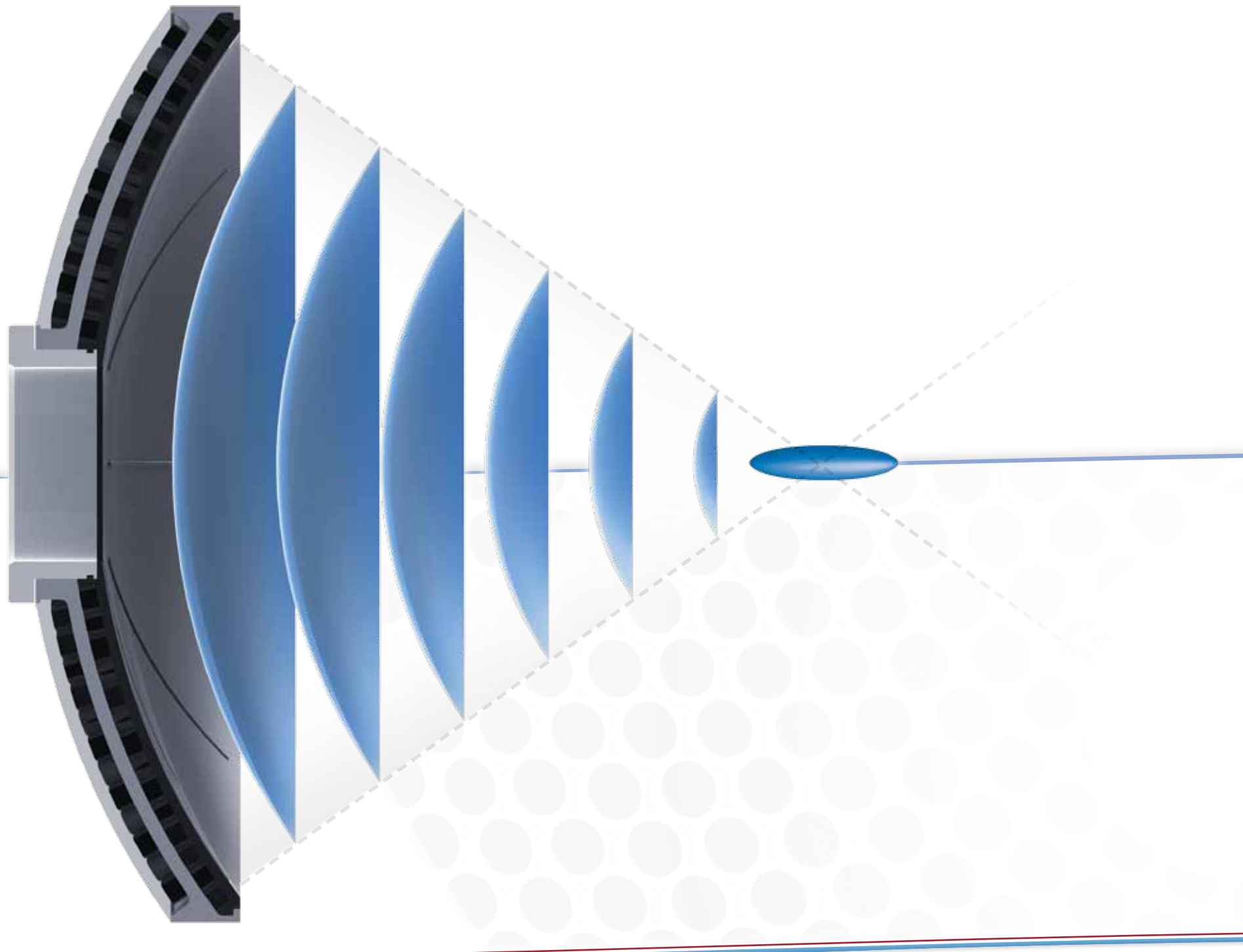
Energy coupling is spread over a broad area, reducing the energy density at the surface of the skin and considerably decreasing the pain sensation. The precise focal zone ensures that treatment is focused and offers optimal protection to surrounding tissue.

The therapy source of the PiezoLith 3000Plus is equipped with patented double-layer technology (DLT) which almost doubles the energy output, resulting in excellent disintegration of stones. Users can choose between single pulses or continuous pulse applications of 30-360 shockwaves per minute and ECG synchronization. The PiezoLith 3000Plus has an unusually broad dynamic range with excellent performance data:

Peak pressures of up to 126 MPa

Pulse energies of up to 140 mJ

The penetration depth ranges from 165 mm (-6 dB) centrally to 200 mm (-6 dB) distally

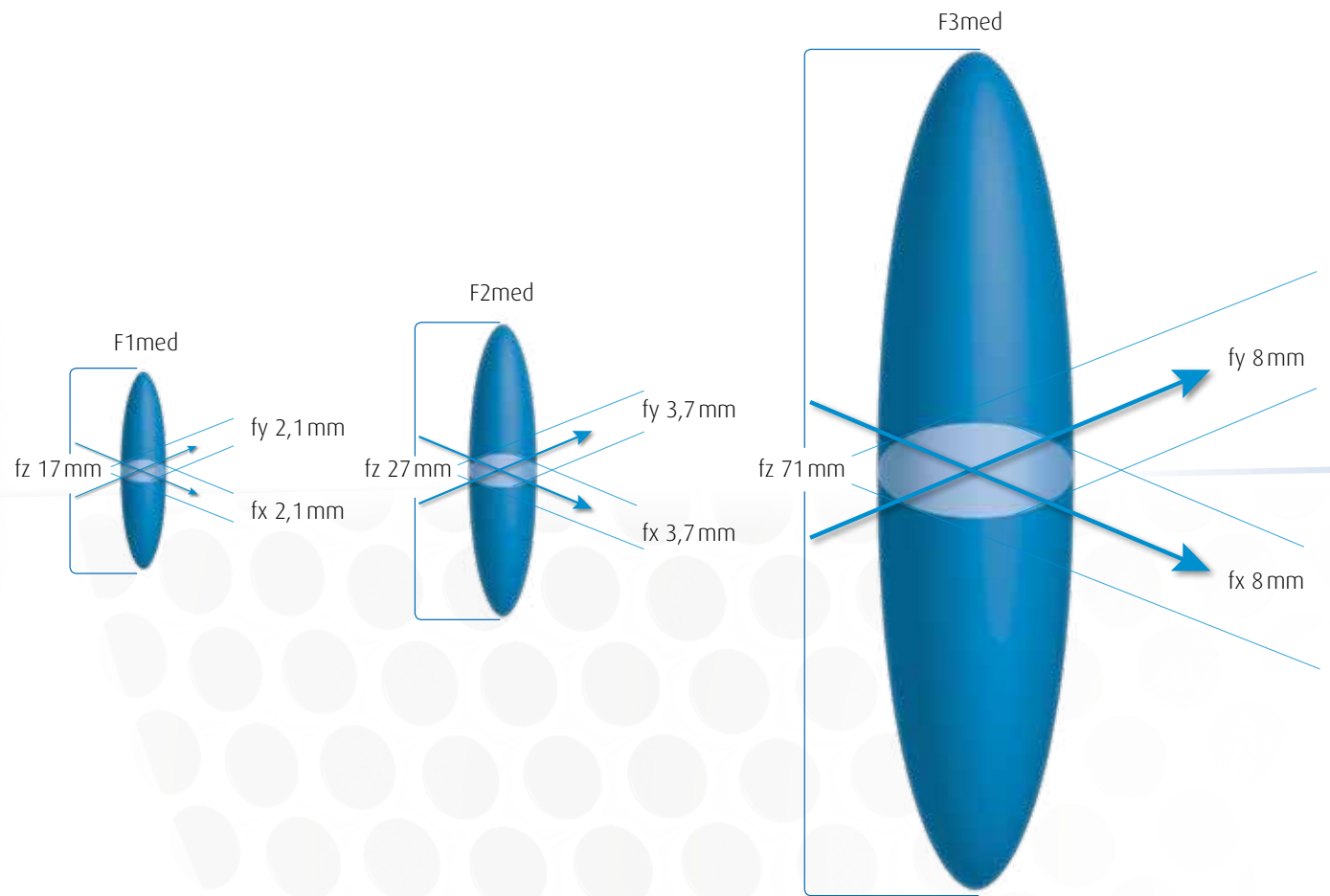


Direct Focusing (DFL) - Three Effective Ways of Eliminating Treatment Pain

The Richard Wolf piezo shockwave is the only shockwave technology to use “direct focusing”. This means that the pressure pulse created by the piezo-elements is focused directly on the focal point without requiring additional reflectors or an acoustic lens. The extremely precise focusing ensures that steepening, which creates the shockwaves, only occurs at the therapy focus. This results in a compact design with a very wide aperture angle. Three characteristics of “direct focusing” help minimize the pain experienced by patients:

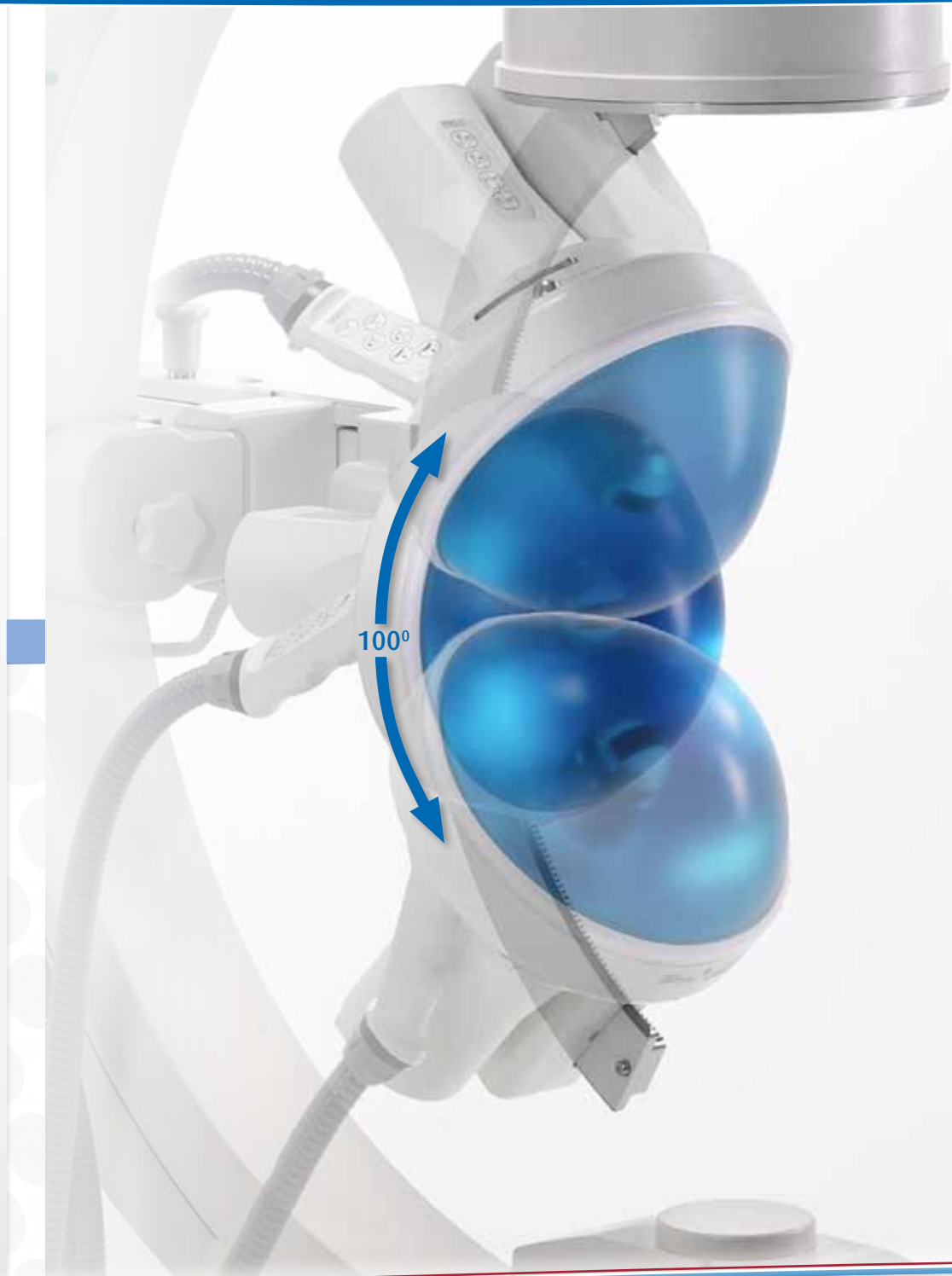
1. No additional pain from uncontrolled reflected waves
2. No pain at the point of interface due to wide aperture angle
3. Reduced impact on tissue in the window of entry as steepening only occurs at the focal point

Experience has shown that in the large majority of cases extracorporeal lithotripsy performed using piezo-shockwaves can be carried out without the need for anesthetics or sedation.



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

The focal size required to break up stones must fulfill various requirements. On the one hand, it needs to be small and compact so that surrounding tissue is preserved while ensuring that harder stones are still broken up effectively. On the other hand the focal size needs to be large enough to break up large stones or stone fragments. The cyclical changes in stone position due to breathing movements often also require a larger therapy focus. To permit such individual adjustments, the PiezoLith 3000Plus uniquely offers the possibility of choosing between one of three differently sized focal zones. The focal zone can be changed even during treatment. This unique variability is due to the way in which piezoelectric shockwaves are generated. Electronic activation of the double piezo layer makes it possible to create different, precisely defined focal areas.



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

DSR localization allows users to carry out ultrasound and X-ray localization either simultaneously, alternately, or separately. All localization systems are motor operated and controlled. The design of the therapy source and the piezo-shockwave concept of Richard Wolf mean that the ultrasound probe can be placed “inline”, allowing continuous monitoring of shockwave lithotripsy procedures.

The “outline” concept used for X-ray localization offers optimal imaging quality and limits patient exposure to radiation. Both X-ray localization and ultrasound localization can be carried out without interrupting the shockwave lithotripsy procedure and without mechanical adjustment.



PiezoLith 3000
plus

X-ray Localization Using the Patented Wolf Lithoarm

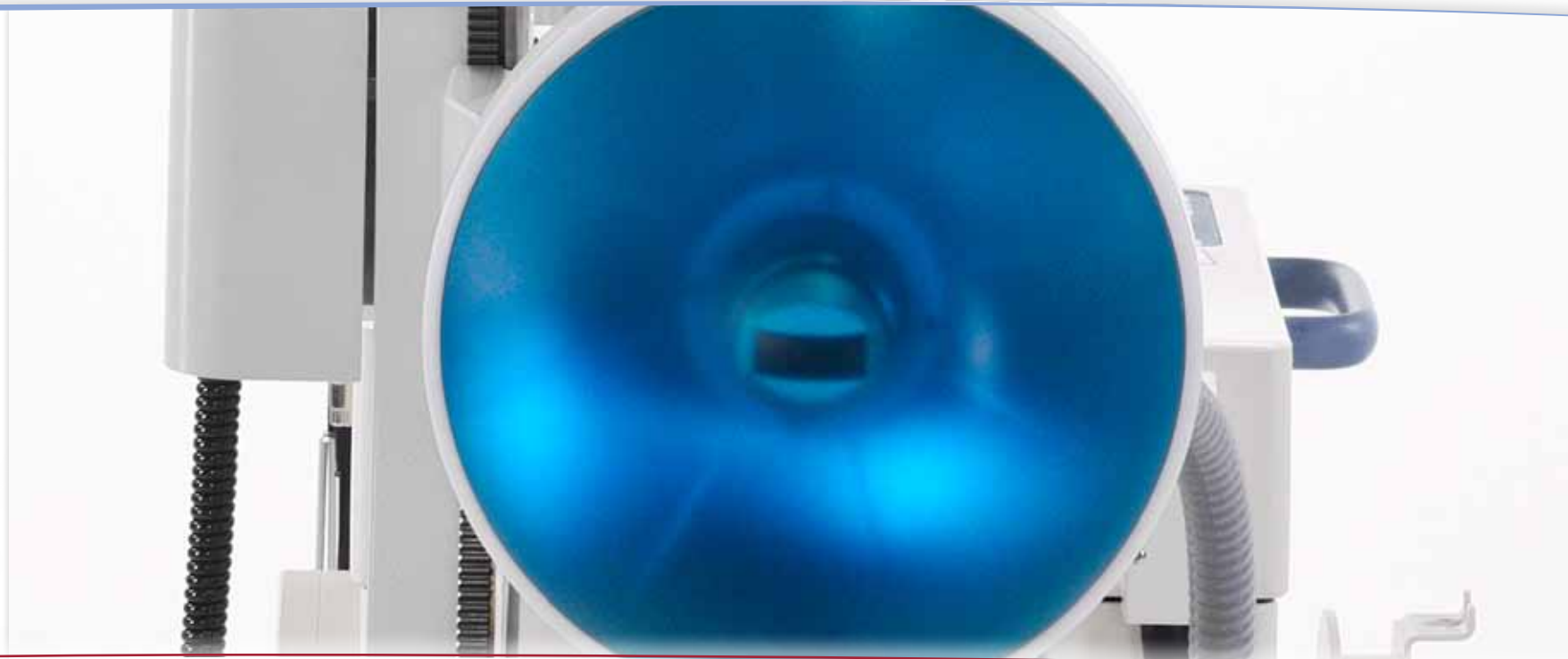
With the development of the Wolf Lithoarm it is now possible to adapt the therapy source of the PiezoLith 3000Plus to different X-ray units while retaining the mobility of the X-ray C-arm and the individual, modular components of the lithotripsy system. Outline localization means that no airbags are required. The X-ray image is not restricted. Scattered radiation is reduced to a minimum. This keeps the radiation exposure of the physician and the patient as low as possible while ensuring that the quality of the images is excellent. The X-ray system is motor operated and controlled and can be infinitely adjusted and rotated laterally from 0° bis +/-30°.

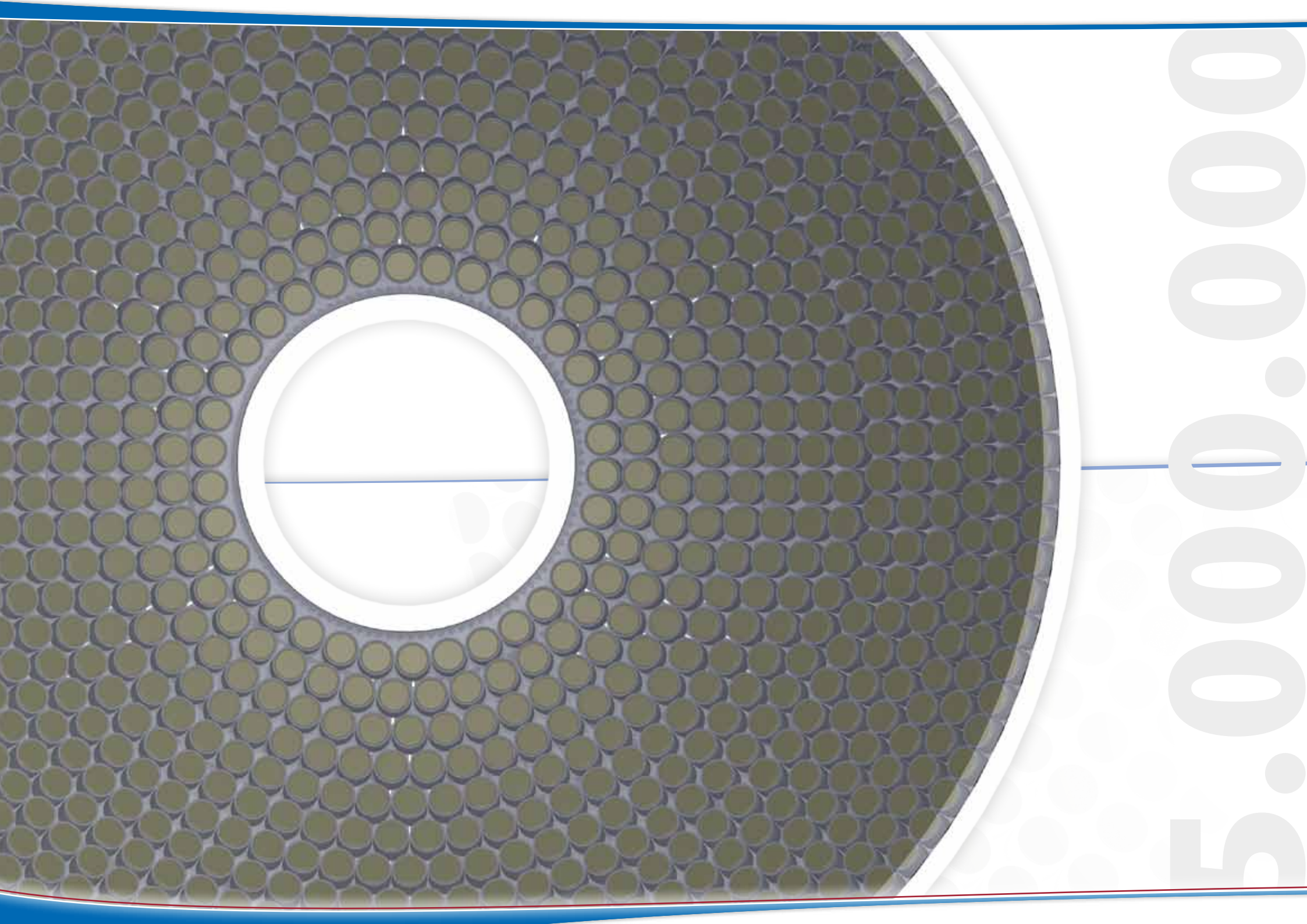


Inline Ultrasound Localization - Continuous Monitoring

The ultrasound probe integrated in the shockwave source means that the therapy region can be located easily and precisely. The rotatable and axially adjusted inline probe is motor operated and controlled and is arranged coaxially and isocentrically to the therapy focus.

Direct contact through axial adjustment of the ultrasound avoids multiple reflections while guaranteeing high-resolution, high-quality images. This localization concept allows continuous ultrasound localization and offers the additional benefit that obstacles which lie in the path of the shockwaves are recognized immediately.





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

The piezo shockwave technology of Richard Wolf is characterized by its superior durability. We guarantee it. The therapy source of the PiezoLith 3000Plus is supplied with a unique guarantee of 5 million pulses or a working life of 2 years.

This is due to the extraordinary durability of the piezo elements, which are only expanded by a few micrometers – an advantage which is also reflected in the unit's acoustic footprint. With maximum sound levels of 82 dB(A), the Richard Wolf piezo-shockwave technology of the PiezoLith 3000Plus is extremely quiet.

PiezoLith 3000Plus

- Unique piezoelectric shockwave technology
- Modular mobile 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 operation possible
- Motor-operated, isocentric system drive
- Outpatient treatment without anesthesia or sedation possible

New multifunctional patient table:

- Easy to adapt to the new PiezoLith using “plug & play”
- Can be converted for use in lithotripsy and urology treatments
- 3 radiolucent CFRP areas for ESWL and endo-urological applications
- Isocentric tilting for ESWL
- Bilateral isoclinic tilting for endo-urology applications
- Multi-control operation using manual control switches or touch panels



Dual simultaneous real-time localization (DSR)

Inline ultrasound localization

- Continuous inline ultrasound monitoring without radiation exposure and without interrupting the shockwave therapy
- The inline probe is motor operated and controlled and aligned coaxially and isocentrically to the therapy focus
- Infinitely variable, motor-driven adjustment of settings between 0 and 120 mm (short, medium, and long range) to monitor individual patients using motor-operated coaxial vertical adjustment
- Coaxial isocentric inline ultrasound localization with motor-driven rotation between 0° bis +/-90°

X-ray outline localization

- All X-ray systems are motor operated and controlled
- Confocal isocentric alignment to the therapy focus
- Infinitely adjustable, motor-driven lateral rotation between 0° bis +/-30°
- Optimal imaging quality and low radiation exposure due to outline localization concept
- X-ray imaging possible at all times without interrupting the shockwave therapy



Therapy source



- Directly focused piezoelectric shockwave technology
- Extremely durable, low maintenance
- No reflection waves, considerably reduced pain
- Unique guaranteed working life of 5 million shockwaves (or 2 years)
- Very compact design due to patented piezo double-layer technology
- Excellent performance data ensures highly effective treatment
 - Peak pressure: 125 MPa
 - Pulse energy: 140 mJ
 - Penetration depth: max. 165mm centrally/200mm distally (-6db)
- Unique triple focus for stone fragmentation adapted to the individual indication
- Broad dynamic range for low, medium and high energy applications
- Single pulses or multiple pulses of 30-360 shockwaves per minute, and ECG synchronization possible
- Low shockwave noise level of max. 82 dB(A)
- Precise focusing protects surrounding tissue, leading to low complication rates and minimal side-effects
- Individual, motor-driven adjustment of confocal therapy source between 0° and ±50°; therapy source can be adjusted for over-table and under-table applications



Control unit

- 19" 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 19" wide-screen monitor for additional clear display of ultrasound or X-ray images; users can switch between ultrasound and X-ray imaging as required
- Mobile monitor cart with accessories
- Multipanel control: multiple controls and remote control operation possible
- Can be configured and expanded according to the requirements of individual users
- Can be installed on a stand on the control unit, on a mobile monitor cart or in a separate control room with a radiation shield wall
- Optional documentation of patient and treatment data



Subject to change without prior notice./Picture may differ from actual product



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