

K. Quality guide lines for shockwave device

- Prerequisites: The appliance must conform with EC Directive 95/42/EEC on Medical Products. It must bear a CE symbol with the number of the notified body. The appliance manufacturer must provide the following data:
 - Positive tip pressure Mpa (1 Mpa = 10 bar)
 - -6dB focal expansion
 - 5Mpa focal expansion
 - Positive focal energies in mJ in the -6dB focal expansion and in the 5 Mpa focal expansion
 - Positive focal energy in the 5mm focal expansion
 - Positive energy density in mj/mm²
- Operative range as regards acoustic energy output: The operative range of the shockwave appliance should cover both low energy and high energy applications.
- Position-finding system/positioning accuracy: It must be possible to set the focus exactly using X-rays (C-arc with image intensifier) or using ultrasound (inline or outline scanner). X-ray positioning is indispensable when treating pseudarthrosis.
- Conformity with EU regulations: The device must be used in accordance with the operating instructions.
- Safety checks: The device must be inspected and subjected to safety checks by authorized persons at the intervals specified by the manufacturer.

The respective national regulations shall apply in all countries in which the device is used. Within the EU, the maintenance intervals are specified in the technical documentation of the manufacturer. The operator is obliged to comply with these maintenance requirement.