Renaissance Robotic System Specification

The Renaissance surgical robotic platform has been specifically configured to aid surgeons in performing delicate spinal procedures. The Renaissance Spine system is indicated for the precise positioning of surgical instruments or implants (screws, plates, etc.) during general spinal surgery and may be used in either open or percutaneous procedures.

The Renaissance Device has been specially designed to assist surgeons in guiding handheld surgical tools in line with computerized, image-based, preoperative plan along given trajectories, with high precision. The system software processes fluoroscopic and CT images with proprietary algorithms. The software automatically transfers the desired coordinates of the Renaissance to the Robotic Arm and tool guide.
Features and benefits

- The following outline highlights the main features and benefits of the Renaissance Spine robotic system:
- Provides a high degree of precision in accordance with an image-based preoperative plan
- Improves accuracy when performing MIS procedures and open procedures
- Easy to setup and use
- Mounted on the bony anatomy, the robot provides a stand-alone solution that does not require a tracking system.
- Reduces X-ray radiation exposure to patient and medical staff
- Miniature device size:
  - occupies minimal operating room space
  - provides free movement and vision during the operation
- Automatic image-based registration that requires no human intervention other than approval
- Does not require dedicated personnel - operated by the surgeon and surgical team.
- Off-site preoperative planning frees surgeons to work when and where they choose For example, in an office or at home (on a PC or laptop computer)
- Robust system design and protocols are unaffected by environmental conditions, such as:
  - Line of sight
  - Noise
  - Vibration
  - Humidity
  - Proven cost efficiency
**Renaissance Robotic System - Main Components**

The Renaissance Robotic System main components are:

1. *Renaissance Workstation*
2. *Renaissance Robotic Device*
3. *Image Adaptor*
4. *Set-up tools*
5. *Renaissance Spine Surgical Accessories Kit*
6. Software for installing on the surgeon’s PC or laptop for preoperative planning – this is optional as the preoperative planning can be done on the Workstation.

**1. Renaissance Workstation**

The Renaissance Workstation (WS), which is the main console from which the surgeon controls operation of the Renaissance system, is equipped with a control panel, multi-touch-screen monitor, rear connectors panel and storage compartments.

The Renaissance Workstation has three main components:

1. *Processing Unit*
2. *Control Unit*
3. *Renaissance Device* (positioning system)

Renaissance WS dimensions: 182 x 105 x 58 cm
Renaissance WS weight: 125 Kg
The Renaissance workstation specification:

- **Operating system** Windows 7 64bit operating system
- **PC** Model HP Z800
- **Mother board** Supports Intel® Core 2™ multi-core and 45nm processors
- **1600 MHz FSB (Front Side Bus) support DDR3**
- **Main Memory** 8GByte 800MHz dual channel DDR3
- **GPU** 1 units of NVIDIA GTX 480 / 580
- **CPU**- Intel Xeon X5680 3.3 12 MB / 1333 6C
- **Hard Disk** 320 Giga Byte
- **Frame grabber** 64bit Frame grabber
- **Monitor** 23.6” Monitor, resolution 1280 x 720 or 1024 x 768
- **Network Connection** 1/10/100 MHz network adapter
- **Com port** Two serial port
- **USB** six USB 2.0 ports
2. Renaissance Robotic Device

The Renaissance Robotic Device (RBT) is controlled by the Renaissance Workstation computer and by a special control unit.

The execution of the surgery is based on a pre-operative planning done with robot’s proprietary software on the patient’s CT scan. The surgeon plans the “blue-print” for the surgery based on the patient's unique anatomy and specific condition. The robot ensures that the surgeon performs the surgery exactly as intended.

The robot is a hexapod robot – a six legged robot with 6 degrees of freedom. The six legs provide very high precision in multi-axis positioning of the surgical instruments. The accuracy of the robot is 200 microns.

The overall accuracy of the system is 1.5 mm; it takes into calculation the image registration, platform’s mechanical rigidity and robot’s accuracy.

The RBT device is placed on a platform which is attached to the bony anatomy of the patient. The system has several platforms designed to support a large variety of posterior spinal procedures, from long deformity corrections to percutaneous, minimally invasive procedures.

Renaissance Device dimensions:
Weight: ~250gr
Height: 100mm
Diameter: 45mm
3. **Image Adaptor**

Image Adaptor is attached to the C-arm as part of the scanning process; used to locate the X-ray position relative to the patient. Embedded molten bead patterns are visible on the X-ray image; the software application recognizes and locates the beads according to their location on the image. Image Adaptor is supplied with accessories (rings, holders, screws and key wrenches) for the assembly process.

4. **Renaissance Spine Surgical Accessories Kit**

The accessories kit includes the accessories required for performing a robotic spinal surgery with Renaissance, such as the different arms, drills and cannulas. All of the accessories in the kit are multiple use tools which require sterilization prior to every surgery.

5. **PC System requirements**

The desktop PC (or laptop computer) used preoperatively for the Planning procedure is not included in the package provided by Mazor Robotics. This item should be purchased by the surgeon and should comply with the specifications

**Planning - Laptop or Desktop PC should include:**

- Operating System Windows XP Home (SP2, or higher), Windows 7
- Memory (RAM) 1024 MB or more
- HD 80G / 20G (including / excluding DB storage)
- CPU P-IV 1.8GHz, 512KB cache
Renaissance Disposable Kits

Clamp-based Disposable Kit
Used for Less-Invasive procedures (includes Clamp, AP Target, Target Extension Kit, sterile covers).

Thoracic Clamp Disposable Kit
Used for Thoracic surgery (includes Thoracic Clamp, AP Target, Target Extension Kit, sterile sheath). The Thoracic Clamp has been specially designed for use on thoracic vertebrae.

Minimally Invasive Disposable Kit
Used for Minimally-Invasive procedures (includes Renaissance Spine Hover-T [external bridge] with side blocks; Sterile covers; AP Target).

Bed Mount Disposable Kit
Used for Minimally-Invasive procedures (includes AP Target; Sterile Covers).
**CT Protocol Parameters**

In order to plan a robotic guided surgery, Importing the patient's CT data into the Renaissance system requires the use of the following CT protocol parameters.

**System parameters**
1. Matrix: 512 or high;
2. Collimation: 16 x 0.75;
3. Thickness: Nominal: 0.6 ± 0.8 mm; Maximum accepted: 1 mm
4. Pitch: 0.4;
5. Filter: L or D (SHARP for Lung on Philips, Bone Edge on GE)
6. Voltage and mAs - according to human size:
   - BMI < 25: 120 kV/110 mAs;
   - BMI 25-35: 140 kV/130 mAs,
   - BMI > 35: 140 kV/200 mAs or more.
7. FOV = Nominal: 200 mm; Maximum accepted: 250 mm.

**Requirements to format of CT data**
1. CT data should consist of one series – of axial slices.
2. Axial series should possess the following properties:
   a) All slices should be parallel to each other;
   b) All slices should be of same dimensions;
   c) Slice spacing should be consistent;
   d) Maximum slice spacing admitted is 0.4 ± 1.0 mm;
   e) The pixel spacing is 200/512 ~ 0.4 mm as stemming from the data above;
   f) The slices saved on CD should not be compressed (DICOM).

**C-arm requirements**

Performing robotic guided surgery requires a C-arm in the operating theater (not supplied with the system)

- 9"/12" C-Arm or Flat Panel C-Arm
- Video Output (BNC) or Di-com output
Technical Specifications

- Environmental Standards
  - Operating Temperature
    - United States and Japan: 50° to 86°F
    - Outside the U.S. and Japan: 10° to 30°C
  - Specifications United States and Japan: 10% to 80% (non-condensing)
  - Outside the U.S. and Japan: 10% to 80% (non-condensing)

- Shipping and Storage Standards
  - Shipping and Storage Temperature
    - United States and Japan: 14° to 140°F
    - Outside the U.S. and Japan: -10° to 60°C

- Performance Limitations
  - Renaissance Device activities: Maximum of 500 procedures
  - Renaissance Device usage time: Maximum of 80 hours
  - Renaissance Device connections: Maximum of 1500 hours

- Power/current/electricity:
  - 110-120 VAC / 60 Hz
  - 220-240 VAC / 50 Hz