Proton Therapy System

Clinical User's Guide

for the Wireless Hand Pendant

Document 52209 A - May 2016

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Abstract

The *Wireless Hand Pendant Clinical User's Guide* provides reference information and instructions for using a specific version of the wireless hand pendant from a clinical point of view.

The *Wireless Hand Pendant Clinical User's Guide* deals specifically with routine operation of the device, in the context of the Proton Therapy System - Proteus 235 (brand names: Proteus Plus and Proteus ONE).

Proprietary Information

Technical Support

If you cannot find the information you require in this manual, you can contact IBA in several ways:

- Phone: +32 10 47 58 31
- Fax: +32 10 47 59 00

- E-mail: customer_support@iba-group.com

Alternatively, you can call the IBA main switch board at +32 10 47 58 11

Notice

The information contained in this document has been checked for agreement with the hardware and/or software described. Since deviations cannot be precluded entirely, we cannot guarantee complete agreement and IBA is not liable for incidental or consequential damages in connection with the use of this document. In addition, IBA assumes no responsibility for technical or editorial errors or omissions that may appear in this document or for the use of this material.

This document provides information for operating the equipment, however, experience with this kind of equipment is required in order to use the document effectively.

Only appropriately qualified personnel may operate or maintain the equipment or work in its vicinity. Qualified personnel are persons familiar with the installation, assembly, startup, operation, and maintenance of this product, and who possess the relevant qualifications for their work in accordance with current standards in safety technology.

An ongoing version release process ensures the quality of the installed version of the Proton Therapy System (PTS) by solving as soon as possible any anomalies that may be found after the delivery.

In the event that an anomaly which may impact the safety or effectiveness of the system is detected, it is listed in the *Delivery Note*, which is part of the delivery to the customer.

CAUTION	Federal law restricts this device to use by or on the order of a physician.

Indication for Use

The wireless hand pendant is to be used as a feature of the Proton Therapy System - Proteus 235 (brand names: Proteus Plus and Proteus ONE).

Quality Certifications

Ion Beam Applications is certified in accordance with the ISO 9001 and ISO 13485 quality systems standards, and approved to produce CE marking certificates according to the European Regulation 93/42/EEC.

CE Marking

According to LRQA approval of conformity Certificate LRQ 0960676/B, IBA is delivering the certificate of conformity for the Proton Therapy System that has been provided to the customer through the latest Delivery Note.

Wireless Hand Pendant

- USA:

  FCC PART 15 Information to user.

  FCC ID: 2AHZSHP-MOB

  FCC ID: 2AHZSHP-FIX

  Pursuant to part 15.21 of the FCC Rules, you are cautioned that changes or modifications not expressly approved by IBA could void your authority to operate the device.

  This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

- Canada:

  This device complies with Industry Canada licence-exempt RSS standard(s). Operation is subject to the following two conditions: (1) This device may not cause interference, and (2) This device must accept any interference, including interference that may cause undesired operation of the device.

  Le présent appareil est conforme aux CNR d'Industrie Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes : (1) l'appareil ne doit pas produire de brouillage, et (2) l'utilisateur de l'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.

- Europe:

  The wireless hand pendant is in conformity with the relevant Union harmonisation legislation: Directive 2014/53/EU (RED) and directive 1999/5/CE (R&TTE).

- Safe and effective use of the wireless device:
  - The wireless hand pendant subsystem contains a Bluetooth radio with the following characteristics:

    Bluetooth Low Energy (BLE) version 4.1 operating in the 2.400 GHz-2.4835 GHz ISM band using F.H.S.S. modulation.

    Effective Isotropic Radiated Power (EIRP): 0 dBm 1 mW Class 1.

    A Smartphone using an IEEE 802.11 WiFi link. Other wireless links in the smartphone are factory disabled to avoid interferences.
  - Wireless QoS: the subsystem has been designed to be fail safe (to stop movements) in case of loss of communication or significant degradation. Only IBA authorized devices can connect to the access points in treatment room.
  - Wireless security measure: The subsystem will only accept a connection from a single IBA Hand Pendant at a time with IBA Unique Identification protocol. The UID is factory set and can not be changed by the user. The IEEE 802.11 WiFi link uses WPA2 for authenticationCross talk between devices in the same vicinity: Due to the unique ID mechanism, it is not possible to operate two devices in the same treatment room. Due to treatment room neutron shielding and low power Bluetooth usage, crosstalk between equipments from outside treatment rooms is very unlikely.

    However we recommend to keep the wireless hand pendant in the docking station when not in use.

Amendment records

Version	Date of Issue	Details of Amendments	Major Changes on Pages ...
1	May 2016	■ Addition of troubleshooting information. ■ Modifications across the manual according to the latest input.	Throughout the manual.

Incorporated by	Checked by	Validated by
Juliana GONZALEZ	Nathalie BOSSCHAERTS Vincent BOSSIER Henri BOURMORK Pierre FRANCO	

Version	Date of Issue	Details of Amendments	Major Changes on Pages ...
0	January 2015	■ Draft version.	

Incorporated by	Checked by	Validated by
Juliana GONZALEZ	Vincent BOSSIER Henri BOURMORK Pierre FRANCO	

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Safety Decisions

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About this Manual

Scope and Contents

This *Wireless Hand Pendant Clinical User's Guide* describes and gives instructions to clinical staff for operating the wireless hand pendant. The *Clinical User's Guide* includes one volume.

WARNING 	This guide is intended for properly qualified personnel who are authorized to operate the Proton Therapy System.

	The wireless hand pendant is a feature of the Proteus 235 system. Before actually using the PTS, users should: ■ Read and fully understand the PTS documentation set, including the emergency recommendations and safety precautions described in the *Safety and Emergency Recommendations document*. ■ Read and fully understand all rules and procedures for operating the equipment issued by the client.

Referenced Documentation

- IEC 60601-1-2:2014 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests.

What to Expect?

This chapter ...	Describes ...
Chapter 1	A general overview of the wireless hand pendant feature.
Chapter 2	A series of safety notices.
Chapter 3	A description of the wireless hand pendant registration process.
Chapter 4	A description of the wireless hand pendant GUI.
Chapter 5	A description of several usual troubleshooting procedures.

This appendix ...	Describes ...
Appendix A	Proteus ONE EMC tables.
Appendix B	Proteus Plus EMC tables.
Appendix C	Wireless hand pendant EMC tables.

Conventions

The following typographic conventions and visual cues are used in this guide.

Warnings

This is the way a Warning is presented:

WARNING	A Warning is provided when: A procedure, practice, etc., may result in personal injury or loss of life if not followed properly. The personnel may be exposed to hazards when carrying out a task on the system.

Cautions

This is the way a Caution is presented:

CAUTION	A Caution is provided when a procedure, practice, etc., may result in damage to the equipment if not followed properly.

Important Notes

This is the way an Important Note is presented:

Important	An Important Note is provided where a task or procedure requires emphasis or additional information essential to completion.

Typographic Conventions

Typeset	Refers to
Button	The name of a command button to be clicked with the mouse
SCREEN	The name of a user interface screen
< entry >	Information to be entered from the keyboard appears inside angle brackets
Label	The label of a field appearing on a screen
`Message`	A message (warning, error, acknowledgment, or request) from the system appearing on a screen

Illustrations

Photos, drawings, and User Interface (UI) screen representations are provided for **reference purposes only** and do not necessarily reflect the actual appearance of system hardware or software.

Visual Cues

The table below lists some visual cues that appear throughout the manual.

Symbol or Phrase	Meaning
	This symbol identifies warnings and cautions as well as other important information.
Important	This is the way Important Notes are presented. An Important Note is provided where a task or procedure requires emphasis or additional information essential to completion.
Note	This is the way Notes are presented. A Note is provided where an operating procedure, condition, etc., requires special attention.
Restriction	This is the way Restrictions are presented. A Restriction is provided where a task or procedure may only be completed under specific conditions. Restrictions are designed into the system in order to prevent the loss of important historical data.

Chapter 1
Introduction

This chapter provides you with an overview of the wireless hand pendant as a feature of the Proteus 235 system.

The Wireless Hand Pendant - Overview

The wireless hand pendant consists of a Graphical User Interface application software unit, implemented as an Android application running on the GUI Terminal, in this case, a smartphone.

The smartphone is encased in a fixed frame that features two buttons, one on each side. These are the motion enable buttons. The motion enable buttons allow you to confirm and enable, as a user, the execution of the movements commanded via the GUI.

Figure 1-1. Wireless Hand Pendant (typical)

The smartphone can be docked for charging onto a docking station.

Chapter 2
Important Notices

Make sure you read and understand the following important notices before using the wireless hand pendant.

Important 	Other wireless devices could interfere with the wireless hand pendant and are therefore proscribed in the treatment room. Interferences could lead to untimely and unexpected motion interruptions. While remaining safe, such situation could impede the normal use of the Proteus 235 system.

Important 	Do not use the wireless hand pendant for another purpose than controlling a Proteus 235 Proton Therapy System. Do not connect the wireless hand pendant manually to any WiFi network. Do not connect the wireless hand pendant to another WiFi network than a Proteus 235 treatment room.

Important 	When leaving the treatment room, you must always put the wireless hand pendant back on its docking station. This ensures that the wireless hand pendant remains protected from irradiation during treatment.

Important	
	The wireless hand pendant is a failsafe device. In case of interruption of the communication between the wireless hand pendant and the rest of the Proton Therapy System, any ongoing movement will be stopped. The loss of communication of the wireless hand pendant is considered as a release of any currently pressed or tapped button. More specifically, if the system looses the communication with the wireless Motion Enable Button during a movement, it will trigger an emergency stop.

Chapter 3
Wireless Hand Pendant Registration

In order to use the wireless hand pendant in a given treatment room, it is necessary to register it to that treatment room.

When as part of the registration process, the GUI application connects via WiFi to the PTS, it retrieves the room configuration of the room to which it is currently registered. The room configuration includes the list of the installed devices and their type. Based on this information, the GUI application adapts itself to provide controls that match the current room configuration. For this reason, there are as many possible GUI configurations as there are possible room configurations, and the same wireless hand pendant can be used in any treatment room as long as it has been successfully registered to that treatment room.

Registering the Wireless Hand Pendant

The wireless hand pendant uses WiFi and Bluetooth Low Energy to connect to the proton therapy system. The registration process takes care of the configuration of these communication channels and guarantees that only one wireless hand pendant is allowed to send commands in a given treatment room.

The registration of a wireless hand pendant to a given room is only possible if another user is not pressing the Motion Enable Buttons on an already registered wireless hand pendant. This rule guarantees that it is not possible to interfere with a user sending commands to the proton therapy system.

When you enter a Treatment Room with a wireless hand pendant that is not registered, the wireless hand pendant automatically prompts you to register it by displaying the **Register** button, which allows you to start the registration procedure.

Although several wireless hand pendants may be present in a given treatment room and they may all be connected to the wireless network, only a single wireless hand pendant can be registered to a single treatment room at any given time. The registered wireless hand pendant is the only one authorized to move treatment room equipment.

In order to register a wireless hand pendant to a given treatment room, proceed as follows:

1. Once the wireless hand pendant is in the treatment room, it automatically connects to the treatment room WiFi network. The following screen appears:

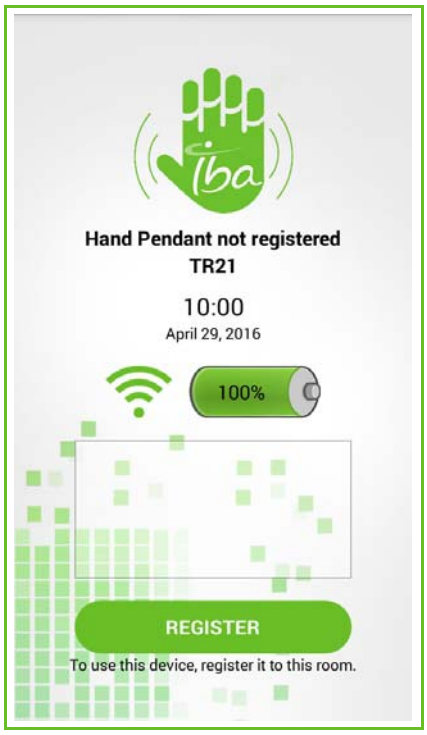

Figure 3-1. Wireless Hand Pendant Connected - Not Registered

2. Press the **REGISTER** button. The REGISTRATION PROCEDURE SCREEN appears. This screen features some animated instructions, indicating the sequence of operations that needs to be performed in order to complete the registration.

Figure 3-2. Registration Procedure Screen (typical)

3. Follow the instructions detailed in the pop-up message:
   a. Push and hold both side buttons.
   b. Release one of the side buttons.
   c. Press and hold both side buttons.
   d. Release the side button that was not released in Step b.
4. After 5 seconds, the registration screen is closed and the locked screen appears:
   - If the registration was performed successfully, you can now unlock and use the device. In order to unlock the device, proceed as detailed in section *Unlocking the Wireless Hand Pendant*.
   - If the registration was not performed successfully, you can run the registration procedure again by pressing the **REGISTER** button (see Figure 3-1).

Note: *A single wireless hand pendant can be registered to a single treatment room at any given time. The successful registration of a wireless hand pendant to a given treatment room has the following consequences:*

- *The wireless hand pendant that was previously registered in this treatment room is automatically unregistered.*

- *The newly registered wireless hand pendant is automatically unregistered from any other treatment room it was previously registered to.*

Note: *It is not possible to register a wireless hand pendant to a treatment room if the user is currently pressing the motion enable buttons of the wireless hand pendant currently registered to that same treatment room.*

Unlocking the Wireless Hand Pendant

In order to unlock the wireless hand pendant, slide the screen as indicated on the locked screen.

Note: *Once a wireless hand pendant is registered to a given treatment room and unlocked, it is automatically locked after 5 minutes of inactivity.*

Chapter 4
Graphical User Interface

This chapter describes in detail the GUI application software unit, which provides the graphical user interface (GUI) of the wireless hand pendant feature. This GUI is implemented as an Android application running on the GUI Terminal, in this case, a smartphone.

This chapter also summarizes the different operations that a user can perform using a wireless hand pendant. It presents various significant screenshots and it explains you how to interact with the application, as a user.

When as part of the registration process, the GUI application connects via WiFi to the PTS, it retrieves the room configuration of the room to which it is currently registered. The room configuration includes the list of the installed devices and their type. Based on this information, the GUI application adapts itself to provide controls that match the current room configuration. For this reason, there are as many possible GUI configurations as there are possible room configurations, and the same wireless hand pendant can be used in any treatment room as long as it has been successfully registered to that treatment room.

Note: *Figures of the wireless hand pendant GUI across this manual show a typical configuration (Gantry Treatment Room with snout and accessory drawer as well as with stereoscopic, beam eye view and orthogonal imagery system). Some details may differ from the GUI displayed by the wireless hand pendant in other room configurations. However, the principles explained are consistent throughout all GUI configurations.*

Operating Modes: Manual and Auto

The GUI offers two operating modes:

- **Manual mode:** this mode concerns all equipment-related operations that the user can perform independently from any patient information and from any saved positions. This covers jog motions as well as the insertion/retraction of various pieces of equipment.

- **Auto mode:** this mode concerns all patient-related operations and GoTo motions to preprogrammed positions. For example, once patient data are available in the PTS, the user can use the AUTO mode to move the patient positioning devices to the prescribed position.

Understanding the GUI: Some Graphical Principles

All screens, both in MANUAL and AUTO modes, were designed following some well-defined graphical principles. Figure 4-1 illustrates the main features that can be found throughout GUI screens.

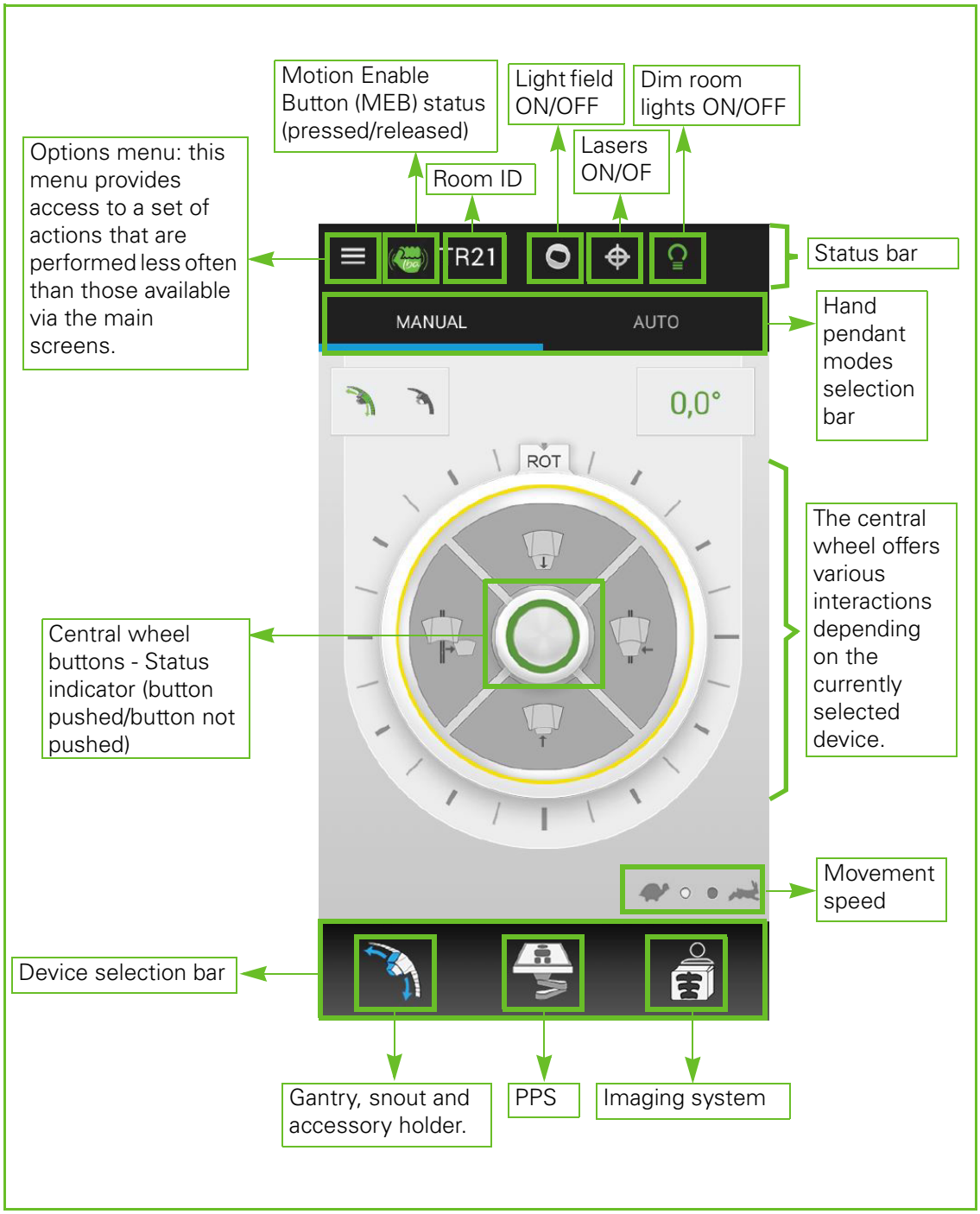

Figure 4-1. Wireless Hand Pendant GUI Screen (typical)

Understanding Color Codes

The following color code applies to all of the GUI screens:

Table 4-1. Wireless Hand Pendant - GUI Color Codes

Feature	Color	Meaning	Explanation
Mode selection bar	Blue	Mode selected	When a mode is selected, it becomes underlined by a blue trait, as is the case of MANUAL mode at the top left of Figure 4-1.
Device selection bar	Blue	Device selected and ready for movement	When a device is selected and ready for movement, the corresponding icon in the device selection bar becomes highlighted with some blue traits, as is the case of the gantry icon at the bottom left of Figure 4-1.
	Orange	Device selected and not ready for movement	When a device is selected but not ready for movement, the corresponding icon in the device selection bar becomes highlighted with some orange traits.
	Red	Device selected and in error	When a device is selected but in error, the corresponding icon in the device selection bar becomes highlighted with some orange traits.
Status bar	Green	Device active	When a device is active, the corresponding icon in the status bar becomes green, as is the case of the 'dim room lights' icon in Figure 4-1.
	Gray	Device inactive	When a device is inactive, the corresponding icon in the status bar becomes gray, as is the case of the 'lasers' icon in Figure 4-1.

Table 4-1. Wireless Hand Pendant - GUI Color Codes

Feature	Color	Meaning	Explanation
Movement speed selection	White	Speed selected	When a speed is selected, the dot next to the corresponding icon (turtle for low speed, hare for high speed) turns white, as is the case of the 'low speed' icon in Figure 4-1.
	Gray	Speed not selected	When a speed is not selected, the dot next to the corresponding icon (turtle for low speed, hare for high speed) turns gray, as is the case of the 'high speed' icon in Figure 4-1.
Central wheel	Gray	Device not in proximity or collision	When the selected device is neither in proximity nor in collision, the circle surrounding the central wheel turns gray.
	Yellow	Device in proximity	When the selected device is in proximity, the circle surrounding the central wheel turns yellow, as is the case in Figure 4-1.
	Red	Device in collision	When the selected device is in collision, the circle surrounding the central wheel turns red.
Central wheel buttons	Dark Green	Button is not pressed.	When a button in the central wheel is not being pressed, its border at the center of the central wheel is highlighted by a dark green line.
	Light Green	Button is pressed and movement is authorized.	When a button in the central wheel is being pressed and movement is authorized, its border at the center of the central wheel is highlighted by a light green line.

Using the GUI: User - Device Interactions

The following sections provide you with the detail of the actions that can be executed with every device, both in manual and auto modes.

Using the GUI in Manual Mode

Manual mode allows you to perform equipment movements that do not require any particular patient information or any saved positions. This covers jog motions as well as the insertion/retraction of various pieces of equipment.

Using Manual Mode to Move the Gantry, Snout and Accessory Holder

Once the gantry, snout and accessory holder subsystem is selected, the interface displays a four buttons wheel:

- The top and bottom buttons allow you to insert and retract the snout.
- The left and right buttons allow you to insert and retract the accessory holder.
- The ROT slider controls gantry rotation, which may be performed either clockwise or counter clockwise.

  A gantry target position may be specified using the field above the central wheel, on the right of the screen.

  A gantry target position may also be selected by touching the dark lines around the central wheel. This allows you to select targets located every 15°.

  To move the gantry to the selected target position, use the ROT slider on the central wheel.

Note: *The GUI is designed to provide quick access to often used functions. To keep the interface as clear as possible, less often used functions are accessible using the menu (top left of the screen).*

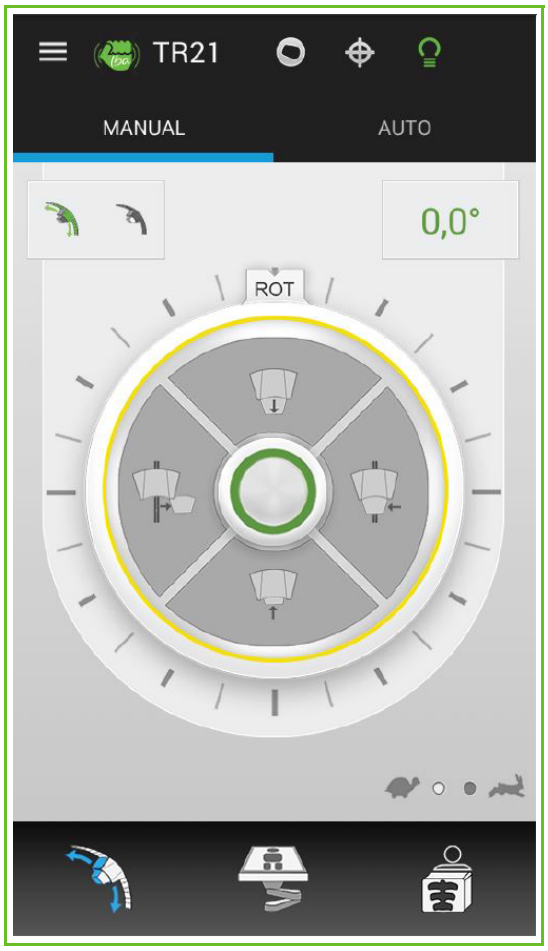

Figure 4-2. Gantry, Snout and Accessory Holder - Manual Mode (typical)

Using Manual Mode to Move the PPS (Patient Positioning System)

Once the PPS subsystem is selected, the interface displays a four buttons wheel:

- The top and bottom buttons allow you to move the PPS along the Y axis.
- The left and right buttons allow you to move the PPS along the X axis.
- The Z slider controls PPS movement along the Z axis (positive movement if the slider is moved clockwise, negative movement if the slider is moved counterclockwise).
- The ROT slider controls PPS top rotation.

Note: *By default, the GUI application displays the X, Y, Z and top rotation controls. You may access the pitch and roll view using the widget located above the central wheel, on the left of the screen.*

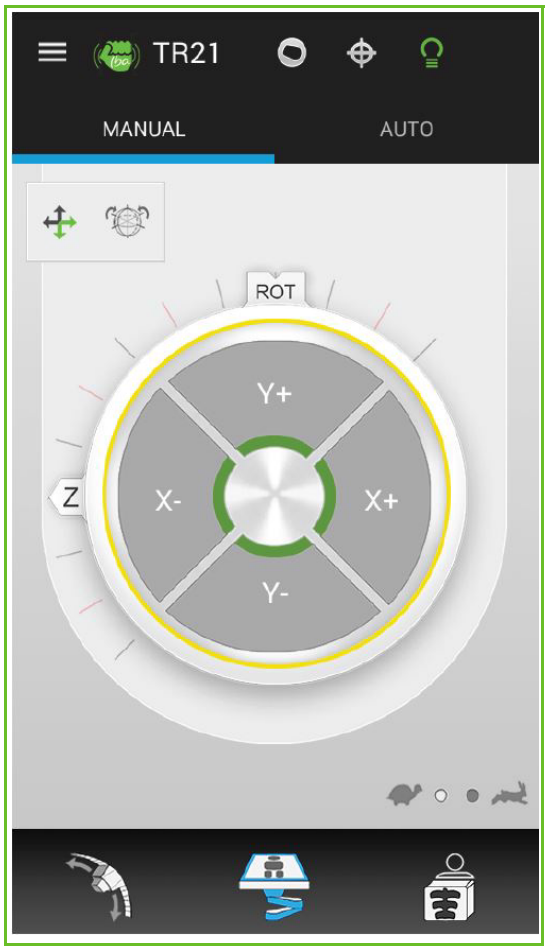

Figure 4-3. PPS - Manual Mode (typical)

Using Manual Mode to Move the Digital Imaging Devices

Once the digital imaging devices subsystem is selected, the interface displays a four buttons wheel:

- The top button allows you to insert the devices needed for performing stereoscopic image acquisition.
- The left button allows you to insert the devices needed for performing orthogonal image acquisition.
- The right button allows you to insert the devices needed for performing beam eye view image acquisition.
- The bottom button allows you to retract all digital imaging devices.

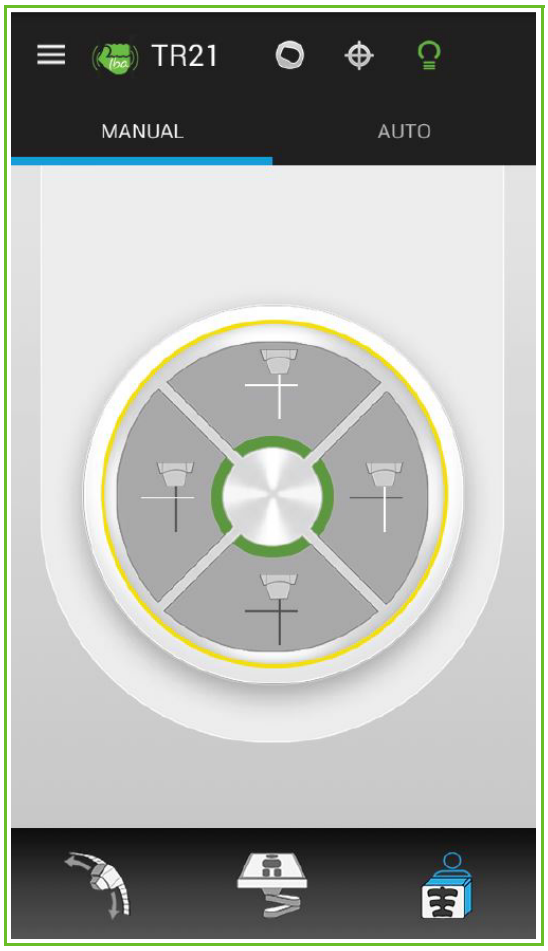

Figure 4-4. Digital Imaging Devices - Manual Mode (typical)

Using the GUI in Auto Mode

Auto mode allows you to perform equipment movements that are patient-related (i.e. that require particular patient information) and GoTo motions to preprogrammed positions.

All prescribed and user-defined positions are available in the options menu accessible via the button located at the top left of the screen (hereafter referred as 'the menu').

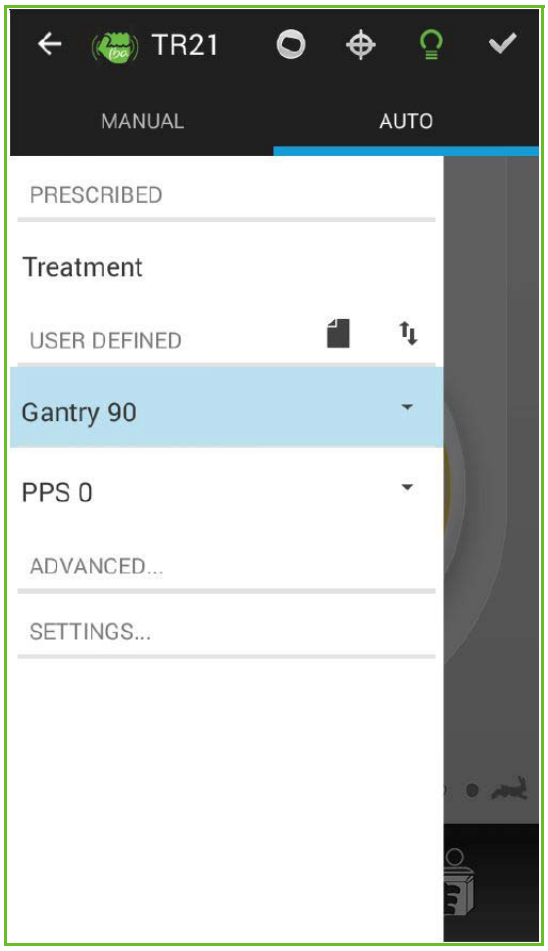

Figure 4-5. Menu (typical)

You may choose any prescribed or user-defined position from the menu.

The selected prescribed or user-defined position is highlighted in blue.

Once you choose a prescribed or user-defined position, you are able to move the devices that need to be moved in order to reach the selected position using the different device screens in auto mode.

In auto mode, the device screens are simpler than in manual mode. The only movement possible for every device is the one required for it to reach the selected position.

Note: *Note that the digital imaging devices screen is identical in auto and manual mode.*

At the bottom left of every device screen, the GUI displays a list of all the devices that need to be moved in order to reach the selected position. The devices in the list that have not been moved to the target position yet are displayed in gray. Those that have already been moved to the target position are displayed in green.

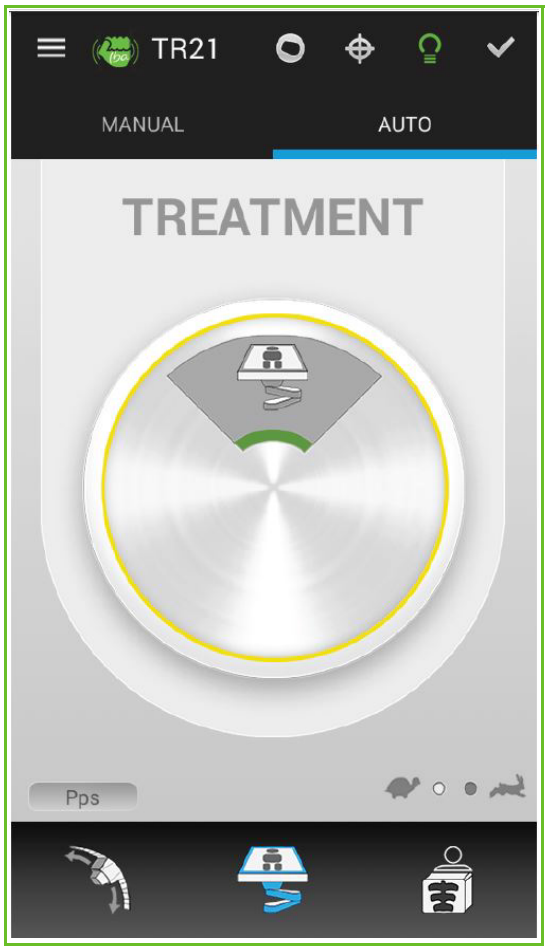

Figure 4-6. Treatment Position - Auto Mode (typical)

Figure 4-6 shows the PPS screen in auto mode, with a treatment position selected. In this case, the PPS panel provides a single button that allows the user to simply move the PPS to the prescribed position. The GUI application always allows the user to switch back and forth between manual and auto modes.

Creating User-Defined Positions

User-defined positions play a major role in the wireless hand pendant GUI. They allow users to define new positions to fit their needs.

Using the menu, it is possible to create a new user-defined position, arrange the list of existing user-defined positions and delete or modify an existing user-defined position.

In order to create a new user-defined position, proceed as follows:

1. Tap on the **Menu** icon at the top left of the screen in order to display the menu.

2. Tap on the **New** icon in order to access the NEW POSITION SCREEN.

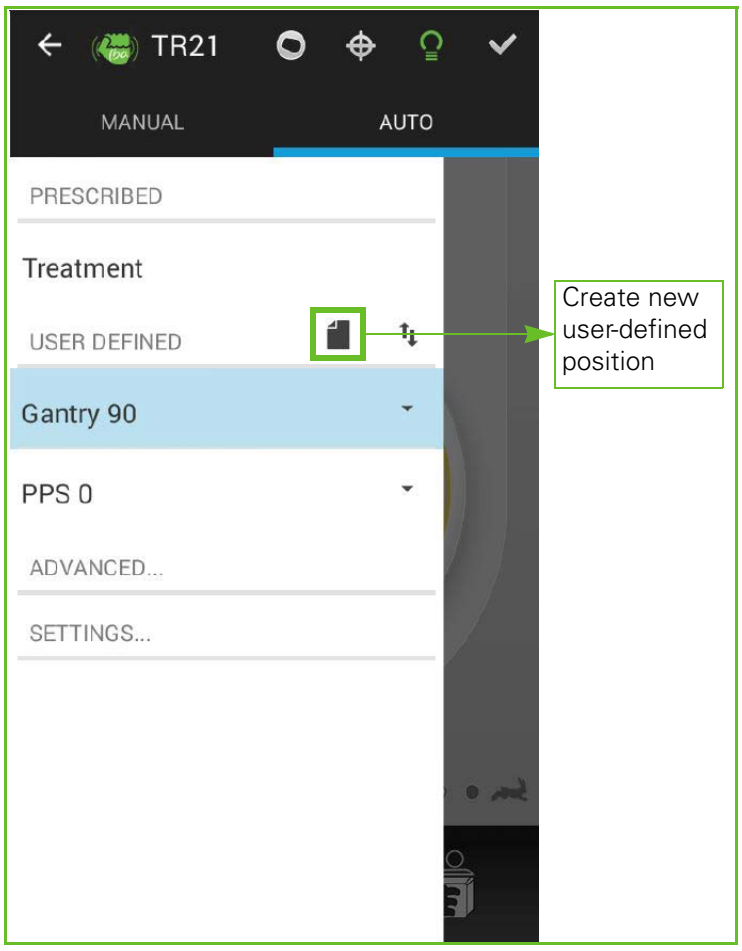

Figure 4-7. Creating a User-Defined Position (typical)

Figure 4-8 shows the interface that allows you to create a new user-defined position or to modify an existing one.

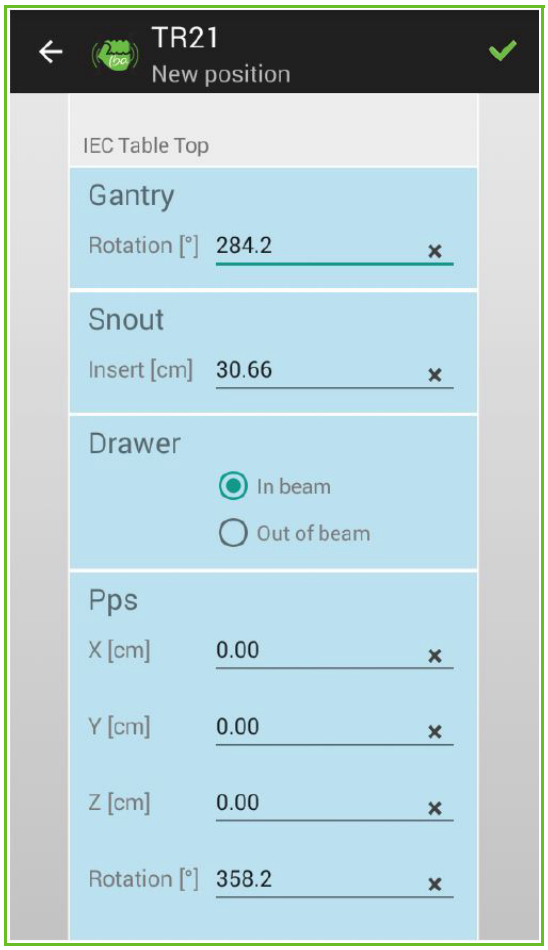

Figure 4-8. New Position Screen (typical)

At this point, you may fill in the required fields.

3. Tap on the **Tick** icon at the top right of the screen to save the newly created position.

   You may also save the new position by tapping on the arrow at the top left of the screen or on the return arrow at the bottom right of the screen.

Managing Prescribed and User-Defined Positions

Using the menu, it is possible to create a new user-defined position, arrange the list of existing user-defined positions and delete or modify an existing user-defined position.

In order to arrange the list of user-defined positions, proceed as follows:

1. Tap on the **Menu** icon at the top left of the screen in order to display the menu.

2. Tap on the **Arrange** icon in order to access screen to arrange the existing positions.

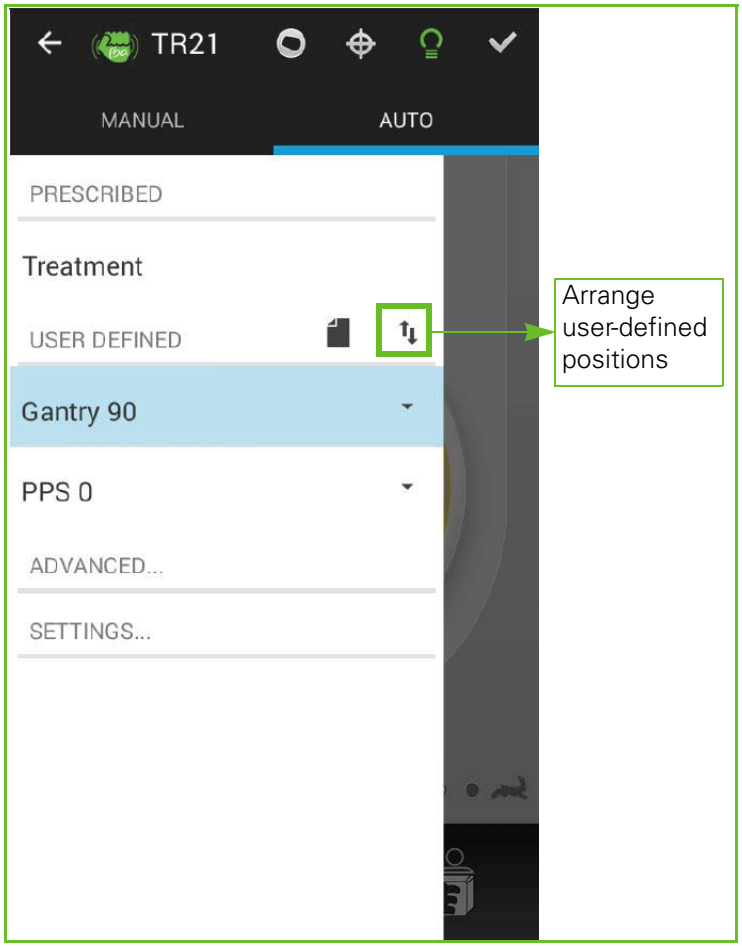

Figure 4-9. Arranging User-Defined Positions (typical)

3. You may now arrange the existing positions by dragging them into the order that suits your preferences.

In order to delete an existing user-defined position, proceed as follows:

1. Tap on the **Menu** icon at the top left of the screen in order to display the menu.
2. Tap on the arrow located to the right of the user-defined position that you want to delete.
3. Tap on the **Delete** icon.

   A pop-up message will prompt you to confirm your action.

In order to modify an existing user-defined position, proceed as follows:

1. Tap on the **Menu** icon at the top left of the screen in order to display the menu.

2. Tap on the arrow located to the right of the user-defined position that you want to modify.
3. Tap on the **Edit** icon.

   You are now able to modify the user-defined position using the NEW POSITION SCREEN.
4. Tap on the **Tick** icon at the top right of the screen to save the newly created position.

   You may also save the new position by tapping on the arrow at the top left of the screen or on the return arrow at the bottom right of the screen.

Using Advanced Options From the Menu

Figure 4-10 shows the functions present in the 'Advanced' section of the menu. These functions include:

- **Dock/Undock**: this function allows you to dock/undock table top extensions.
- **Homing**: this function allows you to home the different pieces of equipment susceptible to be homed.
- **Tare**: this function allows you to tare the PPS.
- **Select all devices**: this function allows you to select all devices.
- **Recover mode**: this function allows you to start recovery mode.

These functions are used less often than those directly available via the manual and auto modes screens.

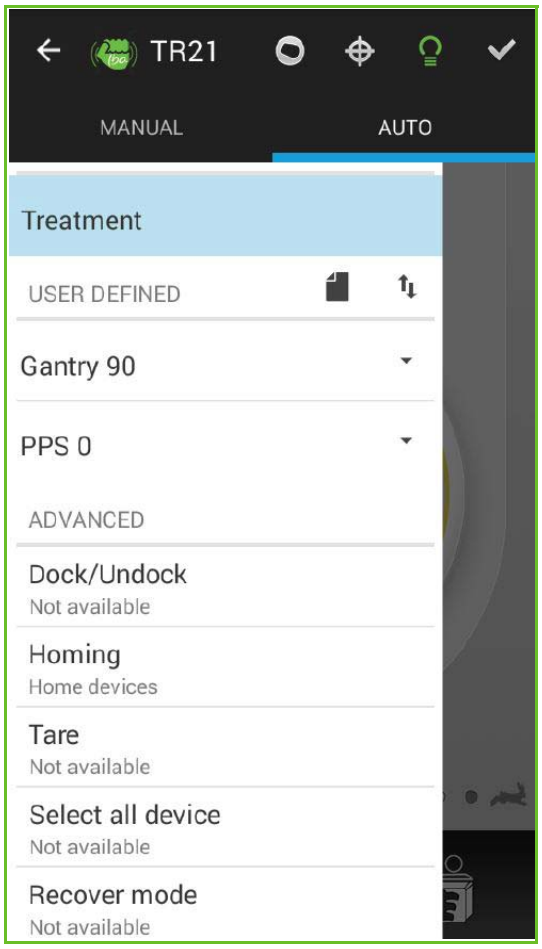

Figure 4-10. Menu - Advanced Options (typical)

Chapter 5
Troubleshooting

Motion Enable Buttons Check

The Motion Enable Button is a safety component of the wireless hand pendant that regularly performs self-tests automatically.

If the wireless hand pendant is not used for a period of time longer than 24 hours, in order to unlock it, you need to perform a Motion Enable Buttons check. In order to perform a Motion Enable Buttons check, proceed as follows:

1. Follow the instructions detailed in the wireless hand pendant screen:
    a. Push and hold both side buttons.
    b. Release one of the side buttons.
    c. Press and hold both side buttons.
    d. Release the side button that was not released in Step b.
2. You may be prompted to repeat this procedure until the check is completed.

If the check is successful, you may proceed to use the wireless hand pendant.

If the check is not successful, the hand-pendant must be serviced.

Sound and Vibration Morning Check

The wireless hand pendant provides sound and vibration feedback to the user. This feedback is important to perform movement commands in a safe way. It is therefore important to regularly check that these functions remain operational. For this purpose, the wireless hand pendant requests the user to check these functions, as follows:

1. Every 24 hours, when the user unlocks the graphical interface, the wireless hand pendant displays a message stating that a sound and a vibration are about to be produced for the sound and vibration check procedure.

2. The wireless hand pendant then prompts the user to confirm whether both have been observed.
3. The user must then manually acknowledge that the check is correct by pressing the **OK** button on the screen.

Monitoring Wireless Hand Pendant Connections

The wireless hand pendant is connected via WiFi to the rest of the PTS. The status of this connection can be monitored via the WiFi icon in the welcome screen:

1. Touch the WiFi icon for over 2 seconds.
2. The WiFi, Notification Server and PMS Controller statuses appear.

Appendix A
Proteus 235 Electromagnetic Compatibility Tables (Proteus ONE)

Table A-1. Guidance and manufacturer's declaration - electromagnetic emissions

Guidance and manufacturer's declaration - electromagnetic emissions		
The Proteus 235 is intended for use in the electromagnetic environment specified below. The customer or the user of the Proteus 235 should assure that it is used in such an environment. The system is compliant with the following standards, according to limits specified here below: ■ IEC 60601-1-2: 2014 Medical electrical equipment Electromagnetic compatibility ■ IEC 62311: 2007 Assessment of electronic and electrical equipment related to human exposure restriction for electromagnetic fields (0Hz -300GHz) ■ European Council recommendation 99/519/EC of 12 July 1999. Limitation of exposure of the general public to electromagnetic fields.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11:2010	Group 1[a]	The Proteus 235 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby external surroundings.

Table A-1. Guidance and manufacturer's declaration - electromagnetic emissions

Guidance and manufacturer's declaration - electromagnetic emissions		
RF emissions CISPR 11:2010	Class A	The Proteus 235 is suitable for use in dedicated establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

a. While the Proteus 235 complies with CISPR 11 requirements for group 1 class A equipment, some of its subsystems produce significant electromagnetic energy during operation. Since these electromagnetic disturbances may result in adverse electromagnetic effects on nearby electrical or electronic equipment, the user is responsible to ensure the compatibility to the Proteus 235 of any foreign electrical or electronic device introduced nearby the Proteus 235 equipment.

Table A-2. Guidance and manufacturer's declaration - electromagnetic immunity (#1)

Guidance and manufacturer's declaration - electromagnetic immunity			
The Proteus 235 is intended for use in the electromagnetic environment specified below. The customer or the user of the Compact Gantry should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	60601-1-2: 2014 levels Indirect discharges VCP and HCP level: ± 8kV Direct discharges level: ± 8kV Air discharges levels: ± 2kV, ± 4kV, ± 8kV, ± 15kV	For equipment located inside the treatment area: ± 8kV contact ± 15kV air[a] For other equipment: ± 4kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.

Table A-2. Guidance and manufacturer's declaration - electromagnetic immunity (#1)

Guidance and manufacturer's declaration - electromagnetic immunity			
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 s	<5 % U_T (>95 % dip in U_T) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Proteus 235 requires continued operation during power mains interruptions, it is recommended that the Proteus 235 be powered from an uninterruptible power supply.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note 1: *U_T is the a.c. mains voltage prior to application of the test level.* ***Note 2:*** *The immunity tests described in this table were conducted on the subsystems of the Compact Gantry.*			

a. With the exception of the flat panels of the two oblique radiographic axes (OB-1 and OB-2), which are provided by a third party manufacturer and have been tested to ± 6 kV contact and ± 8 kV air.

Table A-3. Guidance and manufacturer's declaration - electromagnetic immunity (#2)

Guidance and manufacturer's declaration - electromagnetic immunity			
The Proteus 235 is intended for use in the electromagnetic environment specified below. The customer or the user of the Proteus 235 should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
			Portable and mobile RF communications equipment should be used no closer to any part of the Proteus 235 including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz 6V in ISM bands	3V 6V in ISM bands	$d = 1.2\sqrt{P}$ where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	See NOTE 3	Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 

Table A-3. Guidance and manufacturer's declaration - electromagnetic immunity (#2)

Guidance and manufacturer's declaration - electromagnetic immunity
Note 1: *At 80 MHz and 800 MHz, the higher frequency range applies.* ***Note 2:*** *These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.* ***Note 3:*** *An exemption for large, permanently installed medical electrical systems has been used. The system has been tested for radiated RF immunity over the entire frequency range 80 MHz to 2.5 GHz on authorized frequencies. The system has been tested for radiated RF wireless immunity at the following levels:* • 28V/m in the band 2400 - 2570MHz • 9V/m in the band 5100 - 5800MHz • Non Medical device: Level: 10V/m and 3V/m from 80MHz to 2.7GHz on authorized frequency. ***Note 4:*** *Consider that the use of radio-telecommunication equipment in the frequency band 450 MHz (i.e. talkies and similar radios) is not recommended in the patient treatment environment during treatment sessions.*

a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which some of the Proteus 235 equipment is used exceeds the applicable RF compliance level above, the concerned Proteus 235 equipment should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the concerned Proteus 235 equipment or the fixed RF transmitters.

b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Table A-4. Recommended separation distances between portable and mobile RF communications equipment and the Proteus 235

Recommended separation distances between portable and mobile RF communications equipment and the Proteus 235			
The Proteus 235 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Proteus 235 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Proteus 235 as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter **W**	**Separation distance according to frequency of transmitter** **m**		
	150 kHz to 80 MHz ***d* = 1.2√*P***	**80 MHz to 800 MHz**	**800 MHz to 2,5 GHz**
0.01	0.12	See NOTE 3	See NOTE 3
0.1	0.38		
1	1.2		
10	3.8		
100	12		

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1: *At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.*

Note 2: *These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.*

Note 3: *An exemption for large, permanently installed medical electrical systems has been used. The system has been tested for radiated RF immunity over the entire frequency range 80 MHz to 2.5 GHz on authorized frequencies. The system has been tested for radiated RF wireless immunity at the following levels:*

- 28V/m in the band 2400 - 2570MHz
- 9V/m in the band 5100 - 5800MHz
- Non Medical device:

  Level: 10V/m and 3V/m from 80MHz to 2.7GHz on authorized frequency.

Appendix B
Proteus 235 Electromagnetic Compatibility Tables (Proteus Plus)

Table B-1. Guidance and Manufacturer's Declaration - Electromagnetic Emissions

The Proteus 235 is intended for use in the electromagnetic environment specified below. The customer or the user of the Proteus 235 should assure that it is used in such an environment.

The system is compliant with the following standards, according to limits specified here below:

- ICNIRP Guidelines Vol.74 #4
- IEEE C95.1:2005
- IEEE C95.3:2002
- FCC Part 18, Section 18.305b
- Medical electrical equipment Electromagnetic compatibility:
- IEC 60601-1-2: 2014 Fourth edition - Third edition - Edition 2.1, including A1
- IEC 60601-2-64: 2014 Edition 1.0 Section 201.17 only for EMC

Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11:2010	Group 1[1]	The Proteus 235 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby external surroundings.
RF emissions CISPR 11:2010	Class A	The Proteus 235 is suitable for use in dedicated establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

1. While the Proteus 235 complies with CISPR 11 requirements for group 1 class A equipment, some of its subsystems produce significant electromagnetic energy during operation. Since these electromagnetic disturbances may result in adverse electromagnetic effects on nearby electrical or electronic equipment, the user is responsible to ensure the compatibility to the Proteus 235 of any foreign electrical or electronic device introduced nearby the Proteus 235 equipment.

Table B-2. Guidance and Manufacturer's Declaration - Electromagnetic Immunity (#1)

The Proteus 235 is intended for use in the electromagnetic environment specified below. The customer or the user of the Proteus 235 should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2: 2008	60601-1-2: 2014 levels Indirect discharges VCP and HCP level: ± 8kV Direct discharges level: ± 8kV Air discharges levels: ± 2kV, ± 4kV, ± 8kV, ± 15kV	For equipment located inside the treatment area: ± 8kV contact ± 15kV air For other equipment: ± 4kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4: 2012	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5: 2006	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11: 2004	<5 % U_T (>95 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 s	<5 % U_T (>95 % dip in U_T) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Proteus 235 requires continued operation during power mains interruptions, it is recommended that the Proteus 235 be powered from an uninterruptible power supply.

Table B-2. Guidance and Manufacturer's Declaration - Electromagnetic Immunity (#1) (Cont'd)

Power frequency (50/60 Hz) magnetic field IEC 61000-4-8: 2009	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note 1: *U_T is the ac mains voltage prior to application of the test level.*			

Table B-3. Guidance and Manufacturer's Declaration - Electromagnetic Immunity (#2)

The Proteus 235 is intended for use in the electromagnetic environment specified below. The customer or the user of the Proteus 235 should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the Proteus 235 including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1.2\sqrt{P}$
Conducted RF IEC 61000-4-6: 2013	3 Vrms 150 kHz to 80 MHz 6V in ISM bands	3V 6V in ISM bands	where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m).
Radiated RF IEC 61000-4-3: 2010	3 V/m 80 MHz to 2.5 GHz	See Note 3	Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[1] should be less than the compliance level in each frequency range.[2] Interference may occur in the vicinity of equipment marked with the following symbol: 

Note 1: *At 80 MHz and 800 MHz, the higher frequency range applies.*

Note 2: *These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.*

Note 3: *An exemption for large, permanently installed medical electrical systems has been used. The system has been tested for radiated RF immunity over the entire frequency range 80 MHz to 2.5 GHz on authorized frequencies. The system has been tested for radiated RF wireless immunity at the following levels:*

Table B-3. Guidance and Manufacturer's Declaration - Electromagnetic Immunity (#2) (Cont'd)

Frequency (MHz)	Modulation Frequency (Pulse)	Minimum Calibrated RF Field Strength (V/m)	Results
385	18 Hz	27	Pass
450	18 Hz	28	Pass
710	217 Hz	9	Pass
745	217 Hz	9	Pass
780	217 Hz	9	Pass
810	18 Hz	28	Pass
870	18 Hz	28	Pass
930	18 Hz	28	Pass
1720	217 Hz	28	Pass
1845	217 Hz	28	Pass
1970	217 Hz	28	Pass
2450	217 Hz	28	Pass
5240	217 Hz	9	Pass
5500	217 Hz	9	Pass
5785	217 Hz	9	Pass

The following test data applies to the equipment listed directly below:

D301	Treatment Control Unit N°3	Gantry 3
G307	Nozzle 3 Electronic Units Cabinet N°1	Gantry 3
G308	Nozzle 3 Electronic Units Cabinet N°2 (ICEUs)	Gantry 3
G309	Gantry 3 Electronic Cabinet N°3 (BPMEU)	Gantry 3
D011	SRCU0	MCR
U001	MCR Electronic Cabinet 1	MCR
B001	Cyclotron Main Coil PS	PSR
B017	FPA Anode PS	PSR
B010	Power Distribution PS (STD or EMG for Cyclo)	PSR
B200	Modular Quad Power Supply	PSR
B300	Modular Dipole Power Supply	PSR
B400	SMPS (Scanning Magnet Power Supply)	PSR
B480	PSR Pyramid Scanning Controller	PSR
B491	SMPS Switching	PSR
B391	Dipole Switching Cabinet	PSR
B141	Water/Vacuum/T°/Electronic Cabinet	PSR
D002	BLCU	PSR
D001	ACU Cabinet	PSR
B500	Trim Power Supply Cabinet	PSR
B093	UPS Panel	PSR
D302	Positioning Control Unit N°3	Pulling Room 3
G311	Robot Controller Unit TR3 (PPS)	Pulling Room 3
D311	SRCU3	Pulling Room 3
A057	Water Cooling Pump Elect Cabinet	Water Cooling Room
A058	Cooling room water Cooling CTRL cabinet	Water Cooling Room

Table B-3. Guidance and Manufacturer's Declaration - Electromagnetic Immunity (#2) (Cont'd)

Side(s) of EUT Exposed to Antenna	Frequency Range (MHz)	Minimum Calibrated RF Field Strength (V/m)	Results
Front Rear Right Side Left Side Top Bottom	50	27	Pass
	53.98	28	Pass
	458.65	22	Pass
	465.53	22	Pass
	52.02	14	Pass
	144.49	20	Pass
	146.55	16	Pass
	147.93	25	Pass
	446.0	32	Pass
	449.0	23	Pass
	448.675	20	Pass
	1246.0	3.6	Pass
	1294.0	8.4	Pass
	842.25	8.2	Pass
	162.48	26	Pass

1. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which some of the Proteus 235 equipment is used exceeds the applicable RF compliance level above, the concerned Proteus 235 equipment should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the concerned Proteus 235 equipment or the fixed RF transmitters.
2. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Table B-4. Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the Proteus 235

The Proteus 235 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Proteus 235 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Proteus 235 as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (expressed in W)	**Separation distance according to frequency of transmitter (expressed in m)**		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	**80 MHz to 800 MHz**	**800 MHz to 2,5 GHz**
0.01	0.12	See NOTE 3	See NOTE 3
0.1	0.38		
1	1.2		
10	3.8		
100	12		

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1: *At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.*

Note 2: *These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.*

Note 3: *An exemption for large, permanently installed medical electrical systems has been used. The system has been tested for radiated RF immunity over the entire frequency range 80 MHz to 2.5 GHz on authorized frequencies. The system has been tested for radiated RF wireless immunity at the following levels:*

- 28V/m in the band 2400-2570MHz
- 9V/m in the band 5100-5800MHz

Non Medical device:

- Level: 10V/m and 3V/m from 80Mhz to 2.7GHz on authorised frequency.

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Appendix C
Wireless Hand Pendant Electromagnetic Compatibility Tables

Compliance to the following standards has been verified by an external accredited laboratory (Emitech France).

Table C-1. Guidance and manufacturer's declaration - Bluetooth Radio Emissions

Bluetooth Radio Tests	Compliance Level	Electromagnetic environment – guidance
FCC Part 15.247 intentional radiated emissions. Operation within the bands 902–928 MHz (FHSS and other FHSS), 2400–2483.5 MHz (FHSS and other FHSS), and 5725–5850 MHz (only FHSS).	See standard.	See Table A-1.
EN 300 328 V1.9.1	See standard.	See Table A-1.

Table C-2. Guidance and manufacturer's declaration - EMC Emissions

EMC Emission Tests	Compliance Level	Electromagnetic environment – guidance
IEC 60601-1-2:2014	Same requirements as Proteus 235 equipment.	Same requirements as Proteus 235 equipment.
IEC 62311:2007	See standard.	See Table A-1.

Table C-3. Guidance and manufacturer's declaration - Electromagnetic Immunity

Immunity test	Test level	Compliance level	Electromagnetic environment - guidance
60601-1-2:2014	Same requirements as Proteus 235 equipment.	Same requirements as Proteus 235 equipment.	Same requirements as Proteus 235 equipment.

Table C-4. Guidance and manufacturer's declaration - Safety

Safety	Test level	Compliance level
60601-1:2012 ed 3.1	Same requirements as Proteus 235 equipment.	Same requirements as Proteus 235 equipment.

Other wireless devices used in the HPV3 subsystem are off-the-shelf devices, compliant with their own standards and directives: WiFi routers, smart-phones.

Identification of Immunity Pass/Fail Criteria

For details on the identification of immunity pass/fail criteria, refer to IEC 60601-1-2:2014, Appendix I.3.

Examples of Test Failures

The following list contains examples of test failures:

- Malfunction.
- Non-operation when operation is required.
- Unwanted operation when no operation is required.
- Deviation from normal operation that poses an unacceptable risk to the patient or the operator.
- Component failures.
- Change in programmable parameters.
- Reset to factory defaults (manufacturer's presets).
- Change of operating mode.
- A false positive alarm condition.

- A false negative alarm condition (failure to alarm).
- Cessation or interruption of any intended operation, even if accompanied by an alarm signal.
- Initiation of any unintended operation, including unintended or uncontrolled motion, even if accompanied by an alarm signal.
- Error of a displayed numerical value sufficiently large to affect diagnosis or treatment.
- Noise on a waveform in which the noise would interfere with diagnosis, treatment or monitoring.
- Artefact or distortion in an image in which the artifact would interfere with diagnosis, treatment or monitoring.
- Failure of automatic diagnosis or treatment ME equipment or ME system to diagnose or treat, even if accompanied by an alarm signal.

Example of Performance During and After the Applied Testing Stimulus Required to Pass the Test

The following list contains examples of test-passing performances:

- Safety-related functions perform as intended.
- False operation of alarms, "fail safe" modes and similar functions do not occur.

Note: *Each test may need to be performed twice – once to ensure that the functions occur as expected and again to ensure they do not occur falsely.*

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Safety Decisions

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