Operators and Service Manual

SmartPReP® 2 Centrifuge System

For Platelet, Bone Marrow
And Adipose Tissue Concentration

HARVEST®
TERUMO

4531200 / 1042

SmartPReP® 2 SYSTEM

OPERATOR'S AND SERVICE MANUAL

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ABOUT THIS MANUAL

Messages that are headed by “NOTE:” indicate information or procedures that if not followed correctly can cause improper results.

Messages that are headed by “CAUTION:” indicate information or procedures that if not followed correctly can cause improper results and damage to the equipment.

Messages that are headed by “WARNING:” indicate information or procedures that if not followed correctly can cause improper results, damage to the equipment, injury to personnel, or serious patient harm.

INTENDED USE

- The SmartPReP 2 System is designed to be used for the safe and rapid preparation of autologous platelet-rich-plasma (PRP) from a small sample of blood at the patient’s point of care. The PRP can be mixed with autograft or allograft bone grafting materials prior to application to an orthopedic surgical site as deemed necessary by the clinical use requirements.

- The SmartPReP2 System is intended to be used in the clinical laboratory or intraoperatively at point-of-care for the safe and rapid preparation of platelet poor plasma and platelet concentrate from a small sample of blood and for preparation of a cell concentrate from bone marrow.

- The AdiPrep™ Adipose Transfer System is used in medical procedures involving the harvesting and transplanting of autologous tissue. The AdiPrep system is used for concentrating adipose tissue harvested with a legally marketed lipoplasty system. The AdiPrep™ Adipose Transfer System is intended for use in the following surgical specialties when the concentration of harvested adipose tissue is desired: Arthroscopic Surgery, Gastrointestinal Surgery, General surgery, Gynecological Surgery, Laparoscopic Surgery, Neurosurgery, Plastic and Reconstructive Surgery, Thoracic Surgery, and Urological Surgery.

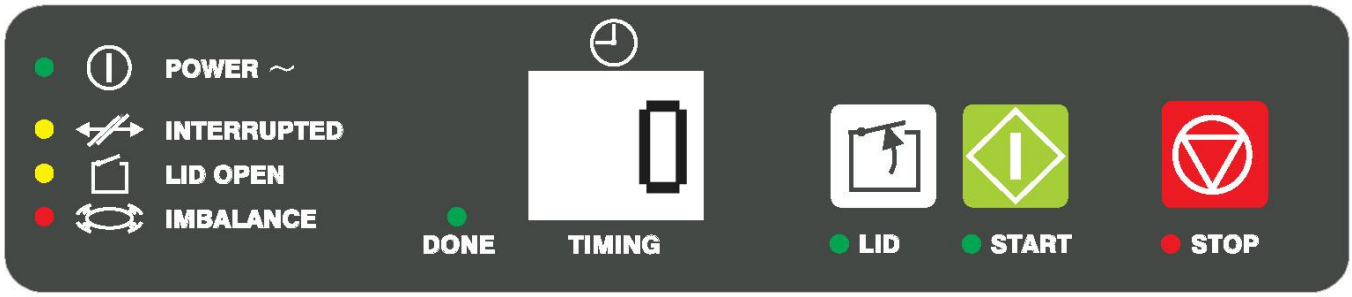
SYSTEM CONCEPT

The SmartPReP 2 System consists of a microprocessor-controlled, centrifuge with automated decanting capability using a dual chamber sterile processing disposable. The system technology provides a reproducible process for concentrating desired cells without user interaction beyond loading and starting the centrifuge.

Hardware

The SmartPReP 2 System (SN 0101-5999) is similar to a general purpose swinging bucket centrifuge with the following exceptions:

- The bucket insert accepts only the Harvest processing disposable (PD)
- The bucket orientation (horizontal or vertical) is automatically controlled in order to perform decanting
- The automated dual-spin centrifugation process is fixed and cannot be modified by the user, thus ensuring reproducible results
- The control panel is simple and intuitive, providing only three controls: LID, START and STOP
- The (LCD) liquid crystal display indicates the time remaining until the process is complete.



Control Panel

POWER Illuminates when the unit is plugged in.

INTERRUPTED Upon initial power up the INTERRUPTED LED will illuminate, this is normal operation. It also illuminates when the control system senses an electronic failure. If this condition is detected, the centrifuge is brought to a stop and cannot be restarted until the fault condition is corrected. The INTERRUPTED LED is also illuminated whenever the STOP keypad is pressed during a process cycle.

LID OPEN Illuminates when LID is open or improperly closed. When this LED is illuminated, the centrifuge is prevented from operating.

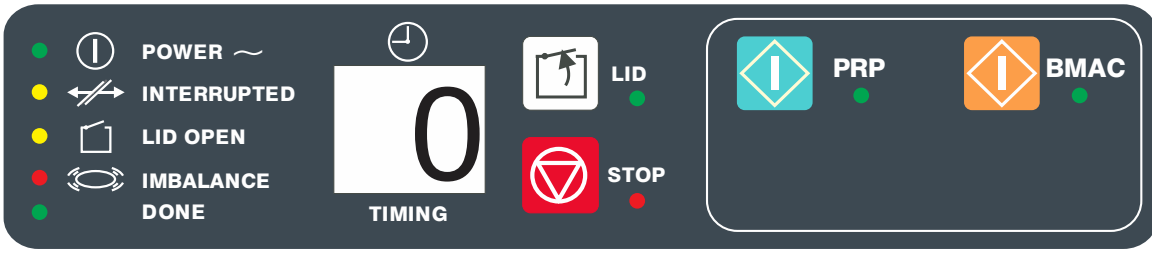
IMBALANCE Illuminates when the control system senses an imbalance in the rotor. If this condition occurs, the centrifuge is brought to a stop and cannot be restarted until the imbalance condition is corrected.

TIMING Displays the time remaining in the process cycle.

Hardware

The SmartPReP 2 System (SN 6000 and greater) is similar to a general purpose swinging bucket centrifuge with the following exceptions:

- The bucket insert accepts only the Harvest processing disposable (PD)
- The bucket orientation (horizontal or vertical) is automatically controlled in order to perform decanting
- The automated dual-spin centrifugation process is fixed and cannot be modified by the user, thus ensuring reproducible results
- The control panel is simple and intuitive, providing only four controls: LID, PRP (START), BMAC (START) and STOP.
- The (LCD) liquid crystal display indicates the time remaining until the process is complete.



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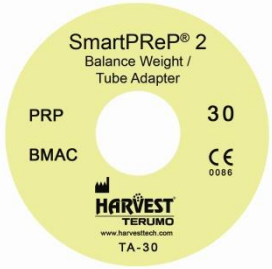
TIMING Displays the time remaining in the process cycle.

SMP2 Control Panels	Serial Number 0101- 5999	Serial Number 6000 >
Open Lid		
Process Platelet Concentrate		
Process Adipose Concentrate		
Process Bone Marrow Concentrate		
Stop System		

ACCESSORIES

The SmartPREP 2 System is compatible with Autologous Platelet Concentrate (APC+) Procedure Packs, Bone Marrow Aspirate Concentrate (BMAC) Procedure Packs, and AdiPrep Adipose Transfer System (AATS). Please refer to the Instructions for Use provided with each of the kits listed below for proper use of those kits.*HAT kits not available in the U.S.

Balance Weight Chart			
BW-20 Balance Weight	***TA-20*** Balance Weight/ Tube Adapter Used with **HAT Kit*.** BW-20 is needed for opposing rotor	***BW-60*** Balance Weight	***TA-60*** Balance Weight/ Tube Adapter Used with **HAT Kit*.** BW-60 is needed for opposing rotor
			
BW-30 Balance Weight	***TA-30*** Balance Weight/ Tube Adapter Used with **HAT Kit*.** BW-30 is needed for opposing rotor	***AA-1*** AdiPrep Adapter Used with **AATS Kits** 2- AA-1 are required to process	***BW-ADI*** AdiPrep Balance Weight Used with AA-1 Adapter and **AATS Kits**
			

APC-120 & BMAC-120 kits do not require balance weights
BWAT-20 & BWAT-60 balance weights are avialable for international use with AT Pro Kits

HARDWARE SET-UP

The SmartPReP 2 System is packaged in one box. Verify that the box contains one (1) SmartPReP 2 centrifuge, line cord, and Operator's and Service Manual.

NOTE: Save box, packaging and rotor support foam for future use.

1. Remove the SmartPReP 2 centrifuge from the box and place on a sturdy counter or stable cart. Remove all shipping restraints and inspect for damage.
2. Install line cord and plug into the appropriate mains voltage.
3. Visually inspect the display panel and verify the Green "Power" light and the yellow "Interrupted" light are illuminated. Press the LID keypad and open the lid. The "Interrupted" light should go out and the yellow "Lid Open" light should be illuminated.
4. Remove all shipping material. Verify that the rotor assembly is correctly installed and secure on the motor shaft.
5. Remove the balance weights from the rotor assembly and set aside.
6. Commence a test run by closing the lid firmly; verify that only the POWER light is illuminated; press START, PRP or BMAC. The centrifuge should start and the automated cycle should be complete in approximately 14 minutes. At the end of the cycle, the "DONE" indicator light should be illuminated and audible tone sounds, indicating the rotor has come to a complete stop and it is safe to open the centrifuge cover. The centrifuge is now ready to process blood, marrow or adipose tissue.

NOTE: Follow established protocols and procedures prior to placing the SmartPReP 2 System into service.

NOTE: If additional protective earthing (grounding) is required use the green/yellow terminal on the back of the instrument.

CAUTION: Do not force processing disposable into rotor trunnion (swinging buckets). The processing disposable(s) should fit snuggly but should not require excessive force to install. If resistance is experienced, check for obstructions in the rotor and/or debris on the process disposable or proper orientation of the process disposable to the swinging bucket.

INSTRUCTIONS FOR USE

Once the hardware is set up and has successfully completed a test run the unit is ready to operate. Any one of the following five scenarios will automatically balance the unit if the Process Disposables (PD) are filled properly. (Refer to the kit's Instructions for Use for detailed filling instructions). The standard centrifuge is equipped with a two place rotor. An optional four place rotor is available through special order.

CAUTION**:** Do not process a combination of 20, 30 and 60mL APC or BMAC PD's in the same cycle as they will not balance.

CAUTION**:** Do not process APC or BMAC PD's with the AdiPrep PD in the same cycle as they will not balance.

CAUTION: Always have another PD or BW of equal weight in the trunnion opposing the PD to ensure balance.

Two Place Rotor

- Scenario 1 – One properly filled equal volume PD in each trunnion. (2 total)
- Scenario 2 – One properly filled PD in one trunnion and one balance weight (of equal weight) in the opposing trunnion.

Four Place Rotor

- Scenario 3 – Same as above for one or two PD's
- Scenario 4 – One properly filled equal volume PD in each swinging trunnion. (4 total)
- Scenario 5 – One properly filled PD in three of the trunnion and one balance weight (of equal weight) in the fourth trunnion bucket. (3 total)

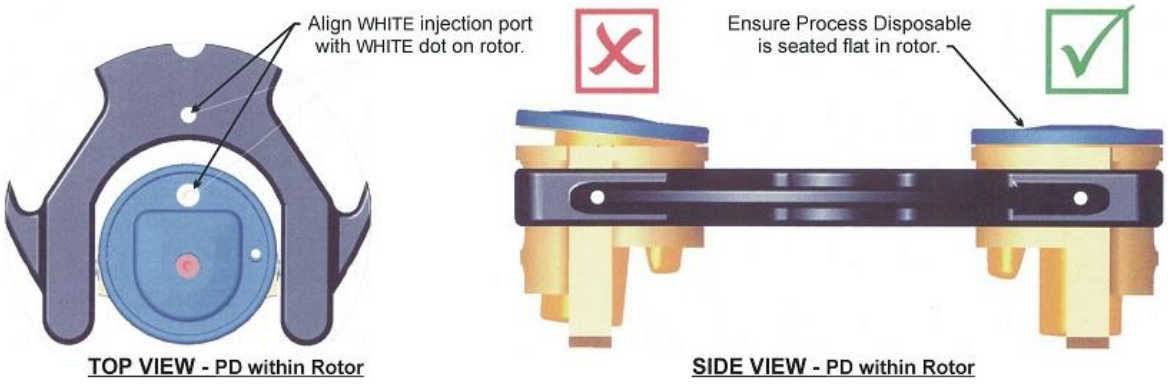
CAUTION: If the unit is not loaded with one of the five scenarios listed above the unit will IMBALANCE and not continue.

CAUTION: The process disposables are single patient use only. Do not re-use or re-sterilize. Reuse of disposable products may cause illness, injury or even death. Discard all unused components at the end of the procedure.

Loading the Process Disposables – APC & BMAC

1. Press the LID button and open the lid
2. Load the swinging trunnions as described in one of the five scenarios. Be sure to line up the "white dot" indicator on the trunnion with the white dot on the PD. Rotate the PD as necessary to ensure proper alignment.

CAUTION: Be sure the PD is properly seated as shown

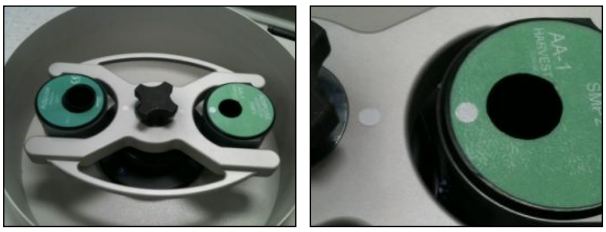


3. Close the lid
4. Press the START button in SMP2 with serial numbers 0101-5999: For SMP2 Systems with serial numbers 6000> press the blue PRP button for platelet concentrate or orange BMAC button for bone marrow concentrate.
5. The TIMING window will display the remaining time till the end of the cycle. When the cycle is complete the DONE led will flash and an audible alarm will sound.
6. Press the LID button and remove the PDs.
7. Refer to the Instructions for Use accompanying the Processing Kits.

Loading the Process Disposable – AdiPrep Adipose Transfer System

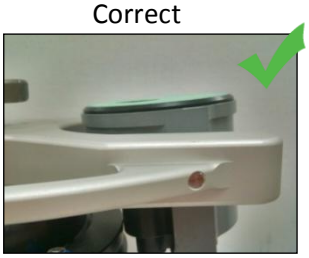
Note: The Adipose Hardware Kit (AHK-1) is required to operate the SMP2 System with the AdiPrep process disposable. See Scenarios 1 and 2 for adipose processing.

Install the two adapters into the rotor trunnions with the white dots aligned as shown.



Be sure the adapter is properly seated as shown below

Correct

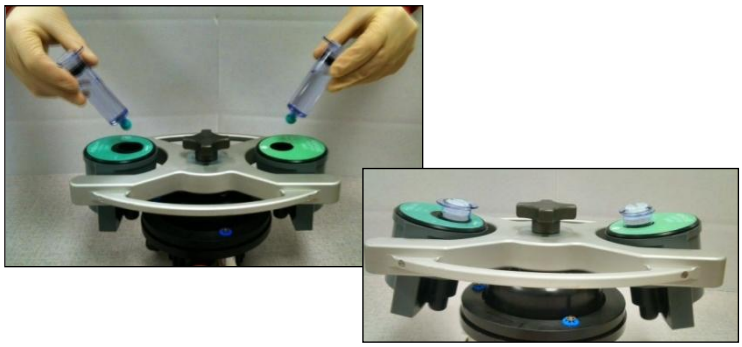


Incorrect

To process adipose tissue in the SMP2 System:

Scenario 1 - Install one AdiPrep process disposable into one AA-1 Adapter and the BW-ADI AdiPrep Balance Weight into the opposing adapter, as shown below.

Scenario 2 - Install two (2) AdiPrep process disposables, one in each AA-1 Adapter, as shown below.



1. Close the lid.
2. Press the green START or the blue PRP button.
3. The TIMING window will display the remaining time of the cycle. When the display indicates 10 (approximately 4 minutes have passed) press the red STOP button.
4. When the rotor has stopped, press the LID button and remove the PDs.

CONTRAINDICATIONS

The use of the SmartPReP 2 System may be contraindicated when there is: Clinical or laboratory evidence of septicemia for patients who have taken aspirin, or other medications that alter platelet function, within 3 days prior to surgery, or patients with disorders associated with platelet dysfunction.

WARNINGS

- Federal law (USA) restricts this device to sale by, or on the order of a physician. The physician is solely responsible for the use of this device.
- Safe and effective use of this device requires proper set-up and operation by trained personnel.
- This device should not be used in the presence of flammable agents.

- Risk of electrical shock, do not attempt to service electrical components; refer servicing to qualified personnel.
- Plasma, platelets and cell concentrate prepared with this system are not intended for transfusion.
- Changes or modifications to this unit not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.
- BMAC Processing: The safety and effectiveness of this device for in-vivo indications for use has not been established.

CAUTIONS

- Read all instructions prior to use.
- Health professionals responsible for blood collection must be trained in the practice of venipuncture and be aware of the inherent risks. Aseptic technique, proper skin preparation and continued protection of the venipuncture site are essential.
- Bone marrow aspirate should be collected by or under the supervision of a qualified physician trained in this procedure.
- All blood and marrow components should be handled as if infectious. To minimize the potential for exposure to blood-borne pathogens observe UNIVERSAL PRECAUTIONS when handling blood and blood components.
- Disposables that have come in contact with blood, bone marrow, or adipose tissue are to be considered hazardous waste. Follow established hospital protocols and procedures for handling hazardous waste including but not limited to: discard in appropriate, leak-proof container marked with a biohazard symbol, double bag or place hazardous waste in a protective container, discard sharps in rigid, puncture-proof and leak-proof “sharps” container. Incineration and decontamination by autoclaving are the currently recommended methods for disposing of blood/marrow/adipose tissue samples and blood /marrow/adipose tissue products.
- Aseptic technique should be used when aspirating and dispensing fluids.
- Commercially available solutions (USP, NF) or pharmacy prepared must be sterile.
- Heparin-induced thrombocytopenia may occur in approximately 5% patients receiving heparin therapy. This condition may cause hypercoagulability and may interfere with process results.
- Actual performance may vary depending on operating conditions. Check sample at end of process to confirm that fluids are properly separated. If the separation system fails for any reason, the blood/marrow/adipose tissue should not be recovered or reprocessed by any other method. Blood/marrow/adipose tissue should be disposed of in accordance with policies consistent with disposal of biohazardous waste.
- Report needle sticks immediately and follow established protocol. Percutaneous puncture with a contaminated needle may lead to serious illness such as hepatitis, HIV (AIDS) or other infectious disease. Resheathing needles is dangerous.
- Do not use if the packaging is open or damaged.
- DO NOT RESTERILIZE.
- Disposable is single patient use only. Discard all unused components at the end of the procedure. Re-use may lead to infection or illness/injury/death.
- Separated blood/marrow products should be used within four (4) hours of collection.

SAFETY

Safety features for the SmartPReP 2 System are constantly monitored and controlled to ensure safe operation of the unit. The possible system faults that are monitored are:

- **Open Lid:** A sensor on the lid ensures that the SmartPReP 2 system is never operated with the lid open.
- **Out of Balance:** An out of balance detector has been incorporated into the SmartPReP 2 system to ensure that imbalances in the rotor are not allowed to create an unsafe operating condition.
- **Stop Button:** A stop button is provided on the User Interface Panel to allow the user to stop the process safely and quickly.

SYMBOLS

If applicable, the following symbols may appear on the SmartPReP 2 System:

	Attention, Consult Accompanying Documents		Power on
	Start		WEEE Compliant Producer
	Stop		Do Not Reuse
	Open Lid		Sterilized Using Irradiation, Ethylene Oxide, Steam or Dry Heat
	Equipotential		Lot Code
	Alternating Current		Manufacturer
	Interrupted		Consult Instructions for Use
	Imbalance		Do not use if Package is Damaged
	Hazardous Voltage		Use By
	Do Not Use in the Presence of Flammable Anesthetics		Authorized Representative in the European Community
	Timing (Remaining cycle time)		Caution: Federal law restricts this device to sale by or on the order of a physician
	Process has completed		Catalogue Number

TROUBLESHOOTING CHART

Symptoms	Possible Cause	Possible Solution	Cannot resolve ↵ means go to next step
Interrupted			
Interrupted light is on.	Customer hasn't opened the lid yet	Open the lid and it will clear the interrupt circuit. This is designed to happen on first power up!	↵
Interrupted light is on.	The Stop button was accidentally pushed.	Press the Lid Open button, close the lid and retry.	↵
Interrupted light is on.	The display label is contacting the Stop button.	Cycle the Stop button then retry.	↵
Interrupted light is on.	There was a power drop (brown out).	Press the Lid Open button, close the lid and retry.	↵
Interrupted light is on.	The Printed Circuit has failed. Interference.	Cycle the power a few times. If an emergency call Harvest Tech Service at 877-842-7837	Contact Harvest
Lid Open			
Lid Open light is on	The lid is not completely closed	Open the lid and then close it again. Push down on the lid.	↵
Lid Open light is on	Safety circuit is missing	Check for magnet assembly. Open lid and look to the right of the latch assembly for a small plate with a round magnet attached inside the lid lip.	Contact Harvest.
Imbalance			
Imbalance light is on	Incorrect balance weight used	Confirm that your process disposable volume and the balance weight are correct.	↵
Imbalance light is on	The machine was damaged in shipping	Power cycle the machine and retry.	↵
Imbalance light is on	The machine was bumped after start	Power cycle the machine and retry.	Contact Harvest.
Lid won't open			
Lid won't open	The customer hasn't waited for the rotor to stop spinning	Lid will not open while processing and/or rotor is spinning.	↵
Lid won't open	Lid solenoid has failed.	Machine must be returned	Contact Harvest for RGA#.
No decant			
No decant	Decant solenoid(s) have failed	Verify there is no decant at all. **You can manually decant by tipping the PD, and spin the PD again to finish the process**	↵
No decant	Printed Circuit Board has failed.	Machine must be returned for repair. **You can manually decant by tipping the PD, and spin the PD again to finish the process**	Contact Harvest for RGA#.
No decant	Stuck shelf and/or clotting	Verify the shelf location is not on bottom. Was there separation?	Contact Harvest for RGA#.
No decant	Clotting	Repeat – ensure proper ACD mixing during draw. Poor mixing causes clotting.	Test machine, run empty to verify decant function. ↵

Symptoms	Possible Cause	Possible Solution	Cannot resolve ↵ means go to next step
No power			
No power	Not plugged in	Verify that the machine is plugged into appropriate voltage 100V/115V/230V. Try powering another device. Check wall switch, power strip?	↵
No power	Fuses are blown.	Check the fuses. Fuses must be replaced by approved service technician.	Contact Harvest for RGA#.
No Platelet Concentrate			
No platelet concentrate	See 'No decant' section also	Verify the machine is decanting. Restart process and verify decant.	↵
No platelet concentrate	Clotting	Repeat process with a new PD – ensure proper ACD mixing during draw. Poor mixing causes clotting.	Test the SMP2 machine, run empty to verify decant function. ↵
No platelet concentrate	High RBC count	Verify patient's blood count	Contact Harvest.
Too loud			
Too loud	Rotor is loose	Fully seat and tighten the rotor knob clockwise.	↵
Too loud	Disposables are not seated correctly.	Verify that the disposables are fully seated PD's should not touch lid glass.	Test the SMP2 machine, run empty to verify decant function. ↵
Too loud	Disposable vs. BW. Weights are on the imbalance threshold.	Run the machine empty to verify noise level. If it is quiet empty, then blood volume is not balanced.	Verify weights. ↵
Too loud	Loose hardware or screws near the feet.	Check all hardware. Try to isolate location.	Contact Harvest for RGA#.
Too loud	Missing rubber feet	Check that all 4 feet are intact, Harvest can provide replacement feet.	Contact Harvest
Shipping damage			
Shipping damage	Shipping damage, dents etc.	Replacement machine may be sent	Contact Harvest for RGA#.

Contact Harvest Technical Service Toll Free # 1-877-842-7837

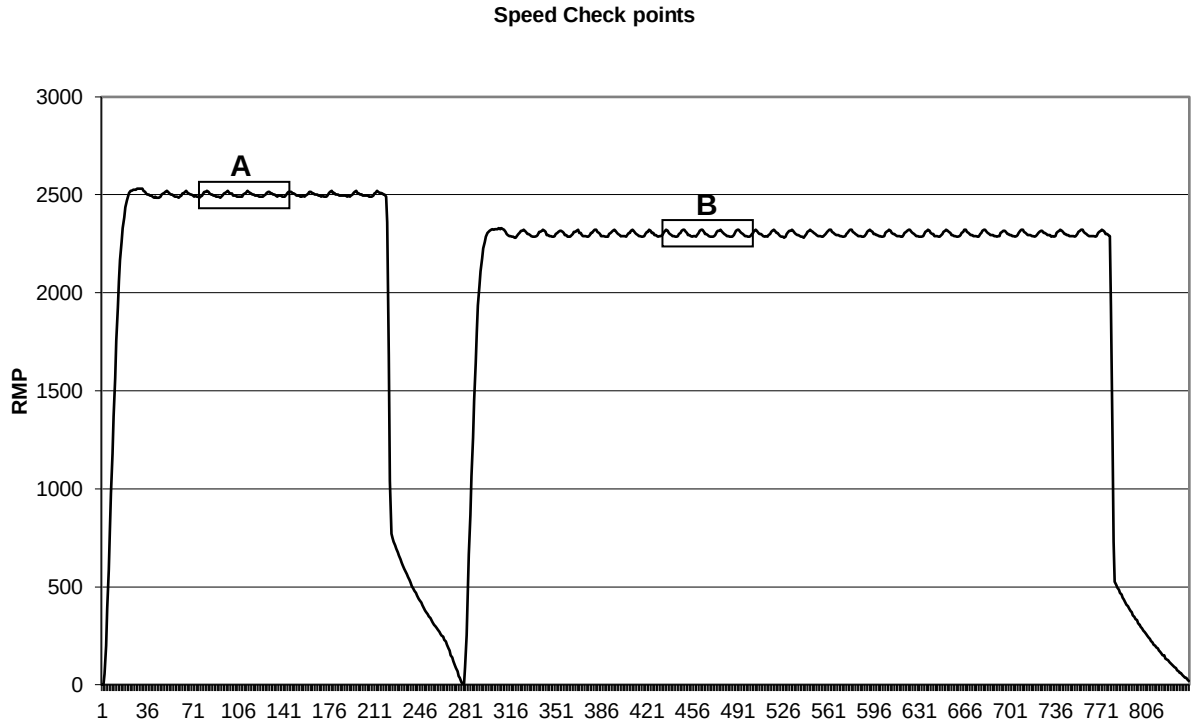
MAINTENANCE

The SmartPReP 2 System requires no calibration and is designed for minimum maintenance. Internal software monitors every process run from start to finish. If the timing or RPM vary more than the specifications listed below the unit will stop and the Interrupted light will illuminate.

Optional - SPEED VERIFICATION

The centrifuge has a set speed protocol with two points that can be confirmed as follows:

	Time	**Speed should be**
A	1-3 minute(s) into process	2500RPM±150 (2350 - 2650)
B	6-9 minutes into process	2300RPM±140 (2160 - 2440)



The following lists the recommended maintenance procedures that should be followed.

CLEANING EVERY USE

CAUTION: Ensure line cord is disconnected from power source prior to cleaning. Do not use abrasive cleaning agents. Do not use solvents or strong alcohol solutions. Do not immerse any part of the SmartPReP 2 System in liquids.

The SmartPReP 2 System should be cleaned after each use and/or after any spill of liquids. For routine cleaning use only mild detergents, water and a soft damp cloth to thoroughly clean the inside and outside of the unit. Allow unit to dry before returning to service. A dry cloth or paper towels can be used to dry the unit.

DECONTAMINATION PROCEDURE AFTER BLOOD SPILLS or AS NEEDED

For disinfecting/decontamination, spray the unit with a 10% bleach/water solution and wipe with a damp cloth that has been wet with the 10% bleach/water solution. Allow unit to dry before returning to service. A dry cloth or paper towels may be used to dry the unit.

CAUTION: Ensure line cord is disconnected from power source prior to cleaning. Do not immerse any part of the SmartPReP 2 System in liquid.

Before using any cleaning or decontamination methods except those recommended by the manufacturer, users should check with the manufacturer that the proposed method will not damage the equipment.

GENERAL INSPECTION EVERY USE

Visually check the condition of the SmartPReP 2 System. Remove from service any unit that shows signs of physical damage or one in which the PD does not easily install. Verify that device has all four rubber feet secured.

ROTOR ASSEMBLY MAINTENANCE Monthly or AS NEEDED BASIS

Check movement of trunnions; there should be no binding or obstructions. Confirm the rotor nut is tight. Hand tighten the nut, do not use a tool. Clean if necessary.

TEST RUN Monthly or AS NEEDED BASIS

Perform verification of centrifuge process from start to finish. Commence a test run by closing the lid firmly; verify that only the POWER light is illuminated; press START, PRP or BMAC. Confirm the system performs a first spin, coast down and stop, second spin, coast down and stop. Process is complete in approx. 14 minutes.

SERVICE

Harvest Technologies, Corp., or its authorized agents must perform all service. Contact Harvest Technologies at 508-732-7500 (Toll Free 1-877-8HARVEST in continental U.S.) or your local distributor or sales representative.

USEFUL LIFE - WARRANTY SERVICE

The SmartPReP2 centrifuge has been validated to perform as intended for up to five (5) years from the date of purchase. Units under warranty that are received for repair, that have not been obviously abused or impact damaged, will be promptly repaired and returned at no charge. See the Limited Warranty section of this manual. A no-charge purchase order is requested for tracking purposes.

NON-WARRANTY WORK

Units received that have suffered obvious abuse or impact damage and units no longer under warranty will be promptly inspected and a verbal estimate of repair cost will be provided. A purchase order is required from the hospital that is consistent with the verbal estimate. A written estimate for repair will be provided upon request.

RETURNED GOODS POLICY

AUTHORIZATION

The customer must receive authorization from Harvest Technologies before merchandise can be returned. Unauthorized returns will not be accepted and will be returned to the customer at the customer's expense.

REQUEST FOR RETURN AUTHORIZATION

The request for Return Goods Authorization Number (RGA) must include:

1. Serial number and/or lot number, catalog number, and quantity.
2. Reason for return.
3. Customer purchase order number and date.
4. Harvest Technologies invoice number and date.
5. Hospital or Doctors name, address and phone number.

CAUTION: The SmartPReP 2 System **MUST BE CLEANED AND DISINFECTED PRIOR TO RETURN** or it will be immediately returned to sender as received. SmartPReP 2 System units returned for service must have an intact Serial Number label. SmartPReP 2 Systems with missing or altered serial numbers will be serviced as Non-Warranty repairs.

FREIGHT (RETURNED GOODS)

When authorized, all merchandise must be returned FREIGHT PREPAID. Any merchandise returned as freight collect will be refused by Harvest Technologies and returned to the customer at the customer's expense.

Ship to:	**Include the following**
Attn: Service Department Returned Goods Authorization # (RGA) Harvest Technologies, Corp. 40 Grissom Rd, Suite 100 Plymouth, MA 02360	Hospital Name Address Telephone Number Contact Person Description of the Problem RGA # PO Number

LIMITED WARRANTY

The SmartPReP 2 System is warranted to be free from material and workmanship defects for a period of one (1) year from the date of purchase; abuse and/or impact damage excluded. Harvest Technologies reserves the right to replace any or all components in lieu of repair. Harvest Technologies will prepay shipping costs, repair or replace the SmartPReP 2 System found to be defective during the warranty period. This warranty does not cover misuse, impact damage, or obvious abuse of the device. No warranty or affirmation of fact, expressed or implied, other than stated above, is made or authorized by Harvest Technologies, and Harvest Technologies' liability in all events is limited to the purchase price paid for the device.

The Harvest SmartPReP 2 Centrifuge meets the requirements for leakage current and hi-pot testing listed in BS EN 60601-1 and UL 2601-1 standards for Medical Electrical Equipment.
(Less than 100µA on model SMP2-100 and SMP2-115)
(Less than 500µA on model SMP2-230)

G force during first spin = 1250
G force during second spin = 1050

Disconnection device	Appliance coupler
Rotor Disposable Capacity	2 or 4
Processing Time	approx. 14 minutes

The power outlet on the back of the unit is for future Harvest accessories and should not be used for anything else. The appliance coupler (also known as the power cord) must always be easily accessible. 2.5 meter power cords supplied by Harvest Technologies, Corp. are the only acceptable means to power the SmartPReP 2 Centrifuge. Power quality should be that of a typical commercial or hospital environment.

PHYSICAL SPECIFICATIONS

Height:	8.73 in. (22.2 cm)	Weight:	34 lb. (15.42 kg)
Width:	16.5 in. (41.91 cm)	Weight, Ship:	42 lb. (19.05 kg)
Depth:	18 in. (45.72 cm)		

STANDARDS

Harvest reserves the right to discontinue or change specifications without prior notice on all products. The SmartPReP 2 System has been tested and conforms to the following standards:

- UL 61010A-1, First Edition, 2002 - Electrical Equipment for Laboratory Use; Part 1: General Requirements
- UL 3101-2-20, First Edition, 1997 - Electrical Equipment for Laboratory Use; Part 2: Laboratory Centrifuges
- IEC 60601-1-2:2001 Medical Electrical Equipment - Part 1: General Requirements For Safety 2. Collateral Standard: Electromagnetic Compatibility - Requirements And Tests
- IEC 61326-1:1998 Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 1: General requirements
- CAN/CSA C22.2 No. 1010.1-92 - Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use, Part 1: General Requirements
- CAN/CSA C22.2 No. 1010.2.020-94 - Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use, Part 2: Particular Requirements for Laboratory Centrifuges
- IEC 61010-1:90 / A1: 93 / A2: 95 - Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use, Part 1: General Requirements
- IEC 61010-2-020: 92 - Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use, Part 2: Particular Requirements for Laboratory Centrifuges
- EN 61326 - Electrical Equipment for Measurement, Control and Laboratory Use
- EMC Requirements Part 1: General Requirements Includes Amendment A1: 1998;
- IEC 61326: 1997 + A1: 1998
- ETL Control # 117553

ELECTRICAL SPECIFICATIONS

Model #	SMP2-100	SMP2-115	SMP2-230
Input Voltage (VAC)	100	115	230
Operating Frequency (Hz)	50/60	50/60	50/60
Rated Current (Amps)	5	5	2.5
Fuse rating	5 Amp, time delay, glass tube, ¼" x 1¼"	5 Amp, time delay, glass tube, ¼" x 1¼"	2.5 Amp, time delay, glass tube, 5 x 20mm

ENVIRONMENTAL CONSIDERATIONS

Temperature limit: Operational: 10°C - 30°C (50°F - 86°F)
Storage: -40°C - 66°C (-40°F - 150 °F)
Humidity Limit: Operation: 10-90% non condensing
Storage: 10-90% non condensing
Minimum clearance distance around unit: 3 inches

There is no need to secure the unit with straps or other mounting hardware. Leveling is not required as long as the unit does not slide off the intended surface.

ELECTROMAGNETIC COMPLIANCE

Special precautions regarding EMC: Do not stack SmartPReP 2 Centrifuges on other medical electrical equipment. Always check for normal operation when the SmartPReP 2 Centrifuge is moved to a new location.

Portable and mobile RF communications equipment can effect medical equipment.

WARNING: This equipment/system is intended for use by healthcare professionals only. This equipment/system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as reorienting or relocating the SMP2 or shielding the location.

The use of accessories, transducers and cables other than those supplied by Harvest Technologies, Corp, may result in increased EMISSIONS or decreased IMMUNITY of the SMP2.

Guidance and manufacturer's declaration – electromagnetic emissions (Table 201)		
The SMP2 is intended for use in the electromagnetic environment specified below. The customer or the user of the SMP2 should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The SMP2 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 electronic equipment.
RF emissions CISPR 11	Class A	The SMP2 is suitable for use in all 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	

Guidance and manufacturer's declaration – electromagnetic immunity (Table 202)			
The SMP2 is intended for use in the electromagnetic environment specified below. The customer or the user of the SMP2 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	± 6 kV contact ± 8 kV air	± 6 kV 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 Not applicable for input/output lines, there are no input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
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 sec	>95%-0.5 cycles 60%-5 cycles 30%-25 cycles >95%-250 cycles	Mains power quality should be that of a typical commercial or hospital environment. If the user of the SMP2 requires continued operation during power mains interruptions; it is recommended that the SMP2 be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m @ 50Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the arc. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity (Table 204)			
The SMP2 is intended for use in the electromagnetic environment specified below. The customer or the user of the SMP2 should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – Guidance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 V	Portable and mobile RF communications equipment should be used no closer to any part of the SMP2, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1{,}2\sqrt{P}$ $d = 1{,}2\sqrt{P}$ 80 MHz to 800 MHz $d = 2{,}3\sqrt{P}$ 800 MHz to 2,5 GHz
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	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). 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: 
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.			
[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 the SMP2 is used exceeds the applicable RF compliance level above, the SMP2 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the SMP2. [b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

Recommended separation distances between portable and mobile RF communications equipment and the SMP2 (Table 206)			
The SMP2 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the SMP2 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the SMP2 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 $d = 1{,}2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1{,}2\sqrt{P}$	**800 MHz to 2,5 GHz** $d = 2{,}3\sqrt{P}$
0,01	**0,12**	**0,12**	**0,23**
0,1	**0,38**	**0,38**	**0,73**
1	**1,2**	**1,2**	**2,3**
10	**3,8**	**3,8**	**7,3**
100	**12**	**12**	**23**
For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in metres (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.			

The Harvest SmartPReP 2 Centrifuge meets the requirements for leakage current and hi-pot testing listed in BS EN 60601-1 and UL 2601-1 standards for Medical Electrical Equipment.
(Less than 100µA on model SMP2-100 and SMP2-115)
(Less than 500µA on model SMP2-230)

G force during first spin = 1250
G force during second spin = 1050

Disconnection device	Appliance coupler
Rotor Disposable Capacity	2 or 4
Processing Time	approx. 14 minutes

The appliance coupler (also known as the power cord) must always be easily accessible. 2.5 meter power cords supplied by Harvest Technologies, Corp. are the only acceptable means to power the SmartPReP 2 Centrifuge. Power quality should be that of a typical commercial or hospital environment.

PHYSICAL SPECIFICATIONS

Height:	8.73 in. (22.2 cm)	Weight:	34 lb. (15.42 kg)
Width:	16.5 in. (41.91 cm)	Weight, Ship:	42 lb. (19.05 kg)
Depth:	18 in. (45.72 cm)		

Harvest reserves the right to discontinue or change specifications without prior notice on all products. The SmartPReP 2 System has been tested and conforms to the following standards:

STANDARDS

Standard #	Description
UL 61010-1	Issued:2004/07/12 Ed:2 Rev:2008/10/28 UL Standard for Safety Electrical Equipment For Measurement, Control, and Laboratory Use; Part 1: General Requirements
CAN/CSAC22.2#61010-1	Issued: 2004/07/01 Ed: 2 Standard for Safety Electrical Equipment For Measurement, Control, and Laboratory Use; Part 1: General Requirements Included when done concurrently with UL/EN/IEC 61010-1.
IEC 61010-2-020	Issue: 2006/05/01 Ed: 2 Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use Part 2-020: Particular Requirements for Laboratory Centrifuges; Amd. 1-1996
CENELEC EN 61010-1	Issued:1993/04/01 Safety Requirements for Electrical Equipment for Measurement, Control and Laboratory Use - Part 1: General Requirements- Includes Amendment A2:1995; IEC 61010-1:1990 + A1:1992, Modified + A2:1995 Included when done concurrently with UL/CSA/IEC 61010-1
IEC 61010-1	Issued: 2001/02/01 Ed: 2 Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use - Part 1: General Requirements; Corrigendum 1:05/2002; Corrigendum 2:04/2003
IEC 60601-1-2	Issued:2007/03/01 Ed:3.0 Medical Electrical Equipment - Part 1-2: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests

IEC 60601-1-2	Issued: 2007/03/01 Ed: 3.0 Medical Electrical Equipment - Part 1-2: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests Requirements for Basic Safety and Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests Evaluation for Japan requirements.
FCC 47CFR 15B clA	Issued:2011/04/21 Title 47 CFR Part 15 Subpart B Unintentional Radiators Class A Verification

Harvest Technologies ETL Control #117553

ELECTRICAL SPECIFICATIONS

Model #	SMP2-100	SMP2-115	SMP2-230
Input Voltage (VAC)	100	115	230
Operating Frequency (Hz)	50/60	50/60	50/60
Rated Current (Amps)	5	5	2.5
Fuse rating	5 Amp, time delay, glass tube, ¼" x 1¼"	5 Amp, time delay, glass tube, ¼" x 1¼"	2.5 Amp, time delay, glass tube, 5 x 20mm

ENVIRONMENTAL CONSIDERATIONS

Temperature limit: Operational: 10°C - 30°C (50°F - 86°F)
Storage: -40°C - 66°C (-40°F - 150 °F)
Humidity Limit: Operation: 10-90% non condensing
Storage: 10-90% non condensing
Minimum clearance distance around unit: 3 inches

There is no need to secure the unit with straps or other mounting hardware. Leveling is not required as long as the unit does not slide off the intended surface.

U.S. Patent Nos.: 5,707,331; 5,895,346. US and foreign patents pending. BSI registered firm. ISO 13485 Registered.

ELECTROMAGNETIC COMPLIANCE

Special precautions regarding EMC: Do not stack SmartPReP 2 Centrifuges on other medical electrical equipment. Always check for normal operation when the SmartPReP 2 Centrifuge is moved to a new location.

Portable and mobile RF communications equipment can effect medical equipment.

Guidance and Manufacturer's Declaration- Emissions
All ME Equipment and ME Systems

Guidance and Manufacturer's Declaration- Emission		
The SmartPReP2 is intended for use in the electromagnetic environment specified below. The customer or user of the SmartPReP2 should ensure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic Environment-Guidance**
RF Emissions CISPR 11	Group 1	The SmartPReP2 uses RF energy only for its internal function. Therefore, its RF emissions are low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class A or B	A
Harmonics IEC 61000-3-2	Class A, B, C, D or N/A	A
Flicker IEC 61000-3-3	Complies or N/A	Complies
		The SmartPReP2 is suitable for use in all establishments, **other than** domestic, and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

Guidance and Manufacturers Declaration – Immunity
All ME Equipment and ME Systems

Guidance and Manufacturer's Declaration-Immunity			
The SmartPreP2 is intended for use in the electromagnetic environment specified below. The customer or user of the SmartPReP2 should ensure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment- Guidance**
ESD IEC 61000-4-2	±6kV Contact ±8kV Air	±6kV Contact ±8kV Air	Floors should be wood, concrete or ceramic tile. If floors are synthetic, the r/h should be at least 30%
EFT IEC 61000-4-4	2kV Mains ±1kV I/Os	2kV Mains ±1kV I/Os	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1kV Differential ±2kV Common	±1kV Differential ±2kV Common	Mains power quality should be that of a typical commercial or hospital environment.
Voltage Dips/Dropout IEC 61000-4-11	>95% Dip for 0.5 Cycle 60% Dip for 5 Cycles 30% Dip for 25 Cycles >95% Dip for 5 Seconds	>95% Dip for 0.5 Cycle 60% Dip for 5 Cycles 30% Dip for 25 Cycles >95% Dip for 5 Seconds	Mains power quality should be that of a typical commercial or hospital environment. If the user of the SmartPrep2 requires continued operation during power mains interruptions, it is recommended that the SmartPreP2 be powered from an uninterruptible power supply or battery.
Power Frequency 50/60 Hz Magnetic Field IEC 61000-4-8	3A/m	3A/m	Power frequency magnetic fields should be that of a typical commercial or hospital environment.

Guidance and Manufacturer's Declaration- Immunity
ME Equipment and ME Systems that are NOT Life-Supporting

Guidance and Manufacturer's Declaration- Immunity			
The SmartPReP2 is intended for use in the electromagnetic environment specified below. The customer or user of the SmartPReP2 should ensure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment- Guidance**
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	(V1)=3Vrms (E1)=3V/m	Portable and mobile communications equipment should be separated from the SmartPReP2 by no less than the distance calculated/listed below: D=(3.5/V1) (Sqrt P) 150kHz to 80MHz D=(3.5/E1) (Sqrt P) 80 to 800 MHz D=(7/E1) (Sqrt P) 800 MHz to 2.5 GHz Where P is the max power in watts and D is the recommended separation distance in meters. Field strengths from fixed transmitters, as determined by an electromagnetic site survey should be less than the compliance levels (V1 and E1). Interference may occur in the vicinity of equipment containing a transmitter.

Recommended Separation Distances between portable and mobile RF Communications equipment and the SmartPReP2
ME Equipment and ME Systems that are NOT Life-Supporting

Recommended Separations Distances for the SmartPReP2			
The SmartPReP2 is intended for use in the electromagnetic environment in which radiated disturbances are controlled. The customer or user of the SmartPReP2 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF Communications Equipment and the SmartPReP2 as recommended below, according to the maximum output power of the communications equipment			
Max Output Power (Watts)	**Separation (m) 150 kHz to 80 MHz** **D=(3.5/V1) (Sqrt P)**	**Separation (m) 80 to 800 MHz** **D=(3.5/E1) (SqrtP)**	**Separation (m) 800MHz to 205 GHz** **D=(7/E1) (Sqrt P)**
0.01	0.11667	0.11667	0.23333
0.1	0.36894	0.36894	0.73785
1	1.1667	1.1667	2.3333
10	3.6894	3.6894	7.3785
100	11.667	11.667	23.333

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