PortaBELL™ III (Dental Field Treatment and Operating System III) (Project 6-23) (10/07)

For UPDATE, click here.

The PortaBELL™ III is a lightweight, portable dental unit/system designed to be used in an austere field deployment environment and is provided in a shipping/storage container which meets military specifications. It has an oil-less compressor providing air to the unit for motor cooling, chip air for the handpiece, pressurization for the water supply and for operation of the three-way syringe. This unit has a self-contained vacuum system for high and low volume evacuation which is independent of the air compressor. Due to the independent/dedicated evacuation system and use of electric handpieces the need for a larger air compressor and associated metal storage tank is eliminated. Instead, the PortaBELL™ III uses a unique, collapsible air-storage bladder. This reduces the weight and volume for shipping purposes. The unit is designed to be used for routine dental prophylaxis, restorative operative dental procedures and oral surgery. It supports the use of a variety of high-speed and low-speed electric handpieces with an E-type motor connection and optional fiber optics. A three-way air/water syringe, high volume evacuation (HVE), low volume evacuation (LVE) saliva ejector and a variable speed foot switch are included. It also has a 500 mL self-contained water system, and a 1500 mL amalgam separator/waste tank. The PortaBELL™ III occupies a volume of 1.5 cubic feet, measuring 13.25” H x 13.25” L x 15.5” W. It weighs 93 pounds and is capable of automatically operating on any power supply from 100 VAC to 240 VAC, and 50/60 Hz.

Manufacturer:
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Suggested Retail Price:
$18,675.35 System Configuration 1
- Dental unit
- Four high-speed fiber-optic handpieces,
- Four reduction fiber-optic slow-speed handpieces
- Two straight non fiber-optic handpieces
- Two electric handpiece motors,
- Spare parts (fiber-optic bulb, o-rings, filters)
- Ground shipping within the continental United States

$13,725.00 System Configuration 2
- Dental unit
- Two electric handpiece motors
- Ground shipping within the continental United States

$1314.60 1:5 high-speed handpiece with fiberoptics (item # 9400225)
$1569.00 10:1 reduction slow-speed handpiece with fiberoptics (item # 9400021)
$1600.00 2.7:1 reduction handpiece with fiberoptics (item # 9400067)
$1163.00 Electric handpiece motor (Item # 9400022)
Government Price:
Purchase prices for the system configurations are the same as the retail price
$755.00 1:5 high-speed handpiece with fiberoptics (item # 9400225)
$902.00 10:1 reduction slow-speed handpiece with fiberoptics (item # 9400021)
$815.00 2.7:1 reduction handpiece with fiberoptics (item # 9400067)
$668.00 Electric handpiece motor (Item # 9400022)

ADVANTAGES:
+ Easy to assemble and operate
+ Shipping/storage case meets military specifications
+ Small volume and weight for deployment
+ Thorough operating and maintenance manual
+ Unit controls are clearly labeled and easy to understand
+ Operates on any power supply from 100 to 240 VAC, 50/60 Hz
+ Multiple electric handpiece configurations available (e.g., prophylaxis, restorative, surgery)
+ HVE improved over previous model (PortaBELL™ II)

DISADVANTAGES:
- Pre-activation of ball valve in waste container shuts suction down
- Clinical evaluators reported that the suction was inadequate
- Complex three-way syringe design may lead to inadvertent inactivation
- Only one handpiece connector/hose
- Handpiece dislodges easily from the handpiece holder on the bracket table
- Objectionable noise level
- Bracket table assembly somewhat unstable and difficult to position ergonomically
- Unit adjustment controls are difficult to reach during procedures
- Waste container near clean water supply—susceptible to cross contamination
- Unit broke down twice during the evaluation (fiberoptic potentiometer and a fuse/loose wire)
- Manufacturer supplied a used/refurbished unit for evaluation; questionable manufacturing base and customer support on a large scale

SUMMARY AND CONCLUSIONS:
The PortaBELL™ III is a portable dental unit/system designed to be used with electric handpieces in an austere field deployment environment. Laboratory tests revealed improved HVE and LVE levels compared to the previous PortaBELL™ II version. While improved, the HVE capabilities of the PortaBELL™ III unit still appear to be marginally acceptable for restorative procedures as the majority (6/9) of clinical evaluators reported that the suction was inadequate. However, it is likely that individuals would be able to adapt to the unit’s HVE capabilities and “make it work” for short periods in a deployed environment.

The pre-activation of the ball float-valve within the unit’s waste container was problematic in previous PortaBELL™ II and III evaluations. This pre-activation shuts the unit’s suction down prematurely and results in a tedious reactivation procedure in the middle of dental treatment. Laboratory tests and clinical evaluation revealed that this problem, first identified in 2003, had not been corrected even though the unit had been redesigned. If only using the unit for short time periods, users are likely to adapt and learn how to minimize or prevent the inadvertent ball float-valve deployment and vacuum shutdown. If used for longer time periods, frequent interruptions caused by this problem would undoubtedly slow patient care and could affect the overall quality of treatment provided.

The operation and maintenance manual is well written with an excellent “Troubleshooting” section complete with diagrams. However, clinical evaluators requested simplified laminated instruction cards due to the complexity of the manual. The unit controls are clearly labeled and easy to understand, but are difficult to access during patient care due to the small footprint of the unit when located on the floor. The bracket table assembly is functional, but a sturdier construction and more ergonomic design are recommended. The dimensions of the plastic holder for the handpiece on the bracket tray assembly are not ideal for the size and weight of the electric handpiece. As a result, the handpiece is easily dislodged from this holder. Evaluators noted several instances of handpieces falling on the floor, nearly missing
patients. Clinicians were also concerned about the potential for cross contamination between the waste container and clean water supply due to the close proximity to each other.

The unit had two minor breakdowns (fiberoptic potentiometer and a fuse/loose wire) during this evaluation. This type of anomaly is not a new occurrence as a problem with wire connections to a circuit board occurred for this same unit in a previous Navy study. The founder and owner of the company directly responded to and quickly corrected these problems. This is the second evaluation of a Bell Dental Products dental unit completed by DECS, where a refurbished previously used unit, was supplied by the company for testing. The need to use the same unit for multiple evaluations indicates that the company likely has a small manufacturing base. The failure to rectify the problem with the pre-activation of the ball float-valve within the waste container combined with a small manufacturing base brings to question the ability of the company to correct deficiencies in a timely manner and to provide support on a larger scale.

The PortaBELL™ III dental unit can provide basic functions to complete routine restorative and surgical procedures required for patient maintenance procedures in austere deployed environments due to its small footprint and portability. However, it should not be considered for less austere deployed environments where sustained high volume routine restorative/surgical patient dental care will continue over prolonged time periods. The PortaBELL™ III dental unit is rated Marginal for short term emergency-type expeditionary dental care in the most austere deployed environment.

**UPDATE (8/08)**

Reevaluation of Premature Activation of Waste Container Shut-off Valve:

A major performance disadvantage, the premature activation of the PortaBELL™ III portable dental field unit’s waste container shut-off valve, has been retested by the Naval Institute for Dental and Biomedical Research (NIDBR). The results of this evaluation were outlined in a NIDBR report entitled: “PortaBELL™ III, December 2007 Results of Performance Testing.”

During previous 2007 tests conducted at DECS, the PortaBELL™ III unit’s suction would prematurely shut down due to the inadvertent pre-activation of the ball float-valve mechanism within the waste container. This pre-activation in the clinical setting resulted in loss of suction which could only be restored by turning the vacuum system pump off, then disconnecting and reconnecting the suction hose at the back of the unit or at the top of the waste container. This problem was first identified in a joint DECS/NIDBR evaluation in 2003 during testing of a previous version of the PortaBELL™ dental unit.1 Although the design of the waste container/ball float-valve had been modified prior to the 2007 DECS laboratory and clinical evaluations, testing confirmed that the problem had not been corrected. Clinically, pre-activation occurred when the low-volume evacuation (LVE) was turned on or off during the use of the high-volume evacuation (HVE) or due to unintended blockages of the HVE (i.e., occlusion by the tongue or cheek). A high rate of pre-activation was seen in the DECS laboratory when the HVE was occluded with the LVE turned off. When the HVE and LVE were operated concurrently with intentional occlusion of the HVE, pre-activations were reduced.

The most recent NIDBR report reevaluated a PortaBELL™ III unit with a redesigned vacuum shut-off (ball float-valve). The report provides photographs (Figures 1-4) of this redesigned feature and describes the changes in design in detail (Discussion section, pages 3 and 4). Laboratory tests as described in the NIDBR report (similar but more extensive than DECS 2007 laboratory testing) confirmed this most recent design change completely eliminated the premature activation of the shut-off valve within the waste container. The NIDBR report concludes that: "Testing of the latest version of the PortaBELL™ III indicates that the redesign has effectively corrected the problem." No clinical testing was conducted during the NIDBR evaluation to corroborate the laboratory results. Due to the complete elimination of the shut-off valve pre-activation in the most recent NIDBR laboratory test setting compared to similar DECS and NIDBR laboratory tests in previous evaluations, it is likely that the occurrence in the clinical setting has at a minimum been reduced; however, this can not be definitely stated without clinical evaluation of the redesigned unit. NIDBR also retested the suction level of the unit and concluded that there was no significant change compared to previous evaluations of the PortaBELL™ III unit.
Bell Dental Products Manufacturing:
Bell Dental Products has announced an association with Byers Peak, Inc. to manufacture the PortaBELL™ III unit. Byers Peak has a 30,000 square foot facility and specializes in contracted low to medium volume, complex system manufacturing of medical devices, industrial instrumentation and system integration. This company is ISO certified and registered with the Food and Drug Administration as a contract manufacturer of medical devices. In addition, Bell Dental Products has its own 5,200 square foot facility with six work stations designed to manufacture the PortaBELL™ III. Bell Dental Products reports that they can produce eight units per week in their own facility and that Byers Peak has reached a production rate of up to ten PortaBELL™ III units per week (which could be expanded).

References