

Paperwork Reduction Act Statement -- OMB number 0910-0500; expiration 1/31/2011

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[Please do NOT return this form to the above address, except as it pertains to comments on the burden estimate.]

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

1. Please select the clinical setting that best describes your affiliation or place of employment.

- Hospital
- Independent home health agency
- Home health agency affiliated with hospital
- Hospice
- Nursing home
- Private practice
- Other _____

2. What makes and models of negative pressure wound therapy systems (NPWT) does your organization use? Please check all that apply.

Manufacturer	Trade/Brand Names	Check
Blue Sky Medical Group (Blue Sky Medical Group is now owned by Smith & Nephew, Inc.)	V1STA Negative Wound Therapy (portable unit)	
	EZCARE Negative Wound Therapy (stationary unit)	
	Unsure of brand name	
Boehringer Wound Systems, LLC	Engenex® Advanced NPWT System	
Innovative Therapies Inc.	SVEDMAN™ Wound Treatment Systems	
	SVED™ Wound Treatment System	
	Unsure of brand name	
Kalypto Medical	NPD 1000 Negative Pressure Wound Therapy System	
KCI, USA Inc. (Kinetic Concepts, Inc.)	InfoV.A.C.® Therapy Unit (stationary unit)	
	ActiV.A.C.® Therapy Unit (portable unit)	
	V.A.C.® Freedom™	
	V.A.C.® ATSTM	
	V.A.C.® Instill System (delivery of topical solutions)	

	Unsure of brand name	
Premco Medical Systems, Inc.	Prodigy™ NPWT System (PMS-800)	
	Prodigy™ NPWT System (PMS-800V)	
	Unsure of brand name	
Prospera (Prospera Technologies LLC owns the Prospera NPWT systems and brand)	PRO-I™ (stationary and portable)	
	PRO-II™ (portable)	
	PRO-III™(stationary and portable)	
	Unsure of brand name	
Smith & Nephew, Inc.	V1STA Negative Pressure Wound Therapy (portable unit)	
	EZCARE Negative Pressure Wound Therapy (stationary unit)	
	RENASYS™ EZ Negative Pressure Wound Therapy	
	Unsure of brand name	
Talley Group, Ltd.	Venturi™ Negative Pressure Wound Therapy (portable or stationary)	

➤ **Device performance and experience**

3. Have you or your patients experienced any of the following issues with the NPWT system(s) your organization uses? Please check all that apply.

- Dressing's foam adhered to or imbedded in the wound
- Foreign body (dressing's foam pieces) retained in the wound
- Bleeding
- Infection
- Vascular graft failure due to improper system function
- Death
- Other, specify: _____
- None of the above
- Don't know

4a. As far as you know, have any of the wound therapy systems your organization uses resulted in better patient outcomes, i.e., better wound healing, no infection?

- YES (Go to Q4b)
- NO (Go to Q5)

4b. Which system(s) have resulted in better patient outcomes?

SHORT ANSWER

5. For which conditions or diagnoses is NPWT prescribed? Please check all that apply.

Chronic and Acute Wounds

- Diabetic foot ulcers
- Pressure ulcers

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- Vascular ulcers (venous and arterial ulcers)
- Burn wounds
- Surgical wounds (sternal wounds)
- Trauma-induced wounds
- Abdominal wound closure
- Excised wounds
- Deep abrasions

Subacute wounds

- Dehiscence
- Open wounds
- Skin grafts
- Skin flaps

Other, specify:

PROGRAMMING NOTE: IF Q1=HOSPITAL, SKIP TO Q14a.

6. Do you have patients who are receiving NPWT, either in the home setting, a nursing home, or in a long-term care facility?

- YES (Go to Q7)
- NO (Go to Q14a)

7. Do patients or their caregivers express concern about using these systems themselves in the home?

- Patients only (Go to Q8)
- Caregivers only (Go to Q8)
- Both patients and caregivers express concern (Go to Q8)
- No concerns expressed by either patient or caregiver (Go to Q9a)

8. What are some of the questions or concerns you typically hear or are aware of?

- o Understanding how to use and operate device (in the home)
- o Troubleshooting the device
- o Alarm issues

- o Monitoring patients in the home
- o Identifying signs and symptoms of an infection
- o How to handle bleeding
- o Concerns about changing the dressing
- o Concerns about cleaning the wound
- o Pain concerns

- o Questions about check-ups
- o Questions about medications, i.e. dosing, side effects, frequency of administration
- o Pressure settings
- o Other, specify: _____

9a. Is material provided to the patient or caregiver at discharge that is specific to the NPWT system?

- YES (Go to Q9b)
- NO (Go to Q10a)

9b. IF YES: Please indicate the material's format. Please check all that apply.

Paper-based:

- Pamphlet
- Handout
- Question & Answer sheet
- Brochure
- Booklet

Multimedia:

- CD
- DVD
- Video
- Website (to refer to for additional materials)

Other, specify: _____

9c. Is the material supplied by your facility or by the manufacturer?

- Facility
- Manufacturer
- Both
- Other, specify: _____

10a. Are patients monitored when using these devices in the home setting?

- YES (Go to Q10b)
- NO (Go to Q11a)
- DON'T KNOW (GO TO Q11a)

10b. Who monitors these patients? Please check all that apply.

- Registered nurse (i.e., home care nurse)
- LPN
- Aide (includes CNAs, techs, etc.)
- Other _____

10c. How often are visits scheduled to check on the patient?

- times per week
- times per month
- Other, specify: _____

➤ **Training and Labeling**

11a. Do patients and their caregivers receive training on the NPWT system?

- YES (Go to Q11b)
- NO (Go to Q12a)

11b. Is training mandatory for patients and caregivers who use the device in the home?

- YES (Go to Q11c)
- NO (Go to Q12a)

11c. Who conducts the training?

- Prescribing physician
- Nurse educator
- Registered nurse (i.e., home care nurse)
- LPN
- Aide (CNAs, techs, etc.)
- Wound care nurse
- Other _____

11d. Where does the patient/caregiver training take place?

- Hospital
- Home
- Long-term care facility
- Other, specify: _____

11e. Please describe the training. Is it: [Please check all that apply.]

- Video-based
- Hands-on
- Demonstration
- Other, specify _____

12a. Do the NPWT systems have labels or other written instructions?

- YES (Go to Q12b)
- NO (Go to Q13a)

12b. In your opinion, are the labels or other device instructions written for a lay audience?

- YES
- NO

13a. Have you observed challenges with caregivers' ability to understand and follow device instructions?

- YES (Go to Q13b)
- NO (Go to Q14a)

13b. Which, of the conditions below do you believe may be the reason for this? Please check all that apply.

- Language barriers
- Patient and caregiver distracted (due to illness, altered consciousness, or other medical situation)
- Material difficult to see/read
- Material does not include pictures/diagrams
- Instructions not organized well
- Other challenges, specify: _____

➤ **Issues associated with gauze or foam dressing**

14a. How often are dressings changed?

- ___ times per day
- ___ times per week
- ___ Other: _____
- ___ Don't know (Go to Q15a)

14b. What factors does your organization use to determine how often dressings should be changed? Please check all that apply.

- Type of wound
- Stage of wound
- Location of wound

- Patient risk factors and co-morbidities
- Patient characteristics
- Doctor's orders

- Labeling provided by manufacturer
- Policy developed by your institution
- Other, specify: _____

14c. Who changes the dressing? Please check all that apply.

- ___ Registered nurse (i.e., home care nurse)
- ___ LPN
- ___ Aide (e.g., CNA, techs)
- ___ Caregiver
- ___ Patient

___ Other, specify: _____

15a. What are the most common reasons or complications you see that warrant dressing removal and change? Please check all that apply.

- Bleeding
- Pain
- Infection
- Odor
- Tissue granulation and in-growth into foam
- Inadequate seal
- Inadequate suction
- Other, specify: _____

15b. How often do these complications occur?

- Frequently
- Occasionally
- Rarely
- Never

16a. Are the dressings you use:

- Pre-cut (Go to Q17)
- Able to be modified, depending on the wound (Go to Q16b)
- Both (Go to Q16b)

16b. How often are the dressings modified?

- Always
- Frequently
- Occasionally
- Rarely
- Never
- Don't know

17. Does your organization use foam or gauze dressing(s)?

- Foam
- Gauze
- Both
- Other, specify: _____

18. Have patients experienced tissue adherence to the dressing, which may contribute to bleeding events?

- YES
- NO

19a. Do patients experience any additional complications during dressing changes?

- YES (Go to Q19b)
- NO (Go to Q20a)

19b. IF YES: Please describe these problems or complications.

TEXT RESPONSE

20a. Have patients experienced any other complications with the dressings?

- YES (Go to Q20b)
- NO (Go to Q21a)

20b. IF YES: Please describe these complications.

TEXT RESPONSE

➤ **Patient outcome**

21a. In your opinion, are patient outcomes dependent upon specific patient characteristics?

- YES (Go to Q21b)
- NO (Go to Q22a)

21b. Of the following patient characteristics, please select up to three that you feel are the most important ones affecting patient outcomes.

- Type of wound
- Stage of wound
- Location of wound
- Patient age
- Patient's capabilities
- Caregiver support
- Provider support
- Other _____

22a. In general, do you think patients can do this kind of wound care safely at home by themselves?

- YES
- NO

22b. Please explain:

TEXT RESPONSE

23. What do you think could be done to better inform patients of the risks/benefits associated with using these systems, especially in the home setting?

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- Better patient-provider communication
- Better training
- Better materials
- Nothing
- Other, specify: _____

Thank you for your time.