



Unit Processed On<sup>FN1</sup>: \_\_\_\_\_

	Whole	Whole Flavored	2%	2% Flavored	1%	1% Flavored	Skim	Skim Flavored
Processing Temperature <sup>FN2</sup>								
Time <sup>FN3</sup>								
Volume <sup>FN4</sup>								
# of Days Processed								

Please do not provide data on non-bovine (e.g., goat's, sheep, etc) milk, cream and cream products, cultured milk and milk products, milk and milk products to be cultured, and vat pasteurized, ultra-pasteurized, or aseptically processed Grade "A" milk and milk products.

**FN 1** Unit Processed On: i.e., HTST #1 or #2 or HTST N or S or HHST #1 or HHST #2.

**FN 2** Temperature: Record actual operating/processing temperature (°F).

**FN 3** Time: Obtain from the most recent pasteurization equipment validation (seconds).

**FN 4** Volume: On a daily average (gallons). If multiple flavored products per fat level are being produced, combine the product volumes to report only one daily volume for all these flavored products per fat level.

Public reporting burden for this collection of information is estimated to average 31 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing burden to:

Food and Drug Administration  
 Center for Food Safety and Applied Nutrition  
 5100 Paint Branch Parkway, HFS-007  
 College Park, Maryland 20740

## **CDRH – NEGATIVE PRESSURE WOUND THERAPY**

***Paperwork Reduction Act Statement -- OMB Number: 0910-0500; expiration 1/31/2011***

Public reporting burden for this collection of information is estimated to average 30 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the address below.

Department of Health and Human Services Food and Drug Administration Office of Chief Information Officer (HFA-710) 5600 Fishers Lane Rockville, MD 20857

[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.

<b>Manufacturer</b>	<b>Trade/Brand Names</b>	<b>Check</b>
Blue Sky Medical Group (Blue Sky Medical Group is now owned by Smith & Nephew, Inc.)	VISTA 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.® ATS™	
	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.	VISTA 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
- 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:*

