



DEPARTMENT OF VETERANS AFFAIRS
Federal Supply Service
Authorized Federal Supply Schedule Price List

On-line access to contract ordering information, terms and conditions, up-to-date pricing, and the option to create an electronic delivery order are available through GSA Advantage![™], a menu-driven database system. The INTERNET address for GSA Advantage![™] is GSAAdvantage.gov

FSC Group 65, Part II, Section A
Medical Equipment and Supplies
FSC Classes: 6515

Contract Number: **36F79719D0088**

Contract Period: **February 15, 2019 through February 14, 2024**

*(For more information on ordering from Federal Supply Schedules, enter the following address into your web browser:
<http://gsa.gov/portal/category/100623>)*

Otoharmonics Corporation

411 SW 6th Avenue

Portland, OR 97204

Phone: 503.336.9906

Fax: 503.595.7199

www.otoharmonics.com

Business Size: Veteran-Owned, Small Business

Customer Information:

1a. List of awarded special item numbers:

SIN: A-34 (Audiometer Equipment)

SIN: A-72 (Stimulators, Muscle, Nerve and Pain Control)

1b. Identification of the lowest priced model number and lowest unit price for that model for each special item number awarded in the contract. This price is the Government price based on a unit of one, exclusive of any quantity/dollar volume, prompt payment, or any other concession affecting price. Those contracts that have unit prices based on the geographic location of the customer, should show the range of the lowest price, and cite the areas to which the prices apply: **See Page 4**

1c. If the Contractor is proposing hourly rates, a description of all corresponding commercial job titles, experience, functional responsibility and education for those types of employees or subcontractors who will perform services shall be provided. If hourly rates are not applicable, indicate "Not applicable" for this item: **Not Applicable**

2. Maximum order: **\$50,000**

3. Minimum order: **None**

4. Geographic coverage (delivery area): **All 50 states, Puerto Rico and Washington, DC**

5. Point(s) of production (city, county, and State or foreign country): **Portland, OR**

6. Prices shown herein are Net (discount deducted)

7. Quantity Discounts: **Available on a case by case basis, based upon order limit and availability of product.**

8. Prompt Payment Terms: **None, Net 30 days**

9a. Notification that Government purchase cards are accepted at or below the micro-purchase threshold: **Accepted at and below the micro-purchase threshold**

9b. Notification whether Government purchase cards are accepted or not accepted above the micro-purchase threshold: **Accepted above the micro-purchase threshold**

10. Foreign items (list items by country of origin): **Not Applicable**

11a. Time of delivery: **Within 30 Days ARO**

11b. Expedited delivery: **Available upon request within 5 days (ARO). Ordering facilities will pay the difference between standard and expedited shipping costs.**

11c. Overnight and 2-day delivery: **Not Offered**

- 11d. Urgent requirements: Available upon request within 5 days (ARO). Ordering facilities will pay the difference between standard and expedited shipping costs.**
- 12. FOB Point: Destination to all 50 states, Puerto Rico and Washington, DC**
- 13a. Ordering address: Same as Contractor**
- 13b. Ordering Procedures: For supplies and services, the ordering procedures, information on Blanket Purchase Agreements (BPA's) are found in Federal Acquisition Regulation (FAR) 8.405-3**
- 14. Payment address: Same as Contractor**
- 15. Warranty provision: See attached Standard Commercial Warranty (Attachment A)**
- 16. Export packing charges, if applicable: Not Applicable**
- 17. Terms and conditions of Government purchase card acceptance (any thresholds above the micro-purchase level): Accepted above the micro-purchase threshold**
- 18. Terms and conditions of rental, maintenance, and repair (if applicable): Not Applicable**
- 19. Terms and conditions of installation (if applicable): Not Applicable**
- 20. Terms and conditions of repair parts indicating date of parts price lists and any discounts from list prices (if applicable): Not Applicable**
- 20a. Terms and conditions for any other services (if applicable): See Levo Patient System Return Policy**
- 21. List of service and distribution points (if applicable): Portland, OR**
- 22. List of participating dealers (if applicable): Not Applicable**
- 23. Preventive Maintenance (if applicable): Not Applicable**
- 24a. Special attributes such as environmental attributes (e.g., recycled content, energy efficiency, and/or reduced pollutants): Not Applicable**
- 24b. If applicable, indicate that Section 508 compliance information is available on Electronic and Information Technology (EIT) supplies and services and show where full details can be found (e.g., contractor's website or other location). The EIT standards can be found at www.Section508.gov/ : Not Applicable**
- 25. Data Universal Number System (DUNS) number: 078763400**
- 26. Notification regarding registration in System for Award Management (SAM) database: Yes, registered**

FSS Contract Products and Pricing

<u>SIN</u>	<u>Product Number</u>	<u>Product Description</u>	<u>FSS Price</u>
A-34	Levo Manager	Levo Manager Device	\$2,386.93
A-34	Levo Patient	Levo Patient Device	\$2,386.93
A-72	Universal Fit	Flexible Fit Ear Buds	\$214.82
A-72	Custom Fit	Personalized Ear Buds	\$286.43

Attachment A

Otoharmonics Corporation

Standard Commercial Warranty

Otoharmonics warrants to Buyer that Products will be free from defects in material and workmanship under normal use for 12 months following delivery to Buyer. The warranty does not cover and Otoharmonics will have no warranty obligation whatsoever with respect to any damage to a Product caused by or associated with: (i) usage not in accordance with Product instructions or usage for a purpose not indicated on the labeling or “off-label use”; (ii) abuse, misuse, neglect, improper maintenance or storage, accident, vandalism, or the negligence of any party other than Otoharmonics. Otoharmonics MAKES NO WARRANTIES, EXPRESS OR IMPLIED, WITH RESPECT TO APPLE PRODUCTS AND OTHER PRODUCTS NOT MANUFACTURED BY OTOHARMONICS. Such Products carry the original manufacturer’s warranty and Buyer must submit warranty claims regarding such Products to Otoharmonics for processing. OTOHARMONICS EXPRESSLY DISCLAIMS ALL OTHER WARRANTIES AND CONDITIONS, EXPRESS OR IMPLIED, STATUTORY OR OTHERWISE, INCLUDING, WITHOUT LIMITATION, WARRANTIES OR CONDITIONS OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE, AS WELL AS WARRANTIES ARISING FROM COURSE OF DEALING AND USAGE OF TRADE, AND OTOHARMONICS DOES NOT REPRESENT OR WARRANT THAT ANY PRODUCT WILL MEET BUYER’S REQUIREMENTS. Notice of a defective Product must be given to Otoharmonics in writing within 10 days following the discovery of such defect prior to the expiration of the warranty period in order to recover under the warranty. Any Products returned due to a defect will be subject to the RMA. Otoharmonics’s SOLE LIABILITY under the warranty will be, at Otoharmonics’s option, to either replace or repair the defective Product(s).

Government Warranty Clauses 52.212-4 (o) (TAILORED), and 52.212-4 (p) (TAILORED):

Warranty: The Contractor warrants and implies that the items delivered hereunder are merchantable and fit for use for the particular purpose described in this contract. In the event that the terms of the contractor’s standard commercial warranty conflict with the warranty terms contained in this clause, the terms of this clause will govern this contract, unless some other resolutions are specified in the award document.

Limitation of liability: Except as otherwise provided by an express warranty, the contractor will not be liable to the Government in a breach of warranty action for consequential damages resulting from any defect or deficiencies in accepted items. In the event that the terms of the contractor’s standard commercial warranty/limitation of liability clause(s) place greater limits on the contractor’s liability than do the terms contained in this clause, the terms of this clause will govern the contract.

Levo Patient System Return Policy

The Levo® Patient System is an FDA-cleared medical device available only by prescription. The “System” includes a mobile digital device, proprietary pre-loaded Levo software and custom-fit Levo ear buds.

In order to ensure patient safety, Otoharmonics® is **required by the FDA** to maintain a current Device History File (DHF) within the company’s Quality Management System (QMS). As such, Otoharmonics:

- Keeps a record of each Levo Patient System sold and shipped to a healthcare provider
- Assigns a unique identifier that matches the Levo Patient System to a single user
- Tracks and tests all Levo Patient Systems returned to the company
- Authorizes the repurposing of a Levo Patient System for a new user only through a prescribed process performed at the company by a qualified Otoharmonics professional

The Levo Patient System provides sound therapy intended to manage the symptoms of tinnitus. Ongoing and consistent use of the System is required in order to be effective, as is use of the System according to manufacturer’s specifications. Otoharmonics suggests a minimum duration of therapy of ninety (90) days (see the Levo Patient Device Instructions for Use), however, the prescribing Healthcare Provider determines the specific therapy parameters based on the individual needs of each patient.

Otoharmonics offers a full refund, less a \$300.00 restocking fee, to any patient that adheres to the appropriate use of the System but does not see an improvement to the tinnitus condition as evidenced by the criteria outlined below. Under these circumstances the Levo Patient System may be returned for a refund:

- 30 days from fitting, which is considered to be the day of the initial sound match using the patient’s custom-fit Levo ear buds and
- Is physically returned to the Otoharmonics Headquarters in its entirety, including the Return Materials Authorization (RMA) form, such that it arrives within 45 days from fitting

Under the following conditions:

- The patient has recorded daily use of the system for each day prior to the end of the first thirty (30) days of treatment;
- No reduction in tinnitus intensity or improvements to quality of life have been achieved as shown by Tinnitus Intensity Measurement (TIM) or Tinnitus Functional Index (TFI);
- The Levo System ear buds supplied by Otoharmonics have not be modified or changed in any way from the manufacturers specifications;
- The patient has used only the Levo System ear buds supplied by Otoharmonics for their specific therapy;
- That the Levo Patient System is not damaged any way;
- The Levo Patient System has not been altered or modified in such a way that it no longer meets the specifications published by Otoharmonics

Once a Levo Patient System has been provisioned and assigned a unique patient identifier, it is subject to the full terms of the Return Policy without exception. Otoharmonics reserves the right to modify the Levo Patient System Return Policy with 90 days notice to Veterans Affairs (VA).

Otoharmonics will refund the purchase price of the Levo Patient System, less a \$300.00 restocking fee, within sixty (60) days of receipt to Otoharmonics Corporation and after the returned Levo Patient System has been determined in good faith to meet the company’s return policy criteria.