



MEDICAL MAINTENANCE EQUIPMENT TIP SHEET

Medical Device Nomenclature

Next Generation Diagnostics System (NGDS)

LIN: N05008

NIIN: 01-666-1626

Manufacturer: BioFire Defense

Model: Film Array 2.0

User and Maintainer Resources

<https://go.usa.gov/xw7dz>

Types of Organizations Who Have the Device:

Hospital Center • Combat Support Hospital • Area Medical Laboratory



Representative Photo Only

Note 1:

NGDS is a replacement for the Joint Biological Agent Identification and Diagnostic System (JBAIDS) but is not currently assigned to any active unit assemblages. This device will be placed in new unit assemblages developed to support field hospital configurations. A Letter of Authority (LOA) dated Dec. 5, 2019 (see below) authorizes units to place, retain, and account for this device until the new requirement and authorizations are documented in a newly published authorization document. The current LOA can be found at: <https://go.usa.gov/xw7pU>.

Note 2:

NGDS is currently being used to test patients for Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2), the virus which causes Coronavirus Disease-2019 (COVID-19). Use of the COVID-19 array has been temporarily approved by the Federal Drug Administration under an emergency use authorization. COVID-19 testing is only authorized for the specific period justifying authorized emergency use of in-vitro diagnostic tests for detection and diagnosis of COVID-19 under Section 564(b)(1) of Title 21 US Code § 360bbb-3(b)(1), unless this authorization is otherwise terminated.

The COVID-19 test kit and External Control Material (ECM) below are available in the electronic catalog:

- **NSN 6550-01-687-2996** - BioFire COVID-19 Test Kit (6 tests) MFG PN# 423745
- **NSN 6550-01-687-3047** - BioFire COVID-19 Test ECM Kit (6 positive controls) MFG PN# 423748

The test kit below is also available but may need to be procured through a sustainment management system transaction:

- **NSN 6550-01-687-3020** - BioFire COVID-19 Test Kit (30 tests) MFG PN# 423744

Level of Support: Field

- This support includes cleaning and inspecting components. NGDS component replacement/repair can only be performed by the Original Equipment Manufacturer (OEM). If equipment failure cannot be resolved using the user manual, troubleshooting steps, or through OEM technical support, sanitize the medical device in accordance with OEM instrument return procedures and coordinate medical device exchange with the next higher level of maintenance support. The impacted medical device should then be shipped to Medical Maintenance Operations Division (MMOD) - Hill Air Force Base Utah for replacement.

Level of Support: Depot

- MMOD-Hill will coordinate with the OEM for repair or replacement of a malfunctioning device.

Continued



Startup List: *There is no official startup list, but the following equipment should be included:*

- **Film Array V2.0G Instrument** - NSN: 6630-01-665-9541
 - **Pouch Loading Station** - NSN: 6665-01-666-0877
 - **Reader, Barcode w/cables** - NSN: 7025-01-616-7740
 - **GETAC, Ruggedized Laptop** - NSN: 7010-01-670-1206
 - **Case, Ruggedized Transport** - NSN: 8145-01-670-1200
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Field Maintenance Tips:

- A film array training video is accessible from the device desktop; click the training icon.
 - Operating conditions are 59°F to 86°F at 20-80% humidity (non-condensing).
Altitude range is -52.5 feet to 10,164 feet. Indoor use only.
 - Shipping and storage conditions are -22°F to 158°F at 5-95% humidity (non-condensing).
Altitude range is -52.5 feet to 34,777 feet.
 - Weekly computer reboot (shutdown and restart) is recommended.
 - Handle all samples and waste materials as though they are capable of transmitting infectious disease. Refer to Biosafety in Microbiological and Biomedical Laboratories which can be found online at the Centers for Disease Control and Prevention and National Institutes of Health.
 - In the event of barcode scanner failure, follow barcode calibration procedures listed in the back of the user manual.
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Warranty Information:

- **Period:** Two years of Contractor Logistics Support (CLS) from date products are given to a carrier/shipper for delivery to customer. It is intended to provide CLS to the DOD in annual increments after expiration of the two-year manufacturer warranty.
 - **Coverage:** Instruments will be free of material and workmanship defect and will perform substantially in accordance with user manual specifications.
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