KIROSHI FOUNDATION
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Report · KF-R-2024-01

# The support gap: discontinued medical implants in six countries

Continuity programme, Kiroshi Foundation

Published 17.06.2024 · Kiroshi Foundation, Kiroshi Foundation Building, 3-9-2 Nihonbashi Honchō, Chūō-ku, Tokyo 103-0023 · Text CC BY 4.0

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## Summary

When the maker of an optical implant stops supporting it, the people wearing it keep needing it. This report follows wearers of four discontinued devices, made by four companies, two of which no longer exist, in six countries, from the announcement that support would end to the years afterwards.

For three of the four devices, wearers went for up to three years with no support from anyone. The commonest failure was a battery. The most dangerous was a software certificate that expired and locked clinics out of the device entirely. The cost of keeping a discontinued device working was, in every case we studied, a fraction of the cost of replacing it.


## 1. Introduction

The Foundation set up its Continuity programme in 2020, after two events in 2019: Kiroshi Opticals, the company in which the Foundation is the largest shareholder, stopped selling the SEIRAN 2 with five years' support, and Raven Microcybernetics, maker of the Corvid implant, was dissolved with none. This report is the programme's first attempt to describe the problem systematically, rather than one wearer at a time.

## 2. Methods

Between May 2023 and March 2024 we interviewed 187 wearers of the four devices, in Japan, the United States, Canada, the Philippines, Kenya and the United Kingdom, and 34 clinicians who treat them. Wearers were recruited through clinics, wearers' associations and the Continuity support line, so the sample over-represents people who had already sought help.

We also read the support notices, user agreements, firmware licences and, where available, the insolvency records of the four makers, and the repair records of the Continuity programme from 2020 to 2023.

## 3. The four devices

Table 1. The four devices studied

| Device | Maker | Sold | Support ended | Wearers, estimated | Firmware |
|---|---|---|---|---|---|

| Device | Maker | Sold | Support ended | Wearers, estimated | Firmware |
|---|---|---|---|---|---|
| **SEIRAN 2** | Kiroshi Opticals | 2008 to 2019 | March 2024 | 41,000 | Placed in escrow, 2024 |
| **Corvid** | Raven Microcybernetics (dissolved 2019) | 2012 to 2019 | August 2019 | 9,800 | Recovered from administrators; escrow agreed |
| **Halcyon V** | Dynalar Optics (dissolved 2018) | 2010 to 2016 | June 2018 | 2,100 | Partly documented by volunteers |
| **Iris 1** | Ono-Sendai | 2010 to 2017 | September 2017 | 1,300 | Maker has declined escrow |

# 4. What happened to wearers

Table 2. Problems reported by the 187 wearers interviewed

| Problem | Wearers reporting it | Share |
|---|---|---|
| **Battery life falling or battery failure** | 121 | 65% |
| **Could not find anyone to service the device** | 98 | 52% |
| **Firmware fault with no fix available** | 57 | 30% |
| **Charger or accessory no longer available** | 49 | 26% |
| **Locked out of service by an expired certificate** | 23 | 12% |
| **Offered only a replacement, by surgery** | 104 | 56% |

More than half had been told, by the maker or a clinic, that the only option was a replacement, which means surgery. Many could not have it: some because of the risks of a second operation, some because of cost, and some because the replacement offered was not approved in their country.

## 5. Four cases

**The certificate.** The Iris 1 checks a security certificate before accepting a service connection. The certificate expired in 2021. From then on, no clinic could connect to the device to diagnose or charge it through its service port. Wearers were left with a device that worked until its first fault and could not be repaired after it. Continuity-funded engineers documented a way round the lock in 2022.

**The dissolution.** When Raven Microcybernetics was dissolved, its firmware and service tools passed to its administrators, who had no reason to maintain them. Corvid wearers organised their own support line within weeks; it became the Raven Wearers' Association.

**The volunteers.** Halcyon V wearers relied for several years on two retired engineers who had worked for Dynalar and kept a set of service tools. Both are now in their seventies.

**The five years.** The SEIRAN 2 was given five years' support from the end of sale, which was more than the law required and less than wearers needed. The device is expected to remain in use by many wearers for another fifteen years.

## 6. Costs

Table 3. Cost of keeping a device working compared with replacing it, Japan, 2023

| Intervention | Typical cost | Frequency |
|---|---|---|
| Battery replacement | ¥310,000 | About every seven years |
| Repair of a common fault | ¥80,000 to ¥240,000 | Varies |
| Firmware fix by an independent engineer, per device family | ¥15 million to ¥40 million | Once |
| Replacement implant with surgery and rehabilitation | ¥4.2 million to ¥6.8 million | Once per wearer |

## 7. Recommendations

**For makers.** Publish a support plan before a device is first sold, of at least fifteen years from the last sale; place firmware and documentation with an independent escrow holder; give at least five years' notice of the end of support.

**For regulators.** Make a support plan a condition of approval, and treat a maker's dissolution as an event requiring a plan for its devices' wearers.

**For hospitals.** Keep a register of the implants fitted, so that wearers can be contacted when support ends, and do not offer replacement as the only option.

## 8. What the Foundation is doing

The Foundation's Continuity programme already pays for repairs, batteries and a spares library for all four devices, and for engineers to document unsupported devices. From 2024 it will also fund the preservation of firmware with an independent archive, starting with the SEIRAN 2 and the Corvid. It continues to ask Ono-Sendai to place the Iris 1 firmware in escrow.

As the largest shareholder of Kiroshi Opticals, the Foundation has asked the company to apply the support-plan section of KF-OS 1, which it has followed for new devices since July 2023, to the devices it sold before then, and will report the company's answer.

# Annex A. Calls to the Continuity support line

Table A1. Calls to the support line by device and year

| Device | 2020 | 2021 | 2022 | 2023 |
|---|---|---|---|---|
| **SEIRAN 2** | 312 | 904 | 1,688 | 2,945 |
| **Corvid** | 1,140 | 1,026 | 1,212 | 1,394 |
| **Halcyon V** | 88 | 131 | 164 | 207 |
| **Iris 1** | 41 | 96 | 143 | 118 |
| **Total** | **1,581** | **2,157** | **3,207** | **4,664** |

Calls about the SEIRAN 2 rose steeply as the end of its support approached, and will rise further. Calls about the Iris 1 fell in 2023 after the certificate workaround was published.

## Annex B. In wearers’ words

Wearers were asked what they would say to a company about to stop supporting a device. A selection of answers, anonymised and translated where necessary:

- “Tell us the date on the day you sell it to us, not the day you stop.”
- “Give the software to someone who will still be there.”
- “I did not choose to have a computer in my head. I chose to see.”
- “A replacement is an operation. Please stop calling it an upgrade.”
- “Make the battery something a clinic can change.”

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# Acknowledgements


We thank the wearers who told us what happened to them, often more than once, and the clinicians and engineers who keep their devices working. The report was written by Yusuf Oduya and the Continuity team, with Dr Liv Marstrander of the Independent Implant Register.


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How to cite: Continuity programme, Kiroshi Foundation (2024). The support gap: discontinued medical implants in six countries. KF-R-2024-01. Tokyo: Kiroshi Foundation.