**Incident Report**

Please immediately report any adverse event or near adverse event with medical devices of Hocoma AG (e.g., patient issue, injury, side-effect, negative consequence or unexpected behavior). This is a valuable source of information to continuously ensure and improve the safety of our medical devices. Please inform Hocoma AG and/or your local distributor by using this incident report form (published on the website [www.hocoma.com/contact-us-2](http://www.hocoma.com/contact-us-2)) or by telephone.

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|  | **Hocoma AG**  Industriestrasse 4  CH-8604 Volketswil  Tel. +41 43 444 22 00  [quality@dih.com](mailto:quality@dih.com) |  |
| **After an adverse event or “near adverse event” the medical device may only be restarted and used again following approval and release by Hocoma AG!** | | |

Note to the user: Any **serious** incident that has occurred in relation to the device should be reported to the manufacturer Hocoma AG and to the competent authority of the country in which the incident has occurred.

**1. Basic Data**

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| **Affected person** |
| Patient  Therapist  None  Third party; please specify: |
| **Date of the event** |
| Date & time: Recurring issue?  No  Yes; please describe details including dates in section 2 |
| **Involved medical device** |
| Device name: Serial number: Operating hours: |
| **Did a notification to the national authority already occur?** |
| No  Yes; authority name, date of report, file number: |

**2. Description of the Incident**

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| **Exact description and assumed cause of the incident** |
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| **Measures taken immediately after the event** |
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**3. Patient Details and Treatment Information**

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| **Patient details** |
| Initials: Gender:  M  F  D Weight (kg): Date of birth (DD.MM.YYYY): |
| **Extent of the adverse event or damage / VAS pain scale** |
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| **Relevant medical examinations, including dates** |
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| **Was it the first time the patient or therapist used the device? Did the patient return to using the device?** |
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| **Relevant patient history, including preexisting medical conditions** |
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| **Additional devices combined with the medical device of Hocoma** |
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| **Relevant other concomitant medical products and therapy dates (exclude treatment of event)** |
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**4. Contact Details**

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| **Customer contact (where device is located)** | **Initial reporter (if different from customer contact)** |
| Name:  Function:  Address:      Tel.:  E-mail: | Name:  Function:  Address:      Tel.:  E-mail: |
| Place:Date: Name:Signature: | |