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VEYRUM ROBOTICS STANDARD



VRS-ASW-201

Assistive & Wearable / Exoskeleton — AR Assessment Protocol

How the Assistive & Wearable Application Rating letter is determined — sector criteria ASW-1...ASW-9, contributing intrinsic criteria, letter bands, tier ceilings and class applicability, with evidence by tier and underwriting use.

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Foreword. This Assessment Protocol determines the **Assistive & Wearable / Exoskeleton (ASW) Application Rating (AR)** letter for a robot model in a declared application class. It scores a **pool** of criteria — the nine sector criteria of Clause 6 (ASW-1...ASW-9, 100 points) plus the named intrinsic criteria of Clause 5, each scored once under its own standard and counted here — and expresses the earned points as a percentage of the applicable pool, which maps to a letter **C < B < A < AA < AAA (AAA best)** by the bands of VRS-GEN-006 §4. Every criterion is bounded by an evidence tier — Unverified, Verified, Certified — so the best attainable letter rises with substantiation, not assertion. This edition supersedes the re-weighted-mean model of the 0.x drafts: no weighting, no separate grade bands and no separate modifiers — the tier limits follow from the per-criterion ceilings of Clause 6. The defining condition of the sector is that **the operating environment is a person**: every failure is delivered directly to a human body, so a single fault can generate a bodily-injury claim far exceeding the unit's own value, and evidence obtained on a mannequin or outside the declared wearer population is inadmissible for a class declared for a vulnerable or dependent wearer. An Assistive & Wearable AR is an opinion above the compliance floor, not a certification, and nothing here implies that any real robot holds a Veyrum rating (ratings are not published). Requirements use “shall”; recommendations use “should”.

1 1 Scope

1.1 This Protocol defines, for the **Assistive & Wearable / Exoskeleton** sector Application Rating: the determination method (Clause 4); the contributing intrinsic criteria drawn into the pool (Clause 5); the nine sector criteria ASW-1...ASW-9 with their point ladders and tier ceilings (Clause 6); the letter bands, pool ceilings and class applicability (Clause 7); the evidence admissible at each tier (Clause 8); underwriting and credit use (Clause 9); result recording (Clause 10); and the assessor checklist (Clause 11). A worked example is at Annex A.

1.2 The AR shall be issued **per application class**. The application classes are **medical exoskeleton (regulated), industrial exoskeleton, consumer/wellness wearable robot and prosthetic/orthotic powered device**, per VRS-ASW-001 §4.3. The ASW-1 anchor differs by class; all nine sector criteria apply to all classes. Sector applicability, the wearable hazard taxonomy and the ASW anchor regime are defined in VRS-ASW-001 and are not restated here.

1.3 The AR shall be assessed at one of three **tiers** — Unverified, Verified, Certified. Each criterion states the maximum points reachable at each tier (Clause 6); the AR tier is the tier whose evidence bar the assessed evidence meets and shall not exceed the model's Intrinsic Rating tier (VRS-GEN-006 §7). The underlying point aggregation and the letter bands are defined in VRS-GEN-005/006 and are not restated here.

2 2 Normative references

- **VRS-ASW-001**, Assistive & Wearable / Exoskeleton — Sector Standard — applicability, application classes, the wearable hazard groups and the ASW anchor regime, including the clinical-evidence module for the medical class.

- **VRS-GEN-005**, Intrinsic Rating – Methodology – point aggregation, tiers and the company-wide fallback rule (§6).
- **VRS-GEN-006**, Application Rating – Scheme – the letter bands, the applicable-pool percentage and the tier rule.
- **VRS-GEN-009**, Robot Risk Passport and Registry Schema – the record that carries the AR result.
- **VRS-GEN-012**, Evidence Grades and Data Requirements – evidence kinds and the tier evidence bars.
- **VRS-GEN-101 ... VRS-GEN-107**, IR Category Standards – the intrinsic criteria contributed under Clause 5.
- **IEC 80601-2-78:2019 + AMD1:2024** and **Regulation (EU) 2017/745 (Medical Device Regulation)** – the ASW-1 anchor regime for the medical-exoskeleton class (with FDA clearance recognised as an equivalent pathway).
- **ISO 13482:2014** (with the **ISO/TR 23482-1:2020** test methods) – the ASW-1 anchor for the consumer/wellness class; **ASTM F3474-20** – the ASW-1 anchor for the industrial-exoskeleton class.
- **IEC 62133-2:2017 + AMD1:2021** – worn-cell battery-safety anchor (ASW-5).
- **IEC 62443-4-2:2019** – technical security requirements for the account/firmware/telemetry plane (ASW-7).
- **ISO 14224:2016** – collection and exchange of reliability and maintenance data for equipment (ASW-8).
- Data twin: **VRS-ASW-501** (generated from this Protocol, never hand-edited).

3 Terms and definitions

Terms per VRS-GEN-001 (aligned to ISO 8373:2021) and VRS-ASW-001. Locally:

- **pool** – the set of criteria whose points determine the AR letter: the nine sector criteria of Clause 6 together with the contributing intrinsic criteria of Clause 5.
- **applicable pool** – the pool for a given application class after criteria not applicable to that class are removed from both the earned points and the pool range (Clause 4; VRS-GEN-006 §6).
- **contributor** – an intrinsic criterion scored once under its own IR category standard and counted again in the sector pool at the same points (Clause 5).
- **tier** – the evidence stringency at which a criterion is assessed: **Unverified** (public evidence only), **Verified** (manufacturer evidence pack examined), **Certified** (behaviour witnessed).
- **ceiling** – the maximum points a criterion awards at a given tier; points earned are held at the ceiling of the assessed tier.
- **evidence bar** – the minimum evidence a criterion requires before any points are awarded; below it the criterion scores 0.
- **company-wide fallback** – the substitute points a criterion allows from manufacturer-wide evidence when model-specific evidence is unavailable (VRS-GEN-005 §6).
- **application class** – a declared category of assessed wearable device (medical exoskeleton, industrial exoskeleton, consumer/wellness wearable robot, prosthetic/orthotic powered device),

recorded as a protocol applicability field with its declared wearer population and body-region coverage.

- **doffing time** — the time, in seconds, to remove or release the device in an emergency, powered or unpowered, recorded per class as an exposure-envelope attribute.

4 Method of assessment

4.1 The Assistive & Wearable AR shall be determined as a percentage of the **applicable pool** and mapped to a letter by the bands of VRS-GEN-006 §4 (Clause 7.1). The pool is the nine sector criteria of Clause 6 (ASW-1...ASW-9, 100 points) together with the contributing intrinsic criteria of Clause 5, each scored once under its own standard and counted here at the same points. For an application class the assessor shall add the points earned across the applicable criteria and divide by the sum of the point ranges of those same criteria; a criterion not applicable to the class (Clause 6 Applicability row; VRS-GEN-006 §6) shall be removed from both the earned points and the pool range. No weighting is applied — each criterion's point range sizes its own importance — and no separate modifiers operate on the letter: the tier limits follow from the per-criterion ceilings of Clause 6 (Clause 7.2; VRS-GEN-006 §8).

4.2 Evidence shall be attributable to the declared **application classes** of the assessed envelope (at minimum one of medical exoskeleton, industrial exoskeleton, consumer/wellness wearable robot or prosthetic/orthotic powered device; Clause 1.2) and to the wearer population and body regions each class is declared for; the AR letter covers only the assessed classes and wearer populations.

4.3 Letters shall be issued **per application class** where evidence diverges materially between classes; the displayed sector letter shall be the **lowest issued class letter**. A class for which no letter can be issued shall be displayed as *not covered*, and the assessed envelope shall contract to the application classes and wearer populations the evidence actually covers rather than the score being stretched to a wearer population never tested.

4.4 Evidence obtained outside a declared application class, wearer population or body region shall be **inadmissible** as support for that class and shall not raise the score. Because every failure is delivered directly to a human body, the ASW-2 biomechanical and ASW-3 egress behaviours shall not be inferred from bench evidence on a mannequin alone where the class is declared for a vulnerable or dependent wearer population: instrumented evidence representative of the declared population is required.

5 Contributing IR criteria

5.1 The sector pool consists of the sector criteria of Clause 6 and the following intrinsic criteria, scored once under their own standards and counted again here at the same points:

IR CRITERION	SCORED UNDER
SF-1	VRS-GEN-101 §6.1
SF-2	VRS-GEN-101 §6.2
SF-3	VRS-GEN-101 §6.3
SF-6	VRS-GEN-101 §6.6
SF-8	VRS-GEN-101 §6.8
RL-2	VRS-GEN-102 §6.2
RL-5	VRS-GEN-102 §6.5
SV-1	VRS-GEN-103 §6.1
SV-6	VRS-GEN-103 §6.6
CY-2	VRS-GEN-105 §6.2
CY-6	VRS-GEN-105 §6.6
MS-1	VRS-GEN-106 §6.1
MS-6	VRS-GEN-106 §6.6
MS-7	VRS-GEN-106 §6.7
SI-1	VRS-GEN-104 §6.1
SI-2	VRS-GEN-104 §6.2
SI-6	VRS-GEN-104 §6.5

5.2 No other intrinsic criterion contributes. Points, ceilings and applicability of a contributing criterion are those of its own standard; where a contributing criterion is not applicable to the assessed application class it is removed from the pool for that class (VRS-GEN-006 §6).

6 Sector criteria

6.0 Summary. Points and tier ceilings per criterion; totals reproduce by addition.

§	CRITERION	POINTS	UNVERIFIED CEILING	VERIFIED CEILING	CERTIFIED CEILING
6.1	ASW-1 Class anchor / regulatory fit (ISO 13482 / IEC 80601-2-78 / medical clearance by class)	0–16	13	14	16
6.2	ASW-2 Joint torque, range and misalignment protection	0–14	7	11	14
6.3	ASW-3 Emergency doffing / egress and entrapment	0–12	8	10	12
6.4	ASW-4 Wearer-intent mismatch and stumble response	0–12	6	10	12
6.5	ASW-5 Body-worn power and thermal safety	0–12	10	11	12
6.6	ASW-6 Fit, adjustment and interface pressure	0–10	7	8	10
6.7	ASW-7 Wearer data (gait/health telemetry) handling	0–10	8	8	10
6.8	ASW-8 Long-term support for dependent users	0–8	7	7	8
6.9	ASW-9 Wearer incident record	0–6	4	6	6
Total		100	70	85	100

6.1 6.1 ASW-1 Class anchor / regulatory fit (ISO 13482 / IEC 80601-2-78 / medical clearance by class) (0–16)

ROW	
What is measured	.
Ladder	16 = third-party certificate or regulatory clearance + validated · 14 = pack-evidenced (documents), not demonstrated · 13 = publicly evidenced only (no pack, no demonstration) · 12 = certificate/clearance public · 8 = self-declared with reports · 4 = declared · 0 = not established
Unverified — evidence & ceiling	Certificate registers; clearance databases. Ceiling 13.
Verified — evidence & ceiling	Certificates + validation. Ceiling 14.
Certified — evidence & ceiling	— (documentary). Ceiling 16.
Company-wide fallback	n/a
Evidence bar	Class declared.
Applicability	medical exoskeleton (regulated) · industrial exoskeleton · consumer/wellness wearable robot · prosthetic/orthotic powered device. ASW-1 anchor differs by class; all criteria apply to all classes.

6.2 ASW-2 Joint torque, range and misalignment protection (0–14)

ROW	
What is measured	Torque/range limits per joint; misalignment tolerance; fault → compliant/free mode.
Ladder	14 = witnessed on test rig · 11 = pack-evidenced (documents), not demonstrated · 10 = certified with published data · 7 = validation report · 4 = documented · 0 = not established
Unverified — evidence & ceiling	Datasheet; certificates. Ceiling 7.
Verified — evidence & ceiling	Validation reports. Ceiling 11.
Certified — evidence & ceiling	Witnessed on a test rig with torque readings; fault injection → compliant mode. Ceiling 14.
Company-wide fallback	n/a
Evidence bar	Limits declared.
Applicability	medical exoskeleton (regulated) · industrial exoskeleton · consumer/wellness wearable robot · prosthetic/orthotic powered device. ASW-1 anchor differs by class; all criteria apply to all classes.

6.3 ASW-3 Emergency doffing / egress and entrapment (0–12)

ROW	
What is measured	Wearer can release/exit within declared time, powered or unpowered; no entrapment on power loss.
Ladder	12 = witnessed (demonstrator, device unpowered where powered test is a hazard) · 10 = pack-evidenced (documents), not demonstrated · 9 = validated · 8 = publicly evidenced only (no pack, no demonstration) · 5 = documented · 0 = not established
Unverified — evidence & ceiling	Manual; tests. Ceiling 8.
Verified — evidence & ceiling	Validation evidence. Ceiling 10.
Certified — evidence & ceiling	Witnessed timed doffing; power-cut behaviour on rig. Ceiling 12.
Company-wide fallback	n/a
Evidence bar	Egress time declared.
Applicability	medical exoskeleton (regulated) · industrial exoskeleton · consumer/wellness wearable robot · prosthetic/orthotic powered device. ASW-1 anchor differs by class; all criteria apply to all classes.

6.4 ASW-4 Wearer-intent mismatch and stumble response (0–12)

ROW	
What is measured	Behaviour against unintended motion (spasticity, stumble): declared safe response every time.
Ladder	12 = witnessed on rig/simulator · 10 = pack-evidenced (documents), not demonstrated · 8 = validated · 6 = publicly evidenced only (no pack, no demonstration) · 5 = documented · 0 = not established
Unverified — evidence & ceiling	Published studies; manual. Ceiling 6.
Verified — evidence & ceiling	Validation evidence. Ceiling 10.
Certified — evidence & ceiling	Witnessed on rig with perturbation inputs. Ceiling 12.
Company-wide fallback	n/a
Evidence bar	Responses declared.
Applicability	medical exoskeleton (regulated) · industrial exoskeleton · consumer/wellness wearable robot · prosthetic/orthotic powered device. ASW-1 anchor differs by class; all criteria apply to all classes.

6.5 6.5 ASW-5 Body-worn power and thermal safety (0–12)

ROW	
What is measured	Battery certification (IEC 62133), skin-temperature limits, actuator runaway/lock protections.
Ladder	12 = certificates + witnessed limits · 11 = pack-evidenced (documents), not demonstrated · 10 = certificates public · 6 = documented · 0 = not established
Unverified — evidence & ceiling	Public certificates. Ceiling 10.
Verified — evidence & ceiling	Certificates + test reports. Ceiling 11.
Certified — evidence & ceiling	Witnessed thermal cut-off and lock/runaway protection on rig. Ceiling 12.
Company-wide fallback	n/a
Evidence bar	Battery and thermal limits declared.
Applicability	medical exoskeleton (regulated) · industrial exoskeleton · consumer/wellness wearable robot · prosthetic/orthotic powered device. ASW-1 anchor differs by class; all criteria apply to all classes.

6.6 ASW-6 Fit, adjustment and interface pressure (0–10)

ROW	
What is measured	Fitting range, pressure-injury mitigation, fitter training.
Ladder	10 = witnessed fitting protocol + training · 8 = documented in detail · 7 = publicly evidenced only (no pack, no demonstration) · 4 = documented · 0 = not established
Unverified — evidence & ceiling	Manual; training materials. Ceiling 7.
Verified — evidence & ceiling	Fitting protocol + training package. Ceiling 8.
Certified — evidence & ceiling	Witnessed fitting protocol on demonstrator (unpowered where needed). Ceiling 10.
Company-wide fallback	n/a
Evidence bar	None.
Applicability	medical exoskeleton (regulated) · industrial exoskeleton · consumer/wellness wearable robot · prosthetic/orthotic powered device. ASW-1 anchor differs by class; all criteria apply to all classes.

6.7 6.7 ASW-7 Wearer data (gait/health telemetry) handling (0–10)

ROW	
What is measured	Health-adjacent data handling, consent, retention, account security.
Ladder	10 = shown + audit · 8 = documented in detail · 5 = partial · 0 = not established
Unverified — evidence & ceiling	Privacy notice; security page. Ceiling 8.
Verified — evidence & ceiling	Data-handling description. Ceiling 8.
Certified — evidence & ceiling	App shows capture/destinations; account controls. Ceiling 10.
Company-wide fallback	n/a
Evidence bar	None.
Applicability	medical exoskeleton (regulated) · industrial exoskeleton · consumer/wellness wearable robot · prosthetic/orthotic powered device. ASW-1 anchor differs by class; all criteria apply to all classes.

6.8 6.8 ASW-8 Long-term support for dependent users (0–8)

ROW	
What is measured	Support horizon, loaner/repair turnaround for dependent wearers, consumables.
Ladder	8 = commitments + record · 7 = evidenced by documents alone (public or pack), not demonstrated · 6 = commitments public · 3 = described · 0 = not established
Unverified — evidence & ceiling	Public support terms. Ceiling 7.
Verified — evidence & ceiling	Commitments + record. Ceiling 7.
Certified — evidence & ceiling	From Verified evidence. Ceiling 8.
Company-wide fallback	Company-wide → 6
Evidence bar	None.
Applicability	medical exoskeleton (regulated) · industrial exoskeleton · consumer/wellness wearable robot · prosthetic/orthotic powered device. ASW-1 anchor differs by class; all criteria apply to all classes.

6.9 ASW-9 Wearer incident record (0–6)

ROW	
What is measured	Incidents/adverse events over the window (MAUDE for medical class — regime-full).
Ladder	6 = none (model) · 5 = company-wide record in place of model-specific data · 4 = null-result rung · 3 = remediated · 0 = not established
Unverified — evidence & ceiling	MAUDE (medical class); press. Ceiling 4.
Verified — evidence & ceiling	Register + exposure. Ceiling 6.
Certified — evidence & ceiling	From Verified evidence. Ceiling 6.
Company-wide fallback	Company-wide → 5
Evidence bar	None.
Applicability	medical exoskeleton (regulated) · industrial exoskeleton · consumer/wellness wearable robot · prosthetic/orthotic powered device. ASW-1 anchor differs by class; all criteria apply to all classes.

7 Letter bands, tier ceilings and class applicability

7.1 Bands (VRS-GEN-006 §4). AAA ≥ 90 % · AA ≥ 75 % · A ≥ 60 % · B ≥ 45 % · C below 45 % of the applicable pool.

7.2 Pool ceilings. Sector criteria alone: Unverified 70/100 (70 %) · Verified 85/100 (85 %) · Certified 100. With the contributing criteria of Clause 5 the pool ceilings are as recorded in VRS-ASW-501; in both forms the best attainable letter is A at Unverified, AA at Verified and AAA at Certified (VRS-GEN-006 §8).

7.3 Application classes. medical exoskeleton (regulated) · industrial exoskeleton · consumer/wellness wearable robot · prosthetic/orthotic powered device. ASW-1 anchor differs by class; all criteria apply to all classes... A criterion whose Applicability row excludes the assessed class is removed from both the numerator and the denominator; the letter is issued per class and the displayed letter is the lowest (Clause 4).

7.4 No modifiers, caps or gates operate on the letter other than the ceilings of Clause 6 and the tier rule of VRS-GEN-006 §7.

7.5 Anchor and admissibility rules (formerly the §7 modifiers). The re-anchoring below states where each former §7 modifier of the 0.x draft now lives, so a reader of the old text finds the new home:

- *Medical class — regulatory clearance (formerly §7.1).* For a medical-exoskeleton class the ASW-1 anchor is regulatory clearance under medical-device law (IEC 80601-2-78:2019+AMD1:2024 within an EU MDR or FDA pathway, or a recorded jurisdictional equivalent). Absence of evidenced clearance scores the ASW-1 not-established rung (0) for that class (§6.1); the model is still rated and the absence recorded (§9.1) — not a gate on the letter.
- *Non-medical class — anchor conformity (formerly §7.2).* The ASW-1 anchor is ISO 13482:2014 (with the ISO/TR 23482-1:2020 test methods) for the consumer/wellness class and ASTM F3474-20 for the industrial class; absence of evidenced conformity scores the ASW-1 low rung for that class (§6.1), not a separate cap.
- *Wearer-recollection evidence (formerly §7.3).* Evidence for ASW-2 or ASW-3 resting on wearer recollection rather than instrumented biomechanical or doffing-time evidence shall not be admitted (Clause 8.4; §4.4): wearer recollection of a biomechanical event is unreliable, instrumented logs are not.

8 Evidence by tier

8.1 Unverified. The assessor works only from evidence obtainable without the manufacturer's cooperation: datasheets, manuals and public safety documentation; the certificate registers and regulatory-clearance databases (ASW-1); published joint-limit, misalignment, battery/thermal, doffing and stumble-response data (ASW-2...ASW-5); public fitting, training, privacy and support documentation (ASW-6, ASW-7, ASW-8); and — for the wearer-incident criterion (ASW-9) — the MAUDE adverse-event database for the medical class and press. Each criterion's Unverified ceiling (Clause 6) is the most an honest reading of such evidence shall earn; the AR tier is **Unverified**.

8.2 Verified. The assessor additionally examines a manufacturer evidence pack and shall accept, by mapping, the conformity artefacts the manufacturer already holds — adoption is a mapping, not new testing: the class certificate or regulatory clearance and its validation, by class (IEC 80601-2-78:2019 test file and the cleared EU MDR/FDA pathway for the medical class; ISO 13482:2014 with ISO/TR 23482-1:2020 for the consumer/wellness class; ASTM F3474-20 for the industrial class) (ASW-1); the joint-torque, range, misalignment, doffing and stumble-response validation reports (ASW-2, ASW-3, ASW-4); the IEC 62133-2:2017 worn-cell and skin-temperature reports with the actuator runaway/lock analysis (ASW-5); the fitting protocol and training package (ASW-6); the data-handling description and the IEC 62443-4-2:2019 evaluation of the account/firmware/telemetry plane (ASW-7); the ISO 14224:2016 support and maintenance record (ASW-8); and the wearer-incident register with its exposure basis (ASW-9). Verified ceilings apply only to criteria whose pack items are present and examined; the AR tier is **Verified**.

8.3 Certified. The assessor witnesses the declared behaviour on the robot or a representative demonstrator (unpowered where a powered test on a wearer would be a hazard): the joint-torque test with fault injection to the compliant mode (ASW-2); a timed emergency doffing and the power-cut behaviour on a rig (ASW-3); the stumble/perturbation response on a rig or simulator (ASW-4); the thermal cut-off and lock/runaway protection on a rig (ASW-5); the fitting protocol on a demonstrator (ASW-6); and the data capture/destinations and account controls shown in the app (ASW-7). The documentary criteria (ASW-1, ASW-8, ASW-9) carry their Certified points from the Verified evidence. The AR tier is **Certified**.

8.4 Evidence bar. Each criterion states an **evidence bar** (Clause 6). Where the bar is not met the criterion shall score **0** — no evidence is 0 points, never a discard from the pool. A manufacturer self-declaration shall not earn points above the rung its independent corroboration (certificate, clearance, test report) supports. Evidence not attributable to a declared application class, wearer population or body region (Clause 4.2) shall be inadmissible for that class; ASW-2 biomechanical and ASW-3 egress behaviour shall not be inferred from a mannequin alone for a vulnerable or dependent wearer population (Clause 4.4), and wearer-recollection-only ASW-2/ASW-3 evidence shall not be admitted (Clause 7.5).

8.5 Null-result rule. For ASW-9 a recorded search of the MAUDE adverse-event database (medical class) and the press, with its coverage and exposure basis stated, shall earn the criterion's null-result rung where no adverse record is found; an unrecorded search shall not.

8.6 Company-wide fallback. Where a criterion offers a company-wide fallback (ASW-8, ASW-9) and model-specific evidence is unavailable, manufacturer-wide records shall earn the stated fallback points (VRS-GEN-005 §6); the substitution shall be recorded per Clause 10.

8.7 AR tier. The AR tier is the lowest tier among the criteria that determined the letter, and shall not exceed the model's Intrinsic Rating tier (VRS-GEN-006 §7).

9 Underwriting and credit use

9.1 The letter is an opinion above the compliance floor, not a certification, and shall not be published or imply that any real robot holds a Veyrum rating. Regulatory clearance or anchor conformity for a class is scored by ASW-1 (§6.1): where evidenced clearance or conformity is absent, ASW-1 scores its not-established rung and the model is still rated, with the absence recorded on the result — it is not a gate on the letter. **A rating is an opinion on the robot, not on the lawfulness of any deployment.**

9.2 The per-class letters and the recorded wearer populations are the underwriting hooks: the letter informs rate relativity, and the covered application classes and wearer populations inform coverage scope, so that use outside the assessed envelope is an exclusion or a condition rather than an implied covered risk. Loss drivers shall be surfaced separately so an underwriter can weigh them independently of the letter: the **on-body bodily-injury severity driver** (ASW-2 joint over-torque and misalignment loading, ASW-3 egress failure and entrapment, ASW-5 worn-battery and skin-thermal events — the operating environment is a person, so a single failure can generate a bodily-injury claim far exceeding the unit's own value, surfaced with the declared wearer population, including any vulnerable or dependent population, rather than averaged into frequency); and the **correlated cyber driver** (ASW-7 — where many devices share one account, firmware or telemetry plane, one intrusion event can expose health-adjacent gait/telemetry data across the fleet at once, so the per-fleet accumulation attribute records whether that plane holds an IEC 62443-4-2:2019 evaluation).

9.3 For credit, the reliability, recoverability and support drivers shall be readable from the recorded per-criterion points to inform LTV, residual curves and end-of-support assumptions: ASW-8 governs the support horizon and obsolescence assumption — acute for a device a dependent wearer relies on daily — while the intrinsic reliability, serviceability and support criteria drawn into the pool (Clause 5, the RL, SV and MS contributors) inform the residual curve.

10 Result recording

The rating record shall carry, per VRS-GEN-009: the displayed sector letter and the per-class letters with the wearer population each was issued for; the **per-criterion points** earned across the sector criteria (Clause 6) and the contributing intrinsic criteria (Clause 5); the **not-applicable set** removed for each class and the resulting applicable-pool range; the contributing intrinsic criteria used; the AR **tier**; the **edition** (VRS 2026); the VRS-ASW-501 data-twin version; the class certificates or regulatory clearances relied on and the declared wearer population; the emergency doffing time in seconds; and the on-body bodily-injury and correlated-cyber attributes (Clause 9.2). For a medical class the regulatory pathway identifier and the MAUDE adverse-event registry-search record shall be retained. Recording flows to the Passport per VRS-GEN-009; no personal information shall be stored (VRS-GEN-012 §5.2), and gait/health telemetry shall be de-identified.

11 Assessor checklist

An assessor with this Protocol and the evidence shall reach the same result by executing the following in order; no step admits an unrecorded judgement call, and any deviation shall be recorded with its basis:

- [] Application class(es) confirmed (medical / industrial / consumer-wellness / prosthetic-orthotic) with each wearer population and body-region coverage (Clause 1.2; VRS-ASW-001 §4.3).
- [] Assessment tier fixed (Clause 8); the not-applicable set recorded per class and the applicable-pool range computed (Clause 4).
- [] Contributing intrinsic criteria drawn from their source standards at their own points and tiers (Clause 5).
- [] **ASW-1** class anchor / regulatory fit scored per class (medical clearance, ISO 13482 or ASTM F3474-20); absence scores the not-established rung, the model still rated (Clause 7.5; §9.1); class declared (evidence bar).
- [] **ASW-2** joint torque, range and misalignment protection scored; limits declared (evidence bar); not inferred from a mannequin for a vulnerable population (Clause 4.4).
- [] **ASW-3** emergency doffing / egress and entrapment scored; egress time declared (evidence bar); recollection-only evidence refused (Clause 7.5).
- [] **ASW-4** wearer-intent mismatch and stumble response scored; responses declared (evidence bar).
- [] **ASW-5** body-worn power and thermal safety scored; battery and thermal limits declared (evidence bar).
- [] **ASW-6** fit, adjustment and interface pressure scored.
- [] **ASW-7** wearer data handling scored; the correlated-cyber accumulation attribute recorded (Clause 9.2).
- [] **ASW-8** long-term support for dependent users scored; company-wide fallback recorded if used.
- [] **ASW-9** wearer incident record scored; null-result search applied per Clause 8.5; company-wide fallback recorded if used.
- [] Points added and divided by the applicable-pool range; letter read from the bands (Clause 7.1).
- [] Letters issued per class; the lowest displayed (Clause 4.3); each award held at its assessed-tier ceiling (Clause 6).

- [] Result recorded to the passport: per-criterion points, not-applicable set, contributors, tier, edition, twin version, clearances relied on and the loss-driver attributes of Clause 9.2 (Clause 10).

12 Annex A (informative) — Worked example

FICTIONAL EXAMPLE — not a real product; illustrates mechanics only.

A fictional powered lower-limb rehabilitation exoskeleton, model code **ASW-RX-01** , is assessed for the **medical exoskeleton (regulated)** application class, declared for a wearer population of adult post-stroke gait-rehabilitation patients under clinician supervision, at the **Verified** tier: a manufacturer evidence pack is examined and no behaviour is witnessed. The manufacturer holds an IEC 80601-2-78:2019+AMD1:2024 essential-performance test file within a cleared EU MDR (Regulation (EU) 2017/745) pathway, joint-torque and misalignment validation reports, an emergency-doffing validation report (unpowered doffing time 9 seconds), IEC 62133-2:2017 worn-cell and skin-temperature reports, a fitting protocol and training package, an IEC 62443-4-2:2019 evaluation of its telemetry plane, ISO 14224:2016 support records, and a wearer-incident register with its exposure basis. All nine sector criteria apply, and the seventeen contributing intrinsic criteria of Clause 5 are drawn from their source standards at their own Verified points.

Sector criteria (Verified tier).

§	CRITERION	VERIFIED CEILING	POINTS EARNED
6.1	ASW-1	14	14
6.2	ASW-2	11	10
6.3	ASW-3	10	9
6.4	ASW-4	10	8
6.5	ASW-5	11	11
6.6	ASW-6	8	7
6.7	ASW-7	8	8
6.8	ASW-8	7	6
6.9	ASW-9	6	6
Sector subtotal		85	79

Contributing intrinsic criteria (Verified tier). Drawn at their own points, the seventeen criteria of Clause 5 have a combined range of **145 points** and a combined Verified ceiling of **118**; this model earns **106** of

them, each at or below its Verified ceiling (for example SI-2 at 17 of its 19-point Verified ceiling and SF-8 at 9 of 10).

Letter. The applicable pool for the medical class is the sector range 100 plus the contributor range 145 = **245 points**. Points earned = 79 (sector) + 106 (contributors) = **185**. As a percentage of the pool, $185 \div 245 = 75.5\%$, which falls in the **AA** band ($\geq 75\%$, below AAA's 90 %). The result is **Assistive & Wearable AR: AA (VRS 2026) – Verified**.

Tier ceiling by construction. At the Verified tier the pool's own ceiling is $(85 + 118) \div 245 = 203 \div 245 = 82.9\%$, so AA is the best letter attainable without a witnessed demonstration (Clause 7.2); AAA would require Certified-tier evidence such as a witnessed joint-torque fault-injection test (ASW-2) and a witnessed timed doffing (ASW-3). No separate modifier is applied – the ceiling does the work.

Refusal variant. Had **ASW-RX-01** lacked a cleared medical-device pathway, ASW-1 would score its not-established rung (0) rather than 14 (Clause 7.5); the letter would fall out of the reduced total, the model would still be rated, and the missing clearance would be recorded on the result (§9.1) – a rating is an opinion on the robot, not on the lawfulness of any deployment. Had the ASW-2/ASW-3 case rested only on wearer recollection rather than instrumented evidence, that evidence would be refused (Clause 7.5/8.4) and those criteria would score at or below their declared-only rungs. Numbers illustrate mechanics only.

13 Bibliography

The full ASW anchor regime is verified in VRS-ASW-001; the following are the specific anchors this Protocol's criteria and evidence tiers (Clauses 6 and 8) rest on, dated at point of use (re-verified 2026-09-16):

- IEC 80601-2-78:2019 + AMD1:2024 – Medical electrical equipment – Part 2-78: medical robots for rehabilitation, assessment, compensation or alleviation (webstore.iec.ch/en/publication/69618; FDA recognised) – ASW-1 medical-class anchor; its exclusion list defines the sector boundary (prosthetics → ISO 22523; wheelchairs → ISO 7176; personal-care robots → ISO 13482).
- ISO 13482:2014 – Robots and robotic devices – Safety requirements for personal care robots (iso.org/standard/53820.html); under revision as ISO/DIS 13482, retitled *Robotics – Safety requirements for service robots* (iso.org/standard/83498.html, 2024 draft) – ASW-1 consumer/wellness-class anchor; re-date when it publishes.
- ISO/TR 23482-1:2020 (safety-related test methods; wearable-robot tests in scope) and ISO/TR 23482-2:2019 (application guidelines) (iso.org/standard/71564.html, [71627.html](https://iso.org/standard/71627.html)) – informative test-method companions to ISO 13482 (ASW-2 test source).
- ASTM F3474-20 – Standard Practice for Establishing Exoskeleton Functional Ergonomic Parameters and Test Metrics (ASTM F48 committee); ASTM F3358-20 (labeling and information for exoskeletons) (astm.org) – ASW-1 industrial/occupational-class anchor.
- Regulation (EU) 2017/745 (Medical Device Regulation) – of 5 April 2017, date of application 26 May 2021 (eur-lex.europa.eu/eli/reg/2017/745) – ASW-1 medical-class market law alongside FDA recognition.
- IEC 62133-2:2017 + AMD1:2021 – Secondary cells and batteries containing alkaline or other non-acid electrolytes – safety requirements for portable sealed secondary lithium cells and batteries

(webstore.iec.ch/en/publication/60049) – ASW-5 worn-cell battery-safety anchor.

- IEC 62443-4-2:2019 (edition 1.0; COR1:2022) – technical security requirements for IACS components (SL-C against FR1–FR7) (webstore.iec.ch/publication/34421) – ASW-7 wearer-data/telemetry anchor.
- ISO 14224:2016 – Collection and exchange of reliability and maintenance data for equipment (iso.org/standard/64076.html) – ASW-8 support and maintenance anchor.
- ISO 8373:2021 – Robotics – Vocabulary (iso.org/standard/75539.html) – robot-term basis.
- VRS-ASW-501 – machine-readable data twin of this Protocol (Clause 5/6/7 values).

14 Change history

DATE	VERSION	STATUS	CHANGE	AUTHORITY
2026-09-16	1.0.0	Draft	VRS 2026 rewrite: criterion tables, tier ceilings, retired forms removed; see GEN-005 §6. Replaced the re-weighted-mean scoring (Clauses 4–8) with a point-summed pool — nine sector criteria ASW-1...ASW-9 (100 points; Clause 6) plus the named contributing intrinsic criteria (Clause 5), expressed as a percentage of the applicable pool and mapped to a letter by VRS-GEN-006 §4; added per-criterion tier ceilings, Clause 7 (bands/pool-ceilings/class-applicability), evidence-by-tier (Clause 8), a Verified-tier worked example (Annex A) and a per-criterion checklist (Clause 11); adopted the four application classes, ASW-1 anchor differing by class. Re-anchored the former §7 modifiers (§7.5): 7.1 medical no-clearance → ASW-1 rung 0, robot still rated (§6.1/§9.1); 7.2 non-medical conformity → ASW-1 low rung; 7.3 recollection-inadmissible → §7.5/§8.4. Added the §9.1 lawfulness sentence (CEO-approved 2026-09-15). Dropped the wearer-hours denominators and AIS/MAIS severity-scoring from procedures (surfaced qualitatively in §9.2); retired confidence/provisional/renormalisation/weighted-mean/assessed-unrated/stage-prior forms and the GEN-201/GEN-202 references. VRS-ASW-501 regenerated by the dispatcher from Clauses 5–7.	VRS 2026 rewrite Stage 4
2026-09-14	0.3.0	Draft	ACTUARIAL: insurance/finance fitness review (5 questions/quantity). Closed two gaps. Q2 severity denominator: added §8.1.1 on-body injury-severity measure — each admissible C1/C3 event coded on the Abbreviated Injury Scale (AIS 2015, AAAM), MAIS3+ serious threshold, recorded as a per-event severity distribution per class, not netted into the wearer-hours frequency rate (mirrors VRS-TRN-201 §8.1.1, reconciled scale); surfaced in §9.2; C1 evidence lane (§8.2) and worked example (Annex A) updated; Bibliography +AIS 2015 anchor (verified 2026-09-14). Q4 computability: §10 now resolves each frequency input to the VRS-GEN-012 §5 evidence-record fields; fixed stale exposure cross-ref §8.1 VRS-GEN-012 §4.1→§7 (GEN-012 renumber, Run #101). Checklist step 9 records the distribution. No weight, band or sufficiency-constant value changed. Twin VRS-ASW-501 re-pointed to 0.3.0 (payload unchanged). GEN-009 AR-recording design-question thread updated (class-typed severity-	Curator Run #132; charter ACTUARIAL

DATE	VERSION	STATUS	CHANGE	AUTHORITY
			distribution field). Net +≈480 words; shall 51→57. No requirements deleted.	
2026-09-13	0.2.0	Draft	DEEPEN: brought to publishable depth on the VRS-SVC-201 v0.2.0 exemplar. Added wearer-hours exposure denominator (§8.1), evidence-lane conformity-artefact reuse (§8.2, dated anchors re-verified 2026-09-13), per-criterion loss-driver mapping incl. on-body severity and emergency-doffing drivers (§5.2), admissibility/refusal gates (§4.3/§4.4/§7/§8.4), underwriting/credit use (§9, GEN-009), passport recording (§10), assessor checklist (§11), worked example producing a medical-class letter with industrial and refusal variants (Annex A), Bibliography with dated anchors. Retired all bare CALIBRATION-PENDING markers → stage prior labels (VRS-GEN-202). No weight, band or sufficiency-constant value changed. Twin VRS-ASW-501 regenerated to 0.2.0 (payload unchanged). Net +≈2,830 words; shall 1→51. No requirements deleted.	Curator Run #89; charter DEEPEN
2026-09-05	0.1.0	Draft	Initial draft — wearer-hour denominators; recollection-inadmissible rule; completes the 11 active sector families	CEO goal 2026-09-05

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