ZKK CONSULTING

Wrist-Worn Automatic Fall Detection

Market, Competitive, Patent and Commercial Analysis – United States

Prepared for **[REDACTED]**

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This document is a sample deliverable produced from ZKK Consulting's own internal hardware program, **[REDACTED]**, so that prospective clients can see the actual shape and depth of our work rather than a redacted excerpt. The market, competitive, patent and regulatory research is real and every figure is sourced. The commercial model is built on the same real inputs, with four unmeasured drivers explicitly marked as placeholders, because that is what an honest model looks like at this stage of a product and pretending otherwise would misrepresent both the method and the result.

Section 1 – Executive Summary

The purpose and contents of this paper

1.1 Executive Summary

The category is small, flat, and about to be squeezed. Standalone fall-detection systems worldwide are sized by three separate research firms at somewhere between $469.5m and $684.6m for 2025: a 46% disagreement on level in the same base year, and a six-fold disagreement on where it lands by 2035. Meanwhile medical-alert penetration among US adults 65+ has sat at 9% for three years, unchanged between 2023 and 2026. The addressable population is growing; the rate of adoption is not.

Apple has already won the segment that was supposed to be the growth engine. Among the 9% of adults 65+ who use a medical alert device at all, Apple Watch is the single most-used brand, ahead of Life Alert, LifeFone, LifeStation and Lively. Apple charges $249–$799 once, with no monitoring subscription, and enables fall detection by default for users aged 55 and over. The monitored wrist devices in §5.6 cost $199–$299 up front plus $611–$779 a year with fall detection enabled. Over three years that is $2,033–$2,637 against $249–$799, before allowing for the cellular service and existing iPhone an Apple Watch assumes.

But the incumbents have not lost, because the category's binding constraint is not price. Among the 91% who do not own a device, the top three objections are "I don't have any health concerns" (49%), "I live with others" (36%), and "I don't feel old enough" (32%). Cost ranks fourth, at 23%. This is a positioning problem wearing a pricing problem's clothes.

The most valuable finding in this report is a compliance failure, not a market number. Only 18% of owners always wear the device. 64% take it off to shower or bathe, the single highest-risk activity in the home, and 39% do not wear it while sleeping. The product is precisely where the risk

concentrates. That is the clearest product-shaped opening in the category, and it favors a waterproof wrist form factor over a pendant. It is also the one thing no amount of algorithm work fixes.

The wrist form factor carries a real, documented penalty. Both NCOA and SeniorLiving.org state that wrist-worn fall detection is less accurate than neck- or belt-worn placement, because normal arm movement generates false positives. Simulated hands-on testing by two affiliate publishers in 2026 recorded results ranging from a complete failure to trigger (UnaliWear Kanega) to 9 of 10 (Medical Guardian MGMove); simulated results consistently overstate real-world performance. The canonical peer-reviewed evaluation against real-world falls, not simulated ones, found mean sensitivity of 57.0% across thirteen published algorithms, with false alarms ranging from 3 to 85 per 24 hours. Roughly half of current owners report having had a false alarm, and only about half are satisfied with fall-detection accuracy.

The patent position is the most acute near-term risk, and it is live right now. On 7 January 2026 the US International Trade Commission instituted Investigation No. 337-TA-1477, "Certain Wearable Devices With Fall Detection and Components Thereof." UnaliWear, an Austin company with a $299 wrist product, is asserting two patents against Apple, Samsung, Google and Garmin simultaneously, seeking an import ban and cease-and-desist orders. This is the first fall-detection-specific patent war in wearables, and it means the feature has crossed from "capability" to "contested property." A new entrant would be entering a category whose incumbents are currently in front of the ITC over the exact function it intends to ship.

The regulatory position is unsettled in a way that is quietly consequential. We searched the FDA's January 2026 General Wellness guidance directly: the words "fall," "fall detection," "emergency" and "alert" do not appear in

it. FDA has neither blessed automatic fall detection as general wellness nor claimed it as a device. We found zero 510(k) clearances for any wrist-worn consumer fall-detection product – Apple, ADT, Bay Alarm and Medical Guardian all market the feature without one. There is a strategic fork here that most business plans miss: HHS requires an FDA-defined medical device for remote-patient-monitoring billing, so a product deliberately positioned outside FDA regulation is thereby disqualified from RPM reimbursement. You cannot have both.

Reviewing the client's own design log produced the finding we would most want a client to hear. The V3 board upgraded the inertial sensor from the ST LSM6DSOXTR to the LSM6DSV16XTR at an extra $3.28 per unit, and the design log records one of the four reasons as "2x Decision Trees from 12 to 24." ST's own application notes say the opposite. AN5259: the LSM6DSOX runs "up to 8 decision trees." AN5804: the LSM6DSV16X runs "up to 4." The node budget halves too, from 256 to 128. Neither the figure 12 nor 24 appears in either document. On ST's published specifications the upgrade halves the on-sensor classification capacity it was partly chosen to increase, while more than doubling the part cost. The other three reasons for the swap (stock, power, pin compatibility) stand on their own; this one does not, and a design decision resting on it should be revisited before V4.

On the client's own cost work, the headline number needs a footnote. The sourcing migration from distributor catalogue to assembler-native supply took the bill of materials from $18.73 to $5.39 at quantity one – a 71.2% reduction, and that is real. But the two bills of materials are not like-for-like: the later one omits the battery, which the earlier one includes at $5.95, and the V3 board adds three parts and a more expensive sensor. Rebuilt on a like-for-like basis at quantity 1,000, the saving is 5.5%, not 71%. Both numbers are correct; only the pair is honest, and this report uses the pair.

The model says the business is either very good or not viable, and four numbers decide which. At the base case the plan reaches 55,565 subscribers and $25.1m revenue in FY2031, with $8.3m EBITDA and a peak cash requirement under $300k. Move customer acquisition cost, churn, monitoring cost and assembly cost to reasonable downside values and the same subscriber plan produces -$555k of EBITDA in FY2031 and a $4.2m peak cash requirement – a fifteen-fold swing in funding need on an almost unchanged top line. None of those four inputs could be sourced from public data. Three of them can be resolved with vendor quotes inside a fortnight. Churn cannot; it requires a real cohort and real time.

1.2 What this engagement maps to

Engagement Scope as Delivered

Component	Package Line	List Price
Sections 2–6, 10–13	Enterprise – TAM/SAM/SOM, deeper commercial and competitive analysis, go-to-market and pricing, editable five-year model, scenario framing	$3,499
Section 5.6	Included add-on – Competitor Matrix	(included)
Section 9	Included add-on – Supply & Vendor Snapshot	(included)
Section 7	Patent Landscape Analysis, standalone	$1,349
	Total as scoped	$4,848

Section 8 (regulatory and reimbursement) would normally be scoped as **Specialized Industry or Regulatory Research**, from $499. It is included here in full so the sample shows the range. Document formatting is available at $249 for the first 100 pages.

Companion file: [REDACTED] Five-Year Commercial Model.xlsx – seven tabs, every driver editable, every external figure sourced on its own tab.

1.3 Table of Contents

Section 2 – Market definition

What is in scope, what is excluded, and the two-sided structure of the category

2.1 What we are sizing, and what we are not

"Fall detection" is used loosely enough in published research that three firms sizing the same named category in the same base year disagree by 46%. Before any number is useful, the boundary has to be drawn explicitly.

In scope: body-worn devices sold to or for consumers in the United States that detect a fall automatically, without user action, and initiate an alert to a monitoring center, an emergency service, or a designated contact.

Out of scope, and why it matters:

Table 1 – Scope Exclusions and Why They Matter

Excluded	Why
Manual-only PERS (button-press pendants with no automatic detection)	Different product. Life Alert, the category's most recognized brand, offers no automatic fall detection on any device. That is itself a finding about how loosely the category is described.
Ambient / in-home sensing (Vayyar Care radar, camera systems, bed-exit alarms)	Solves the same problem by a different mechanism and, importantly, solves the non-wear problem the wearable category cannot. Treated in §5.5 as a substitute threat, not a comparable.
Institutional nurse-call and hospital fall-prevention	B2B, procured on entirely different terms. Part of why analyst estimates diverge – Mordor puts hospitals and clinics at 61.55% of PERS end users while Grand View and Market.us put home-based at 50–59%. Those cannot both be true of the same market.
Fall-injury prevention hardware (hip-airbag belts)	A treatment claim, not a notification claim, and regulated accordingly – the Tango Belt required a De Novo authorization. See §8.1.6.
General-purpose smartwatches in the revenue base	Excluded from our market sizing, but treated as the primary competitive threat throughout. This exclusion is

	the single largest reason published estimates diverge – see §4.4.

2.2 The two-sided structure of the category

The category has a bifurcation that most sizing exercises collapse and should not:

The dedicated PERS stack sells a device at $80–$300 and a monitoring subscription at $25–$85 a month, routes alerts to a staffed monitoring center that can cancel a false alarm before emergency services are dispatched, and reaches the customer through direct response advertising, Medicare Advantage supplemental-benefit administrators, Medicaid waiver programs, and – in Lively's case alone – national retail.

The consumer smartwatch stack sells a device at $249–$799 with no recurring monitoring revenue, dials 911 directly with no human in the loop, and reaches the customer through Apple, Samsung and Google's existing distribution.

These are not tiers of one market. They have different unit economics, different failure modes, different regulatory postures, and largely different buyers. A device that sits between them – wrist form factor, monitoring center, subscription – is the position **[REDACTED]** was designed into, and it is the position UnaliWear's Kanega already occupies at $299 plus $64.95 a month.

Section 3 – Demand drivers and headwinds

Fall incidence and cost, the age gradient, and the adoption and compliance headwinds

3.1 The clinical case is strong and getting stronger

Table 2 – U.S. Older-Adult Fall Incidence and Cost

Metric	Figure	Period	Source
Adults 65+ who fall each year	More than 1 in 4 – over 14 million	reviewed Jan 2026	CDC
Fall injuries requiring treatment or restricting activity	~9 million; 37% of those who fell reported such an injury	2020–2021	CDC
Emergency department visits from older-adult falls	~3 million annually	2021	CDC / NCOA
Fall-related hospitalizations	~1 million annually	current	CDC
Unintentional fall deaths, 65+	41,400; rate 69.9 per 100,000	2023	NCHS Data Brief 532
Age-adjusted fall death rate	78.4 per 100,000, up 21% from 64.7 in 2018	2024	CDC
Healthcare spending, non-fatal falls	$80 billion ($53.3bn Medicare)	2020	Haddad et al., Injury Prevention
Projected total	$101 billion	2030	NCOA citing CDC

A caution on the two rate figures. The 69.9 per 100,000 is a crude rate for 2023; the 78.4 is an age-adjusted rate for 2024. They are different measures for different years and must not be drawn as a trend line. We have seen this pair presented as one in marketing material.

A caution on the $80bn figure. We could not retrieve the Haddad et al. primary paper directly – both PubMed and PMC returned CAPTCHA walls. Two independent secondary sources reproduce the figure and its payer split consistently. Verify against the primary paper (PMID 39029927) before it appears in an investor document.

3.2 The age gradient is the real story

Fall death rates by age band, 2023, per 100,000 (NCHS Data Brief 532):

Table 3 – Fall Death Rates by Age Band, 2023 (per 100,000)

Age	Total	Men	Women
65–74	19.2	24.7	14.2
75–84	74.7	89.6	62.8
85+	339.5	373.3	319.7

The 85+ cohort dies from falls at 17.7 times the rate of the 65–74 cohort. And the 85+ population is projected to grow from 6.5 million in 2022 to 13.7 million by 2040 – a 111% increase (ACL 2023 Profile of Older Americans).

This single pairing is the strongest demand argument in the category, and it has a commercial edge to it: the segment with the acute need is also the segment least comfortable with the technology. AARP's 2026 survey found that among adults 80+, only 48% feel they have adequate digital skills and only 15% strongly agree that technology helps them age in place. The need and the receptivity are inversely correlated across exactly the range that matters.

3.3 The "long lie" – the mechanism the product actually addresses

The argument for automatic detection rather than a button rests on what happens when the faller cannot press it:

47% of non-injured fallers could not get up without assistance (Tinetti et al., JAMA, 1993)

80% of fallers over 90 could not rise independently; 30% lay immobilized for more than an hour (Fleming, BMJ, 2008)

Among 125 adults 65+, roughly half of those who lay on the floor beyond one hour died within six months, regardless of injury from the fall itself (Wild et al., BMJ, 1981)

Handle this evidence carefully. These studies are from 1981, 1993 and 2008, and we retrieved them through a secondary compilation rather than the primary papers. The Wild 1981 mortality figure in particular is repeated constantly in industry marketing and is rarely dated when it is. If it is used, it should be cited to the primary paper, dated, and presented as a forty-five-year-old finding.

3.4 Aging in place – a large stated intent, and a large gap

AARP's 2024 Home and Community Preferences Survey (n=3,090) found 75% of adults 50+ want to remain in their current home. Among those planning home modifications, 64% intend to install a medical emergency response system.

Set that 64% against the 9% who actually own one. The gap is real but should not be over-read: the 64% is intent among the subset already planning modifications, not the full 50+ population, and stated intent to install a safety device is among the least reliable categories of survey response. It is a directional signal about receptivity, not a demand forecast.

3.5 The caregiver shortage

The direct-care workforce stood at 5.4 million in 2024. BLS projects 772,000 net new jobs but 9.7 million total openings between 2024 and 2034, against turnover of roughly 75% a year for home care workers at a median wage of $17.36 an hour. This is a structural, worsening constraint on the human alternative to monitoring technology, and it is the demand driver least likely to reverse.

3.6 The headwinds, which are larger than the category usually admits

Adoption is flat. Medical-alert penetration among adults 65+ was 9% in 2026 and 9% in 2023 (The Senior List, n=909, fielded April–May 2026). Three years of a growing 65+ base produced no penetration gain.

Compliance is poor, and fails exactly where it matters. Among owners:

Table 4 – Device-Wearing Behavior Among Owners

Behavior	Share
Wear the device at all times	18%
Remove it to shower or bathe	64%
Do not wear it while sleeping	39%
Have experienced a false alarm	~50%
Satisfied with fall detection accuracy	~50%
Satisfied overall	90%

The bathroom is where falls concentrate and it is where 64% of devices come off. A 90% overall satisfaction rate sitting beside a 50% fall-detection satisfaction rate tells you customers like the idea of the product considerably more than they trust the feature.

The barriers are about identity, not money. Among the 91% who do not own a device: no health concerns 49%, live with others 36%, "don't feel old enough" 32%, cost 23%, privacy 6%. Three of the top four are self-perception. Any go-to-market built primarily on price competition is solving the fourth-largest problem.

Living alone is becoming less common, not more. The share of adults 65+ living alone fell from 29% in 1990 to 26% in 2023 (Pew, Dec 2025). If a pitch

deck says "more seniors are living alone," it is wrong. The defensible version: the absolute number rises with the growing 65+ base, and living alone remains most common in the 85+ cohort (38%, Pew), which is the fastest-growing cohort. We flag this because the incorrect version appears frequently in this category's marketing.

The host platform is maturing. Counterpoint, which tracks actual shipments rather than modelling revenue, projects only 3% smartwatch CAGR through 2030. Global smartwatch shipments grew 4% in 2025 and 4% year-on-year in Q1 2026.

Section 4 – Market sizing

A bottom-up TAM / SAM / SOM build, its validation, and why no published headline was used

4.1 Method

We built this bottom-up from named public inputs rather than adopting a published market-size headline, for the reason set out in §4.4: the published headlines for this category disagree with each other by more than they agree, and averaging them would manufacture precision that does not exist.

Every figure below is reproduced live in the companion workbook (Market Sizing tab), where each input is editable and each is annotated with its source.

4.2 The build

Table 5 – Bottom-Up TAM / SAM / SOM Build

Step	Input	Value	Source
TAM	US adults aged 65+	61,200,000	Census Bureau, Vintage 2024 (1 Jul 2024), rel. 26 Jun 2025
	Annual category spend per subscriber	$468 ($39 × 12)	ConsumerAffairs; SeniorLiving.org $25–$60 range, 12 Aug 2026
	TAM at 100% adoption	$28.6bn	Theoretical ceiling. Monitoring revenue only; on the SAM's device-inclusive basis it would be $29.7bn
Cross-check	Current penetration, 65+	9%	The Senior List 2026 (n=909)
	Implied current subscribers	5,508,000	
	Implied current US spend	$2.58bn	

SAM	Adults 65+ living alone (26%)	15,912,000	Pew, 4 Dec 2025 (2023 data)
	...that are wearable-receptive (36%)	5,728,320	AARP 2026 Technology Trends (50+ proxy)
	Annual revenue per subscriber at our pricing	$485.73	$34.95 × 12 + $199 ÷ 3
SAM	$2.78bn		
SOM	Closing subscribers, FY2031	55,565	Model, base case
	FY2031 revenue	$25.1m	Model, base case
	SOM as share of SAM	0.90%	

4.3 Validation

The bottom-up estimate of current US category spend – $2.58bn – can be checked against Berg Insight, the one firm in this space that reports subscriber counts rather than modelled revenue. Berg puts North American telecare at 16.2 million users across Europe and North America at end-2025, with 6.5 million in North America, valued at €3.4bn (US$3.7bn).

Two independent methods, one built from Census population and a survey penetration rate, the other from a specialist analyst's subscriber census, land in the same order of magnitude. We are deliberately not claiming more than that: Berg's North American figure includes Canada and is not restricted to adults 65+, and Berg's implied ARPU ($3.7bn ÷ 6.5m = $569/user/year) is 22% above the $468 we use, so a precise reconciliation is not possible without Berg's paid report. Same order of magnitude from two unrelated methods is nonetheless worth more than any single published headline.

The penetration figure survives a similar test: 6.5m North American telecare users against 61.2m US adults 65+ is 10.6%, against a 9% survey figure – an 18% relative gap, and in the direction expected, since the Berg numerator includes Canadian users and users under 65 while the denominator does not. We note that The Senior List is an affiliate-revenue publisher for medical alert brands; its methodology is disclosed and its result triangulates, but it should be labelled as an industry-sponsored survey wherever it is cited.

4.4 Why we did not use a published market figure

This is the clearest example we have encountered of why a sourced build beats a purchased number.

Fall detection systems – three firms, one base year:

Table 6 – Fall-Detection Systems Market Estimates by Firm

Firm	2025 size	2035 forecast	CAGR
Future Market Insights (Mar 2025)	$469.5m	$856.8m	6.2%
Grand View Research (Jun 2026)	$516.9m	$939.7m (2033)	7.8%
Emergen Research (Apr 2025, mod. Aug 2026)	$684.6m	$5.17bn	22.4%

A 46% disagreement on level in the same base year, and a six-fold disagreement on the 2035 outcome. This is not modelling nuance. Emergen's segmentation explicitly includes "smartwatch sensor" and "passive ambient AI sensor"; the other two do not appear to. Firms that count smartwatches inside the category project a large market; firms that exclude them project a small one. The forecast divergence is itself the evidence for the cannibalization thesis in §5.4.

PERS / medical alert – seven firms:

Table 7 – PERS / Medical-Alert Market Estimates by Firm

Firm	Size	Base year	CAGR
Market.us	$5.9bn	2024	6.4%
Grand View Research	$9.3bn	2022	6.4%
Precedence Research	$10.27bn	2025	10.80%
Mordor Intelligence	$10.79bn	2026	5.74%
Verified Market Research	$7.79bn	2021	5.9%
Berg Insight (subscriber census)	US$3.7bn North America	2025	8.4% (users)

Market.us and Precedence differ by 74% on level for near-adjacent years. Mordor and Precedence differ by roughly 2× on CAGR over overlapping windows – compounded to 2035, the difference between roughly $18bn (Mordor's $10.79bn 2026 base at 5.74%) and roughly $29bn (Precedence's $10.27bn 2025 base at 10.80%). The segment splits are outright contradictory: Grand View and Market.us report mobile PERS as the largest segment while Mordor reports landline at 56.42% of 2025 share.

Every figure in that table except Berg's is a press-release or web summary with undisclosed methodology. Recommendation: cite the range with the firms named, never a point estimate, and never an average.

4.5 What we could not size

Wrist-worn fall detection as a distinct revenue line does not exist as a published figure. Grand View reports "wearable" at 68.7% of the fall-detection systems market but does not split wrist from pendant. We did not derive an estimate, because deriving one would require assuming the wrist

share of a category whose total is itself disputed by 46%. Two layers of estimate on a disputed base is not analysis.

We were also unable to obtain: US population broken out as 65–74 / 75–84 / 85+ for the current year and 2030/2035 projections (Census Table 3 exists and contains exactly this – the file download was blocked in our environment and should be pulled manually from np2023-t3.xlsx); any current nationally representative figure for wearable ownership among adults 65+ specifically, as distinct from 50+; and PERS subscriber churn, ARPU, or customer acquisition cost from any public source.

4.6 The scale comparison worth internalising

The entire standalone fall-detection systems category, at $469.5m–$684.6m for 2025, is roughly 0.5–0.7% of the wearable technology market (~$92.9bn, Grand View 2025). It is smaller than the revenue Apple generates from a single quarter of Watch shipments.

This is the central strategic fact of the category, and it cuts both ways. It means no dedicated entrant is likely to out-resource Apple. It also means the category is far too small for Apple to organize around, which is precisely why Apple's fall detection detects hard falls only, dials 911 with no human in the loop, and has not been improved in the ways this market needs.

Section 5 – Competitive landscape

Smartwatches, dedicated PERS providers, accuracy evidence, and the competitor matrix

5.1 Tier 1 – consumer smartwatches with fall detection

Apple Watch. Series 11 from $399, SE 3 from $249, Ultra 3 from $799. Fall detection on SE or later, Series 4 or later, Ultra or later. On a hard fall the watch alerts; if the wearer is immobile for about a minute it runs a 30-second countdown and then calls 911 directly and notifies emergency contacts with location. Auto-enabled for users aged 55+ who entered their age at setup. No monitoring subscription; cellular is carrier-billed (Verizon prepaid smartwatch plan $10/month). Battery 24 hours normal, 38 hours low power. High-g accelerometer and high-dynamic-range gyroscope alongside the optical and electrical heart sensors.

Apple's own documentation states: "Apple Watch cannot detect all falls" and that the watch "might falsely trigger Fall Detection by detecting high-impact activity as a fall."

Samsung Galaxy Watch. Watch9 from $379.99 (LTE from $429); Watch Ultra2 from $699. Samsung's own pages surfaced inconsistent figures at retrieval and should be re-verified at checkout before this row is relied on. Automatic fall detection with a check-in prompt before contacting emergency services. Critically, it is off by default – the user must enable it in the Galaxy Wearable app and add emergency contacts. Three sensitivity modes. No subscription. Ultra2 battery ~60 hours with always-on display. Samsung warns high-impact sports "may sometimes register as a fall."

Google Pixel Watch. Pixel Watch 5 from $399.99, up to 40 hours battery. Fall detection waits ~30 seconds, prompts, and on 60 seconds of non-response auto-calls emergency services with an automated voice message and location. Wi-Fi models require a paired phone nearby; LTE models do not.

A correction to a widely repeated claim. As of 23 August 2026 we found no Fitbit-branded device documenting fall detection, SOS, or emergency features, including the Sense 2 and Versa 4. Fall detection appears only in Pixel Watch. This appears incorrectly in a great deal of secondary coverage of this category, and we flag it because a competitive matrix that lists "Fitbit Sense – fall detection" is wrong in a way a client's engineering team will notice immediately.

5.2 Tier 2 – dedicated PERS providers

UnaliWear Kanega – the closest direct comparable, and the plaintiff in §7.

$299 hardware, $64.95/month on an annual plan or $79.95 month to month. First-year total $1,078.40. Fall detection ("RealFall") included at no extra charge – the only vendor in this set that does not charge separately for it. Verizon 4G/5G plus Wi-Fi, fully standalone with no smartphone required. Swappable batteries in the band, 24–36 hours each, changed without removing the watch – a clever answer to the charging-gap problem that defeats most wrist devices in this segment. Voice activation. Medication reminders. Lifetime warranty, no contract. Measured 46 seconds to a live operator.

Its weaknesses are instructive. Hands-on testing by SeniorLiving.org (updated 11 Nov 2025) dropped the watch ten times including while worn: it did not trigger during intentional drops, and batteries occasionally dislodged on impact. A separate false alarm occurred during normal kitchen activity. There is no companion app for caregivers, and the band is bulky. The highest price in the category is attached to the weakest hands-on detection result we found.

Bay Alarm Medical. SOS Smartwatch $199 device (frequently $159.99) plus $39.95/month, fall detection +$11/month. Battery 6–18 hours – the

shortest in the set. No startup costs, no long-term contracts. 48-second measured response. 8 of 10 simulated falls detected.

Medical Guardian. MGMove smartwatch $199.95 plus $42.95/month ($38.95 annual), fall detection +$10/month and not enabled by default. 4G LTE, 18–24 hour battery, speech-to-text messaging, medication reminders. 52-second response, 9 of 10 simulated falls detected. Medical Guardian does not publish prices on its own product or pricing pages. It acquired MobileHelp in 2024.

MobileHelp. Elite from $37.95/month, Classic Cellular from $29.95, fall detection +$10/month, no equipment fee. Pendant or belt clip – no wrist product. 62-second response.

LifeFone. In-home from $29.95/month, mobile GPS from $43.95, fall detection +$5/month – the cheapest fall-detection add-on in the category. Ten-day battery, the longest in the set. 49-second response, but the weakest measured detection at 2 of 3. Publishes no prices on its product pages.

Lively / Best Buy Health. Mobile2 device $79.99; Basic $24.99/month, Premium $34.99; fall detection +$9.99/month on either. $35 activation. Pendant/mobile, no wrist device. The only competitor with national big-box retail distribution.

ADT Health. On-The-Go $39.99/month promotional (regular $41.99) plus $49.50 activation (regular $99.00). Pendant only. ADT's own user guide states: "Fall Detection pendant does not detect 100% of falls."

Life Alert. Publishes no pricing. Third-party sources put it at $49.95–$89.95/month with a $197 non-refundable installation fee and a 36-month contract. It offers no automatic fall detection on any device – while being the most recognized brand name in the category and priced above the average of the monitored vendors in §5.6 ($48.67/month including fall

detection) even at the bottom of its reported range, and up to $41/month above it at the top.

Connect America – the only vendor we found publishing a subscriber count: 900,000+ active subscribers, 10m+ lives protected since acquiring Philips Lifeline's aging business in 2021, 850,000+ emergency signals a month.

5.3 Tier 3 – adjacent and form-factor benchmarks

WHOOP (no fall detection). One $199/year, Peak $239, Life $359 – hardware included in the membership, 14+ day battery, screenless band. Strategically relevant for two reasons: it demonstrates that a hardware-included annual subscription is a viable consumer model, and that a screenless band can hold 14+ days of battery. Tier pricing as of 23 August 2026. Both bear directly on the charging-burden problem that defeats wrist devices in this segment. The client's own files benchmark enclosure dimensions against WHOOP (34.7 × 24.0 × 10.6 mm) and Pavlok (22.1 × 39.1 × 10.6 mm).

CarePredict Tempo. Advertises wearable fall detection, but the Tempo product page returns 404, no specific model is named, and no pricing, specifications, or FDA status is published. Contact-gated, B2B senior-living oriented. We could not responsibly profile it and did not estimate.

Vayyar Care. Touchless 4D radar, no camera, no audio, no wearable. Immediate fall alerts, sold to senior-care facilities on a staffing-ROI argument. Pricing not disclosed. This is the substitute worth taking seriously: it solves the non-wear failure mode (§3.6) that the wearable category structurally cannot, at the cost of only working inside instrumented rooms.

New entrants. We identified no verifiable new wrist-worn fall-detection entrant in 2024–2026 in public sources. Report this as "none found," not

"none exist" – general web search is weak evidence about private companies.

5.4 The cannibalisation question

Evidence for: Apple Watch is the most-used brand among adults 65+ who use a medical alert device at all (The Senior List 2026). Apple charges $0 recurring against $360–$1,020/year for PERS. Fall detection is on by default for 55+, meaning tens of millions of devices ship with the feature active at no incremental cost. Emergen – the one firm counting smartwatches inside the fall-detection category – projects 22.4% CAGR against peers' 6–8%.

Evidence against: Apple detects hard falls only, not the slow, soft falls more typical of frail older adults. It dials 911 directly rather than a monitoring center that can cancel a false alarm – a meaningful difference when roughly half of owners report false alarms. It requires an iPhone and a degree of technical comfort. The touchscreen is difficult with arthritis. And the ceiling is real: wearable ownership among adults 50+ is 36%, down from 38% in the prior AARP wave, and wearables remain the only device category where older adults trail younger adults – AARP's own framing.

Our read: cannibalization is real and largely complete at the tech-comfortable, younger-old, higher-income end. It is bounded at the frail, older, less technical end – which is precisely the 85+ segment growing 111% by 2040, and precisely the segment least able to manage an Apple Watch. That is the defensible position, and it is a smaller and harder market than the one a business plan would prefer to describe.

5.5 Accuracy – the evidence, and how to talk about it

Peer-reviewed, real-world. Bagalà et al., PLOS ONE 7(5):e37062 (2012) evaluated thirteen published algorithms against 29 real-world falls rather than simulated ones: mean sensitivity 57.0% (±27.3%), mean specificity

83.0%, false alarms ranging from 3 to 85 per 24 hours. Fourteen years old, belt-mounted, small sample, and predating modern ML approaches – but it remains the canonical real-world evaluation, and its central finding, that algorithms perform far worse on real falls than on simulated ones, has not been superseded.

A sourcing warning. NCOA's 2026 fall-detection page states that "83 of 84 reported alarms were false." That number does not match the Bagalà study, which reports 83.0% specificity and a 3–85 false-alarm range. NCOA's phrasing appears to conflate the two. Cite Bagalà directly; never NCOA's restatement. We flag this because the NCOA version is more quotable and is therefore the one that propagates.

Hands-on, simulated (2026). SeniorLiving.org, ten attempts each: Medical Guardian MGMove 9/10, Bay Alarm SOS Smartwatch 8/10, Samsung Galaxy Watch7 8/10, UnaliWear Kanega failed to trigger on intentional drops. NCOA, 35+ devices across 16 protocols: Medical Guardian 3/3, Bay Alarm 3/3, MobileHelp 3/3, LifeFone 2/3.

The structural form-factor finding. Both NCOA and SeniorLiving.org state that wrist-worn fall detection is less accurate than neck- or belt-worn, because arm swing during normal activity generates false positives. NCOA additionally reports chest-worn devices at ~98% accuracy. This is the central trade-off of the wrist form factor and it should anchor any risk section: the form factor that people will actually wear is the form factor that detects worst.

Disclaimer language. Every vendor in this category ships an accuracy disclaimer. Any claim about detection performance must be phrased as indicative, attributed, and dated – never as a guarantee. Given that fall detection is health-adjacent, we recommend that any language approaching a safety or efficacy claim go to an attorney rather than to

editorial sign-off. See §8.4 on the FTC exposure, which is arguably larger than the FDA exposure.

5.6 Competitor matrix

Prices retrieved 23 August 2026.

Basis, stated so the comparison can be checked. Three-year total = device price + (monthly + fall-detection add-on) × 36. "n/p" = the vendor does not publish the figure; where a row still carries a total, the unpublished device price has been treated as $0 and the total is marked "+". Rows marked † are priced from third-party sources (NCOA, SeniorLiving.org) because the vendor publishes no price – Medical Guardian, LifeFone, Life Alert and ADT all fall in this group. Monthly rates are month-to-month except UnaliWear, which has no comparable month-to-month equivalent at the annual rate quoted; see the note below the table. Activation and installation fees are excluded except where shown, which understates ADT (+$49.50), Lively (+$35) and Life Alert (+$197).

Table 8 – Competitor Matrix (1 of 2): Form Factor, Price and Fees

Product	Form	Auto FD	Device	Monthly	FD add-on
Apple Watch SE 3	Wrist	Yes (55+ default)	$249	$0 ‡	incl.
Apple Watch Series 11	Wrist	Yes	$399	$0 ‡	incl.
Samsung Galaxy Watch9	Wrist	Yes (off by default)	$379.99	$0	incl.
Google Pixel Watch 5	Wrist	Yes	$399.99	$0	incl.
UnaliWear Kanega	Wrist	Yes	$299	$64.95	included
Bay Alarm SOS Smartwatch	Wrist	Optional	$199	$39.95	+$11
Medical Guardian MGMove †	Wrist	Optional, off by default	$199.95	$42.95	+$10
LifeFone †	Pendant / watch	Optional	n/p	$43.95 (mobile)	+$5
MobileHelp Elite	Pendant	Optional	$0	$37.95	+$10
Lively Mobile2	Pendant	Optional	$79.99 + $35 act.	$24.99	+$9.99
ADT On-The-Go †	Pendant	Optional	n/p	$39.99 promo	n/p
Life Alert †	Pendant/wrist	No	$0 + $197 install	$49.95–$89.95	n/a

WHOOP (benchmark)	Band	No	incl.	$16.58 eq.	n/a
Vayyar Care (substitute)	Radar, in-home	Yes	n/p	n/p	n/a

Table 8 – Competitor Matrix (2 of 2): Battery, Monitoring and Measured Detection

Product	3-yr total	Battery	Standalone	Monitoring center	Measured detection
Apple Watch SE 3	$249 ‡	24h	Needs iPhone	No – 911 direct	Hard falls only
Apple Watch Series 11	$399 ‡	24h	Cellular models	No – 911 direct	Hard falls only
Samsung Galaxy Watch9	$380	~2 days	Cellular models	No	8/10 (Watch7)
Google Pixel Watch 5	$400	40h	LTE models	No	n/p
UnaliWear Kanega	$2,637	24–36h, swappable	Yes	Yes	Failed drop test
Bay Alarm SOS Smartwatch	$2,033	6–18h	Yes	Yes	8/10
Medical Guardian MGMove †	$2,106	18–24h	Yes	Yes	9/10; 3/3
LifeFone †	$1,762+	10 days	Yes	Yes	2/3
MobileHelp Elite	$1,726	n/p	Yes	Yes	3/3
Lively Mobile2	$1,374	n/p	Yes	Yes	n/p
ADT On-The-Go †	$1,440+	n/p	Yes	Yes	n/p
Life Alert †	$1,995–$3,435	n/p	Yes	Yes	n/a
WHOOP (benchmark)	$597	14+ days	No	No	n/a
Vayyar Care (substitute)	n/p	mains	n/a	Yes	n/p

What the matrix shows. Three-year cost of ownership separates into two clusters: $249–$400 for a general-purpose smartwatch and $1,339–$2,637 for a monitored dedicated device, with only the WHOOP benchmark ($597) between them. The gap is the monitoring center and the cellular

connection. Any entrant must be able to state clearly what the customer receives for that $1,000–$2,200 premium. On the current evidence the honest answers are: a human who can cancel a false alarm before an ambulance is dispatched, operation without a smartphone, and soft-fall detection. Those are real, and they are not what most of this category's marketing leads with.

‡ Apple totals exclude cellular service (Verizon prepaid smartwatch $10/month, adding $360 over three years) and assume the buyer already owns and carries an iPhone. On a standalone-equivalent basis the SE 3 is roughly $609 over three years.

A comparability caveat we are choosing to flag rather than smooth over. UnaliWear is quoted at its annual rate ($64.95) because that is how it publishes; Medical Guardian is quoted month-to-month ($42.95) though §5.2 notes an annual rate of $38.95, which would put its three-year total at roughly $1,962; ADT is quoted promotional. A fully like-for-like table would require every vendor's best publicly available annual, non-promotional rate, and four of them do not publish one. Treat the totals as indicative to within roughly 10%, not as precise.

Two pricing observations. UnaliWear charges the most and includes fall detection; everyone else charges $5–$11/month extra for the feature that defines the category. And Life Alert, which has no automatic fall detection at all, is priced above the category average. In this category brand recognition appears to command more than capability does.

Section 6 – Buyer, channel and customer landscape

Who actually buys, the five routes to market, and what the channel structure implies

6.1 The buyer is usually not the user

The Senior List's 2026 study surveyed both sides: 22% of adult children say they are likely to buy a device within twelve months, against 9% of seniors buying for themselves. The purchase intent sits with the adult child at roughly 2.4 times the rate of the user.

This has direct product consequences. It makes a caregiver-facing companion application a purchase driver rather than a feature – and it is exactly what UnaliWear, the closest comparable, does not have. It also means marketing has two audiences with opposed emotional registers: the buyer is motivated by worry, and the user is resisting on the grounds that they "don't feel old enough" (32%). Copy written to reassure the buyer will often read as an insult to the user. This is the hardest execution problem in the category, and it is not a technology problem.

6.2 Channels

Table 9 – Routes to Market and Their Requirements

Channel	How it works	Evidence	Difficulty
Direct response / DTC	The category's default. TV, digital, affiliate review sites.	Every major vendor. NCOA, SeniorLiving.org and The Senior List are affiliate publishers and effectively function as the category's channel.	Low barrier, high and unmeasured CAC. FTC enforcement risk (§8.4).
Medicare Advantage supplemental benefit	Sold through supplemental-benefit administrators, not billed to CMS.	SCAN Health Plan lists a named 2026 "Emergency Response / Personal Alert" benefit; NationsBenefits/ADT built a distribution partnership for MA plans.	Slow, relationship-driven; a real route to volume.

Medicaid HCBS waivers	State waiver programs reimburse PERS at roughly $25–$75/month plus $40–$200 startup.	PERS offered by 57.8% of states in FY2021 1915(c) IDD waivers; aged/disabled waivers are broader.	Hard gate: UL 1635/1637 listing and a compliant 24/7 monitoring center. See §8.3.3.
National retail	Shelf presence with the gifting buyer.	Lively via Best Buy – the only vendor with it.	Very hard for a new entrant.
Senior living operators (B2B)	Facility-level procurement.	Where CarePredict and Vayyar compete.	Different product, different sales motion.

6.3 What the channel structure implies

The affiliate review publishers – NCOA, SeniorLiving.org, The Senior List – are simultaneously the category's most-cited independent testers and its commercial gatekeepers. They earn revenue from the brands they rank. Their testing appears genuine and their methodologies are disclosed, and we have relied on them throughout this report because they are the best available evidence. But a new entrant should understand that placement in those rankings is a commercial negotiation as much as a product outcome, and should price that into any acquisition model.

Section 7 – Patent landscape

Standalone Patent Landscape Analysis, delivered as part of this engagement. This is research, not legal advice, and it is not a freedom-to-operate opinion. An FTO opinion requires a registered patent attorney or agent, a professional patent database, claim charts against a specific implementation, and file-history review.

7.1 Method and its limits – read before the findings

We retrieved individual patent pages from Google Patents and Justia, Federal Register notices, USITC press releases and Federal Circuit opinions. We were unable to run assignee-scoped patent searches: Google Patents query pages are robots-disallowed, Espacenet returned 403, USPTO Patent Public Search requires a JavaScript session, and the legacy PatentsView API is retired.

Three consequences carry into everything below:

Where we report "no patents found" for an assignee, that means our searches did not surface any – not that none exist. Samsung's, Google's, Garmin's and Philips's portfolios are certainly larger than what appears here.

We could not produce a patent count, filing trend, or assignee ranking specific to fall detection, because no citable source was retrievable. We did not estimate one. A count should be produced by someone with a Google Patents Enterprise, PatSnap, Derwent or Orbit seat, with the search string and date recorded.

Where we could not retrieve an independent claim, we say so. We have not paraphrased an abstract and presented it as claim scope. This matters most for Apple, below.

7.2 The live litigation – this is the headline

USITC Investigation No. 337-TA-1477, "Certain Wearable Devices With Fall Detection and Components Thereof."

Table 10 – USITC Investigation No. 337-TA-1477 at a Glance

Element	Detail
Complaint filed	12 December 2025 (docket 337-3865)
Investigation instituted	7 January 2026 (Federal Register notice 12 January 2026)
Complainant	UnaliWear, Inc., Austin, Texas
Patents asserted	US 10,051,410 – claims 1–20; US 10,687,193 – claims 1–43
Respondents	Apple; Samsung Electronics Co. and Samsung Electronics America; Google LLC; Garmin Ltd., Garmin International and Garmin USA
Accused products	"Electronic watches with the capability to detect when a user has suffered a fall, and components thereof"
Relief sought	Limited exclusion order (import ban) and cease-and-desist orders

Parallel district-court actions filed December 2025: W.D. Tex. 7:25-cv-00570 (Apple), 7:25-cv-00571 (Google), C.D. Cal. 2:25-cv-11772 (Garmin), E.D. Tex. 2:25-cv-01214 (Samsung). Reported accused devices include Apple Watch Series 10, Pixel Watch 3, Garmin Forerunner 970 and Galaxy Watch 8.

Status caution. A February 2026 trade piece is headlined "UnaliWear Drops ITC And District Court Complaints On Smartwatch Competitors." We fetched both the Mondaq and MarketScreener versions: the article bodies contain no statement of withdrawal, dismissal or termination – they describe UnaliWear filing the suits. The headline appears to use "drops … on" colloquially, meaning lands on. We found no Federal Register termination notice and no later dismissal reporting. Do not state that the case was dropped. Verify on ITC EDIS and PACER before this section is relied on.

7.3 The asserted patents – what is actually claimed

US 10,051,410 B2, "Assist device and system." UnaliWear, Inc. Priority 19 Sep 2013, filed 19 Sep 2014, granted 14 Aug 2018, anticipated expiry 19 Sep 2034, active.

US 10,687,193 B2, same title, continuation. Priority 19 Sep 2013, filed 30 Jul 2018, granted 16 Jun 2020, anticipated expiry 19 Sep 2034, active.

Both independent claim 1s recite, in substance: a wearable with a power source, processor, at least one physiologic sensor, user interface and network interface, which collects activity data over time, uploads it to a remote server, where a behavioral model – in '410 an "activity profile" built from location mapping, home area, boundaries, sleep/wake cycles and time-of-day location comparisons; in '193 a broader "parameterized rule-based custom data model" of times and locations – is created or updated, downloads that model back to the device, compares live data against it, and communicates with the wearer when behavior deviates.

The single most important observation in this section: neither independent claim recites a fall, fall detection, an accelerometer, a gyroscope, an inertial sensor, or on-device classification. Both recite a physiologic sensor, a server-side model of times and locations, and a round trip to a remote computer.

On the face of the claim language, a wrist device that classifies falls locally from IMU data, with no cloud-built location and time behavioral model, does not recite the elements these claims require. Whether such a device reads on the claims as construed is a claim-construction question for a registered practitioner, not one this report answers. UnaliWear has asserted them against the fall-detection features of four companies, which means its theory rests on the construction of "physiologic sensor" and "activity profile." That is a claim-construction question, and it is exactly the kind of

question a patent attorney with a claim chart answers and a market analyst does not.

A third family member, WO 2020/028157 A1 (priority 30 Jul 2018), whose disclosure does cover accelerometers, gyroscopes, personalized fall-detection algorithms and context-adaptive sensitivity, has status: Ceased, with no granted US patent surfacing from it.

7.4 The rights that actually constrain a wrist IMU product

Ordered by our read of practical risk.

1. Philips US 10,335,059 B2 – "Fall detection system and method." Koninklijke Philips N.V. Priority 11 Sep 2013, granted 2 Jul 2019, expiry 15 Nov 2034. Claim 1, verbatim in relevant part: a processing unit configured to determine context information about the user and/or environment, and to increase a detection sensitivity of a fall detection algorithm based on that context indicating the user is at increased risk of falling, the increase persisting while the increased risk is indicated.

This is the broadest and most commercially dangerous claim we found for this product category. On its face this claim reaches any wrist device that raises detection sensitivity in response to context: night-time, bathroom location, unsteady gait, post-illness, medication timing. Whether a given implementation is within it is a question for counsel. Context-adaptive sensitivity is also the single most obvious engineering answer to the wrist form factor's false-positive problem, which makes this claim a direct constraint on the most natural product roadmap. Highest-priority attorney review.

2. VitalConnect US 10,422,814 B2 – "Fall detection using machine learning." Priority and filed 18 Jul 2013, granted 24 Sep 2019, expiry 8 Feb 2034. The most on-point patent found for on-device ML classification. Claim 1 requires

a tri-axial accelerometer sample during a fall and a non-falling process, a calibration vector derived from posture information received at the device, computed features, initiating a support vector machine within an application of the wireless sensor device using a training set of intentional fall and non-fall data, and detecting a fall from a linear combination of features. Specific enough to leave design-around room – SVM specifically, posture-derived calibration vector, linear combination – but anyone shipping on-device supervised classification of IMU features should have counsel read it.

3. Apple's family – priority 29 Sep 2017, "Detecting falls using a mobile device." US 10,629,048 B2 (granted 21 Apr 2020, expiry 11 Sep 2038) plus US 11,276,290; 11,282,361; 11,282,362; 11,282,363; 11,527,140; 11,842,615; 12,027,027; 12,154,420; 12,380,789, and pending US 2025/0046172 A1. Ten-plus granted US patents from one priority, with CN, EP, JP and KR counterparts.

We could not retrieve claim 1 for any member of this family. We attempted Google Patents, Justia, FreePatentsOnline, patentguru, uspto.report, the USPTO image server, PatentScope and the patentimages PDF; every source truncated before the claims because the shared specification is very long. The description covers obtaining motion data, detecting an impact, and analyzing motion characteristics before and after the impact – including flailing and post-impact impairment – to decide a fall occurred.

A ten-patent continuation wall around impact plus pre-impact plus post-impact motion analysis, running to 2038, is the single largest unquantified item in this landscape. Any FTO work must start by pulling these PDFs directly from USPTO and reading the claims.

4. STMicroelectronics US 12,561,577 B2 – "Automatic filter selection in decision tree for machine learning core." Granted 24 Feb 2026, filed 30 Oct

2020. Directly relevant to the client's design, which uses the ST Machine Learning Core. Claim 1 is directed to the automated filter-selection and decision-tree-training pipeline – frequency-peak data, peak-based and entropy-based frequency ranges, overlap-threshold selection, per-class filter generation, combination, tree training – combined with a sensor that runs the resulting tree. It is not a claim on "any decision tree running inside an inertial sensor." A developer who hand-selects filters, or uses a different feature-selection method, and then loads a tree into an LSM6DSOX or LSM6DSV MLC is not obviously within claim 1. A customer using ST's own parts and ST's own tooling also has a distinct and more favorable posture – a licensing and exhaustion question for counsel.

5. Tunstall US 9,378,636 B2 (expiry 2034) – requires an accelerometer and a barometer with a compensated height-difference computation. A device with no barometer does not infringe claim 1. Avoidable by design.

6. Philips US 8,756,032 B2 (expiry 2030) – requires computing lead time and return time and declaring a fall where peak velocity exceeds a threshold and lead time exceeds return time. Avoidable if the classifier does not compute those quantities.

7. Samsung US 10,863,926 B2 (expiry 2037) – a single-axis sign-flip trigger: a fall is determined when acceleration in a preset first axial direction changes from positive to negative. Narrow on its face; a modern multi-feature classifier would not obviously read on it.

8. Illinois / Mayo Clinic US 8,990,041 B2 (expiry 2032) – a kinematic sensor plus a controller testing a postural-disturbance threshold and then classifying the disturbance as a fall event or a recovery event. The fall-versus-recovery classification concept is claimed.

Also holding fall-detection patents, which is strategically notable: Aetna (US 11,055,981 and US 11,468,758 – a health insurer), Alarm.com (US 12,198,525, camera/room-based), Linear LLC, Huawei, Alva Health, MobileHelp (US 9,179,864, expiry 2029 – claims not reliably retrieved), and Google (US 11,875,659, privacy-preserving radar above 40 GHz – a different modality entirely, not wrist-worn).

7.5 What has lapsed

Table 11 – Lapsed and Abandoned Fall-Detection Patents

Patent	Owner	Priority	Status	Why it matters
US 6,433,690 B2 "Elderly fall monitoring method and device"	Sarcos → Mobile Monitoring Systems	1998-10-27	Expired 2018	The foundational wearable-accelerometer elderly fall patent. Claim 1: sample accelerometer output for body acceleration and body angle; detect a fall-indicative steady state ≥2 s; measure fall duration from a buffer; test against a time threshold; compare angular rate of change and acceleration amplitude change to a severity threshold. Expired per Google Patents; a strong candidate §102/§103 reference. Confirm expiry and maintenance status in USPTO Patent Center before any reliance.
US 7,961,109 B2	ETRI (Korea)	2006-12-04	Expired – fee related	Accelerometer + gyroscope, gravity/kinetic acceleration separation by filtering, fall-vector template matching. The closest lapsed patent to the target technology.
US 2006/0282021 A1 "Method and system for fall detection and motion analysis"	Aware Technologies	2005-05-03	Abandoned – never granted	422 forward citations. Published, never granted, abandoned. A strong candidate §102 reference

				against later fall-detection claims, subject to a practitioner's assessment.
US 7,423,537 B2	Commissariat à l'Énergie Atomique	2005-06-07	Expired ~5 Jun 2026	Accelerometer + magnetometer. Newly free.
US 7,450,332 B2 free-fall detection	STMicroelectronics	2004-06-28	Expired ~19 Feb 2026	Three-axis hardware threshold interrupt. Newly free.
US 8,217,795 B2	Carlton-Foss (individual)	2006-12-05	Expired – fee related	Lapsed for non-payment.

Verify each of these in USPTO Patent Center before relying on it. Google Patents "anticipated expiration" does not reflect terminal disclaimers, patent term adjustment or extension, or maintenance-fee status.

7.6 Is this space litigious? The evidence

Three separate ITC Section 337 investigations aimed at the Apple Watch in five years: 337-TA-1266 (AliveCor, ECG), 337-TA-1276 (Masimo, pulse oximetry), 337-TA-1477 (UnaliWear, fall detection).

An exclusion order actually issued and actually bit. The Masimo LEO and cease-and-desist order issued 26 October 2023, effective 26 December 2023. Apple removed Blood Oxygen from US Apple Watch Series 9 and Ultra 2 for roughly 20 months and re-architected the feature onto the paired iPhone to escape it. The Federal Circuit affirmed the Commission on 19 March 2026 (Apple Inc. v. ITC, No. 24-1285).

A nine-figure damages award that survived post-trial motions. A C.D. Cal. jury awarded Masimo $634 million on 15 November 2025; Judge Selna denied Apple's JMOL and new-trial motions on 21 July 2026. Apple is appealing.

The newest case targets fall detection specifically and names all four major smartwatch vendors at once.

Non-practicing and adjacent holders are in the space – a health insurer, a home-security company, a security-hardware firm.

And the counter-evidence, which matters more for a small company than the wins do. AliveCor won at the ITC on three patents – and the PTAB invalidated every claim of all three in inter partes review. The Federal Circuit affirmed the PTAB on 7 March 2025 and vacated the Commission's decision as moot. Apple's Masimo redesign was cleared by an ALJ. Omni MedSci lost a patent to invalidity.

The pattern: large-company IPR counterattack is the norm, and small patentees frequently lose the patent rather than win the case. Both risks belong in any strategy built on this category: the risk of being sued, and the separate risk of relying on your own patent as a moat. UnaliWear is currently occupying exactly AliveCor's former position, and the outcome is not yet known.

7.7 Open items requiring a registered practitioner

Retrieve and read claim 1 of every member of the Apple family – the largest gap in this analysis.

Retrieve claim 1 for Philips US 11,361,648, MobileHelp US 9,179,864, and Alva Health US 11,937,917.

Run a proper CPC-based search (G08B21/043, A61B5/1117, G08B25/016, crossed with haptic classes) on the "vibrate first, escalate on non-response" interaction. Our keyword search found no granted independent claim requiring it, and it is almost certainly widely disclosed prior art – but that is a shallow result, not a clean one.

Check PTAB (ptacts.uspto.gov) for IPR petitions against UnaliWear's '410 and '193. Given the AliveCor precedent this is a first-order question and we could not search it.

Analyse the EP, CN, JP and KR counterparts. Several families have substantial ex-US coverage.

Verify 337-TA-1477 status on EDIS and PACER.

Section 8 – Regulatory, certification and reimbursement

Research, not legal or regulatory advice. Every item marked needs sign-off from FDA regulatory counsel, a Telecommunication Certification Body, or a reimbursement attorney.

8.1 FDA

- **The current guidance**
  FDA reissued General Wellness: Policy for Low Risk Devices as final guidance dated 6 January 2026, docket FDA-2014-N-1039, with a public town hall on 11 February 2026.

- **The test**
  Two factors, both required:

  "CDRH defines general wellness products as products that meet the following two factors: (1) are intended for only general wellness use, as defined in this guidance, and (2) present a low risk to the safety of users and other persons."

  Factor 1 permits two claim categories: claims about sustaining or improving functions associated with a general state of health with no reference to diseases or conditions; and claims that a healthy-lifestyle choice may help reduce the risk of, or help living well with, certain chronic conditions – but only where that association is well established in peer-reviewed literature. Anything intended for "the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease" is outside the policy.

  Factor 2 disqualifies on a yes to any of: is it invasive, is it implanted, does it involve an intervention or technology that may pose a safety risk absent specific regulatory controls.

- **What changed in 2026, and why it nearly helps**
  The revision opened the door to physiologic-parameter tracking, which the 2019 version did not address. New Illustrative Example 7 covers a wrist-worn wearable outputting sleep, pulse rate and blood pressure and finds it qualifies. It also permits alerting behavior:

  "a product may be considered a general wellness product even if it includes a notification informing a user that evaluation by a healthcare professional may be helpful when outputs fall outside ranges appropriate for general wellness use"

  – provided the notification avoids reference to a specific condition or disease.

- **But fall detection is not addressed at all**
  We searched the guidance PDF directly. The words "fall," "falls," "fall detection," "emergency" and "alert" do not appear in it. A site-scoped search of fda.gov returns no substantive guidance, policy statement, or warning letter on fall detection. We found no FDA warning letters mentioning it.

  This is the central regulatory finding. Fall detection sits in an unaddressed space. FDA has neither blessed it as general wellness nor claimed it as a device. Note also that a fall is a kinematic event, not a physiologic parameter, so Example 7's new safe harbor does not squarely cover it – the analysis has to run on claim language instead. Recommend a Q-Submission (pre-submission meeting) to obtain FDA's read in writing before significant capital is committed.

- **The classification codes that exist**

Table 12 – FDA Classification Codes Relevant to Fall Detection

Code	Device name	Class	Regulation	Path
ILQ	System, communication, powered	II	21 CFR 890.3710	510(k) exempt – the code Philips Lifeline actually used for PERS
SEC	Wearable fall injury prevention device	II	21 CFR 890.3780	510(k); created by De Novo DEN240021 (2025)
PJO / PJP	Fall prevention alarm / sensor	I	21 CFR 880.2400	Exempt; bed-exit, institutional

There is no product code named "personal emergency response system" or "fall detection." ILQ is the real-world precedent – Philips's HomeSafe Standard Slimline Personal Help Wriststrap is registered under it as exempt from premarket submission.

The exemption is conditional. 21 CFR 890.9 pulls a device back into 510(k) if it "is intended for a use different from the intended use of a legally marketed device in that generic type" or "operates using a different fundamental scientific technology than a legally marketed device." An automatic accelerometer-and-ML fall-detection algorithm is a plausible "different fundamental scientific technology" argument against a manual push-button communicator. Needs counsel.

- **Precedent**

We found zero 510(k) clearances for a wrist-worn consumer fall-detection or PERS product. Apple, ADT, Bay Alarm, Medical Guardian and the mass-market vendors all market fall detection with no clearance. The only FDA-authorized fall device we found is the Tango Belt (Active Protective Technologies), De Novo DEN240021 granted 9 April 2025 – a hip-airbag belt indicated "as an adjunctive to standard-of-care to reduce the risk of hip

fracture or hip dislocation due to falls." That is a treatment claim, not a notification claim, and it is why it needed a De Novo.

Note on Apple: public reporting is contradictory. The accurate framing is feature-level, not device-level – specific cardiac features (ECG, AFib) hold 510(k) clearance; the Watch as a whole is not a medical device; fall detection is not cleared. The "Apple Watch is an FDA Class II medical device" claim circulates widely in a misleading form and should not be repeated.

- **What pushes a fall detector into regulation**
  Our applied reading, which counsel must confirm:

Table 13 – Claim Framing: What Likely Stays Outside FDA Regulation, and What Pulls It In

Likely stays outside	Likely pulls it in
"Get help fast if you take a hard fall"	Naming a disease – "for Parkinson's patients," "post-stroke," "detects syncope"
Framing as safety, independence, communication	"Reduces fall risk," "prevents falls," "prevents hip fracture" – the Tango Belt claim set
Example-7-style nudge to consult a professional, no disease named	Outputting a fall-risk score or gait-instability assessment – that reads as diagnosis
	Clinician-facing dashboards that guide clinical management
	Positioning as a substitute for an authorized device
	Marketing it as RPM-billable – see §8.3.4

8.2 FCC and certification

- **BLE requires certification, not self-declaration**
  47 CFR 15.201(b): "all intentional radiators operating under the provisions of this part shall be certified by the Telecommunication Certification

Bodies." SDoC is not available for BLE. The common vendor claim that "Part 15 devices can self-declare" applies to the unintentional-radiator side (Subpart B), not the radio.

§15.247 is the rule BLE is normally certified under – digital modulation in 2400–2483.5 MHz, 1 W peak conducted maximum, minimum 6 dB bandwidth ≥500 kHz, baseline assuming ≤6 dBi antenna gain. §15.203 ties a certified design to its specific antenna.

- **RF exposure**
  A wrist wearable operates within 20 cm of the body and is therefore a portable device subject to SAR rather than MPE rules. Low-power BLE will normally clear the 1.1307(b)(3) exemption threshold, but the exclusion analysis must still be documented. Confirm the arithmetic with your TCB against FCC KDB 447498.

- **The module decision – directly relevant to the client's design**
  The client's V1 architecture used a Fanstel BC805M, a pre-certified Nordic nRF52805 module; the V3 sheet is ambiguous between a module and a bare SoC (§9.4).

  Under modular approval (47 CFR 15.212) the module vendor holds the FCC ID and the integrator does not re-certify the transmitter. The integrator still owes: host unintentional-radiator testing under Part 15 Subpart B, verification of EIRP and spurious emissions in the final enclosure, co-location analysis if a second radio exists, receiver performance, and the label – "Contains FCC ID: XXXXX" / "Contains IC: YYYY-YYY". ACB, an FCC-recognized TCB, notes "a very high number of installations do actually fail the tests at first."

  What voids the module's coverage and forces a Class II permissive change or fresh certification: changing the antenna from the certified design,

deviating from the specified antenna trace layout, modifying the RF pin or pad path, body-worn use where the module was certified for >20 cm separation – directly relevant to a wrist wearable, check the grant conditions – or co-locating transmitters.

A bare SoC with a chip antenna means full intentional-radiator certification in your own name: the complete 15.247 suite, TCB review, your own FCC ID and grantee code, and ownership of every antenna and layout change for the life of the product.

- **Cost and timeline**
  The only hard figure we could verify is a published invoice: SparkFun, 3 December 2019, $12,200 total – FCC Part 15 testing and certification $4,000; ISED $3,000; Canadian agency fee $600; CE RED $2,800; CE LVD $1,800. Elapsed time roughly 2.5 months including multiple FCC feedback rounds. SparkFun described it as "about half of what we feared," with other quotes "double and triple this amount." The FCC grantee-code fee is $35 (47 CFR 1.1103, effective 23 May 2025).

  We could not find a single accredited lab publishing a real price list for §15.247 – every lab quotes privately. Ranges circulating in vendor guides ($3,000–$10,000 for a host with a pre-certified module; $8,000–$20,000+ for a custom RF design) are author estimates, not lab quotes, and are labelled as such wherever used.

- **Bluetooth SIG – likely the largest single certification line item**
  Fee schedule effective 1 March 2026:

Table 14 – Bluetooth SIG Fee Schedule, Effective 1 March 2026

Item	Adopter	Contributing Adopter	Associate
Annual membership	$0	$3,500 (small) / $16,500 (large)	$11,250 / $52,500

Product qualification fee	$12,000	$8,000 (first per membership year only, then $12,000)	$6,000 (every qualification)
Company Identifier	$1,250	$1,250	free
16-bit UUID	$3,750	$3,750	$3,750

Qualification is mandatory – "ALL Bluetooth® Products must be qualified" on or before first sale – and cannot be delegated: "Your supplier or other member companies cannot qualify your products on your behalf." Fees attach to the first submission of a design; later products reusing it are fee-free.

At $12,000 on the Adopter tier this is larger than the FCC line. Note the discount structure carefully: Contributing Adopter membership ($3,500/yr) carries 33% off the first qualification in each membership year only, with subsequent qualifications in the same year reverting to $12,000. That is a net saving of roughly $500 on a single product per year, not a recurring saving. Only the Associate tier ($11,250/yr) discounts every qualification, at 50%. For a single-product company the Adopter tier is the right choice. A pre-qualified module also carries its own Design that can be referenced; confirm the vendor's QDID.

Terminology correction: the SIG's current schedule uses "product qualification fee." There is no line item called a "Declaration fee." The older Declaration ID / DID vocabulary appears retired; do not use it in a business plan.

- **Other regimes**
  ISED (Canada) RSS-247 and ICES-003, IC number and bilingual labelling. EU RED 2014/53/EU, EN 300 328 – and note that Article 3(3)(d)(e)(f) cybersecurity became mandatory on 1 August 2025 via EN 18031-1/-2/-3, requiring a security risk assessment, documentation, and vulnerability

handling and patching. RoHS (ten restricted substances, 0.1% threshold, ten-year records) and REACH SVHC obligations.

8.3 Reimbursement

- **Traditional Medicare: no**
  There is no national coverage determination for PERS, and the exclusion is structural rather than discretionary – PERS fails the durable medical equipment definition. Per SSA POMS HI 00610.200, DME must be "primarily and customarily used to serve a medical purpose… and generally is not useful to a person in the absence of an illness or injury," with comfort, convenience and preventive items expressly excluded.

  The HCPCS codes confirm it directly:

Table 15 – HCPCS Codes for Emergency Response Systems

Code	Descriptor	Medicare status
S5160	Emergency response system; installation and testing	Not payable
S5161	Emergency response system; service fee, per month	Coverage code I – "Not payable by Medicare"
S5162	Emergency response system; purchase only	Not payable
A9280	Alert or alarm device, not otherwise classified	Coverage code S – "Non-covered by Medicare statute"

- **Medicare Advantage: yes, as a supplemental benefit – but the data is coarse**
  CMS's public Plan Benefit Package files do not break out PERS as a discrete reportable category. Neither KFF nor Avalere publishes a PERS-specific number. Anyone quoting "N% of MA plans cover PERS" is extrapolating. Do not put such a figure in a deliverable without a primary source.

The closest proxies. KFF's Medicare Advantage in 2026 (share of enrollees): in-home support services 10% individual plans / 38% SNPs; bathroom safety devices 21% / 60%; remote access technologies and/or telemonitoring 43% / 39%, but telemonitoring specifically only 2% / 1%. Better Medicare Alliance / Avalere (share of plans): in-home support services 7% / 25%; at least one SSBCI 12% / 87%, with Avalere cautioning that its "counts may be an underestimate… due to varying naming conventions used by plans." KFF's 10% and Avalere's 7% count different things and must not be merged.

The channel is nonetheless real. SCAN Health Plan lists a named 2026 "Emergency Response / Personal Alert" supplemental benefit, and NationsBenefits and ADT built a PERS supplemental-benefit distribution partnership for MA plans. The commercial route into MA is through supplemental-benefit administrators, not direct CMS billing.

- **Medicaid HCBS waivers: the most established payer, with a hard product gate**
  An analysis of all FY2021 Medicaid 1915(c) waivers found PERS offered by 57.8% of states for people with intellectual and developmental disabilities, though with only 1.1% of recipients expected to use it and enormous state variation (0.03% in Illinois to 20.5% in New Jersey). That count covers IDD waivers only; aged and disabled waivers – where the older-adult market is – are broader, and we could not source a current count for them.

  What a state actually buys imposes product requirements. Virginia 12VAC30-122-470 requires equipment "approved by the Federal Communications Commission" meeting UL 1635 (Digital Alarm Communicator System Units) and UL 1637, with the UL listing mark accepted as evidence. The monitoring agency must run primary and independent interchangeable backup receivers, backup power, separate

telephone service, and staffing 24 hours a day, 365 days a year. Massachusetts has a parallel regulation at 130 CMR 409.429.

UL 1635/1637 listing is a hard gate for Medicaid channel access, and a BLE-to-phone architecture does not satisfy it automatically. If the Medicaid channel is in the plan, this constrains the system architecture from day one – it is not a certification you add later.

- **Remote patient monitoring: almost certainly not available, and the reason is a trap**
  Two independent blockers. First, the data must be physiologic: the CPT descriptors specify "Remote monitoring of physiologic parameter(s) (eg, weight, blood pressure, pulse oximetry, respiratory flow rate)." A fall is a kinematic safety event. Second, and decisively, HHS states: "The device used to collect and transmit the data must meet the definition of a medical device as defined by the FDA."

  This is the strategic fork. A product deliberately positioned as a general wellness product to stay outside FDA regulation is thereby disqualified from RPM billing. You cannot have both. Any business plan that assumes general-wellness positioning and RPM revenue is internally inconsistent, and we have seen this combination in the category's investor materials.

  For completeness, the CY2026 code set (from the PFS final rule published 5 November 2025) added lower-threshold codes: 99445 (device supply, 2–15 days of data) and 99470 (treatment management, first 10 minutes) alongside existing 99453, 99454, 99457 and 99458, with RTM parallels at 98984, 98985 and 98979. We have deliberately not reproduced payment amounts: the figures circulating come from vendor blogs, they disagree with each other, and they are non-geographically-adjusted. Pull the CY2026 PFS Relative Value File from CMS directly.

- **VA: unverified**
  We could not find any authoritative va.gov source establishing PERS or medical alert devices as a defined VA benefit. VA Prosthetic and Sensory Aids Service lists artificial limbs, hearing aids, home modifications, implants, DME, wheelchairs, home oxygen, eyeglasses and service-dog insurance – PERS is not listed. Every "VA covers medical alert" claim we found traces to commercial marketing sites. Report as unverified. Plausible but unconfirmed routes – clinician-prescribed assistive technology case by case, the Veteran-Directed Care flexible budget, or Aid and Attendance pension used out of pocket – warrant a written query to VA Central Office PSAS.

8.4 FTC, liability and licensing

- **The FTC exposure is arguably larger than the FDA exposure, and this category has been an enforcement target**
  FTC v. Lifewatch, Inc., with the Florida Attorney General, alleged at least a billion unsolicited robocalls for medical alert systems, false claims of endorsement by organizations including the American Heart Association, and "free" system claims concealing monthly monitoring fees and cancellation penalties. The order prohibits misrepresenting terms of sale and bans the defendants from telemarketing. The FTC returned $1,808,260 to 71,899 consumers in December 2021.

  The FTC Health Products Compliance Guidance (20 December 2022) expressly reaches "health equipment, diagnostic tests, and health-related apps." Three standards matter here:

  Competent and reliable scientific evidence: "tests, analyses, research, or studies that (1) have been conducted and evaluated in an objective manner by experts in the relevant disease, condition, or function… and (2) are generally accepted in the profession to yield accurate and reliable results."

Implied claims: "A marketer is equally responsible for the accuracy of claims suggested or reasonably implied in advertising."

Disclaimers: must be "clearly and conspicuously" presented and "difficult to miss… and easily understandable," cannot "directly contradict a claim," and – decisively – "If a significant minority of consumers take a misleading claim from an ad despite a disclosure, the disclosure isn't sufficient."

The practical consequence. A claim like "detects 95% of falls" requires competent and reliable scientific evidence, and a fine-print disclaimer does not cure a headline claim. Given the real-world sensitivity evidence in §5.5, any specific accuracy claim in this category is difficult to substantiate.

- **How the incumbents paper the liability**
  ADT: "An ADT Medical Alert system is not an intrusion detection system or medical device; ADT is not a '911' emergency medical response service." Its pendant user guide: "Fall Detection pendant does not detect 100% of falls." Apple: "Apple Watch cannot detect all falls." LifeCall's terms cap liability at "six (6) times the monthly payment… or to the sum of $250, whichever is greater."

  Do not copy incumbent contract language as a model. Courts treat these caps unevenly: the majority rule reviews them as exculpatory clauses for unconscionability and generally enforces them, but Ohio and California apply a liquidated-damages penalty test with opposite outcomes on identical $50 caps, and courts "will not enforce exculpatory clauses that attempt to insulate a tortfeasor from gross – willful or wanton – negligence." Legal commentary (Cohen, Fordham Law Review) indicates courts generally will not enforce exculpatory clauses reaching gross negligence; whether LifeCall's clause survives in any given state is a question for counsel. Attorney drafting with state-by-state review is required.

- **Alarm and telecare licensing**

  We could not verify a clean current count. Verified: the NSCA Guide to State Licensing identifies 27 states with statewide alarm or security licensing, with several (Indiana, Kansas, Colorado, Kentucky) having none statewide; some states license monitoring station operators separately (Alabama, for example). Wolters Kluwer/CT confirms most states require a license, naming Colorado and Wisconsin as exceptions.

  Whether PERS falls inside or outside the alarm licensing scheme varies. Kirschenbaum & Kirschenbaum, the leading alarm-industry firm: "in many jurisdictions, PERS is not considered an alarm system and is not included in the alarm license" – but the central station "will have to [be] authorized to provide monitoring services in the jurisdiction." They add that PERS agreements "will be held to strict scrutiny by the courts," that PHI handling may trigger HIPAA, and – a notable commercial signal – that insurers are "reluctant to write the insurance for alarm companies who provide only PERS service."

  Do not state a state count for PERS-specific licensing. The defensible statement: statewide alarm licensing exists in a majority of states, some license monitoring centers separately, and PERS treatment must be determined jurisdiction by jurisdiction. This is a 50-state survey for a regulatory attorney.

8.5 The strategic fork, stated plainly

Table 16 – Regulatory Path Comparison: General Wellness vs. Regulated Device

Dimension	Path A – General wellness / consumer	Path B – Regulated device
Claims	Non-disease notification only	Fall-risk, prevention, or disease-specific

FDA	No submission, no user fee	ILQ registration (890.9 risk), or 510(k) $26,067 / $6,517 small business, or De Novo $173,782 / $43,446
Ongoing	–	Establishment registration $11,423/yr (FY2026), listing, QMSR, MDR, UDI
Certification	FCC + Bluetooth SIG (~$12,000 Adopter)	Same, plus the above
Revenue	Cash-pay, MA supplemental via administrators, Medicaid HCBS (requires UL 1635/1637)	The above plus RPM billing
Precedent	What Apple, ADT and every PERS incumbent do	Tango Belt (De Novo, 2025)

Our read: Path A. Every commercial precedent in the category is on it, the cost differential is roughly two orders of magnitude, and RPM revenue – the only thing Path B unlocks – is not demonstrably available for a kinematic event even with device status. But this decision belongs to regulatory counsel with the actual marketing claims in front of them, and it should be made before the marketing copy is written, not after.

Section 9 – Supply chain and bill of materials

Delivered as the Supply & Vendor Snapshot add-on. Component prices are as retrieved by the client in March 2026 and will have moved.

9.1 The architecture

The V3 design comprises: a BLE microcontroller module; a six-axis inertial measurement unit with an on-sensor machine learning core; lithium-polymer charge management; power-only USB-C input; low-dropout regulation; a MOSFET-driven eccentric rotating mass haptic motor with flyback protection; TVS/ESD protection; a JST battery connector; and passives. The design targets an enclosure envelope benchmarked against Pavlok (22.1 × 39.1 × 10.6 mm) and WHOOP (34.7 × 24.0 × 10.6 mm).

9.2 The sourcing migration, and what it delivered

The client migrated the entire bill of materials from distributor catalogue sourcing to an Asian assembler's native supply, part by part, grading each substitution as exact, equivalent or alternate and annotating it with live stock levels. This is careful work and it produced a large number. It also produced a comparison that does not hold up, and both facts belong in the report.

Table 17 – Bill-of-Materials Cost by Configuration

Configuration	Qty 1	Qty 1,000	Notes
V1, distributor sourcing (incl. battery)	$18.73	$14.06	Omits LDO, TVS and JST
V1, re-sourced to assembler (excl. battery)	$5.39	–	71.2% below distributor at qty 1
V3, assembler sourcing (excl. battery)	$11.10	$7.33	Quantity-weighted; upgraded IMU plus three added parts

V3 plus battery – like-for-like	$17.05	$13.28	The only valid comparison against $14.06
Like-for-like saving at qty 1,000	–	5.5%	–

Three problems with the headline number:

The battery is missing from both assembler bills of materials. The distributor list carries a 150 mAh 3.7 V cell at $5.95. Neither LCSC sheet includes one. At $5.95 the battery is 45% of the like-for-like quantity-1,000 bill of materials, and 81% of the electronics cost it sits beside. It is not a rounding error.

The battery's quantity-1,000 price in the client file equals its quantity-1 price. That is almost certainly a copied cell rather than a volume quote. A real 150 mAh cell at 1,000 units should quote materially lower, and correcting it would restore some of the apparent saving. Re-quote before any of these numbers are used.

The two bills of materials are not the same design. V3 adds an LDO, a TVS diode and a JST connector that the distributor list omits, and upgrades the IMU from a $2.40 part to a $5.68 part.

Where the saving went – the bridge from $5.39 to $11.10 at quantity one:

Table 18 – Cost Bridge, V1 Re-Sourced to V3 (Qty 1)

Line	Delta	Note
IMU: LSM6DSOXTR → LSM6DSV16XTR	+$3.28	The documented upgrade. See §9.3 for a serious problem with its stated rationale.
MCU: $1.34 → $3.62	+$2.28	Unexplained. 40% of the erosion, on the same row §9.4 flags as internally contradictory about which chip it is.
Vibration motor substitution	+$0.25	

Three added parts (LDO, TVS, JST)	+$0.35	
Battery charger: BQ25180 → MCP73831T	−$0.52	Undocumented substitution.
Total	+$5.71	

The MCU delta is the finding here. The report's own §9.4 cannot determine which microcontroller V3 uses, and that same row carries the second-largest cost increase in the design. Until it is resolved, neither the cost figure nor the certification budget (§8.2.3) is reliable.

The summary we recommend using: the sourcing migration reduced component cost by 71% at prototype quantities; a sensor upgrade, an unexplained MCU cost increase, and three added protection components spent most of that back at production volume, leaving a like-for-like saving of about 5% at 1,000 units.

9.3 The sensor decision

The migration from the ST LSM6DSOXTR ($2.40) to the LSM6DSV16XTR ($5.68) was recorded in the client's 25 March 2026 design log against four criteria: recurring assembler stock backlog on the incumbent part; lower power consumption on the replacement; pin-compatible layout, avoiding a Bosch alternative that would have forced a full redesign; and "2x Decision Trees from 12 to 24."

The fourth criterion does not reconcile with ST's published specifications, and it points the wrong way.

ST's application notes state the opposite of what the design log records:

Table 19 – On-Sensor Machine-Learning Capacity, LSM6DSOX vs. LSM6DSV16X

Part	Decision trees	Total nodes	Source
LSM6DSOX (the part replaced)	up to 8	256	ST AN5259
LSM6DSV16X (the replacement)	up to 4	128	ST AN5804

"The LSM6DSOX can be configured to run up to 8 decision trees simultaneously and independently" (AN5259). "The LSM6DSV16X can be configured to run up to 4 decision trees simultaneously and independently" (AN5804). Neither the figure 12 nor the figure 24 appears in either document.

On ST's published specifications the migration halves available on-sensor decision trees and halves the node budget, while raising the part cost by $3.28 per unit. We have not been able to identify a source for the 12-to-24 figure and we are not able to reconcile it.

This matters more than its size suggests. The wrist form factor's structural weakness is false positives from arm movement (§5.5), and the resource that addresses it is on-sensor classification capacity. If the log is wrong, the upgrade reduced the resource it was partly chosen to increase. Recommend re-reading AN5259 and AN5804 against the design intent before V4. Retrieved 23 August 2026.

The other three criteria stand on their own. Stock availability, power consumption and pin compatibility are real, verifiable reasons to move parts, and any one of them can justify the change independently. The LSM6DSV16X also carries capabilities the LSM6DSOX does not, including a sensor-fusion low-power engine. The point here is narrow: the specific

decision-tree justification recorded in the log is not supported by ST's documentation, and a design decision resting partly on it should be revisited rather than inherited.

In neither case does the sensor create a defensible position. The LSM6DSV16XTR is available to every competitor at the same price, and ST holds a granted patent on the automated pipeline that generates decision trees for its own machine learning core (§7.4). Any differentiation lies in the training data and the feature selection, not in the silicon.

9.4 Sourcing risks

Table 20 – Sourcing Risks

Risk	Detail
Unresolved MCU identity	The V3 sheet labels the MCU row "ESP32-C3-MINI-1" while the description reads "Nordic nRF52805 SoC (bare chip)" and the datasheet link points to Espressif. These are different parts from different vendors with different radios, power profiles and certification consequences (§8.2.3). This must be resolved before anything downstream is trusted.
Bare SoC versus pre-certified module	The V1 list used a Fanstel BC805M, a pre-certified module. The V3 description says "bare chip – pair with pre-cert module," which is ambiguous. A bare SoC moves full intentional-radiator certification onto the client and makes every antenna and layout change a recertification event.
Single-source concentration	Whole bill of materials sourced from one assembler's catalogue. Excellent for cost and assembly, and a single point of failure for supply.
Stock annotations are stale, and V3 carries none	The 78-unit stock note on the TI BQ25180 charger sits in LCSC_BOM.xlsx (the V1 re-source). V3 replaced it with a Microchip MCP73831T-2ACI/OT at $0.74, which resolves that exposure but is an undocumented substitution from an I^2C charger with power path to a simpler linear charger. Confirm it was deliberate. Separately, V3_PARTSCOMPS.xlsx carries no stock annotations at all, so no current stock-depth risk can be sourced from it.
Unquoted non-BOM cost	PCB assembly, enclosure, strap, packaging, freight, duty and tooling are all unquoted. Together they are roughly half the fully loaded unit cost in the model.
Tariff exposure	Not modelled. Chinese-assembled consumer electronics carry duty and tariff risk that has moved repeatedly.

Battery logistics	Lithium cells carry UN 38.3 testing, shipping classification and packaging requirements not captured anywhere in the client's files.

9.5 Fully loaded unit cost

Table 21 – Fully Loaded Unit Cost

Line	Per unit	Status
Bill of materials, qty 1,000, incl. battery	$13.28	Sourced (client files)
PCB fabrication and assembly	$4.50	Placeholder
Enclosure, strap and hardware	$6.00	Placeholder
Packaging and literature	$1.50	Placeholder
Inbound freight and duty	$2.00	Placeholder
Subtotal	$27.28	
Warranty and returns reserve (5%)	$1.37	Placeholder
Fully loaded cost per unit	$28.65 (unrounded $28.6488)	
Device price	$199.00	Benchmarked to competitors
Hardware gross margin	85.6%	

Read that margin with care. Four of the five cost lines are unquoted. It is a structure, not a result. The scenario run in §12 moves assembly and enclosure alone from $10.50 to $18.00 and the margin falls accordingly.

Section 10 – Positioning, pricing and go-to-market

The defensible position, the price against the field, and the channel sequence

10.1 Where the position is

On the evidence, the defensible position has four components, all four drawn from documented category failures rather than from feature aspiration:

Wear it in the shower. 64% of owners remove their device to bathe, and the bathroom is where falls concentrate. A genuinely waterproof wrist device that people keep on is worth more than an algorithm improvement.

A human in the loop. Roughly half of owners have had a false alarm. Apple dials 911 directly with no one to cancel it. A monitoring center that can verify before dispatch is the clearest justification for the $1,000–$2,200 three-year premium over a smartwatch.

A caregiver app. Adult children are 2.4× more likely to buy than users are to self-purchase, and the closest comparable – UnaliWear – has no companion app at all. This is an open flank on the direct competitor.

Fall detection included, not an add-on. Every vendor except UnaliWear charges $5–$11/month extra for the feature that defines the category. Including it is a clean, defensible differentiator that costs nothing to explain.

10.2 What the position is not

It is not "more accurate." The evidence does not support anyone making that claim, the wrist form factor is structurally disadvantaged, and §8.4 makes an unsubstantiated accuracy claim an FTC problem rather than a marketing one.

It is not "cheaper." Cost is the fourth-ranked objection, at 23%. And the entrant cannot win on price against a $249 Apple Watch SE with $0 recurring.

It is not "for seniors." 32% of non-adopters say they "don't feel old enough." The category's own language is one of its largest barriers.

10.3 Pricing

The model uses $199 device, $34.95/month with fall detection included. Against the field:

Table 22 – Proposed Pricing Against the Field

Product	Device	Monthly incl. FD	3-year total
UnaliWear Kanega	$299	$64.95	$2,637
Medical Guardian MGMove	$199.95	$52.95	$2,106
Bay Alarm SOS Smartwatch	$199	$50.95	$2,033
Proposed	$199	$34.95	$1,457
Lively Mobile2 (pendant)	$79.99 + $35 act.	$34.98	$1,374
Apple Watch SE 3	$249	$0	$249

This positions at the price of a pendant with the form factor and inclusions of a premium watch – roughly 45% below UnaliWear over three years, 28% below Bay Alarm at its month-to-month rate and about 26% below Medical Guardian at its annual rate, while remaining nearly six times an Apple Watch SE before cellular service is added. The gap to Apple cannot realistically be closed on price and should not be argued there; it is argued on the monitoring center, standalone cellular operation, and soft-fall detection.

Two cautions. First, the price sits below every monitored wrist competitor, which invites the question of what has been removed – the answer must be ready. Second, at $34.95 the subscription carries the whole business: hardware contributes $170 of one-time gross profit against $278 a year of recurring service gross profit, so anything that raises churn destroys the model faster than anything that raises hardware cost.

10.4 Channel sequence

Phase 1 – direct-to-consumer, adult-child targeted. The only channel a new entrant can open unilaterally. Budget for placement in the affiliate review publishers, which function as the category's gatekeepers (§6.3). CAC here is completely unmeasured and is the model's most sensitive input.

Phase 2 – Medicare Advantage supplemental benefits, through administrators such as NationsBenefits rather than CMS. Slow, relationship-driven, and the realistic route to volume. Begin conversations in Phase 1; the sales cycle is long.

Phase 3 – Medicaid HCBS waivers, contingent on UL 1635/1637 listing and a compliant 24/7 monitoring center (§8.3.3). This is an architectural decision, not a later certification – if Medicaid is in the plan it constrains the system design from the start.

Not attempted: national retail. Lively has it through Best Buy's ownership and it is not otherwise winnable at this scale.

Section 11 – Five-year commercial model

*Delivered as **[REDACTED]** Five-Year Commercial Model.xlsx. Every driver is editable; every external figure is sourced on its own tab. Estimates based on the stated assumptions. Not forecasts, guarantees, or investment advice.*

11.1 Base case

Table 23 – Base-Case Five-Year Model

Line item	FY2027	FY2028	FY2029	FY2030	FY2031
Gross additions	1,200	4,500	11,000	22,000	36,000
Closing subscribers	1,068	4,838	13,564	30,160	55,565
Device revenue	$238,800	$895,500	$2,189,000	$4,378,000	$7,164,000
Subscription revenue	$223,960	$1,238,497	$3,858,839	$9,168,783	$17,976,365
Total revenue	$462,760	$2,133,997	$6,047,839	$13,546,783	$25,140,365
Gross profit	$352,776	$1,586,982	$4,430,026	$9,821,290	$18,040,505
Gross margin	76.2%	74.4%	73.2%	72.5%	71.8%
Total operating expense	($639,200)	($1,485,000)	($3,230,000)	($6,120,000)	($9,760,000)
EBITDA	($286,424)	$101,982	$1,200,026	$3,701,290	$8,280,505
Cumulative EBITDA	($286,424)	($184,441)	$1,015,585	$4,716,875	$12,997,380

Gross margin declines across the period, and that is correct rather than an error. Hardware carries an 85.6% margin against 66.2% on service, so as the subscription mix rises from 48% to 72% of revenue the blended margin falls. A model in this category that shows margin expanding with scale has usually mis-specified the service cost line.

Peak cumulative cash requirement: $286,424, in FY2027. This excludes working capital, inventory build and capital expenditure; a financing plan needs all three added.

Subscriber unit economics at base assumptions: annual subscription revenue $419.40, annual service cost $141.58, annual service gross profit $277.82; hardware gross profit $170.35 one-time; average subscriber life 4.55 years (1 ÷ 22%); undiscounted lifetime value $1,433; CAC $250; LTV/CAC 5.73×; CAC payback 3.4 months.

11.2 What to distrust in that table

An LTV/CAC of 5.7× with a 3.4-month payback would be an exceptional consumer subscription business. That is a warning, not a result. It is produced by three placeholder inputs – CAC at $250, churn at 22%, monitoring at $6.00 a month – that were chosen as plausible midpoints in the absence of any public data, and it is sensitive to all three.

Two structural simplifications that are not visible in the table. The model applies the quantity-1,000 bill-of-materials price at every volume, from 1,200 units in FY2027 to 36,000 in FY2031; no component price curve is modelled, which understates cost early and overstates it late. And although the Assumptions tab carries a three-year device replacement cycle, that assumption drives the SAM calculation only: the revenue build books device revenue on gross additions alone, so the FY2027 cohort never generates a replacement sale. Replacement revenue is therefore unmodelled upside, and the SAM's per-subscriber figure is not on the same basis as modelled revenue.

The subscriber ramp is likewise a placeholder. Year five reaches 0.90% of the SAM. That is small enough to be reachable in principle, and it says nothing about whether this particular company would reach it.

The context that makes it defensible at all: the category leader, Connect America, reports 900,000+ subscribers. A five-year plan reaching 55,565 is a rounding error on the market. In a category this concentrated that is a reason for confidence in the plan's arithmetic rather than against it – the constraint is execution and acquisition cost, not available demand.

Section 12 – Scenarios and sensitivity

The four drivers that decide the outcome, and how far they move it

12.1 The four drivers

Table 24 – The Four Decisive Drivers

Driver	Downside	Base	Upside	Why it decides the outcome
Customer acquisition cost	$400	$250	$150	No public figure exists. Sales and marketing is the largest operating line in every year.
Annual churn	35%	22%	14%	No public figure exists. Sets subscriber life and therefore lifetime value.
Monitoring cost per subscriber	$9.00	$6.00	$4.00	Unquoted. Sits directly in service gross margin, every month, permanently.
Assembly + enclosure per unit	$18.00	$10.50	$7.00	Unquoted. Most of the hardware cost that is not the bill of materials.

12.2 What happens

Table 25 – Scenario Outputs, FY2031

Output (FY2031)	Downside	Base	Upside
Total revenue	$22,349,869	$25,140,365	$27,080,662
EBITDA	($554,977)	$8,280,505	$14,437,815
EBITDA margin	(2.5%)	32.9%	53.3%
Closing subscribers	46,528	55,565	61,914
Peak cumulative cash requirement	$4,244,176	$286,424	$141,954
Lifetime value to CAC	2.13×	5.73×	15.53×
Months to recover CAC	11.8	3.4	0.0

12.3 The finding

Revenue barely moves, a −11% to +8% band around the base, while EBITDA swings from negative $555,000 to positive $14.4 million and the peak cash requirement moves by a factor of thirty across the full range, from $142,000 to $4.24 million, and by roughly fifteen times against the base case.

The same subscriber plan is either a business that funds itself out of a founder's line of credit, or a business that needs a $4.2 million round. Nothing separates those outcomes except four numbers that have not been measured.

At the downside, LTV/CAC falls to 2.13× and CAC payback stretches to 11.8 months. Below roughly 3×, paid acquisition stops working as a growth engine, and the plan would have to be rebuilt around channel partnerships – which is Phase 2, which takes years.

12.4 What to do about it

Three of the four are resolvable quickly and cheaply:

Assembly and enclosure cost – request quotes from three contract manufacturers at 1,000 and 10,000 units. Two weeks, no cost.

Monitoring cost per subscriber – request wholesale pricing from three UL-listed central stations. Two weeks, no cost. Ask for UL 1635/1637 status in the same conversation (§8.3.3).

Customer acquisition cost – a $15,000–$25,000 paid test against the adult-child audience will bound it within a quarter. Not precise, but the difference between $150 and $400 is knowable long before a product ships.

Churn cannot be shortcut. It requires a real cohort observed over real time. Until it exists, every lifetime-value figure in this model is provisional, and it should be labelled that way in any document shown to an investor. The

honest interim approach is to run the plan at the downside churn assumption and treat anything better as upside.

We deliberately did not build a one-way data table. The four drivers interact – churn affects both revenue and marketing efficiency, while monitoring cost and assembly cost hit different margin lines – and a one-way sensitivity would understate the range. The paired downside and upside runs above are the honest width of the uncertainty.

Section 13 – Strategic considerations

Research-supported considerations, not recommendations. Each is grounded in a specific finding above; none should be actioned without the verification steps named.

1. The category's constraint is identity, not price – and the product decisions follow from that. Three of the top four non-adoption reasons are self-perception, and cost is fourth at 23%. A device that reads as a watch rather than as a medical device, marketed on independence rather than frailty, addresses the actual barrier. This is a design and copy problem more than an engineering one, and it is where a small team can genuinely outperform an incumbent.

2. The compliance gap is the largest unexploited opening. 64% remove the device to bathe; 39% do not wear it at night; only 18% wear it always. Wear time and detection accuracy compound: a device that is not being worn has no detection rate at all. Given that only 18% of owners wear the device continuously, wear time is plausibly the higher-leverage variable, and almost nobody in the category competes on it. We have not quantified that trade-off and no published data supports quantifying it. WHOOP's 14-day battery and UnaliWear's swappable in-band cells both point at the same insight from different directions.

3. Do not compete with Apple; compete for the people Apple cannot serve. Cannibalization is largely complete at the tech-comfortable, younger-old end. The remaining position is the frail, older, less technical user, the 85+ cohort growing 111% by 2040, where fall death rates run 17.7× the 65–74 rate and 38% live alone. It is a smaller and harder market than the one a plan would prefer to describe, and it is the one that is actually available.

4. Treat the patent environment as a business risk with a live case in it, not as a background condition. ITC Investigation 337-TA-1477 is instituted and, as of retrieval, not confirmed terminated. Philips US 10,335,059 claims

context-adaptive sensitivity – the most natural answer to the wrist form factor's false-positive problem – through 2034. Apple holds ten-plus granted patents from a 2017 priority running to 2038 whose claims we could not read. Before significant engineering commitment: engage a registered practitioner, pull the Apple claims, run a CPC-based search, and check PTAB for IPR petitions against the UnaliWear patents.

5. Do not treat a provisional application as a moat. AliveCor won at the ITC and lost all three patents in IPR. Omni MedSci lost a patent to invalidity. The dominant outcome for a small patentee against a large defendant in this space is losing the patent, not winning the case. A provisional application is a filing date and twelve months of optionality. It is not protection, and it should not appear in a business plan as though it were.

6. Decide the regulatory path before the marketing copy is written. General wellness and RPM billing are mutually exclusive (§8.3.4). Every commercial precedent in the category is on the general-wellness path. Choosing it means the marketing claims are constrained permanently and from day one, and it means the RPM revenue line comes out of the model.

7. Decide about Medicaid before the architecture is frozen. UL 1635/1637 listing and a compliant 24/7 monitoring center are a hard gate on the most established payer channel in the category. That is a system-architecture decision, not a certification to add later.

8. Re-examine the sensor decision, and treat the design log as a source that needs checking. The stated decision-tree rationale for the LSM6DSV16XTR upgrade contradicts ST's own application notes, and on those notes the upgrade halves the on-sensor classification capacity. The change may still be right on stock, power and pin-compatibility grounds. The process point is larger than the part: a figure written into a design log became the justification for a recurring per-unit cost, and nobody checked it against the

manufacturer's documentation. That is worth a habit change, not just a correction.

9. Resolve the MCU ambiguity immediately. The V3 sheet is internally inconsistent about whether the design uses an Espressif ESP32-C3-MINI-1 or a bare Nordic nRF52805, and the choice between a pre-certified module and a bare SoC determines whether FCC certification is a $3,000–$10,000 host-testing exercise or a full intentional-radiator certification the client owns forever. Nothing downstream – cost, certification budget, timeline – is reliable until this is settled.

10. Get three quotes before the model is shown to anyone. Contract manufacture, enclosure tooling, and wholesale monitoring. Two weeks of work moves three of the four decisive drivers from placeholder to sourced, and it is the difference between a model that supports a decision and a model that illustrates a structure.

11. Confirm the charger substitution, and re-quote the battery. V3 replaced the TI BQ25180 with a Microchip MCP73831T without a recorded rationale; the two parts differ materially in capability. And on the battery: At $5.95 it is 81% of the quantity-1,000 electronics cost and 45% of the like-for-like bill of materials, and the file's quantity-1,000 price is identical to its quantity-1 price, which is not a volume quote. It is the single largest correctable error in the cost work.

Appendix A – Assumptions register

Every assumption in the model, and whether it has a source.

A.1 Sourced

Table 26 – Sourced Assumptions

Assumption	Value	Source	As of
US adults 65+	61,200,000	US Census Bureau, Vintage 2024	1 Jul 2024
Share of 65+ living alone	26%	Pew Research Center	2023 data, pub. Dec 2025
Wearable ownership, 50+	36%	AARP 2026 Technology Trends (n=3,838)	fielded Sep–Oct 2025
Medical-alert penetration, 65+	9%	The Senior List (n=909)	fielded Apr–May 2026
Category average monthly fee	$39.00	ConsumerAffairs; SeniorLiving range $25–$60	Aug 2026
Device price benchmark	$199	Bay Alarm $199; Medical Guardian $199.95	23 Aug 2026
Subscription price benchmark	$34.95	Between Lively $24.99+$9.99 and Bay Alarm $39.95+$11	23 Aug 2026
Bill of materials, electronics, qty 1,000	$7.33	Client V3_PARTSCOMPS.xlsx; quantity weighting applied by ZKK, as the client's own total row is an unweighted sum	Mar 2026
Battery, qty 1,000	$5.95	Client All Parts and Components.xlsx. Not a volume quote – the file's qty-1,000 price equals its qty-1 price. Re-quote required (§9.2)	Mar 2026
Certification cost	$12,200	SparkFun published invoice	3 Dec 2019
Bluetooth SIG qualification	$12,000	SIG fee schedule, Adopter tier	eff. 1 Mar 2026
FCC grantee code fee	$35	47 CFR 1.1103	eff. 23 May 2025
Payment processing	3.0%	Standard merchant rate	–

A.2 Placeholders – no public source exists

Table 27 – Placeholder Assumptions (No Public Source)

Assumption	Value	Sensitivity
Customer acquisition cost	$250	Decisive
Annual churn	22%	Decisive
Monitoring center cost	$6.00/sub/mo	Decisive
PCB assembly + enclosure	$10.50/unit	Decisive
Cellular connectivity	$4.00/sub/mo	High
Cloud, app and support	$0.75/sub/mo	Low
Packaging	$1.50/unit	Low
Inbound freight and duty	$2.00/unit	Moderate – tariff risk unmodelled
Warranty and returns reserve	5%	Moderate
Injection mold tooling	$45,000	One-time
Device replacement cycle	3 years	Moderate
Gross additions ramp	1,200 → 36,000	Structural
R&D and G&A expense	See workbook	Structural
Component price curve with volume	Not modelled	Moderate – BOM held flat at the qty-1,000 quote across a 30× volume range
Device replacement revenue	Not modelled	Upside – drives the SAM only, not the revenue build

Not modelled at all: working capital and inventory build; capital expenditure; tariffs and duties beyond the freight placeholder; UN 38.3 lithium battery compliance cost; UL 1635/1637 listing cost; state alarm licensing cost; product liability insurance (noted as difficult to obtain for PERS-only operators); patent litigation defense reserve; FDA Q-Submission cost.

Appendix B – What we could not verify

Presented as a finding. In this category, several of the numbers that do not exist are the ones a business plan would otherwise rest on.

Market and demographics

US population by 65–74 / 75–84 / 85+ for the current year, and 2030/2035 projections. Census Table 3 (np2023-t3.xlsx) contains this; download blocked in our environment. Retrieve manually.

Wearable ownership among adults 65+ specifically, from a current nationally representative survey. AARP publishes 50+ only.

Wrist-worn fall detection as a distinct revenue line. No firm sizes it; we did not derive one.

PERS subscriber churn, ARPU, or CAC from any public source.

Berg Insight's mobile-versus-in-home user split (in the paid report only).

Per-company PERS market share. Only Connect America publishes a subscriber count.

Competitive 7. CarePredict Tempo pricing and specifications – product page 404s, contact-gated. 8. Vayyar Care pricing – not disclosed. 9. Any 2024–2026 new wrist entrant. "None found," not "none exist." 10. Samsung Galaxy Watch9 pricing showed internal inconsistencies on Samsung's own site; re-verify at checkout. 11. Whether Medical Guardian's MGMove includes automatic fall detection by default – Medical Guardian's own page does not mention it; two third parties call it a $10/month add-on. Verify by phone.

Patent 12. Claim 1 of every member of the Apple fall-detection family. The largest gap in this report. 13. Claim 1 for Philips US 11,361,648, MobileHelp

US 9,179,864, Alva Health US 11,937,917. 14. Any assignee-scoped patent search, and therefore any patent count, filing trend or assignee ranking specific to fall detection. 15. PTAB / IPR petitions against the UnaliWear patents. 16. Current status of ITC 337-TA-1477 – verify on EDIS and PACER.

Regulatory and reimbursement 17. FDA's position on automatic fall detection. Confirmed absence, not a search failure – no guidance, policy statement, or warning letter exists. 18. Any VA benefit covering medical alert devices. 19. A PERS-specific Medicare Advantage plan count – CMS PBP files do not break it out. 20. Accredited-lab pricing for §15.247 – all labs quote privately. 21. CY2026 RPM payment amounts – vendor blogs only, and they disagree. Pull the CMS RVU file. 22. A current authoritative state count for PERS-specific licensing.

Client design record 23. The source of the client's "12 to 24 decision trees" figure. It appears in neither ST AN5259 nor AN5804, and we could not reconcile it with any published ST specification. 24. Whether a V2 board exists. The files evidence a V1 parts list and a "Version 3.0.0" design entry; no V2 record appears. 25. Whether the BQ25180 to MCP73831T charger substitution between the V1 re-source and V3 was deliberate. No rationale is recorded.

Also flagged 26. The Haddad et al. 2024 $80bn figure – primary paper CAPTCHA-blocked; two secondaries agree. Verify (PMID 39029927). 27. NCOA's "83 of 84 alarms were false" claim – does not match the underlying Bagalà study. Cite Bagalà directly. 28. The "UnaliWear drops complaints" headline – article body contains no statement of withdrawal. Do not repeat as fact.

Appendix C – Sources

All retrieved 23 August 2026 unless otherwise stated.

Government and primary CDC, Facts About Falls (rev. 27 Jan 2026) · CDC, Older Adult Falls Data · NCHS Data Brief No. 532, Unintentional Fall Deaths in Adults Age 65 and Older: United States, 2023 · US Census Bureau, Older Adults Outnumber Children, Vintage 2024 (rel. 26 Jun 2025) · US Census Bureau, 2023 National Population Projections · ACL, 2023 Profile of Older Americans · WHO, Falls Fact Sheet (26 Apr 2021) · PHI, Understanding the Direct Care Workforce (BLS-based) · Apple, Use Fall Detection with Apple Watch · FDA, General Wellness: Policy for Low Risk Devices, final guidance 6 Jan 2026, docket FDA-2014-N-1039 · FDA product classification records ILQ, SEC, PJO/PJP · 21 CFR 890.3710, 890.9, 880.2400 · FDA De Novo DEN240021 (Tango Belt) · AccessGUDID DI 00884838071827 · Federal Register, Medical Device User Fee Rates FY2026 · 47 CFR 15.201, 15.247, 15.249, 15.212 · Federal Register, Schedule of Application Fees (23 Apr 2025) · FCC KDB 447498 · SSA POMS HI 00610.200 · Medicare.gov DME coverage · HCPCS S5160, S5161, S5162, A9280 · telehealth.hhs.gov RPM billing guide · Federal Register, CY2026 PFS Final Rule (5 Nov 2025) · Virginia 12VAC30-122-470 · 130 CMR 409.429 · VA Prosthetic and Sensory Aids Service

Peer-reviewed Bagalà F et al. (2012), PLOS ONE 7(5):e37062 · Florence CS et al. (2018), JAGS 66(4):693-698 · Haddad et al. (2024), Injury Prevention (PMID 39029927, not directly verified) · Moreland et al. (2024), Journal of Aging and Health · Reider et al. (2024), Injury · Tinetti et al. (1993), JAMA · Fleming (2008), BMJ · Wild et al. (1981), BMJ · Cohen, Sound the Alarm: Limitations of Liability in Alarm Service Contracts, Fordham Law Review

Survey and analyst AARP 2026 Technology Trends Among Adults 50-Plus · AARP 2025 Technology Trends · AARP 2024 Home & Community Preferences Survey · Pew Research Center (4 Dec 2025) · The Senior List 2026 Medical Alert Device Usage Report · Berg Insight via IoT Business News (28 Feb 2026) · IDC Q1 2025 wrist-worn shipments · Counterpoint Q1 2026 and FY2025 smartwatch · KFF, Medicare Advantage in 2026 · Better Medicare Alliance / Avalere · Grand View Research (PERS, fall detection, wearable technology) · Precedence Research · Mordor Intelligence · Market.us · Future Market Insights · Emergen Research · Verified Market Research · PatSnap, Wearable Health Sensors Patent Landscape (8 Jul 2026)

Vendor primary apple.com · samsung.com · store.google.com · unaliwear.com · bayalarmmedical.com · medicalguardian.com · mobilehelp.com · lifefone.com · adt.com · lifealert.com · shop.lively.com · connectamerica.com · whoop.com · pavlok.com · carepredict.com · vayyar.com · bluetooth.com qualification fee schedule · verizon.com prepaid smartwatch plans

Third-party testing and commercial publishers NCOA (best medical alert watches, rev. 23 Jul 2026; with fall detection, rev. 13 Aug 2026; Apple Watch as medical alert, 27 Jan 2026) · SeniorLiving.org (best watches, rev. 16 Apr 2026; Kanega review, rev. 11 Nov 2025; costs, rev. 12 Aug 2026) · ConsumerAffairs · Retirement Living · AgingToday

Patents US 10,051,410 B2 · US 10,687,193 B2 · WO 2020/028157 A1 · US 10,629,048 B2 and family (US 11,276,290; 11,282,361; 11,282,362; 11,282,363; 11,527,140; 11,842,615; 12,027,027; 12,154,420; 12,380,789; US 2025/0046172 A1) · US 2025/0316155 A1 · US 10,863,926 B2 · US 11,875,659 B2 · US 8,756,032 B2 · US 10,335,059 B2 · US 11,361,648 B2 · WO 2012/146957 A1 / US 9,489,815 B2 · US 9,378,636 B2 · US 9,179,864 B2 · US 10,422,814 B2 · US 12,198,525 B2 · US 11,055,981 · US 11,468,758 · US 8,933,801 B2 · US 8,990,041 B2 · US 11,937,917 B1 · US 11,928,947 B2 · US 12,561,577 B2 · US 7,450,332 B2 · US 6,433,690 B2 · US 7,423,537 B2 · US 7,961,109 B2 · US 8,217,795 B2 · US 2006/0282021 A1 · US 2023/0127315 A1 – all via patents.google.com and patents.justia.com

Litigation Federal Register, Notice of Institution, Inv. No. 337-TA-1477 (12 Jan 2026) · USITC press release ER0108-67946 (8 Jan 2026) · Federal Register notices, Inv. No. 337-TA-1276 (1 Nov 2023; 18 Nov 2025; 22 Apr 2026) · Apple Inc. v. ITC, Fed. Cir. No. 24-1285 (19 Mar 2026) · AliveCor, Inc. v. ITC, Fed. Cir. Nos. 2023-1509, 2023-1553, 2023-1512/-1513/-1514 (7 Mar 2025) · Fed. Cir.

Rule 36 judgments Nos. 21-1229, 21-2213 (8 Jun 2022) · Bloomberg Law, Law.com Texas Lawyer, 9to5Mac, MacRumors, Forbes, IPWatchdog, Mintz, Patent Progress

Regulatory commentary Troutman Pepper · DLA Piper · King & Spalding · Womble Bond Dickinson · ACB Cert · Kirschenbaum & Kirschenbaum · NSCA Guide to State Licensing · Wolters Kluwer/CT Corporation · FTC Health Products Compliance Guidance (20 Dec 2022) and FTC v. Lifewatch press releases (2014, 2015, 2021)

Component manufacturer documentation ST AN5259, LSM6DSOX: Machine Learning Core · ST AN5804, LSM6DSV16X: Machine Learning Core · ST LSM6DSOX and LSM6DSV16X datasheets · TI BQ25180 datasheet · Microchip MCP73831 datasheet – all via st.com, ti.com, microchip.com

Client-supplied All Parts and Components.xlsx · LCSC_BOM.xlsx · V3_PARTSCOMPS.xlsx · design logs dated 25 and 26 March 2026

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Estimates, not forecasts. All market sizing, unit economics, and five-year projections are estimates derived from the assumptions stated in Appendix A. They are indicative and based on stated assumptions; they are not forecasts, predictions, or guarantees of any outcome. Actual results will differ and may differ materially. The scenario analysis in Section 12 illustrates a range of outcomes and is not exhaustive.

Sourcing and currency. Figures are current as of the retrieval dates shown and were accurate to the best of our knowledge at that time. Consumer electronics pricing, analyst estimates, regulatory guidance, and litigation status all change; several figures in this report are expected to be out of date within one quarter. Where a figure could not be verified from a primary source, this report says so rather than estimating; Appendix B lists all such items. Third-party market research figures are reproduced as published and their methodologies were not independently verified.

Client-supplied material. Component pricing, part numbers, and design decisions in Section 9 derive from files supplied by the client and were not independently verified against vendor systems. Sections 9.2 to 9.4 identify

specific inconsistencies within those files, including one (§9.3) that contradicts the component manufacturer's published documentation.

Scope. No primary research, buyer interviews, device testing, or manufacturing quotations were performed. No patent claim charts were prepared. No FDA, FCC, or state regulatory body was consulted.

Performance claims. Nothing in this report should be read as a representation of the detection accuracy, reliability, or safety performance of any product, including any product the client may develop. The evidence in Section 5.5 indicates that no fall-detection product achieves complete accuracy, and every vendor in the category publishes a disclaimer to that effect.