
SHIFTING THE BURDEN: APPORTIONING TORTIOUS LIABILITY BETWEEN PHYSICIANS, HOSPITALS, AND AI DEVELOPERS FOR DIAGNOSTIC ERRORS

Vijayaraghavan K, LLM, School of Criminal Law and Criminal Justice Administration,
Tamil Nadu Dr. Ambedkar Law University, School of Excellence, Taramani, Chennai
600113, Tamil Nadu, India

ABSTRACT

The integration of Artificial Intelligence (AI) into clinical diagnostics has revolutionized the healthcare delivery system, yet there exist profound challenges to traditional medical malpractice frameworks. In the absence of the AI diagnosis the diagnostic errors were attributed to individual physician negligence or institutional systemic failures under the doctrine of respondeat superior. However, the opacity of "black-box" machine learning algorithms disrupts this binary paradigm. When an AI diagnostic tool generates a misdiagnosis, false positive, or false negative that results in patient harm, identifying the legally responsible party becomes a complex jurisdictional and doctrinal knot. As AI systems transition from passive assistive tools to autonomous diagnostic agents, traditional tort law frameworks face significant strain. The analysis evaluates how concepts of negligence, vicarious liability, and strict products liability apply to each stakeholder. It explores the "black box" problem of AI transparency, the evolving standard of care for physicians relying on algorithmic recommendations, and the institutional duties of hospitals in vetting and monitoring digital health technologies. The evolving standard of care for physicians argues that doctors face a dual risk: "automation bias," where they blindly rely on erroneous AI outputs, and "automation rejection," where they override accurate algorithmic insights. As the inquiry shifts to hospital the institution faces direct liability under corporate negligence doctrines which could arise due to inadequate procurement vetting, deficient staff training, and failure to implement algorithmic oversight protocols. In the case of AI developers, the traditional product liability frameworks such as specific manufacturing, design, and warning defects are evaluated in order to classify either as product or service. This article examines the complex triadic relationship between physicians, healthcare institutions, and AI developers when diagnostic errors occur. It also explores the shifting burdens of tortious liability among three primary stakeholders: the attending physician, the healthcare institution, and the AI software developer.

Keywords: Artificial intelligence, medical malpractice, tort liability, diagnostic errors, product liability, hospital negligence, standard of care.

1. Introduction

Artificial intelligence (AI) is rapidly transitioning from an experimental clinical tool to the backbone of modern diagnostic medicine. By analysing complex medical imaging, pathology slides, and genomic data at superhuman speeds, AI diagnostic tools promise to radically minimize human error. However, this technological leap introduces a profound legal crisis. When an AI tool generates a high false-negative rate for a specific patient demographic, the resulting diagnostic failure is not merely a technical glitch but a legally material risk. If a patient suffers injury or death due to an algorithmic blind spot, current tort law faces a critical question: how should liability be distributed among the physician who relied on the tool, the hospital that procured it, and the developer who coded it.¹

The current medical malpractice framework is ill-equipped for this emerging reality. Historically, tort law has viewed software as a mere instrument, holding the treating physician primarily liable under the doctrine of professional negligence. Yet, as machine learning models become highly autonomous, treating them as simple stethoscopes is legally untenable. When a physician lacks the technical capacity to look inside the "black box" of an algorithm, holding them solely responsible for an embedded software bias ignores the reality of modern clinical practice. Conversely, traditional product liability doctrines often fail to hold AI developers accountable due to strict regulations regarding "learned intermediaries" or the legal classification of software as a service rather than a tangible product.²

This regulatory vacuum leaves hospitals caught in the middle. Healthcare institutions face escalating exposure under theories of systemic negligence and vicarious liability. Hospitals are responsible for credentialing technologies and training staff. However, they are frequently left blind to the specific demographic biases hidden within proprietary software. The result is a fragmented liability triad where each party can deflect blame, leaving injured patients facing immense hurdles to recovery. The traditional boundaries of tortious liability must be fundamentally reapportioned to match the realities of AI integration. To prevent the legal burden from unfairly shifting entirely onto clinicians or leaving patients without recourse, tort law must evolve. Apportioning liability for AI diagnostic errors requires abandoning single-

¹ Mezrich JL. Is artificial intelligence (AI) a pipe dream? Why legal issues present significant hurdles to AI autonomy. *AJR Am J Roentgenol.* (2022) 219:152–6. 10.2214/AJR.21.2722

² Cestonaro C, Delicati A, Marcante B, Caenazzo L, Tozzo P. Defining medical liability when artificial intelligence is applied on diagnostic algorithms: a systematic review. *Front Med (Lausanne).* 2023 Nov 27;10:1305756. doi: 10.3389/fmed.2023.1305756. PMID: 38089864; PMCID: PMC10711067.

point-of-failure liability models. The physician remains the ultimate clinical gatekeeper, legally responsible for identifying obvious automated errors and resisting automation bias. However, when an error stems from unexplainable algorithmic anomalies or systemic implementation flaws, liability must shift. It moves laterally to the hospital for corporate negligence and backward to the developer under strict product liability frameworks. As diagnostic AI gains autonomy, the legal system must transition toward a hybrid comparative fault model. This framework treats the AI system not merely as a static tool, but as an active agent in a collaborative diagnostic environment.^{3,4}

This article proposes a framework that distributes liability based on each party's distinct sphere of control: strict product liability for developers who conceal material demographic risks; systemic corporate negligence for hospitals with flawed procurement protocols; and professional negligence for physicians who fail to exercise independent clinical oversight. Thus argues, that the legal burden must be aggressively reapportioned to reflect the realities of digital medicine. It also aims to dismantle the assumption that the physician is always the ultimate shield. Instead, the dynamic framework of shared responsibility: holding developers strictly liable for hidden demographic defects, hospitals accountable for systemic procurement failures, and physicians responsible only for their independent clinical judgment. Only by modernizing these legal boundaries can the healthcare system encourage technological innovation while strictly safeguarding patient safety. The future of healthcare innovation depends on fixing this legal crisis before the machines take over the courtroom.

2. The Physician: Negligence, Standard of Care, and Cognitive Biases

The physician's liability shifts from traditional diagnostic skill to algorithmic literacy and oversight. The law should evaluate clinicians not on whether they out-thought the AI, but on how they managed the AI's output. Physicians remain the primary shield for patient safety. However, AI alters the parameters of medical negligence under traditional tort law.⁵

³ Medical Technology, International Multispeciality Journal of Health, May 6, 2026 <https://imjhealth.org/blog/the-black-box-of-ai-diagnostics-liability-gaps-legal-challenges-and-future-accountability-models>

⁴ Aagaard L. Artificial intelligence decision support systems and liability for medical injuries. *J Res Pharm Pract.* (2020) 9:125–7. 10.4103/jrpp.JRPP_20_65

⁵ Nickel, P.J. Trust in medical artificial intelligence: a discretionary account. *Ethics Inf Technol* **24**, 7 (2022). <https://doi.org/10.1007/s10676-022-09630-5>

2.1 The Evolution of the Medical Standard of Care

The Standard of Care refers to the "Reasonable Physician" Rule, the legal benchmark becomes the "Reasonable Algorithmic User". A physician is negligent if they commit Automation Bias (blindly following an AI recommendation that contradicts obvious clinical signs) or Automation Rejection (dismissing a high-confidence AI warning without a justifiable, documented medical reason).⁶

The legal benchmark for medical malpractice relies on the standard of care—the custom of a reasonably competent professional under similar circumstances. AI shifts this definition in two ways:

1. *The Affirmative Duty to Use AI*: As diagnostic AI achieves superior statistical accuracy over human practitioners in specific domains (e.g., detecting diabetic retinopathy), failing to deploy AI may eventually constitute a breach of the standard of care.
2. *The "Customary Practice" Trap*: If standard medical custom lags behind technological capability, courts may invoke the classic *The T.J. Hooper* doctrine. This rules that an entire profession can be held negligent for failing to adopt readily available, life-saving technology.

2.2 Cognitive Traps: Automation Bias vs. Automation Distrust

The "Black-Box" Defence Limitation: Physicians cannot use the opacity of the AI as a shield for poor outcomes. If the AI's recommendation is highly anomalous, the physician has an affirmative duty to cross-check standard clinical guidelines. The physician's liability often hinges on how they manage algorithmic discrepancies (Table 1).

Table 1: Physician liability with respect algorithmic discrepancies

Scenario	Cognitive Driver	Tortious Basis
Blind Reliance	Automation Bias: The tendency to trust automated systems over human intuition or clinical signs.	Negligence: Relinquishing independent clinical judgment; failing to cross-examine a flawed AI output.

⁶ Chadwick F. AI-Involved Medical Malpractice. J Fam Med Care. 2025; 3(2): 1007.

Unjustified Rejection	Automation Distrust: The dismissal of algorithmic alerts due to professional hubris or alert fatigue.	Negligence: Disregarding an accurate, high-confidence machine warning without a documented clinical rationale.
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2.3 Informed Consent in Algorithmic Medicine

Actionable Pleading: Plaintiffs must prove the physician failed to act as a competent gatekeeper of the technology. The doctrine of informed consent requires physicians to disclose all material risks of a proposed treatment or diagnostic strategy.

- *Materiality*: If an AI diagnostic tool has a known high false-negative rate for a specific demographic, that risk is legally material. Example: Imagine a skin cancer AI that detects melanoma with 95% accuracy on light skin, but has a 40% false-negative rate on dark skin. Under this rule, that 40% failure rate is legally material. The manufacturer must explicitly warn hospitals about this gap, or face legal prosecution.
- *The Explanation Dilemma*: If a physician cannot explain how a deep-learning model reached a specific diagnostic conclusion, they cannot truly obtain informed consent. This exposes them to battery or negligence claims if an undisclosed diagnostic error occurs.

3. The Healthcare Institution: Vicarious Liability and Corporate Fault

Hospitals are no longer mere venues for medical practice; they are active curators of the technological ecosystems where medicine occurs. Hospitals can no longer hide behind the defence that independent physicians made the final diagnostic call. The institution is responsible for the infrastructure and environment in which the AI operates.

3.1 Respondeat Superior and Vicarious Liability^{7,8}

Under the doctrine of *respondeat superior*, hospitals face strict vicarious liability for the torts committed by their employees within the scope of employment. If a hospital-employed

⁷ Part III: Clinical implementation and evaluation, Physician AI liability and regulatory compliance - The Physician AI Handbook, <https://physicianaihandbook.com/implementation/liability.html>

⁸ Shenoy A., Shenoy, G.N., Shenoy G.G. Respondeat superior in medicine and public health practice: The question is – Who is accountable for whom?, Ethics, Medicine and Public Health, 2021, 17, 100634. <https://doi.org/10.1016/j.jemep.2021.100634>.

radiologist commits a negligent error driven by automation bias, the hospital is financially liable for the resulting damages. The hospital remains vicariously liable if an employed physician commits clinical negligence while using the tool.

3.2 Corporate Negligence and Systemic Failure

Corporate Negligence (Systemic Failure): Hospitals face direct liability for negligent procurement. Did the hospital vet the AI for demographic or data bias? Did they fail to update the software, leading to "model drift" where the AI's accuracy degraded over time?⁹

Hospitals owe an independent, non-delegable duty to patients to maintain safe facilities, select competent staff, and oversee care quality. Institutional liability emerges when systemic failures enable diagnostic errors:

- *Negligent Vetting and Procurement*: Hospitals face direct liability if they procure an AI tool without verifying its clinical validation metrics, or if they deploy software trained on data that does not match the hospital's patient demographics.
- *Failure to Maintain and Update*: Algorithms suffer from **data drift**—a decline in accuracy over time as clinical environments, scanning technologies, or patient populations evolve. A hospital's failure to implement software updates, monitor calibration, or run routine quality assurance is a corporate breach of duty.
- *Inadequate Training Ecosystems*: If an institution purchases an AI tool but fails to train its medical staff on its limitations, error rates, and user interface, the hospital is liable for a systemic failure to supervise. Inadequate Training and Credentialing makes the hospital liable for deploying a complex diagnostic AI without training its staff on the system's specific limitations, false-positive rates, and failure modes.

4. The AI Developer: Product Liability and the Challenge of Autonomy

When a diagnostic error stems from a flaw in the software code, training architecture, or risk communication, liability shifts to the software developer under product liability frameworks.

⁹ <https://www.matzuslaw.com/hospital-vicarious-liability-in-pennsylvania-medical-malpractice/>

4.1 Categorizing AI: Product vs. Service

The developer's desk moves away from the "software as a service" loophole and is firmly anchored in strict product liability.

A foundational legal hurdle is whether diagnostic software qualifies as a product (subject to strict liability) or a service (subject to standard negligence).

- Pure software has historically been treated as a service or intellectual property.
- Modern courts increasingly view embedded medical AI especially software regulated as a medical device (SaMD) as a commercial product. This shift opens developers up to strict liability claims where intent or negligence does not need to be proven.

4.2 The Triad of Product Defects

4.2.1. Design Defects and Algorithmic Bias

Design Defects (The Black Box Problem): The developer is liable if the algorithm is fundamentally unsafe because it lacks explainability due to "unexplainable AI". If a clinician cannot understand *why* a system reached a conclusion, the design itself may be legally defective.

A design defect exists when the inherent architecture of the product makes it unreasonably dangerous. In AI diagnostics, this usually appears as algorithmic bias:

- If an algorithm is trained on data heavily weighted toward a single demographic, its error rate rises when deployed on minority populations.
- This systemic discrepancy represents a design defect, making the developer strictly liable for downstream diagnostic injuries.

4.2.2. Manufacturing and Coding Defects

Manufacturing Defects (Data Corruption): If a specific software patch introduces a bug that corrupts the diagnostic pipeline, strict liability applies. A manufacturing defect occurs when a specific item deviates from its intended design. In AI, this includes corrupted code during

compilation, broken APIs that distort pixel data from imaging systems, or bugs introduced during data pipeline delivery.

4.2.3. Information Defects (Failure to Warn)

Warning Defects (Failure to Instruct): Developers must provide dynamic, clear boundaries of use. If the software fails to warn the hospital that its diagnostic accuracy drops by 40% when reading scans of a specific patient demographic or machine model, it constitutes a marketing/warning defect.¹⁰

Developers must provide adequate warnings regarding the limitations of their products. A developer faces liability if they fail to clearly communicate:

- The boundaries of the AI's training data.
- The exact confidence thresholds of its outputs.
- Explicit instructions that the software is a diagnostic aid, not a replacement for human judgment.

4.3. The "Black Box" Problem and Affirmative Defences

Deep learning neural networks operate via millions of interconnected nodes, creating an opaque "black box" where the exact logical path to a conclusion cannot be audited. This opacity disrupts traditional tort mechanics (Fig. 1):

[Flawed Input Data] —► [Opaque Neural Network] —► [Erroneous Diagnosis]

THE PROOF VACUUM (Black Box) Plaintiff cannot isolate the exact mechanism of failure, making it difficult to prove standard design negligence.

Fig. 1: The algorithmic black box

¹⁰ Hashimoto, D.A., Marwaha, J.S., Lee, S.A. *et al.* Risk and liability in the deployment of AI systems for surgery: a SAGES white paper. *Surg Endosc* (2026). <https://doi.org/10.1007/s00464-026-12881-8>

Developers routinely deploy two affirmative defences to shield themselves from this liability:

1. *The Learned Intermediary Doctrine*: Developers argue that because a highly trained physician reviews the AI's output, the physician acts as a breaking force. This breaks the chain of causation between the developer's software and the patient's injury.
2. *State-of-the-Art Defence*: Developers argue that the black-box nature of deep learning represents the absolute limit of scientific knowledge at the time of manufacture. They contend they cannot be held liable for risks that were scientifically unknowable during development.

5. Comparative Framework: Apportioning Fault

The Table 2 below outlines how liability shifts across stakeholders based on the precise mechanism of a diagnostic failure.

Table 2: Criteria for shifting liability among the stakeholders.

Mechanism of Diagnostic Failure	Primary Liable Entity	Secondary Liable Entity	Core Legal Theory
Physician ignores a high-confidence, accurate AI warning due to alert fatigue.	Physician	Hospital	Professional Medical Negligence; <i>Respondeat Superior</i>
AI misses a lesion due to a software bug introduced during a mandatory cloud update.	AI Developer	Hospital	Strict Product Liability; Negligent Corporate Maintenance
Hospital deploys an imaging AI validated only for adults on pediatric patients to cut costs.	Hospital	Physician	Direct Corporate Negligence; Failure of the Standard of Care
AI misinterprets a scan because it was trained on a demographically restricted dataset.	AI Developer	Hospital	Design Defect (Algorithmic Bias); Negligent Procurement

When a lawsuit is filed, the court or jury will use a comparative negligence matrix to distribute the financial burden based on the specific failure mode of the diagnostic error (Table 3).

Table 3: Comparative negligence matrix fixing financial burden.

Scenario / Failure Mode	Physician Share	Hospital Share	AI Developer Share	Legal Rationale
AI gave a flawed output; doctor followed it blindly despite conflicting physical symptoms.	High	Low	Medium	Doctor failed as the human-in-the-loop; developer shares blame for the flawed output.
AI gave a flawless, correct warning; doctor ignored it out of alert fatigue.	Maximal	Low	Zero	Pure clinical negligence (Automation Rejection).
AI errored because the hospital failed to install a critical software update.	Zero	Maximal	Zero	Institutional maintenance failure broken the chain of causation for the developer.
AI suffered an unexplainable "hallucination" due to poor training data; doctor had no way to verify.	Zero	Low	Maximal	Classic design defect. Developer is best positioned to absorb and distribute the risk.

6. Case Laws

6.1 Physician Liability & The Standard of Care

6.1.1 The Customary Standard / Medical Malpractice Framework

While traditional malpractice cases rely on local or national peer customs, modern analysis notes that a physician deviates from the standard of care and faces direct liability by either blindly relying on flawed AI output (over-reliance) or negligently rejecting an accurate algorithmic diagnosis (under-reliance).^{11,12,13} Doctors have been held accountable by reference

¹¹ Glenn C.I., Andrew S., and Sara G. Chapter 7 - Medical AI and tort liability, Editor(s): Joseph J.Y. Sung, Cameron Stewart, Artificial Intelligence in Medicine, Academic Press, 2024, Pages 89-104. ISBN 9780323950688, <https://doi.org/10.1016/B978-0-323-95068-8.00007-8>.

¹² Nicholson Price II W., Sara G., and Glenn Cohen I. Liability for use of artificial intelligence in medicine. Edward Elgar Publishing. 2024. Bookshelf ID: NBK613216 PMID: 40245228 DOI: 10.4337/9781802205657.ch09

https://www.ncbi.nlm.nih.gov/books/NBK613216/pdf/Bookshelf_NBK613216.pdf

¹³ Research Handbook on Health, AI and the Law. Solaiman B, Cohen IG, Editors. Cheltenham, UK: Edward

to the Bolam standard of care since 1957. If the doctor practice accords with a “responsible body of practitioners”, they shall not be held guilt of negligence. But the application of that test in a world of AI assisted medicine may be challenging.¹⁴ In Hollis (1995) case¹⁵ the doctrine of learned intermediary states that a manufacturer fulfills its duty to warn by informing the physician rather than the patient, as the physician acts as the final gatekeeper or “learned intermediary”. This keeps the primary burden of diagnostic oversight squarely on the clinician unless the software contains an invisible defect.

6.2. Hospital & Institutional Liability

6.2.1 Corporate Negligence (Independent Institutional Duty)

The Darling (1965) case¹⁶ established that hospitals owe an independent duty of care directly to patients to supervise the medical operations within their facility. In AI malpractice, hospitals face direct corporate liability under Darling if they fail to properly vet, audit, or safely procure a diagnostic algorithm.

The court upheld hospital liability in Aldoroty (Kan. 1998) case when diagnostic errors arose due to failing to detect changes on X-rays because the hospital failed to provide radiologists with previous films for proper comparison. Transferred to AI, a hospital bears direct liability if it fails to furnish the system with requisite data infrastructure or fails to adequately train its medical staff on an algorithm's known limitations.

The concept of respondeat superior (vicarious liability) comes into picture, if the treating physician who misinterprets or mishandles the AI diagnostic data in the capacity as an employee of the hospital. The hospital is automatically held vicariously liable for the employee's negligence.¹⁷

6.3 AI Developer & Manufacturer Liability

6.3.1 Strict Product Liability (Design & Marketing Defects)

The application of strict product liability arises if courts classify diagnostic AI software as a

Elgar Publishing. 2024.

¹⁴ Bolam v. Friern Hospital Management Committee (1957) 1 WLR 582.

¹⁵ Hollis v. Dow Corning Corp. (1995) 4 S.C.R. 634.

¹⁶ Darling v. Charleston Community Memorial Hospital, 33 Ill. 2d 326, 211 N.E.2d 253 Ill. (1965).

¹⁷ Supra²

"product" rather than a service, developers face strict liability if the algorithm is inherently defective. This applies to design defects (e.g., training an algorithm on a non-representative demographic dataset that yields biased diagnostic errors) or marketing defects (e.g., failing to provide instructions about "edge cases").^{18,19}

6.3.2 Rebuttable Presumption & Shifted Burdens (The Modern AI Frontier)

As the deep-learning models suffer from the "black box problem" making it nearly impossible for an injured patient to prove exactly why a machine misdiagnosed them this framework modernizes the tort burden. It establishes a rebuttable presumption of causal links, requiring developers to disclose technical logs and prove their system operated safely once a plausible case of harm is presented.^{20,21}

7. Case Law under Indian Context

Under the present Indian tort law, there is no specific statutory framework or singular landmark precedent that explicitly apportions liability across the three-tier matrix of physicians, hospitals, and AI developers for algorithmic diagnostic errors. While the judiciary and legal scholars evaluate the contemporary issue by adapting classic tortious doctrines such as the Bolam Test, Vicarious Liability, and Product Liability under the Consumer Protection Act 2019 and established medical negligence precedents.^{22,23}

7.1 The Physician's Liability: The "Learned Intermediary" and Ultimate Duty

Under Indian law, AI is strictly viewed as an assistive diagnostic tool rather than a replacement for human judgment. A physician cannot shift the burden of an incorrect diagnosis to an algorithm if a reasonable, competent professional would have cross-checked or questioned the

¹⁸ Elemegious M. Algorithmic Malpractice: Reimagining Medical Negligence and Product Liability in AI - Assisted Clinical Decisions in the U.S. and Canada. 2025. https://www.researchgate.net/publication/395677069_Algorithmic_Malpractice_Reimagining_Medical_Negligence_and_Product_Liability_in_AI-Assisted_Clinical_Decisions_in_the

¹⁹ Restatement (Third) of Torts: Prods. Liab. § 2(b) (Am. Law Inst. 1998).

²⁰ EU Product Liability Directive (2024/2843)

²¹ Robert K. AI in Healthcare: Redefining Liability for Doctors and Hospitals, British Journal of Hospital Medicine, 2025, 86(9), 1-6. doi: 10.12968/hmed.2025.0212.

²² Rachana K, Medical negligence in the era of artificial intelligence: Redefining accountability and responsibility in India's healthcare framework, Indian Journal of Law and Legal Research, 2026, 8(2), 7928-7946

²³ Kedia A. When Algorithms Kill Liability for AI Medical Misdiagnosis in India (July 04, 2026). <https://ssrn.com/abstract=7053418> or <http://dx.doi.org/10.2139/ssrn.7053418>

machine's output. If a doctor blindly relies on a "black-box" AI system, it constitutes a breach of their standard duty of care. When a diagnostic tool yields an incorrect result, the court must isolate whether the human failed to read it or if the system itself was inherently flawed.²⁴

Jacob Mathew (2005) case²⁵ the Supreme Court of India established that a medical professional must exercise a "reasonable degree of skill and knowledge". Relying blindly on technology without human verification falls below this accepted standard.

The Supreme Court in the Dr. Laxman Balkrishna Joshi (1969)²⁶ affirmed that a doctor owes a duty of care in deciding whether to undertake the case and what treatment/diagnosis to give. Unvalidated or unverified algorithmic reliance breaches this core duty.

The Supreme Court ruled that in V. Kishan Rao 2010 case,²⁷ the hospital cannot rely on a defence of "error of judgment" when a diagnostic pathway is fundamentally ignored or misread. This case pertains to treatment of typhoid based on clinical assumption, while the lab test explicitly showed malaria. Thus creates a strict boundary against the Automation Bias of physicians. If an AI diagnostic tool flags a high probability of a specific condition, and the physician ignores it without counter testing or conversely, if the AI misses a symptom that a standard manual clinical examination should have caught the physician remains primarily at fault.

7.2 The Hospital's Liability: Vicarious Responsibility and Systemic Infrastructure

Hospitals face primary and vicarious liability under the doctrine of *Respondeat Superior* (let the master answer). If a hospital procures, deploys, or mandates an unvalidated AI system, or fails to properly train its staff to interpret AI suggestions, the hospital is liable for a "deficiency in service" under the Consumer Protection Act, 2019.^{28,29}

The Supreme Court in M/s Spring Meadows Hospital (1998) case³⁰ held that a hospital is

²⁴ Varshini B and Satya Sanjana G.R. Legal and Ethical Challenges of Ai-Based Diagnostics in India. International Journal for Multidisciplinary Research, 2025, 7(6), 1-13

²⁵ Jacob Mathew v. State of Punjab (2005) 6 SCC 1

²⁶ Dr. Laxman Balkrishna Joshi v. Dr. Trimbak Bapu Godbole (1969) SCR (1) 206:

²⁷ V. Kishan Rao v. Nikhil Super Speciality Hospital (2010) 5 SCC 513

²⁸ Vikas Verma and Pooja Bali, Medical Malpractice and Vicarious Liability and Judicial Analysis, Law Audience Journal, 2025, 5(6), 319-346.

²⁹ Ritika R. Can AI Be Held Accountable for Medical Negligence, International Journal of Legal Science and Innovation, 2020, 2(2), 325-328.

³⁰ M/s Spring Meadows Hospital v. Harjol Ahluwalia (1998) 4 SCC 39

directly liable for systemic or administrative negligence, and vicariously liable for the actions of its doctors. In an AI context, the hospital is viewed as the "master" that introduced the autonomous tool into the patient care pipeline.

In the Indian Medical Association (1995) case³¹ the medical services was brought under the consumer protection framework. If a hospital's technology package (including diagnostic AI) inflicts harm, the institution faces direct liability for deficient consumer service.

Jaspal Singh (2009) case,³² addressed the scenarios where diagnostic failure stems from complex medical equipment or robotic tools. The Supreme Court in this case evaluated vicarious and direct liability regarding medical equipment malfunction and mismatched blood transfusion coupled with machinery issue. The court established that a hospital is under a non-delegable duty to maintain its operational diagnostic infrastructure in perfect working order. If an AI developer pushes an unvalidated software update that crashes, produces systemic glitches, or exhibits a "hallucination" that corrupts radiological imaging, the hospital faces direct liability under its administrative duty to secure and monitor its tech infrastructure before exposing patients to it.

Generally the patient carries the burden of proving negligence, but shifting the burden via *res ipsa loquitur*. This process reversing the burden is permitted in technical circumstances. However, in highly technical "black box" scenarios, the burden can shift to the defenders.³³ In Prasanth S. Dhananka (2009) case,³⁴ the Supreme Court held that once a patient proves a prima facie case of an unexpected, catastrophic medical outcome following a technical procedure, the burden of proof shifts entirely to the hospital and doctors to show they acted with due care. Since AI software models operate on complex neural networks that are unreadable to an ordinary patient, thus patient only needs to show a stark mismatch between the AI diagnosis and actual health outcomes. The hospital and the physician must then bear the burden of proving their reliance on that AI framework was medically justified and risk-mitigated.

7.3 The AI Developer's Liability: Product Defect and Strict Liability

Shifting liability to AI developers requires moving out of professional medical negligence and

³¹ Indian Medical Association v. V.P. Shantha (1995) 6 SCC 651

³² Post Graduate Institute of Medical Education and Research (PGIMER), Chandigarh v. Jaspal Singh (2009) 7 SCC 330

³³ Amy L.S. Assuming the risks of artificial intelligence. Boston University Law Review, 2022, 102, 979-1035

³⁴ Nizam's Institute of Medical Sciences v. Prasanth S. Dhananka (2009) 6 SCC 1

into Product Liability as codified under Chapter VI of the Consumer Protection Act, 2019. If a diagnostic error is caused by a latent software defect, data pathology (e.g., biased training datasets), or algorithmic failure, the developer can be held strictly liable for manufacturing or design defects. However, if the developer explicitly warns that the software requires doctor verification, the developer may be protected by the "learned intermediary" defence.³⁵

In India the software has been recognized as medical device,³⁶ by enlarging the definition of drug.³⁷ In February 2020, India's Ministry of Health and Family Welfare issued notifications under the Medical Devices (Amendment) Rules, 2020, which officially expanded the definition of a "drug" under the Drugs and Cosmetics Act to include standalone software and mobile applications used for medical purposes. This change officially brought Software as a Medical Device (SaMD) under the regulatory oversight of the Central Drugs Standard Control Organisation (CDSCO).^{38,39}

7.3.1 Statutory Anchors

Section 84 of the Consumer Protection Act, 2019: Explicitly outlines the liability of a product manufacturer for manufacturing defects, design deviations, or inadequate instructions. This is the primary legal mechanism used to rope AI developers into Indian tort claims.

NCDRC Principles on Medical Device Failures: The National Consumer Disputes Redressal Commission (NCDRC) routinely rules that equipment manufacturers are strictly liable if a baseline, inherent defect causes an adverse clinical outcome, provided active maintenance contracts are in place.⁴⁰

The direct corporate & design liability (i.e. The Enterprise Doctrine) illustrates how the AI developer can be sued independently of the doctor's actions, as the courts turn to enterprise

³⁵ Li Y, Yi X, Fu J, Yang Y, Duan C, Wang J. Reducing misdiagnosis in AI-driven medical diagnostics: a multidimensional framework for technical, ethical, and policy solutions. *Front Med (Lausanne)*. 2025 Oct 31;12:1594450. doi: 10.3389/fmed.2025.1594450. PMID: 41244777; PMCID: PMC12615213.

³⁶ Medical Devices Rules 2017

³⁷ Drugs and Cosmetics Act, 1940

³⁸ Lenin B., Razdan A., Kataria Y. Medical Device As Software: Has CDSCO Guidance Changed The Rules?, January 29, 2026. <https://corporate.cyrilamarchandblogs.com/2026/01/medical-device-as-software-has-cdsko-guidance-changed-the-rules/>

³⁹ Anjali Raja K, Isn't the liability of AI-induced medical devices a legal requirement?, IndiaAI, September 21, 2022 <https://indiaai.gov.in/article/isn-t-the-liability-of-ai-induced-medical-devices-a-legal-requirement>

⁴⁰ Mahip S., Samir M., Maitri S. Medical Device Failures in India - Determining the Liability, SCC Online Times, February 10, 2025. <https://www.sconline.com/blog/post/2025/02/10/medical-device-failures-in-india-determining-the-liability/>

strict liability.⁴¹ The environmental tort case,⁴² established the Doctrine of Absolute Liability in Indian law. The Supreme Court ruled that an enterprise engaged in an inherently hazardous or highly specialized technological activity owes an absolute, non-delegable duty to the public that no harm will result.

The legal scholars use *M.C. Mehta* verdict alongside Section 84 of the Consumer Protection Act, 2019 to target AI developers. If an AI developer deploys an autonomous deep-learning model into a diagnostic pipeline that functions with complete opacity, it can be argued that they are engaging in a highly specialized, risk-bearing enterprise. They cannot hide behind the doctor's signature if their algorithmic design possessed inherent data bias or a fatal software architecture flaw from inception.⁴³

8. Conclusion

The integration of Artificial Intelligence into clinical diagnostics does not merely strain existing tort frameworks; it exposes a fundamental mismatch between 20th century fault-based doctrines and decentralized, algorithmic decision-making. As medical AI evolves from a passive decision-support tool into an autonomous diagnostic agent, the traditional legal silos dividing professional negligence, corporate liability, and product liability collapse. Forcing AI driven diagnostic injuries into these rigid, antiquated boxes creates an unsustainable zero-sum game: either physicians are unfairly penalized for technological opacity they cannot control, or injured patients are left without legal recourse due to the formidable evidentiary barriers of "black-box" discovery. To prevent this systemic failure, legal regimes must transition from a fragmented, fault-hunting approach to a unified hybrid liability model. Through a tripartite apportionment strategy incorporating physicians, hospitals and healthcare institutions and AI developers in the liability desk.

⁴¹ Shaik R. A conflicting regime over companies liability with respect to medical health. Manupatra Articles: Law of Medicine May 11, 2022. <https://articles.manupatra.com/article-details/A-CONFLICTING-REGIME-OVER-COMPANIES-LIABILITY-WITH-RESPECT-TO-MEDICAL-HEALTH>

⁴² *M.C. Mehta v. Union of India* (1987) 1 SCC 395 (Oleum Gas Leak Case)

⁴³ *Supra*¹⁶

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