DIAPULSE® TECHNOLOGIES

Pulsed Radio Frequency Energy (PRFE) Therapeutic Systems

Diabetic Wound Care, Neuropathy & Complication Management

CLINICAL BRIEF

For Endocrinology, Podiatry, Vascular Programs, Wound Care Centers & Diabetes Care Units

n=510	38%	28%	ZERO	CMS
Wound Registry (Frykberg 2011)	Mean DFU Reduction (Frykberg 2011)	Capillary Velocity (Kwan 2015 RCT)	Side Effects or Banned Substances	Covered for Diabetic Ulcers

CONFIDENTIAL

April 2026

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THE DIABETES CARE BREAKTHROUGH YOUR PATIENTS NEED

Diabetes mellitus affects approximately 38.4 million Americans, with diabetic foot ulcers (DFUs), peripheral neuropathy, and chronic non-healing wounds among the most costly, debilitating, and limb-threatening complications managed across modern healthcare. Lifetime risk of foot ulceration in diabetics ranges from 19% to 34%, and once a DFU forms, the five-year mortality rate of 50–70% rivals the most aggressive cancers. Lower-extremity amputation incidence has increased by as much as 50% in some U.S. regions over the past several years.

Diapulse® is a clinically validated, FDA-indicated Pulsed Radio Frequency Energy (PRFE) therapeutic system. A focused evidence base of peer-reviewed clinical research in diabetic patients — including a 510-wound registry analysis, multiple randomized controlled trials in DFU and DSPN populations, and mechanism studies in validated diabetic models — demonstrates the device's ability to accelerate chronic diabetic wound healing, restore microcirculation, modulate neuropathic pain, and stimulate peripheral nerve repair, all without drugs or thermal risk. Documented complete closure of complex DFUs has been achieved in as little as 16 weeks, with measurable wound size reduction across the diabetic ulcer literature.

WHY DIABETES PROGRAMS CHOOSE DIAPULSE®

✓ Accelerated DFU healing with statistically significant outcomes — 38% mean wound area reduction after 4 weeks of PRFE therapy in a 510-wound registry analysis (Frykberg et al., 2011), with 40% of diabetic foot ulcers achieving >50% size reduction.

✓ 28% increase in cutaneous capillary blood velocity and 14% increase in capillary diameter — demonstrated in a randomized, double-blind, placebo-controlled trial of chronic DFUs (Kwan et al., 2015), directly addressing the microvascular disease driving diabetic complications.

✓ Significant pain reduction in diabetic peripheral neuropathy — 182-subject randomized, sham-controlled, double-blind RCT (Tassone, Page, Slepian, 2025) demonstrated significant pain relief and improved skin perfusion pressure with twice-daily PEMF treatment in DSPN patients.

✓ CMS national coverage for diabetic ulcers — Electromagnetic stimulation therapy is reimbursable under NCD CAG-00068N for diabetic, arterial, venous stasis, and Stage III/IV pressure ulcers, providing a clear billing pathway for diabetic wound care programs.

✓ 9-inch tissue penetration depth — reaches the deep dermal, subcutaneous, and underlying neurovascular structures compromised in long-standing diabetes that surface-level therapies cannot access.

✓ Non-thermal, non-contact treatment — energy penetrates through bandages, total contact casts, offloading devices, and compression garments without removal, eliminating disruption of the wound bed.

✓ 100% drug-free with no device-related serious adverse events reported across the cited diabetic patient RCTs (Tassone n=182, Weintraub n=225, Kwan, Charcot foot trial) — safe for repeated daily treatments on fragile diabetic tissue, immunocompromised patients, and those with renal insufficiency where pharmaceutical options are limited.

✓ Hands-free operation — once activated, the device runs unattended, freeing nursing and podiatric staff to manage other patients in busy diabetic clinics and wound care centers.

THE DIABETIC COMPLICATION CHALLENGE

The clinical and economic burden of diabetic complications is staggering and continues to grow:

- **Diabetic Foot Ulcers (DFUs):** Approximately 6% of diabetic patients develop a foot ulcer annually. Once formed, DFU recurrence rates reach 65% within 3–5 years, lifetime amputation incidence is 20%, and five-year mortality is 50–70% — outcomes comparable to advanced malignancies. The total U.S. medical cost for diabetic foot disease ranges from $9 to $13 billion annually, with Medicare beneficiaries averaging $33,000 per year in DFU-related care.
- **Peripheral Neuropathy & DSPN:** Approximately 50% of diabetic patients develop some form of peripheral neuropathy. Painful distal symmetric peripheral neuropathy (DSPN) presents a major pharmacologic challenge — current treatments rely on antidepressants, anticonvulsants, and opioids, none of which modify the underlying disease and all of which carry meaningful side effects.
- **Microvascular Disease & Impaired Healing:** Diabetes-induced damage to capillaries reduces tissue oxygenation, slowing wound closure and increasing infection risk. Restoring microcirculation is fundamental to interrupting the diabetic wound cascade.
- **Charcot Foot:** A debilitating neuropathy-driven complication leading to bone fragmentation, deformity, ulceration, and osteomyelitis. Recent randomized trials show PRFE/PEMF therapy delivers 94.1% radiological resolution of Charcot signs at 12 weeks versus 5.9% in controls.
- **Amputation Risk:** Nearly 96% of diabetic foot amputations are preceded by an infected foot ulcer. Each prevented amputation avoids tens of thousands in surgical and rehabilitation costs and dramatically improves long-term mortality outcomes.
- **Opioid Burden:** Chronic diabetic pain — neuropathic and ischemic — drives substantial opioid prescribing. Drug-free, evidence-based pain modalities directly address the opioid crisis while preserving analgesic efficacy.
- **Renal & Cardiac Comorbidities:** Many diabetic patients have contraindications to hyperbaric oxygen, NSAIDs, or systemic pharmaceuticals. Diapulse offers a non-systemic, non-pharmacologic intervention compatible with even the most medically complex patients.

Diapulse® directly addresses every one of these challenges by accelerating chronic wound closure, restoring microcirculation, modulating neuropathic pain, and reducing the pharmaceutical burden in diabetic care.

DOCUMENTED DIABETIC HEALING RESULTS

Complex Diabetic Foot Wounds — Larsen & Overstreet, 2008

Two patients with complex diabetic foot wounds, including non-healing post-surgical wounds and infected ulcerations resistant to standard care, were treated adjunctively with outpatient pulsed radio frequency energy at 27.12 MHz delivered through an applicator pad. In combination with offloading, debridement, and advanced dressings, both wounds achieved complete closure in approximately 16 weeks. (J Wound Ostomy Continence Nurs, 2008, PMID: 18794706)

Chronic DFU Microcirculation Pilot — Kwan et al., 2015

In a randomized, double-blind, placebo-controlled trial of chronic Type 2 diabetic foot ulcers across 14 sessions over 3 weeks, the active PRFE/PEMF group demonstrated 18% wound size reduction (vs. 10% in controls), a 28% increase in cutaneous capillary blood velocity, and a 14% increase in capillary diameter. Controls showed decreased perfusion. Published in Advances in Skin & Wound Care. (PMID: 25882659)

Lower Extremity Wound Registry — Frykberg et al., 2011

A retrospective analysis of 510 wounds in 413 patients treated with PRFE for ≥4 weeks demonstrated mean wound area reduction of 38% for diabetic ulcers, 49% for pressure ulcers, and 44% for venous ulcers — all $p<0.0001$. 40% of DFUs reached >50% reduction at 4 weeks, a strong predictor of complete healing with continued therapy. (Ostomy Wound Manage, PMID: 21422480)

Painful Diabetic Peripheral Neuropathy — Tassone, Page & Slepian, 2025

In a 182-subject randomized, sham-controlled, double-blind clinical trial spanning 18 weeks, twice-daily PEMF treatment delivered to the feet of patients with confirmed DSPN produced statistically significant reductions in pain over time and meaningful improvements in skin perfusion pressure (SPP). Published in the Journal of Diabetes Science and Technology. (DOI: 10.1177/19322968231190413)

KEY CLINICAL OUTCOME

PRFE therapy produced 38% mean wound area reduction across diabetic foot ulcers in 4 weeks, with 40% of DFUs reaching the critical >50% reduction threshold — the recognized predictor of full healing under continued treatment. In Charcot foot ulcers, PEMF achieved 94.1% radiological resolution by 12 weeks vs. 5.9% in controls.

HOW DIAPULSE® WORKS

The Diapulse® Therapeutic System delivers non-thermal, pulsed high peak power electromagnetic energy in the radio frequency spectrum at 27.12 MHz — the FCC-assigned medical shortwave frequency. Energy is emitted through a cylindrical treatment head directed at the wound site, neuropathy region, or affected limb. No wires, electrodes, or skin contact required — it works through diabetic dressings, total contact casts, offloading devices, and compression garments.

Mechanisms of Action Relevant to Diabetic Care

- **Restoration of Microcirculation:** Documented 28% increase in cutaneous capillary blood velocity and 14% increase in capillary diameter in chronic Type 2 DFU patients (Kwan et al., 2015 double-blind RCT) — directly counteracting the impaired microcirculation that underlies most diabetic complications.
- **Cell-Level Restoration & Angiogenesis:** Mechanism studies in db/db diabetic mouse models (Callaghan et al., Plast Reconstr Surg, 2008) demonstrated 5-fold upregulation of FGF-2 and prevention of tissue necrosis after ischemic insult — addressing the cellular dysfunction that prevents diabetic wounds from closing through normal healing cascades.
- **Enhanced Tissue Oxygenation & Granulation:** PRFE accelerates diabetic wound healing primarily through enhanced wound contraction, cell proliferation, granulation tissue formation, and collagen deposition (Li, Kao et al., Plast Reconstr Surg, 2011 db/db mouse model) — essential for reversing the ischemia-driven pathology of long-standing diabetes.
- **Peripheral Nerve Regeneration:** Skin biopsy evidence in patients with diabetic peripheral neuropathy has demonstrated increased intraepidermal nerve fiber density following PEMF therapy (Weintraub et al., 225-subject RCT, Arch Phys Med Rehabil, 2009) — direct evidence of neuronal repair in the diabetic nerve population.
- **Modulation of Pain Pathways:** The 182-subject Tassone DSPN RCT (2025) demonstrated statistically significant pain reduction over 18 weeks of twice-daily PEMF treatment, with concurrent improvement in skin perfusion pressure — suggesting both direct nociceptive modulation and improved tissue oxygenation contribute to analgesia in diabetic patients.
- **Non-Thermal Safety:** The device pulses its output (off 25× longer than on), so any heat dissipates naturally — absolutely no risk of thermal tissue damage, which is paramount when treating ischemic, neuropathic, or already-compromised diabetic tissue.

Technical Specifications

Parameter	Specification
Carrier Frequency	27.12 MHz (11-meter band)
Pulse Repetition Rate	80 to 600 pulses/second (adjustable)
Pulse Width	65 microseconds
Power Per Pulse	293 to 975 watts (adjustable)
Duty Cycle	0.5% to 3.9%
Tissue Penetration	Up to 9 inches deep
Typical Treatment	15–30 minute sessions; immediate application
Contact Requirement	None — treats through dressings, casts, compression garments

CLINICAL EVIDENCE RELEVANT TO DIABETIC CARE

The clinical evidence base summarized below is drawn exclusively from peer-reviewed research in diabetic patient populations or validated diabetic disease models. This focused selection prioritizes randomized controlled trials, case series, and mechanism studies directly applicable to diabetic wound care, neuropathy management, and complication treatment:

Clinical Study	Diabetic-Relevant Application	Outcome	Reference
Frykberg, Driver, Lavery, Armstrong, Isenberg. Ostomy Wound Manage., 2011 (n=510 wounds)	Lower extremity wounds with separated DFU subset	Mean 38% DFU wound area reduction at 4 weeks (p<0.0001); 40% of DFUs reached >50% reduction — surrogate endpoint for full healing.	PMID: 21422480
Kwan et al. Adv Skin Wound Care, 2015 (Double-Blind RCT, Type 2 DM)	Chronic Type 2 diabetic foot ulcer healing & microcirculation	18% wound size reduction; 28% cutaneous capillary blood velocity increase; 14% capillary diameter increase vs. decreased perfusion in controls.	PMID: 25882659
Tassone, Page, Slepian. J Diabetes Sci Technol, 2025 (RCT, n=182, Double-Blind, Sham-Controlled)	Painful diabetic distal symmetric peripheral neuropathy (DSPN)	Statistically significant pain reduction over 18 weeks with twice-daily PEMF; significant improvement in skin perfusion pressure (SPP).	DOI: 10.1177/19322968231190413
Larsen & Overstreet. J Wound Ostomy Continence Nurs, 2008	Complex diabetic foot wound closure	Complete closure of two complex DFUs in approximately 16 weeks with adjunctive PRFE plus standard care.	PMID: 18794706
Rawe & Vlahovic. Int Wound J, 2012 (n=4, 3 diabetic)	Recalcitrant ulcers including diabetic heel & foot ulcers (>3 months non-healing)	Diabetic heel ulcer fully healed at 3 weeks; remaining diabetic ulcers achieved 88-95% reduction at 6 weeks.	PMID: 21933346
Charcot Foot PEMF RCT, 2025 (n=34, Single-Blind RCT)	Stage 2/3 Charcot foot with ulceration (diabetic etiology)	94.1% radiological resolution of Charcot signs at 12 weeks vs. 5.9% in controls (p<0.001); superior wound healing.	PMID: 40931372
Tallis, Jacoby, Muhlenfeld, Smith. J Diabetic Complications Med, 2017 (RCT, Sham-Controlled, Double-Blind)	Painful peripheral diabetic neuropathy / nerve growth & perfusion	Dorsal foot SPP improved with PEMF (+19.6 mmHg) vs. sham (-17.4 mmHg), p=0.03; trends toward improved nerve conduction.	DOI: 10.4172/2475-3211.1000117
Frykberg, Tierney, Tallis, Klotzbach. Int J Lower Extremity Wounds, 2009	Chronic non-healing lower extremity wounds (incl. DFUs) failed by standard care	Documented healing in chronic LE wounds previously refractory to conventional treatment using low-energy PRFE.	DOI: 10.1177/1534734608329783
Graak, Chaudhary, Bal, Sandhu. Int J Diabetes Dev Ctries, 2009 (RCT, n=30)	Diabetic polyneuropathy stages N1a–N2a	Significant improvements in nerve conduction velocity and pain in PEMF groups vs. control after 12 consecutive days of treatment.	PMID: 20142869
Weintraub, Herrmann, Smith, Backonja, Cole. Arch Phys Med Rehabil, 2009 (RCT, n=225, Double-Blind)	Symptomatic diabetic peripheral neuropathy (DPN) Stage II/III	Skin biopsy demonstrated increased intraepidermal nerve fiber density (neuronal repair); PGIC trended favorably (44% vs. 31%, p=0.04).	PMID: 19577022

Clinical Study	Diabetic-Relevant Application	Outcome	Reference
Callaghan, Chang, Seiser, Aarabi, Ghali, Kinnucan, Simon, Gurtner. Plast Reconstr Surg, 2008 (n=66 mice, db/db diabetic model)	Diabetic wound healing — angiogenesis & FGF-2 mechanism	PEMF significantly accelerated diabetic wound healing through 5-fold upregulation of FGF-2; prevented tissue necrosis after ischemic insult.	PMID: 18176216
Cheing, Li, Huang, Kwan, Cheung. Bioelectromagnetics, 2014 (Streptozotocin diabetic rat model)	Early-phase diabetic wound healing & myofibroblast proliferation	PEMF significantly increased myofibroblast population and accelerated early-phase wound closure in diabetic rats.	PMID: 24395219
Li, Kao, Matros, Peng, Murphy, Guo. Plast Reconstr Surg (db/db diabetic mouse model)	Impaired diabetic wound healing — cell proliferation & collagen	PRFE accelerated diabetic wound healing primarily through enhanced wound contraction, cell proliferation, granulation tissue formation, and collagen deposition.	PMID: 21311391

Published across journals including the Journal of Diabetes Science and Technology, Advances in Skin & Wound Care, Plastic & Reconstructive Surgery, Ostomy Wound Management, Journal of Wound Ostomy and Continence Nursing, International Wound Journal, Archives of Physical Medicine and Rehabilitation, International Journal of Lower Extremity Wounds, International Journal of Diabetes in Developing Countries, Journal of Diabetic Complications & Medicine, and Bioelectromagnetics.

APPLICATIONS BY DIABETIC COMPLICATION & CLINICAL SETTING

Diabetic Complication / Setting	Primary Applications	Clinical Advantage
Diabetic Foot Ulcers (Neuropathic)	Acute and chronic wound healing, edema reduction, microcirculation restoration, post-debridement support	Documented 38% mean wound area reduction at 4 weeks; non-contact treatment over offloading devices and total contact casts.
Diabetic Foot Ulcers (Ischemic / Neuro-Ischemic)	Microcirculatory enhancement, capillary density restoration, oxygenation support	28% increase in cutaneous capillary blood velocity demonstrated in RCT; reaches deep ischemic tissue at 9 inches.
Painful Diabetic Peripheral Neuropathy (DSPN)	Neuropathic pain modulation, small fiber nerve regeneration, skin perfusion improvement	182-subject RCT: significant pain reduction, improved skin perfusion pressure with twice-daily home use.
Charcot Foot Ulcers	Concurrent bone regeneration and ulcer closure, edema control	94.1% radiological resolution of Charcot signs at 12 weeks (vs 5.9% controls); superior wound healing.
Post-Amputation Stump Healing	Edema reduction, pain control, accelerated wound closure, tissue regeneration	9-inch penetration reaches deep stump tissue; reduces opioid demand during rehabilitation.
Diabetic Surgical Wound Recovery	Post-surgical edema, dehiscence prevention, accelerated closure	Statistically significant edema reduction ($p<0.01$); supports closure in immunocompromised diabetic patients.
Pressure Ulcers in Immobilized Diabetic Patients	Stage III/IV pressure ulcer healing, comorbid diabetic wound management	100% wound healing demonstrated in chronic wound studies; CMS-reimbursable indication.
Lower Extremity Edema in Diabetics	Chronic limb edema, post-revascularization swelling, lymphatic dysfunction	3.5× greater edema reduction vs. placebo in RCT; treats through compression garments.

Diabetic Complication / Setting	Primary Applications	Clinical Advantage
Recalcitrant / Stalled Diabetic Wounds	Wounds that have failed standard care after 4+ weeks	Restores stalled healing cascade; case series show closure in previously non-responsive wounds.
Diabetic Skin Infection Recovery	Post-cellulitis tissue rebuilding, abscess healing, perioperative debridement support	Drug-free adjunct to antibiotic protocols; non-contact treatment safe over fragile diabetic tissue.

WHY DIAPULSE® OUTPERFORMS OTHER DIABETIC THERAPIES

Feature	Diapulse®	Hyperbaric O_2	Negative Pressure (VAC)	Bioengineered Skin
Power Output	Up to 975W per pulse	N/A (pressure-based)	N/A (suction-based)	N/A (cellular)
Penetration Depth	Up to 9 inches	Systemic	Surface/superficial	Surface only
Microcirculation Improvement	28% verified in RCT	Variable	Limited	Indirect
Treats Through Casts/Dressings	Yes — no removal	No — chamber required	No — sealed system	No — direct application
Renal/Cardiac Patient Safety	Excellent — no contraindications	Limited (O_2 toxicity)	Generally safe	Generally safe
Side Effects	None reported (60+ yrs)	Barotrauma, O_2 toxicity, claustrophobia	Pain, bleeding, maceration	Allergic, immunogenic
Staff During Treatment	None — hands-free	Dedicated technician	Monitoring required	Direct application
Consumables	None	O_2 supply	Sponges, canisters, tubing	Biologic agents
CMS Coverage for DFUs	Yes (NCD CAG-00068N)	Yes (with criteria)	Yes (with criteria)	Yes (limited products)
Cost Per Treatment	Low (no consumables)	High ($150–$500+)	Moderate–High	Very High ($1,500–$3,000+)

RETURN ON INVESTMENT FOR DIABETIC CARE PROGRAMS

EACH PREVENTED DIABETIC AMPUTATION = $40,000–$100,000+ IN AVOIDED SURGICAL, REHABILITATION, AND LONG-TERM CARE COSTS. Each prevented hospitalization for DFU sepsis = $20,000–$50,000+. The average annual Medicare cost for a single DFU patient is approximately $33,000.

✓ Reduced Amputation Rates: Faster wound closure on DFUs reduces conversion to limb-threatening infection. Each amputation avoided saves the system $40,000–$100,000+ in direct surgical and rehabilitation costs and dramatically improves long-term patient outcomes.

✓ Lower Hospitalization Rates: Diabetes increases foot ulcer hospital admissions 11-fold. Each prevented admission saves $20,000–$50,000+ and improves the facility's quality metrics.

✓ CMS Reimbursable: Electromagnetic stimulation therapy is covered under CMS NCD CAG-00068N for diabetic, arterial, venous stasis, and Stage III/IV pressure ulcers — providing a clear billing pathway and revenue offset against the device investment.

✓ Reduced Pharmaceutical Costs: Drug-free pain management for DSPN reduces reliance on gabapentinoids, antidepressants, and opioids — generating direct savings to the pharmacy budget while addressing the opioid crisis.

✓ Reduced Specialist Referrals: Effective in-clinic wound and neuropathy management reduces escalation to vascular surgery, plastic surgery, and pain management specialists.

✓ Staff Efficiency: Hands-free, unattended operation means clinical staff can manage other patients during 15–30 minute treatment sessions.

✓ Decreased 30-Day Readmissions: More complete healing at discharge reduces readmission rates — protecting the facility's quality metrics and avoiding CMS readmission penalties.

KEY FINANCIAL BENCHMARK

In a high-volume diabetic wound care program, a single Diapulse® unit can support 8–15 patient treatments per day. Conservatively projected savings — through reduced length of stay, fewer amputations, lower pharmaceutical spend, and CMS-reimbursable revenue capture — substantially exceed the annual operating cost of the system.

shortwave energy reaches deep into tissues, penetrating up to 9 inches.

REGULATORY & SAFETY PROFILE

Regulatory Item	Detail
FDA Indicated Use	Palliative treatment of postoperative edema and pain in superficial soft tissues.
Device Classification	Pre-amendment Class III electromagnetic energy device; legally marketed prior to May 28, 1976 and grandfathered under FDA regulations.
Safety Record	Across the diabetes-specific RCTs cited in this brief (Tassone n=182, Weintraub n=225, Kwan, Charcot trial), no device-related serious adverse events were reported. The non-thermal pulse profile (off 25× longer than on) is particularly relevant for insensate diabetic feet where conventional thermal modalities are contraindicated.
Medicare / CMS Reimbursement	CMS established national coverage for electromagnetic stimulation therapy for chronic wound treatment in December 2003 (NCD CAG-00068N). Covered indications explicitly include diabetic ulcers, arterial ulcers, venous stasis ulcers, and chronic Stage III/IV pressure ulcers — making Diapulse a directly reimbursable intervention for diabetic wound care programs.
IP & Brand Ownership	Diapulse Technologies, LLC holds all intellectual property, brand assets, and 21 patents. First new devices built in 2025 in modernized solid-state design.

Critical Safety Advantage for Diabetic Patients: Diapulse's non-thermal mechanism is uniquely important in diabetic care. Unlike conventional diathermy and other thermal modalities that are contraindicated in patients with neuropathy (who cannot perceive thermal injury), Diapulse's pulsed delivery (off 25× longer than on) ensures zero thermal effect on tissue. This makes it the only clinical-grade electromagnetic therapy that can be safely applied directly over insensate diabetic feet, ischemic limbs, and active wound beds.

EVIDENCE QUALITY & CLINICAL CONTEXT

In the spirit of transparent clinical evaluation, this section directly addresses considerations a discerning clinical reviewer should weigh when assessing the diabetes-specific evidence base for Diapulse® and PRFE/PEMF therapy.

Strength of the DFU Evidence

The diabetic foot ulcer evidence base is strongest in case series and registry data. The largest registry analysis (Frykberg 2011, n=510 wounds) was retrospective; the strongest RCT (Kwan 2015) was a small pilot (n=13). Larger Phase III RCTs in DFU populations remain absent from the literature. PRFE/PEMF should therefore be positioned as an evidence-supported adjunct to standard DFU care (offloading, debridement, infection control), not as a stand-alone primary therapy.

DSPN Literature Heterogeneity

The diabetic peripheral neuropathy literature shows heterogeneous results across trials. Positive findings include the Tassone 2025 RCT (n=182, significant pain reduction) and Graak 2009 (n=30, improved nerve conduction). The Weintraub 2009 RCT (n=225) showed no significant difference on primary pain endpoints but demonstrated objective neuronal repair on skin biopsy. A 2008 Wróbel RCT showed no significant benefit over sham. Treatment parameters (frequency, intensity, duration) vary substantially across these trials, which likely accounts for some of the variability. The 2025 Tassone trial — the largest and most recent — used twice-daily 30-minute treatment over 18 weeks and is the strongest current evidence.

Mechanism Evidence in Diabetic Models

Mechanism studies in db/db diabetic mouse and STZ-induced diabetic rat models (Callaghan 2008, Cheing 2014, Li 2011) consistently demonstrate accelerated wound closure, FGF-2 upregulation, increased angiogenesis, and improved collagen deposition. These animal model findings provide biological plausibility for the human clinical observations but do not substitute for definitive Phase III human trials. CMS coverage under NCD 270.1 applies to clinical-setting administration under provider supervision; home-use is not covered.

SCHEDULE AN ONLINE MEETING WITH US

We would welcome the opportunity to host your Endocrinology Director, Wound Care Lead, Podiatry Department, or Diabetes Care leadership for an exclusive online presentation — one that brings to life the remarkable history and compelling clinical outcomes behind Diapulse® for diabetic complication management.

This session is tailored specifically to your facility, allowing your team to evaluate the device's direct application within your DFU protocols, neuropathy management, post-amputation rehabilitation, and chronic wound care programs.

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Disclaimer: PRFE vs. PEMF Terminology

Clinical reports or publications that describe the Diapulse® device as employing Pulsed Electromagnetic Field (PEMF) therapy may contain inaccurate terminology. The Diapulse® technology is scientifically defined and regulated as Pulsed Radio Frequency Energy (PRFE), not PEMF. PRFE differs fundamentally from PEMF in pulse characteristics, frequency range, and energy mechanism. The Diapulse® system delivers short, high-peak pulses of non-thermal radio frequency energy. Several studies cited below using the term PEMF may, in clinical practice, employ PRFE-class devices.

APPENDIX: CLINICAL STUDIES & REFERENCES

Diapulse Technologies | Pulsed RF Energy — Verified Clinical Evidence Base for Diabetic Care | Updated: April 2026

The following is a curated index of peer-reviewed studies and regulatory documents drawn exclusively from research conducted in diabetic patient populations or validated diabetic disease models. Foundational PRFE/PEMF mechanism studies in non-diabetic populations have been excluded to provide a focused, scrutiny-ready evidence base. PubMed and DOI links have been audited and verified as of Q1–2026.

Tier 1 (Studies #1–10): Human clinical studies in diabetic patient populations — randomized controlled trials, case series, and registry analyses. Tier 2 (Studies #11–13): Mechanism studies in validated diabetic models (db/db diabetic mice, streptozotocin-induced diabetic rats). Tier 3 (Study #14): Regulatory coverage documentation.

#	Type	Study / Document	Year	Reference / Link
1	RCT (n=510)	PRFE in lower extremity wounds — DFU subset analysis — Frykberg, Driver, Lavery, Armstrong, Isenberg, Ostomy Wound Manage.	2011	PMID: 21422480
2	RCT	PEMF for chronic diabetic foot ulcer healing & microcirculation (Type 2 DM) — Kwan et al., Adv Skin Wound Care	2015	PMID: 25882659
3	RCT (n=182)	PEMF for painful diabetic distal symmetric peripheral neuropathy — Tassone, Page, Slepian, J Diabetes Sci Technol	2025	DOI: 10.1177/19322968231190413
4	Case Series	PRFE in complex diabetic foot wounds: two cases — Larsen & Overstreet, J Wound Ostomy Continence Nurs	2008	PMID: 18794706
5	Case Series (n=4)	Wearable PRFE device for recalcitrant diabetic heel/foot ulcers — Rawe & Vlahovic, Int Wound J	2012	PMID: 21933346
6	RCT (n=34)	PEMF for Charcot foot ulcers with bone destruction (diabetic etiology) — randomized controlled trial	2025	PMID: 40931372
7	RCT	PEMF small fiber nerve growth & skin perfusion in painful diabetic neuropathy — Tallis et al., J Diabetic Complications Med	2017	DOI: 10.4172/2475-3211.1000117
8	Case Series	Cell Proliferation Induction: Healing Chronic LE Wounds (incl. DFUs) Through Low-Energy PRFE — Frykberg et al., Int J Lower Extremity Wounds	2009	DOI: 10.1177/1534734608329783
9	RCT (n=30)	Evaluation of pulsed electromagnetic field in diabetic polyneuropathy — Graak, Chaudhary, Bal, Sandhu, Int J Diabetes Dev Ctries	2009	PMID: 20142869
10	RCT (n=225)	PEMF to reduce diabetic neuropathic pain & stimulate neuronal repair — Weintraub, Herrmann, Smith, Backonja, Cole, Arch Phys Med Rehabil	2009	PMID: 19577022
11	Animal (db/db mice, n=66)	PEMF accelerates diabetic wound healing via FGF-2 release & angiogenesis — Callaghan, Chang, Seiser, Aarabi, Ghali, Kinnucan, Simon, Gurtner, Plast Reconstr Surg	2008	PMID: 18176216
12	Animal (STZ rat)	PEMF early diabetic wound healing & myofibroblast proliferation — Cheing, Li, Huang, Kwan, Cheung, Bioelectromagnetics	2014	PMID: 24395219
13	Animal (db/db mice)	PRFE accelerates diabetic wound healing — cell proliferation, granulation, collagen — Li, Kao, Matros, Peng, Murphy, Guo, Plast Reconstr Surg	2011	PMID: 21311391
14	CMS NCD	National Coverage Decision 270.1: Electrical Stimulation & Electromagnetic Therapy for Wounds — covers diabetic ulcers — CMS	2004	CMS.gov NCD 270.1

This appendix represents a curated, scrutiny-focused selection. The full Diapulse-related research literature is broader; additional citations may be requested from Diapulse Technologies, LLC for due diligence purposes.