DPNCheck®

Compendium of Clinical Studies

44 peer-reviewed publications + 10 NEURODiab abstracts (2025–2026) · Updated September 2026

Covering diagnostic performance in T1DM and T2DM, pediatric populations, microvascular complication prediction (retinopathy, nephropathy, cardiac autonomic neuropathy), CIPN in oncology, real-world clinical utility, and long-term outcome tracking.

2006–2026 Publication Span

Recent Publications

2023–2026

2026 No. 1

Yang et al. *ESMO Open. 2026* PubMed — Original Research

RCT of 110 cancer patients. DPNCheck used as objective CIPN severity measure. Combined qigong + acupressure significantly reduced self-reported CIPN severity, improved physical performance and quality of life vs. waitlist control.

2026 No. 2

Ito H; Yamamoto M; Inoue H et al. *Clinical and Experimental Nephrology. 2026* PubMed — Original Research

Propensity score-matched retrospective cohort (323 T2DM patients; 174 matched) at Edogawa Hospital, Tokyo. DPN assessed by DPNCheck independently predicted renal events over 5 years (adjusted HR 3.18) with steeper annual eGFR decline (−1.9 vs. −1.1 mL/min/1.73 m^2/year) — even in patients with normoalbuminuria. Supports routine objective neuropathy screening for renal risk stratification.

2026 No. 3

Pleven S; Papanas N et al. *International Journal of Lower Extremity Wounds. 2026* PubMed — Original Research

Objective tools including DPNCheck detect neuropathy missed by subjective screening; supports use of quantitative devices for DPN screening.

2026 No. 4

Fukuda T; Fujii A et al. *Journal of Diabetes Investigation. 2026;17(2):291-300* PubMed — Original Research

DPN diagnosed by DPNCheck independently associated with accelerated renal function decline in T2DM, even after adjusting for albuminuria. May help identify patients at high risk for end-stage kidney disease.

2025 No. 5

Tatsuhito H; Hideki K et al. *Journal of Diabetes Investigation. 2025* PubMed — Original Research

Electrophysiological diagnosis using CVR-R intervals combined with DPNCheck (314 patients) was highly correlated with conventional electromyograph-based diagnosis of diabetic polyneuropathy.

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2025 No. 6

Sakai M; Kato T et al. *Frontiers in Clinical Diabetes & Healthcare. 2025* PubMed — Original Research

DPNCheck eMBC significantly associated with diabetic retinopathy (DR) stage, independent of HbA1c. eMBC ≥1.51 strongly predicts preproliferative/proliferative DR — supports use as trigger for ophthalmology referral.

2024 No. 7

Damm J et al. *Journal of Diabetes and its Complications. 2024* PubMed — Original Research

High prevalence of neuropathy found in children and adolescents with T1D despite short diabetes duration. DPNCheck highlighted as key modality for large-fiber neuropathy assessment.

2024 No. 8

Morita et al. *Journal of Diabetes Investigation. 2024* PubMed — Original Research

Retrospective study (304 T2DM patients, CGM). Sural NCV strongly associated with glycemic variability, particularly in well-controlled patients (HbA1c <7%). Even well-controlled T2DM patients are at risk for peripheral neuropathy.

2024 No. 9

Hayashi et al. *Journal of Diabetes Investigation. 2024* PubMed — Original Research

DPNCheck combined with electrocardiogram produced an accurate DPN diagnosis with excellent diagnostic performance, making assessment more accessible, reproducible, and reliable.

2024 No. 10

477-P (ADA 2024) — DPNCheck vs. mTCNS in T1D *Diabetes / ADA. 2024* Article — Original Research

DPNCheck showed high sensitivity and specificity against classical NCS in 88 adults >50 years with T1D; evaluated against the validated modified Toronto Clinical Neuropathy Scale.

2024 No. 11

11-OR (ADA 2024) — DPNCheck + SUDOSCAN (229 pts, 7-yr follow-up) *Diabetes / ADA. 2024* Article — Original Research

Significantly increased risk of incident clinical DPN in patients with abnormal baseline DPNCheck + SUDOSCAN readings; supports use as a screening tool for early DPN diagnosis, when cardio-metabolic intervention may halt progression.

2023 No. 12

Dunker et al. *BMJ Open Diabetes Research and Care. 2023* PubMed — Original Research

Multicenter study demonstrated poor diagnostic performance for the monofilament test. Concluded: the monofilament test should not be used to diagnose DPN nor as an inclusion tool in diabetes research — positions DPNCheck as the superior alternative.

2023 No. 13

Grabowska W et al. *Scientific Reports. 2023* PubMed — Original Research

Post-hoc analysis of the ACUDPN RCT (62 patients, DPNCheck measured every 8 weeks over 6 months). Reliability moderate-to-good at single time points and moderate for repeated measures.

2023 No. 14

Fukuda et al. *Journal of Clinical Medicine. 2023* PubMed — Original Research

Patients with DPNCheck-determined DPN had significantly higher urinary albumin excretion than those without — validating DPNCheck's ability to identify microvascular complication risk.

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2023 No. 15

Ke et al. *Diabetes, Metabolic Syndrome and Obesity. 2023* PubMed — Original Research

Sural nerve conduction impairment (DPNCheck) was a strong predictor of vision-threatening diabetic retinopathy — more effective than HbA1c and duration of diabetes.

2023 No. 16

Goonoo et al. (489-P ADA) *Diabetes / ADA. 2023* Article — Original Research

Abnormal combined DPNCheck + SUDOSCAN results predict all-cause mortality after adjusting for other risk factors. Monofilament and TCNS — which diagnose DPN late — did not predict all-cause mortality.

Key Validation & Clinical Evidence 2020–2022

2022 No. 17

Nattero-Chavez et al. *Journal of Diabetes Investigation. 2022* PubMed — Original Research

DPNCheck recordings combined with clinical variables were accurate enough to effectively rule out asymptomatic cardiac autonomic neuropathy (CAN) in T1D patients at the clinical setting.

2022 No. 18

Lew et al. (Review) *Journal of Diabetes Science and Technology. 2022* PubMed — Review Article

Comprehensive review of DPN subtypes and screening technologies. Concluded DPNCheck, approved by the FDA, is sufficiently accurate and reliable for use as a DPN screening technology.

2021 No. 19

Kamiya et al. *Journal of Diabetes Investigation. 2021* PubMed — Original Research

DPNCheck nerve conduction parameters successfully predict the severity of diabetic polyneuropathy; developed a quantitative, easy-to-use DPN prediction model using sural nerve data.

2021 No. 20

Carmichael et al. (Review) *Frontiers in Endocrinology. 2021* PubMed — Review Article

DPNCheck validated in T1D and T2D populations. Comparison with Neuropathy Disability Score and standard NCS reported high sensitivity of 92–95% for detecting abnormalities.

2020 No. 21

Sheshah et al. *J Diabetes Metab Disord Control. 2020* Scholar — Original Research

DPNCheck detected DPN prevalence of 40.9% vs. 13.8% by NDS gold standard and 19.5% by monofilament — demonstrating substantially greater sensitivity in a one-stop microvascular clinic.

2020 No. 22

Pafili et al. *Diabetes Therapy. 2020* PubMed — Original Research

Abnormal DPNCheck sural nerve conduction parameters associated with a threefold higher likelihood of cardiac autonomic neuropathy (CAN) in T2DM patients.

2020 No. 23

Himeno et al. (Review) *Journal of Diabetes Investigation. 2020* PubMed — Review Article

Comprehensive DPN diagnosis review. DPNCheck noted to provide accessible, objective, and repeatable assessment even in developing areas with limited medical resources.

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Foundational Validation Studies

2017–2019

2019 No. 24

Papanas et al. *Rev Diabet Stud. 2019* PubMed — Original Research

DPNCheck yields high sensitivity and specificity for DPN diagnosis in T1DM (53 patients). There is a role for DPNCheck for more widespread DPN screening in both diabetes types.

2019 No. 25

Shibata et al. *Journal of Diabetes Investigation. 2019* PubMed — Original Research

DPNCheck has excellent reproducibility and good agreement with standard EMG system (57 patients); excellent intraclass correlation coefficients for both velocity and amplitude.

2019 No. 26

Selvarajah et al. (Review) *The Lancet Diabetes & Endocrinology. 2019* PubMed — Review Article

DPNCheck has very good reliability (inter-observer ICC 0.83, intra-observer ICC 0.97) and 95% sensitivity, 71% specificity for DPN diagnosis. Landmark Lancet review.

2019 No. 27

Pafili et al. *Diabetes Research & Clinical Practice. 2019* PubMed — Original Research

Correlation of cardiac autonomic neuropathy with small and large peripheral nerve function (measured by DPNCheck) in T2DM patients.

2018 No. 28

Kural et al. *Muscle & Nerve. 2018* PubMed — Original Research

DPNCheck evaluated against gold-standard NCS in 168 T2DM patients. Concluded DPNCheck may be used as a suitable screening tool for detection of DPN.

2018 No. 29

Christensen et al. *Diabetes Technology & Therapeutics. 2018* PubMed — Original Research

156 young adults with T1D assessed with DPNCheck; found high prevalence of DPN in this population, with association to insulin pump therapy.

2018 No. 30

Hirayasu K et al. *Journal of Diabetes Investigation. 2018* PubMed — Original Research

Study of 463 non-neuropathic Japanese participants found significantly different nerve conduction normal limits vs. US reference values. Applying US ranges to Japanese patients may misclassify results — critical for global market expansion.

2018 No. 31

Andersen et al. (ADDITION-Denmark) *Diabetes Care. 2018* PubMed — Original Research

13-year longitudinal follow-up of 452 participants. Higher baseline HbA1c and steeper HbA1c increase over time were associated with DPN as measured by DPNCheck.

2018 No. 32

Binns-Hall et al. *Diabetic Medicine. 2018* PubMed — Original Research

DPNCheck showed 51.5% DPN prevalence (84.3% sensitivity, 68.3% specificity) vs. only 14.4% detected by monofilament in a one-stop microvascular screening service.

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2018 No. 33

Scarr et al. (Canadian Study of Longevity in T1D) *PLOS One. 2018* PubMed — Original Research

DPNCheck has strong agreement and diagnostic accuracy for identifying polyneuropathy in older high-risk T1D adults; may represent a sufficiently accurate and rapid test for routine electrophysiological detection.

2017 No. 34

Pafili et al. (Review) *Expert Review of Medical Devices. 2017* PubMed — Review Article

NC-stat/DPNCheck could play an important role in primary care as a screening tool for DPN. First dedicated expert review of the device.

2017 No. 35

Hamasaki H, Hamasaki Y. *Frontiers in Endocrinology. 2017* PubMed — Original Research

Large retrospective study (740 patients). DPNCheck sural NCS inversely associated with diabetes duration, glucose, and HbA1c, and positively associated with ankle-brachial index — linking neuropathy to vascular risk.

2017 No. 36

Kato Y; Bando H et al. *Journal of General Practice. 2017* Article — Original Research

Assessed influence of diabetes and hemodialysis on DPNCheck nerve conduction findings; demonstrated utility for neuropathy assessment in CKD/ESRD populations beyond diabetic neuropathy.

2017 No. 37

Vogt et al. *J Clinical & Translational Endocrinology. 2017* PubMed — Original Research

Assessment of DPN in Zanzibar comparing traditional clinical methods to DPNCheck; validated utility and practicality in resource-limited global settings.

2017 No. 38

Brown et al. *Journal of Diabetes Research. 2017* PubMed — Original Research

Comparison of screening tools (DPNCheck, monofilament, tuning fork, QOL-DN) for early detection of peripheral neuropathy in adults with and without T2DM.

Landmark Original Research

2006–2016

2016 No. 39

Matsuoka et al. *Cancer Science. 2016* PubMed — Original Research

First validation of DPNCheck for CIPN in 50 cancer patients. SNAP significantly correlated with CTCAE neuropathy grade — enabling objective, quantitative chemotherapy neuropathy assessment.

2016 No. 40

Chatzikosma et al. *Archives of Medical Science. 2016* PubMed — Original Research

NC-stat DPNCheck exhibits high sensitivity (90.5%) and specificity (86.1%) for diagnosis of DPN in T2DM (114 patients), using Neuropathy Disability Score as reference.

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2015 No. 41

Poulose et al. *Canadian Pharmacists Journal. 2015* PubMed — Original Research

DPNCheck used by pharmacists in a community pharmacy diabetes clinic in Ontario. Demonstrated feasibility for non-physician administration as an educational and screening tool for glycemic control and foot self-care.

2015 No. 42

Sharma et al. *Journal of Diabetes Science and Technology. 2015* PubMed — Original Research

NC-stat/DPNCheck shows highly significant correlations with both the LDIFLARE technique and clinical neuropathy scores across all DPN severity stages — an excellent adjunctive diagnostic tool.

2014 No. 43

Lee et al. *PLOS One. 2014* PubMed — Original Research

DPNCheck demonstrated excellent reliability and acceptable accuracy (AUC 0.88) for identifying diabetic neuropathy; SNAP sensitivity 88%, SNCV sensitivity 94%.

2006 No. 44

Perkins et al. *Diabetes Care. 2006* PubMed — Original Research

Landmark first validation study. Novel point-of-care device has excellent diagnostic accuracy for detecting electrophysiological abnormality in the sural nerve of patients with diabetes.

NEURODiab 2026 Abstracts

2026

2026 No. 45

Sloan G; Binns-Hall O; Goonoo MS et al. (PI: Tesfaye S)

NEURODiab 2026 (OR.01) · University of Sheffield / Sheffield Teaching Hospitals NHS Foundation Trust

Conference — Conference Abstract

Subclinical and painful DPN in adolescents and young adults with T1D (Sheffield Microvascular Screening One-Stop Shop). DPN-Check (alongside SUDOSCAN) used as POC device in 285 young T1D patients (mean age 20.6 years). Found 8% subclinical DPN by POC devices vs. <1% by monofilament; diabetes duration >10 years strongly associated with abnormal DPN-Check (OR 5.4, p<0.0001). Concluded conventional screening substantially underestimates neuropathy in young T1D populations.

2026 No. 46

Graversen JL et al. *NEURODiab 2026 (OR.03) · Steno Diabetes Center North Denmark, Aalborg* Conference

Conference Abstract

Bone microarchitecture in T2D (Deep Phenotyping Study). NC-Stat DPNCheck used alongside VPT and cardiac autonomic testing to characterize large-fiber dysfunction. Neuropathy was associated with lower bone density and trabecular deterioration, particularly in patients under 65 years.

2026 No. 47

Low KA et al. *NEURODiab 2026 (OR.06) · Sheffield Teaching Hospitals / University of Sheffield, UK* Conference

Conference Abstract

The headline DPNCheck abstract. Evaluated DPNCheck (SNCV and SNAP) against the Toronto Consensus Panel gold standard in 132 T2D patients. DPNCheck outperformed conventional bedside tools (AUROC ~0.74). Concluded a stepwise approach — vibration/symptom screening followed by DPNCheck — could significantly improve early DPN detection.

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2026 No. 48

Borbjerg MK et al.

NEURODiab 2026 (P.04) · Steno Diabetes Center North Denmark / Weill Cornell Medicine-Qatar Conference

Conference Abstract

DPNCheck used alongside thermal perception testing and corneal confocal microscopy in 84 T1D participants without clinical neuropathy. Sural nerve conduction velocity was lower in T1D versus controls even when sural amplitude was preserved, while corneal nerve parameters were comparable between groups.

2026 No. 49

Steno Diabetes Center Copenhagen / Aarhus, Mayo Clinic *NEURODiab 2026 (P.10)* Conference

Conference Abstract

Phase II RCT of eptinezumab (CGRP-targeting monoclonal antibody) in painful DPN. DPNCheck (or abnormal nerve conduction studies) served as one of three inclusion criteria for confirmed DPN. 90 participants enrolled; final efficacy results to be presented at the conference.

2026 No. 50

Japan (institution not specified in abstract book) *NEURODiab 2026 (P.25)* Conference Conference Abstract

Validated Japan's new 2026 simplified DPN diagnostic criteria against the Baba classification in 162 patients. DPNCheck achieved specificity 85.7%, sensitivity 69.8%, and agreement 81.5% (κ=0.539), outperforming symptom/sign-based criteria alone (agreement 68.9%, κ=0.274).

2026 No. 51

Kontoninas Z; Didangelos T et al.

NEURODiab 2026 (P.62) · Aristotle University of Thessaloniki / AHEPA University Hospital, Greece Conference

Conference Abstract

DPNCheck used to measure sural nerve conduction velocity and amplitude as part of objective DPN assessment in 80 T2DM patients (48.8% DPN prevalence), in a study of holotranscobalamin (active B12 fraction) as a potential DPN marker. HbA1c, BMI, and diabetes duration were the only independent predictors of DPN in multivariate regression.

NEURODiab 2025 Abstracts

2025

2025 No. 52

Goonoo MS; Selvarajah D; Fanous T; Tesfaye S et al.

NEURODiab 2025 (OR.21), Bucharest · Sheffield Teaching Hospitals / University of Sheffield Abstract book

Conference Abstract

Concurrent validity of screen-detected abnormal DPNCheck against Toronto-confirmed DPN in 89 screen-positive T2DM patients. DPNCheck sural amplitude identified confirmed DPN (Toronto criteria, including skin biopsy) with AUROC 0.81; velocity 0.75. Significant correlations with conventional sural NCS (r=0.56, r=0.44) and skin-biopsy IENFD (r=0.41, r=0.33). Authors concluded findings support routine use of DPNCheck in clinical practice.

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2025
No. 53

Goonoo MS; Selvarajah D; Binns-Hall O; Vollert J; Tesfaye S et al.

NEURODiab 2025 (P.48), Bucharest · Sheffield Teaching Hospitals / University of Sheffield Abstract book

Conference Abstract

Nine-year prospective study of 245 consecutive patients. Abnormal baseline DPNCheck carried adjusted relative risk of 2.5 for all-cause mortality, 4.3 for incident clinical neuropathy, and 2.8 for foot ulceration. Combined DPNCheck + SUDOSCAN detected 85% of deaths, 80% of incident DPN, and 88% of foot ulcers (specificities 40% / 64% / 37%) — better predictive validity than monofilament or tuning fork. Monofilament identified only 4% of patients who developed clinical neuropathy.

2025
No. 54

Kontoninas Z; Nakas A; Didangelos T et al.

NEURODiab 2025 (P.37), Bucharest · Aristotle University of Thessaloniki / AHEPA University Hospital

Abstract book Conference Abstract

Six-month double-blind placebo-controlled RCT of saffron extract in 61 T1DM patients. DPNCheck and SUDOSCAN used together as the objective large-fibre and small-fibre endpoint instruments; trial result neutral. Supports the DPNCheck + SUDOSCAN pairing as an accepted instrument set in interventional research.

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