

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property
Organization
International Bureau

(43) International Publication Date
23 November 2023 (23.11.2023)



(10) International Publication Number
WO 2023/222771 A1

(51) International Patent Classification:

G01N 21/78 (2006.01) G16H 30/40 (2018.01)
G01N 21/84 (2006.01) G16H 50/70 (2018.01)
G16H 10/40 (2018.01) G01N 21/77 (2006.01)
G16H 30/20 (2018.01)

(21) International Application Number:

PCT/EP2023/063276

(22) International Filing Date:

17 May 2023 (17.05.2023)

(25) Filing Language:

English

(26) Publication Language:

English

(30) Priority Data:

22174532.6 20 May 2022 (20.05.2022) EP

(71) Applicant (for all designated States except DE, US): **F. HOFFMANN-LA ROCHE AG** [CH/CH]; Grenzacherstrasse 124, 4070 Basel (CH).

(71) Applicant (for DE only): **ROCHE DIABETES CARE GMBH** [DE/DE]; Sandhofer Strasse 116, 68305 Mannheim (DE).

(71) Applicant (for US only): **ROCHE DIABETES CARE, INC.** [US/US]; 9115 Hague Road, Indianapolis, Indiana 46250 (US).

(72) Inventors: **HAILER, Fredrik**; c/o Roche Diabetes Care GmbH, Sandhofer Strasse 116, 68305 Mannheim (DE). **BERG, Max**; c/o Roche Diabetes Care GmbH, Sandhofer Strasse 116, 68305 Mannheim (DE). **LIMBURG, Bernd**; c/o Roche Diabetes Care GmbH, Sandhofer Strasse 116, 68305 Mannheim (DE).

(74) Agent: **KIERIG, Elisabeth**; c/o Roche Diabetes Care GmbH, Patent Department, Sandhofer Strasse 116, 68305 Mannheim (DE).

(81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CV, CZ, DE, DJ, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IQ, IR, IS, IT, JM, JO, JP, KE, KG, KH, KN, KP, KR, KW, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, MG, MK, MN, MU, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, WS, ZA, ZM, ZW.

(54) Title: METHOD OF INDIVIDUALIZING ANALYTE VALUE RANGES USED TO CATEGORIZE A CONCENTRATION OF AN ANALYTE

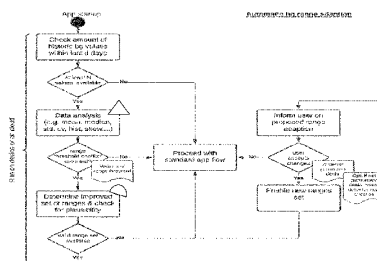


FIG. 1 (part)

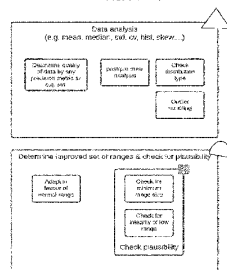


FIG. 1 (part)

(57) Abstract: A method of individualizing analyte value ranges used to categorize a concentration of an analyte in a sample of a bodily fluid of a subject applied to a reagent test region and determined using a mobile device having a processing device, as well as a corresponding computer program, a non-transitory computer-readable storage medium with corresponding instructions, a corresponding mobile device, and a corresponding kit. The method comprises the steps of determining a numerical analyte result value from an image of a color formation of the reagent test region, attributing the numerical analyte result value to a corresponding analyte value range, and adapting one or more range limit values based on a plurality of numerical analyte result values previously determined for different samples of the subject's bodily fluid taken at different points in time.

WO 2023/222771 A1

[Continued on next page]

(84) Designated States (*unless otherwise indicated, for every kind of regional protection available*): ARIPO (BW, CV, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SC, SD, SL, ST, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, ME, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

Published:

- *with international search report (Art. 21(3))*
- *in black and white; the international application as filed contained color or greyscale and is available for download from PATENTSCOPE*