SIEMENS Healthineers

Syva®

EMIT® II LSD Assay

Shading indicates technical content that differs from the previous version.

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LSD Assay

1 Intended Use

The Emit® II LSD Assay is a homogeneous enzyme immunoassay with a 0.5 ng/mL cutoff. The assay is intended for use in the qualitative and semiquantitative analyses of lysergic acid diethylamide (LSD) in human urine.

The Emit® II LSD Assay provides only a preliminary analytical test result. A more specific alternative chemical method must be used to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS)* is the preferred confirmatory method.[1] Other chemical confirmation methods are available. Clinical consideration and professional judgment should be applied to any drug-of-abuse test result, particularly when preliminary positive results are used.

**** Throughout this document, GC/MS refers to GC/MS or GC/MS/MS or both.***

2 Summary and Explanation of the Test

Measurements obtained with the LSD method are an aid to diagnosis of lysergic acid diethylamide use. A more specific alternative chemical method must be used to obtain a confirmed analytical result.[2]

Lysergic acid diethylamide (LSD, lysergamide, lysergide, Delysid) is one of the most potent hallucinogenic agents known. LSD produces vivid hallucinations in all of the sensory modalities. Patients experiencing a "bad trip" may exhibit hysterical behavior, hyperactivity, life-threatening hyperthermia, restlessness, anxiety, numbness, vomiting, collapse, coma, catatonia, fever, diarrhea, and blood coagulation disorders. Delayed psychotic reactions can occur weeks after ingestion. Acute symptoms generally last for 6 to 12 hours, gradually declining in intensity.[3,4]

A common side effect of LSD use is the flashback, a recurrence of hallucinations weeks, months, or even years after the last dose. Fatalities associated with LSD are almost always due to injuries received while under the influence of the drug. Death as a direct result of LSD toxicity is extremely rare, but has been reported.[5] LSD is taken orally, usually by swallowing drug-impregnated blotter paper. In the 1960s, a typical dose of LSD ranged from 105–300 micrograms, but in recent years, the dosage amount has decreased to 20–80 micrograms.[6] LSD and its metabolites can be detected in urine for several days following ingestion.[4]

The Emit® II LSD Assay is an automated assay that detects lysergic acid diethylamide in human urine. Positive results for samples containing other compounds structurally unrelated to LSD have not been observed. The cutoff level for distinguishing positive from negative samples is 0.5 ng/mL.

Methods historically used for detecting LSD in biological fluids include radioimmunoassay, GC/MS, thin-layer chromatography, and fluorimetry.

While confirmation techniques other than GC/MS may be adequate for some drugs of abuse, GC/MS is generally accepted as a vigorous confirmation technique for all drugs, since it provides the best level of confidence in the result.

3 Principle

The Emit® II LSD Assay is a homogeneous enzyme immunoassay technique used for the analysis of specific compounds in human urine.[7] The assay is based on competition between drug in the specimen and drug labeled with the enzyme glucose-6-phosphate dehydrogenase (G6PDH) for antibody binding sites. Enzyme activity decreases upon binding to the antibody, so the drug concentration in the specimen can be measured in terms of enzyme activity. Active enzyme converts nicotinamide adenine dinucleotide (NAD) to NADH, resulting in an absorbance change that is measured spectrophotometrically. Endogenous serum G6PDH does not interfere because the coenzyme NAD functions only with the bacterial (*Leuconostoc mesenteroides*) enzyme employed in the assay.

4 Reagents

REF	Product Description	Volume
9L039UL	**Emit® II LSD Assay** **Antibody/Substrate Reagent 1** Mouse monoclonal antibodies reactive to lysergic acid diethylamide (0.15 µg/mL),* G6P (22 mM), NAD (18 mM), preservatives, and stabilizers	26 mL
	Enzyme Reagent 2 lysergic acid diethylamide labeled with bacterial G6PDH (0.18 U/mL),* preservatives, and stabilizers	13 mL

**** The antibody titer and enzyme conjugate activity may vary from lot to lot.***

Note: Reagents 1 and 2 are sold as a matched set. They should not be interchanged with components of kits with different lot numbers.

Risk and Safety

Safety data sheets (MSDS/SDS) available on siemens-healthineers.com

CAUTION

This device contains material of animal origin and should be handled as a potential carrier and transmitter of disease.

Precautions

- Reagents 1 and 2 contain nonsterile mouse monoclonal antibodies.
- This kit contains streptomycin sulfate. Please dispose of appropriately.
- Contains sodium azide (<0.1%) as a preservative. Sodium azide can react with copper or lead pipes in drain lines to form explosive compounds. Dispose of properly in accordance with local regulations.

Dispose of hazardous or biologically contaminated materials according to the practices of your institution. Discard all materials in a safe and acceptable manner and in compliance with prevailing regulatory requirements.

For Professional Use.

Caution: Federal (USA) law restricts this device to sale by or on the order of a licensed healthcare professional.

For *in vitro* diagnostic use.

Preparation and Storage of Assay Components

Reagents Preparation

The Emit® II LSD Assay reagents are provided in liquid form, ready to use and may be used directly from the refrigerator. Close the reagent bottles when not in use.

Note: Caps must always be replaced on the original containers.

Storage

When not in use, reagents must be stored at 2–8°C (36–46°F), upright and with screw caps tightly closed. Do not freeze reagents. Avoid prolonged exposure to temperatures above 32°C. **Improper storage of reagents can affect assay performance.**

Stability

If stored as directed, reagents are stable until the expiration date printed on the label. Refer to the application sheet for on instrument stability information.

5 Specimen Collection and Preparation

- Urine specimens may be collected in plastic (i.e., polypropylene, polycarbonate, polyethylene) or glass containers. Some plastics can adsorb certain drugs.
- If not analyzed immediately, specimens may be stored unrefrigerated for up to 7 days following collection. After 7 days, specimens should be stored frozen.
- LSD degrades with prolonged exposure to light. Store specimens in opaque containers or wrap them in opaque paper or aluminum foil and store frozen.[8]
- Frozen specimens must be thawed and mixed thoroughly prior to analysis.
- Specimens should be at 18–25°C (64–77°F) for testing.
- Specimens with high turbidity should be centrifuged before analysis.
- Urine specimens within the pH range of 4.5–8.0 do not require prior adjustment of pH.
- When samples are outside the normal pH range, suspect adulteration.
- Adulteration of the urine specimen may cause erroneous results. If adulteration is suspected, obtain another specimen.
- Human urine specimens should be handled and treated as if they are potentially infectious.

6 Procedure

Materials Provided

Emit II LSD Assay

Antibody/Substrate Reagent 1
Enzyme Reagent 2

Materials Required But Not Provided

9L009UL	Emit LSD 0 ng/mL Calibrator
9L109UL	Emit LSD 0.5 ng/mL Calibrator
9L209UL	Emit LSD 1.5 ng/mL Calibrator
9L309UL	Emit LSD 2.5 ng/mL Calibrator
9L419UL	Emit LSD Control Level 1 (0.25 ng/mL)
9L519UL	Emit LSD Control Level 2 (1 ng/mL)

Instruments

Siemens Healthineers provides instructions for using this assay on a number of chemistry analyzers. Contact the Technical Assistance Center in the USA or your local Siemens Healthineers representative for application sheets.

Analyzers must be capable of maintaining a constant reaction temperature, pipetting specimens/reagents and measuring enzyme rates precisely, timing the reaction accurately, and mixing reagents thoroughly.

Assay Sequence

To run the assay, see the instrument operator's manual and the application sheets available from Siemens Healthineers.

Calibration

Note: These reagents are qualified for use with these calibrators only. However, other control material may be used for quality control purposes.

Table 1 — Emit® LSD Calibrators for use in Qualitative or Semiquantitative Analysis

Desired Cutoff Level (ng/mL)	Additional Recommended Calibrators for Qualitative Analysis to be used as Quality Control (ng/mL)	Required Calibrators for Semiquantitative Analysis (ng/mL)
0.5	0 1.5 2.5	0 0.5 1.5 2.5

Note: For any individual cutoff level, a calibrator is used as either a calibrator or as a control when the assay is used for qualitative analysis. When a calibrator is used as a calibrator for an individual cutoff level, the other level calibrators (above or below it, as listed above) are used as controls.

Qualitative Analysis

Calibrate by running the appropriate Emit® LSD Calibrator Level for the desired cutoff listed in Table 1 in duplicate. Validate the calibration by running controls (see Quality Control). Refer to the Emit® LSD Calibrators instructions for use and the application sheet for additional information and instrument settings. Recalibrate as indicated by control results.

Semiquantitative Analysis

Prepare a calibration curve by running the appropriate Emit® LSD Calibrators listed in Table 1. Validate the calibration by running controls (see Quality Control). Refer to the Emit® LSD Calibrators instructions for use and the application sheet for additional information and instrument settings. Recalibrate as indicated by control results.

Quality Control

Qualitative Analysis

Validate the calibration by assaying controls. Ensure that the result from Emit® LSD Calibrator 0 ng/mL or Emit® LSD Calibrator 1.5 ng/mL or 2.5 ng/mL relates appropriately to the result from the cutoff calibrator chosen from column 1 in Table 1. That is,

- If Emit® LSD Calibrator 0 ng/mL was run, ensure that the result is negative relative to the selected cutoff calibrator level.
- If Emit® LSD Calibrator 1.5 ng/mL or 2.5 ng/mL was run, ensure that the result is positive relative to the selected cutoff calibrator level.

If appropriate, run low and high controls (e.g., the Emit® LSD Control Level 1 and Emit® LSD Control Level 2) with every run. Ensure that the low control tests negative and the high control tests positive relative to the 0.5 ng/mL calibrator (cutoff). Once the calibration is validated, run patient samples.

Semiquantitative Analysis

Validate the calibration curve by assaying commercial controls. Ensure that control results fall within acceptable limits as defined by your laboratory. (See Table 4, Qualitative Analysis Precision, for typical rate separations for the SYVA®-30R Biochemical System).

Once the calibration curve is validated, run urine specimens.

Qualitative and Semiquantitative Analysis

At least once each day of use, analyze two levels of Quality Control (QC) material with known LSD concentrations. For assistance in identifying a quality control material, refer to *Syva Drug Testing Quality Control Material Supplement* available on siemens-healthineers.com.

Additional quality control material can be used at the discretion of the laboratory. Use the quality control material in accordance with the quality control instructions for use.

In addition, perform quality control:

- Following a valid calibration
- With use of a new lot of reagent
- When troubleshooting test results that do not match clinical conditions or symptoms

Follow government regulations or accreditation requirements for quality control frequency. Individual laboratory quality control programs and procedures may require more frequent quality control testing.

Acceptable performance is achieved when the analyte values obtained are within the expected control interval for the system, as indicated by the manufacturer of the control material or within the interval determined by an internal laboratory quality control procedure.

Follow your laboratory's quality control procedures if the results obtained do not fall within the acceptable limits. For information about entering quality control definitions, refer to the system operating instructions.

7 Results

Qualitative Analysis

Refer to Table 1 for the appropriate cutoff Emit® Calibrator. Table 1 contains the concentration of lysergic acid diethylamide present in the selected Emit® Calibrator selected as a cutoff for distinguishing "positive" from "negative" specimens.

Positive Results. A specimen that gives a change in rate value greater than or equal to the Emit® Calibrator cutoff rate value is interpreted as positive. The sample contains LSD.

Negative Results. A specimen that gives a change in rate value less than the Emit® Calibrator cutoff rate value is interpreted as negative: Either the specimen does not contain LSD or LSD is present in concentrations below the cutoff level for this assay.

Semiquantitative Analysis

The semiquantitation of positive results enables the laboratory to determine an appropriate dilution of the specimen for confirmation by GC/MS. Semiquantitation also permits the laboratory to establish quality control procedures and assess control performance. Refer to the Analytical Recovery section for the semiquantitative range.

Using the Emit® II LSD Assay, it is possible to make semiquantitative determinations of LSD. An estimate of relative total drug concentrations may be obtained by running the appropriate Emit® LSD Calibrators: 0 ng/mL, 0.5 ng/mL cutoff, 1.5 ng/mL, 2.5 ng/mL. Refer to the application sheet for instructions.

Immunoassays that produce a single result in the presence of multiple detectable components cannot fully quantitate the concentration of individual components. Interpretation of results must take into account that urine concentrations can vary extensively with fluid intake and other biological variables. A more specific alternative chemical method must be used to obtain a confirmed analytical result (see Section 1, Intended Use).

Results of this test should always be interpreted in conjunction with the patient's medical history, clinical presentation and other findings.

Siemens Healthineers has validated use of these reagents on various analyzers to optimize product performance and meet product specifications. User defined modifications are not supported by Siemens Healthineers as they may affect performance of the system and assay results. It is the responsibility of the user to validate modifications to these instructions or use of the reagents on analyzers other than those included in Siemens Healthineers Application Sheets or these instructions for use.

8 Limitations

- The assay is designed for use with human urine only.
- A positive result from the assay indicates the presence of LSD but does not indicate or measure intoxication.
- Boric acid is not recommended as a preservative for urine.
- There is a possibility that substances and/or factors not listed (e.g., technical or procedural errors) may interfere with the test and cause false results.
- Samples from patients taking chlorpromazine (Thorazine®) may produce positive results with this assay.
- Interpretation of results must take into account that urine concentrations can vary extensively with fluid intake and other biological variables.
- Immunoassays that produce a single result in the presence of a drug and its metabolites cannot fully quantitate the concentration of individual components.

9 Expected Values

When the Emit® II LSD Assay is used as a qualitative assay, the amount of drugs and metabolites detected by the assay in any given specimen cannot be estimated. The assay results distinguish between positive and negative specimens; positive indicating specimens that contain LSD.

When used semiquantitatively, the assay yields approximate, cumulative concentrations of the metabolites detected by the assay (see Section 7, Results).

10 Specific Performance Characteristics

The data appearing in this section were collected on the SYVA®-30R Biochemical System using the Emit® II LSD Assay and radioimmunoassay (RIA) (Reference Method).

Method Comparison

Qualitative Results

118 samples were analyzed by the Emit® II LSD Assay and by RIA (Reference Method).

Fifty-Nine (59) samples showed positive results by both methods, while 57 samples showed negative results by both methods. Two samples showed positive by the Emit® II LSD Assay and negative by RIA. Data are summarized in Table 2.

Table 2 — Qualitative Results for the 0.5 ng/mL Cutoff

		Reference Method RIA +	Reference Method RIA –
Emit® II LSD Assay	+	59	2
	–	0	57

Percent agreement: 98%

Semiquantitative Results

Ten (10) of the 57 samples that showed negative results by the Emit® II LSD Assay and RIA qualitatively were also tested semiquantitatively by these methods. All 10 samples showed negative results by both methods.

The 2 samples that showed positive results by the Emit® method and negative results by the RIA method qualitatively were tested semiquantitatively by both methods. Both samples showed positive results by the Emit® method; however, 1 sample showed a negative result and 1 sample showed a positive result by the RIA method. (Both samples produced results very near the cutoff level of each assay.)

Fifty-seven (57) of the 59 samples that showed positive results by the Emit® method and RIA qualitatively were tested semiquantitatively by both methods. Two (2) samples were not included in this comparison because Emit® or RIA semiquantitative results or GC/MS quantitative results could not be obtained. All 57 samples showed positive results by both methods; their concentrations were determined using GC/MS.

Table 3 shows the distribution of the samples according to where their results lie within one of three incremental ranges. Also shown is the sample concentration range, determined by GC/MS, for each incremental range.

Table 3 — Emit® II LSD Assay Comparative Analysis Semiquantitative Results

	Emit®		RIA	
Range (ng/mL)	Distribution of Samples	GC/MS Concentration Range (ng/mL)	Distribution of Samples	GC/MS Concentration Range (ng/mL)
<0.5	10	N/A	11	0.04*
0.5–1	7	0.02–0.28	11	0.02–1.09
>1	52	0.03–16.86	47	0.18–16.86

Concentration for the sample >0.5 ng/mL by the Emit® method and <0.5 ng/mL by RIA.

The Emit® II LSD Assay (range 0.25 to 2.5 ng/mL) and RIA (range 0.25 to 1 ng/mL) showed good overall semiquantitative agreement.

Ten (10) samples that showed negative results by the Emit® method also showed negative results by RIA. Seven (7) samples tested by the Emit® method had concentrations in the 0.5 ng/mL to 1 ng/mL range. Of the 7 samples, 6 also had concentrations in the 0.5 ng/mL to 1 ng/mL range when tested by RIA. The remaining 1 of the 7 samples was borderline negative by RIA and borderline positive by the Emit® method. Five (5) of the 11 samples that had concentrations in the 0.5 ng/mL to 1 ng/mL range when tested by RIA were >1 ng/mL when tested by the Emit® method. The differences in the sample concentrations between the two methods ranged from 0.03 ng/mL to 0.61 ng/mL.

Fifty-two (52) of the positive samples had concentrations greater than 1 ng/mL by the Emit® method; 47 of the 52 samples had concentrations greater than 1 ng/mL by RIA.

Concentrations generated by the Emit® method and RIA showed a similar overall relationship to the corresponding concentrations generated by GC/MS.

Precision

Qualitative precision was determined by assaying 6 samples on 20 days, 2 runs per day in replicates of 6 (N = 240). Semiquantitative precision was determined by assaying 4 samples on 20 days, 2 runs per day in replicates of 4 (N = 160). Precision data were calculated according to the National Committee of Clinical Laboratory Standards (NCCLS) Guideline EP5-T2 (March 1992). Results are summarized in Tables 4 and 5.

Table 4 — Precision: Qualitative Analysis

Calibrator or Control	Mean (mAU/min)	SD	CV (%)
Within-Run			
0 ng/mL Calibrator	151	0.83	0.55
Control Level 1 (0.25 ng/mL)	158	0.89	0.56
0.5 ng/mL Calibrator	164	0.85	0.52
Control Level 2 (1 ng/mL)	176	0.81	0.46
1.5 ng/mL Calibrator	184	0.85	0.46
2.5 ng/mL Calibrator	189	0.92	0.49
Total			
0 ng/mL Calibrator	151	0.94	0.62
Control Level 1 (0.25 ng/mL)	158	0.92	0.59
0.5 ng/mL Calibrator	164	0.94	0.57
Control Level 2 (1 ng/mL)	176	0.88	0.50
1.5 ng/mL Calibrator	184	0.98	0.53
2.5 ng/mL Calibrator	189	1.03	0.54

Table 5 — Precision: Semiquantitative Analysis

Calibrator or Control	Mean (ng/mL)	SD	CV (%)
Within-Run			
Control Level 1 (0.25 ng/mL)	0.25	0.03	13.5
0.5 ng/mL Calibrator	0.5	0.04	7
Control Level 2 (1 ng/mL)	1.1	0.03	3.2
1.5 ng/mL Calibrator	1.5	0.10	6.9
Total			
Control Level 1 (0.25 ng/mL)	0.25	0.04	15
0.5 ng/mL Calibrator	0.5	0.04	8.8
Control Level 2 (1 ng/mL)	1.1	0.04	3.6
1.5 ng/mL Calibrator	1.5	0.13	8.7

Based on internal testing, the overall reproducibility is estimated to be ≤ 5% CV for samples tested and includes multiple reagent lots, instruments, days, and replicates.[9] Performance of the assay at individual laboratories may vary.

Analytical Recovery

Qualitative Results

In qualitative spike analysis, the Emit® II LSD Assay correctly identified the mean rate of spiked specimens containing less than the cutoff listed in Table 1 as negative and the mean rate of spiked specimens containing greater than the cutoff listed in Table 1 as positive 84% of the time.

Semiquantitative Results

Negative human urine was spiked with concentrations of LSD at levels throughout the semiquantitative range of 0.25 to 2.5 ng/mL. For each known concentration, drug recovery was calculated using the average concentration obtained by the Emit® II LSD Assay. All spikes were analyzed in triplicate. Semiquantitative results are shown in Table 6.

Table 6 — Emit® II LSD Assay Spike Recovery Semiquantitative Results

Expected LSD Concentration (ng/mL)	Average LSD Concentration by Emit® II LSD Assay (ng/mL)	Recovery (%)
0.28	0.27	96
0.37	0.37	100
0.45	0.42	93
0.58	0.49	84
0.59	0.57	97
0.75	0.76	101
1.03	1.08	105
1.90	2.03	107

Specificity

The Emit® II LSD Assay detects LSD in human urine.

Table 7 lists the concentrations of compounds that produce a result that is approximately equivalent to the 0.5 ng/mL calibrator cutoff.

These concentrations are within the range of levels found in urine following use of the compound or, in the case of metabolites, the parent compound. If a specimen contains more than one compound detected by the assay, lower concentrations than those listed in Table 7 may combine to produce a rate equal to or greater than that of the cutoff calibrator. Data presented are representative of typical performance of this assay.

Table 7 — Concentrations that Produce a Result Approximately Equivalent to the 0.5 ng/mL LSD Cutoff

Compound	Concentration (µg/mL) at the 0.5 ng/mL Cutoff
D-Amphetamine	500
M-Chlorophenylpiperazine	33
Ergonovine	1
Methadone	400
D-Methamphetamine	100
Methysergide	3
Phencyclidine	30

Table 8 lists the compounds that produce a negative result by the Emit® II LSD Assay. Specificity testing was performed at the 0.5 ng/mL cutoff, which represents the greatest potential for cross-reactivity. Positive results for compounds structurally unrelated to LSD have not been observed.

Table 8 — Concentrations of Compounds Showing a Negative Response

Compound	Concentration Tested (µg/mL) at the 0.5 ng/mL Cutoff
Benzoylecgonine	1000
α-Ergocryptine	20
Ergotamine	100
Lysergic Acid	100
Methaqualone	1000
Morphine	1000
Oxazepam	250
Propoxyphene	1000
Psilocin	100
Psilocybin	100
Secobarbital	1000
Serotonin	1000
11-nor-Δ^9-THC-9-COOH	150
L-Tryptophan	100

Analytical Sensitivity

The sensitivity level of the Emit® II LSD Assay is 0.13 ng/mL. This level represents the lowest concentration of LSD that can be distinguished from 0 ng/mL with a confidence level of 95%.

11 Bibliography

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Definition of Symbols

The following symbols may appear on the product labeling:

Symbol	Symbol Title	Source
	Manufacturer	5.1.1[a]
	Use-by date	5.1.4[a]
	Catalog number	5.1.6[a]
	Consult Instructions for Use	5.4.3[a]
	Internet URL address to access the electronic instructions for use	Proprietary
	*In vitro* diagnostic medical device	5.5.1[a]
	Prescription device (US only)	FDA[c]
	CE Marking with Notified Body	EU IVDR[d]
	Temperature limit	5.3.7[a]
	Upper limit of temperature	5.3.6[a]
	Do not re-use	5.4.2[a]
	Recycle	1135[e]
	Biological risks	5.4.1[a]
	Common Units	Proprietary
	Document face up[f]	1952[e]
	Non-sterile	Proprietary

Symbol	Symbol Title	Source
	Authorized representative in the European Community	5.1.2[a]
	Authorized representative in Switzerland	Proprietary
	Batch code	5.1.5[a]
	Contains sufficient for <n> tests	5.5.5[a]
	Version of Instructions for Use	Proprietary
	Revision	Proprietary
	Unique Device Identifier	5.7.10[b]
	CE Marking	EU IVDR[d]
	Keep away from sunlight	5.3.2[a]
	Lower limit of temperature	5.3.5[a]
	Do not freeze	Proprietary
	This way up	0623[e]
	Caution	5.4.4[a]
	International System of Units	Proprietary
YYYY-MM-DD	Date format (year-month-day)	N/A
YYYY-MM	Date format (year-month)	N/A

Symbol	Symbol Title	Source	Symbol	Symbol Title	Source
→	Reconstituted volume	Proprietary	CONTENTS	Contents	Proprietary
FORENSIC TOXICOLOGY	For forensic/toxicology use only	Proprietary	LEVEL	Level	Proprietary
DROPPER	Dropper	Proprietary	CASSETTE	Cassette	Proprietary
	Not for self-testing	EU IVDR[d]		Not for near-patient testing	EU IVDR[d]

[a] International Standard Organization (ISO). ISO 15223-1 Medical Devices- Symbols to be used with medical device labels, labelling and information to be supplied.

[b] ISO 15223-1:2020-04

[c] Federal Register. Vol. 81, No 115. Wednesday, June 15, 2016. Rules and Regulations: 38911.

[d] IVDR REGULATION (EU) 2017/746

[e] International Standard Organization (ISO). ISO 7000 Graphical symbols for use on equipment.

[f] Indicates Assay-*e*Note

For technical assistance, call Siemens Healthineers:
1-800-227-8994 in the USA
1-800-264-0083 in Canada
Outside the USA and Canada, call your local Siemens Healthineers representative.

Technical Assistance
According to EU regulation 2017/746, any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the EU Member State in which the user and/or patient is established.
siemens-healthineers.com

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